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(54) Title: MEDICAL DEVICE FOR PLACEMENT OF CONTINUOUS REGIONAL ANESTHESIA CATHETERS

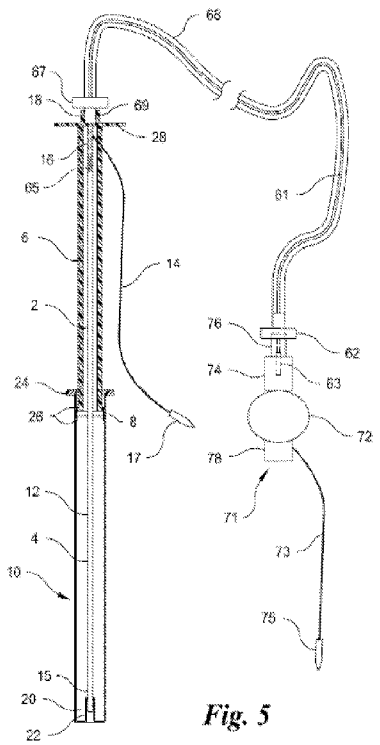

Fig. 5

(57) Abstract: A medical device for placement of regional anesthesia catheters. The device comprises a hollow shaft needle, a plunger attached to the posterior end of the needle, a housing dimensioned so that plunger can slide inside the housing with friction, a regional anesthesia catheter preloaded inside the needle, a protective cover sheath covering the catheter, and a catheter adaptor attached to posterior end of the sheath and the catheter. The medical device allows a practitioner to quickly and effectively place a regional anesthesia catheter inside an organism without the use of an assistant, and with minimal risk of contaminating the catheter before it enters the organism's body. At the end, the needle is withdrawn inside the housing and disposed.

Medical Device for Placement of Continuous Regional Anesthesia Catheters

Cross-reference to Related Applications

This application claims priority of U.S. provisional patent application number 61/153,277 filed on February 17, 2009, and U.S. non-provisional patent application number 12/700,529 filed February 4, 2010, titled: "Medical Device for Placement of Continuous Regional Anesthesia Catheters," the disclosure of which is herein incorporated by reference.

Statement Regarding Federally Sponsored Research

Not Applicable.

Field of invention

The invention relates generally to medical devices that enable the placement of catheters into body of an organism, and more specifically to medical devices designed to assist the placement of regional anesthesia catheters for continuous infusion of local anesthetics.

Background

[001] Regional anesthesia catheters are hollow body flexible catheters that are designed to be placed next to a nerve or nerve plexus of the human body, and kept in place for up to a few days. Liquid medicine is injected into proximal end of the catheter. The medication then exits from distal end of the catheter and is deposited around the nerve that is intended to be anesthetized. The dispersal of medication around the nerve causes the area innervated by that nerve to become anesthetized. In current anesthesia practice, hollow shaft metal needles are used to place such catheters into position.

[002] Such needles are covered with an electrically insulating covering over the outer surface of most of their length, except the tip and proximal end. An electric impulse sent to the needle is conveyed axially down to the tip of the needle and not radially to surrounding tissues. This allows for more precise placement of the needle tip. A stimulating wire is attached to the proximal end of the needle and is used to connect the needle to an electric supply source or so-called a nerve stimulator device. The distal end of the needle is placed through the skin of the patient and is advanced toward the target nerve. The amount of electric impulse that is sent toward the needle tip is gradually decreased as the needle advances into the patient's body, which helps to localize the target nerve. A muscle contraction at a specific low current verifies the proximity of the needle tip to that nerve. Next, the catheter is placed through needle.

[003] Needles and catheters come in different gauges and lengths, and it is imperative to use catheters with matching needles. Catheters are either stimulating or non-stimulating. Non-stimulating catheters are composed of an elongated hollow body and generally are similar to epidural catheters. Stimulating catheters generally have a hollow body and means for conveying electric current from the proximal end of the catheter to its distal tip. Only a small portion of the distal and proximal ends of the catheter are electrically exposed, while the body is electrically nonconductive. This allows for precise placement of catheter tip next to a nerve.

[004] These days some practitioners use ultrasound devices to visualize the target nerve and place the needle tip, followed by the catheter tip, next to the target nerve. Practitioners may choose to perform the procedure, using ultrasound alone, or they may employ ultrasound and a nerve stimulator simultaneously. In current practice, however, the majority of practitioners prefer to use nerve stimulators.

[005] Placement of regional anesthesia catheters is done using strict sterile techniques to avoid catheter and needle contamination, and thus patient infection. For example, the skin area were the needle and catheter will be inserted into the patient is prepped and extensively draped. The long resilient catheter is always prone to contamination from surrounding objects. It is also necessary for the practitioner to wear a mask, hat and sterile gloves and even sterile gown in some instances. An assistant is needed to help open sterile packages,

connect and disconnect stimulating wires of needle and catheter to nerve stimulator, and operate the nerve stimulator. The assistant will help utilize the ultrasound device as well, if one is used.

Summary

[006] The current invention is directed to a device that:

- Reduces chance and frequency of catheter and needle contamination.
- Reduces time needed to place the catheter adjacent to the target nerve.
- Eliminates need for an assistant in most parts of a procedure .
- Eliminates the need for anesthesia provider to wear hat, mask, sterile gloves, and gown.
- Eliminates the need to drape insertion site.
- Reduces risk of needle injury to medical staff because the needle is housed safely in a protective covering.

[007] In this invention, a metal hollow shaft needle is manufactured to a size that is almost twice as long as commercially-available similar needles. The needle is electrically insulated throughout most of its length, on the outer surface, except its proximal end and distal tip. The needle's proximal end may be attached to a stimulating wire which is adapted to allow it to be connected to a nerve stimulator device. The proximal portion of the needle shaft is permanently placed inside a plunger and the plunger is placed inside a housing. The plunger is situated inside the housing so that it can slide up and down the housing with friction. A removable protective cap is placed over distal end of the housing to ensure sterility.

[008] In the present invention, a stimulating regional anesthesia catheter is preloaded inside the needle. The catheter tip may be electrically in touch with electrically conductive inside surface of the needle. A protective sheath made of clear collapsible plastic covers most of the length of the catheter, which is left proximal to the needle. The sheath has a proximal hub and a distal hub and is secured and sealed at the peripheral ends of the hubs. The distal hub is attached to the proximal end of the needle, while the proximal hub is placed around the

proximal end of catheter, leaving a small portion of the catheter (approx. 1-2 cm.) out. A regional anesthesia catheter adaptor is attached to the sheath's proximal hub in a releasable manner. This adaptor accepts and rigidly maintains the catheter's proximal end. It has components to electrically connect the nerve stimulator to the catheter's proximal end and provides fluid access into the interior lumen of the catheter for injection of liquid medicine using a syringe or infusion pump.

[009] After prepping the insertion site, the catheter adaptor is connected to a nerve stimulator device. The housing distal protective cap is removed and the distal end of the housing is placed over the insertion site. The needle is then advanced toward the target nerve by advancing the plunger into the housing. At this time, the catheter is manipulated, through the catheter sheath, to bring the catheter's tip into electrical contact with the inside lumen of the needle. The anesthesia provider can operate the nerve stimulator to send a decreasing amount of electric impulse to the catheter tip, and simultaneously advance the needle tip through the patient's body towards the target nerve. After the needle tip is placed in close proximity to the target nerve, the catheter is pushed through the catheter sheath by the practitioner and advanced until the desired length of the catheter's distal end exits beyond the needle tip.

[010] At this point, any satisfactory muscle contraction is a result of direct stimulation of the nerve by the catheter's tip and will confirm that the catheter tip has been correctly placed near the target nerve. Next, the proximal end of the catheter is released from the catheter adaptor to free the catheter, and then the needle is withdrawn while the catheter is maintained in place. Finally, the catheter adaptor is detached from the sheath's proximal hub and securely reattached to the catheter's proximal end. Care should be taken not to touch and contaminate the proximal end of the catheter and the distal part of the adaptor. At this time the catheter should be properly secured to the patient.

[011] In an alternative method of using this embodiment, a first impulse is sent to the needle using the needle's stimulating wire. The catheter is advanced beyond the needle's distal tip, then a second impulse is sent to the catheter to verify the catheter's correct placement.

[012] In alternative embodiments, a non-stimulating catheter is used. In non-stimulating catheter embodiments, the needle may be comprised of components that connect the needle to a supply source of electricity.

Brief description of drawings

Fig. 1 is a side elevational view of a prior art needle.

Fig. 2 is a side sectional view of a needle and plunger inside the housing according to an embodiment.

Fig. 2A is a side sectional view of a needle and plunger according to an embodiment .

Fig. 2B is a side sectional view of a housing according to an embodiment.

Fig. 2C is a side sectional view of a beveled distal end of a housing according to an embodiment.

Fig. 3 is a side sectional view of a regional anesthesia catheter placed inside covering sheath according to an embodiment.

Figs. 4A and **4B** are side elevational views of a catheter adaptor according to an embodiment.

Fig. 5 is a side sectional view of a fully-assembled invention according to an embodiment.

Fig. 6 is a side sectional view of one embodiment of the invention having a stylet placed inside needle.

Fig. 6A is a side sectional view of a plunger and needle, with the plunger having a side slot for insertion of the stylet, according to an embodiment.

Fig. 6B is a side sectional view of a stylet according to one embodiment of the invention.

Fig. 7 is a side sectional view of one embodiment of the housing with side longitudinal slot.

Fig. 7A is a side sectional view of one embodiment of the needle with curved proximal end.

Fig. 7B is a side sectional view of one embodiment of the invention with the needle placed inside the housing and with the curved proximal end of the needle placed inside side slot.

Fig. 8 is a side sectional view of one embodiment of the invention fully assembled with schematic depiction of switch pad and nerve stimulator device (NS).

Fig. 9A is a side sectional view of one embodiment of the invention with distal conduit in the released position.

Fig. 9B is a side sectional view of one embodiment of the invention with distal conduit in the locked position.

Detailed description

[013] Referring to **Fig. 1**, a conventional hollow shaft metal needle **11** is shown. These needles are well known to prior art. They are made in different lengths and gauges suitable for intended use. The needle shown in **Fig. 1** has a shaft **12**, a proximal end **16** and a distal tip **15**. The tip **15** may be straight or beveled, or it may be made with an angle at the end of the straight shaft **12**. The proximal end **16** is provided with a hub **18**. The stimulator wire **14** has a first end attached to proximal end **16** and a second end adapted to connect to nerve stimulator device using connection plug **17**. Using a nerve stimulator, electric impulse is sent through connection plug **17**, which conveys the impulse to tip **15**.

[014] Needles, such as the one shown in **Fig. 1**, are usually manufactured with a shaft **12** that is covered with electrically non-conductive material on its outer surface, except along its proximal end **16** and its tip **15**, which are not coated with the non-conductive material. This allows for precise placement of the tip **15** next to a nerve. A stylet (not shown) may be placed inside the shaft **12**. In such an embodiment, the stylet is removed after the needle tip

15 penetrates the patient's body. Stylets are generally used to facilitate needle insertion into the patient's body and to prevent body tissues from plugging needle lumen.

[015] Referring to **Fig. 2**, a hollow shaft metal needle **11** is made almost twice as long as commercially-available, similar needles. The needle **11** has a shaft **12**, a proximal end **16**, and a tip **15**. Using standard industry methods that are well known in the art, the shaft **12** is coated with a thin layer of non-conductive material over the shaft's **12** outer surface; the tip **15** and the proximal end of the shaft **16** are not coated. The tip **15** may be straight or beveled or it may make an angle with the shaft **12**. The proximal section of the needle **11** is permanently and coaxially placed inside the plunger **6**. The plunger **6** has a proximal end **7**, a distal annular ring **8**, a thumb rest **28**, and an entry hub **18**. The plunger **6** divides the shaft **12** into sections **2** and **4**. Section **2** is coaxially disposed within the plunger **6**. The hub **18** is in fluid communication and provides access to the inside of the lumen of the needle shaft **12** and the needle tip **15**.

[016] The proximal end **16** may be attached to a stimulating wire **14** which is adapted to connect the needle **11** to a electric supply source. The plunger **6** is placed inside the housing **10**. The housing **10** preferably has a cylindrical body. It has a distal end **20**, a proximal end **23**, and a distal conduit **22**. The housing **10** has a length that allows the needle **11** to be withdrawn completely inside the housing **10**. The inner diameter of the conduit **22** is slightly larger than the outer diameter of the needle **11**, and the inner diameter of the conduit **22** will guide the needle **11** out of the distal end of the housing **10**. A finger flange **24** may be attached to the proximal end **23** of the housing **10**.

[017] Minimal friction exists between the distal annular ring **8** and the housing **10**. The proximal end **23** of the housing **10** may be provided with anterior and posterior inner annular stop rings **26**. These rings **26** will maintain the needle **11** completely inside the housing **10** in such a way that the needle tip **15** will rest inside the conduit **22** at a position slightly proximal to the distal end of the conduit **22**. Slight force should be needed to move the annular ring **8** passed the annular stop rings **26** in either direction. The distal end **20** of the housing **10** may be beveled almost 30-45 degrees, this conforms to the angle with which the needle **11** will penetrate the patient's body. Except for the needle **12**, which is preferably made of metal, the other component parts of the embodiment of the invention depicted in **Fig. 2** can be made of

any solid material, preferably plastic. The annular ring **8** may alternatively be made of a soft elastic material like plastic or rubber.

[018] Marks may be placed along the plunger **6**, the needle **11**, or the housing **10** to help the user determine the depth of penetration of the needle **11**. This could be accomplished by applying alternating colors of specific length to the outer surface of the plunger **6**, the needle **11**, or the housing **10**, or alternatively marking lines of different thickness along the outer surface of the plunger **6**, the needle **11**, or the housing **10**. In an alternative embodiment, the needle **11** can be attached to the distal end of the plunger **6** instead of being coaxially placed within the plunger **6**. In this embodiment an axial central conduit should exist within the plunger **6** to provide fluid communication between the hub **18** and the needle **11** and to allow catheter placement into the needle **11**.

[019] In one embodiment of the present invention shown in **Fig. 9**, a catheter assembly is shown with a locking mechanism. The locking mechanism is accomplished by constructing the conduit **22** out of a soft but resilient material. The anesthesia provider can lock the needle **11** in position by simply pinching the conduit **22** between his/her fingers. Upon the release of the pressure created by the provider's fingers, the conduit **22** will resume its straight shape and free the needle **11** from its locked position. This locking mechanism may be used during the advancement of the catheter through the needle **11**, so the needle **11** can be maintained in its position.

[020] Referring to **Fig. 3**, a conventional stimulating regional anesthesia catheter is shown placed inside of a protective sheath. As described earlier, only the distal tip and the proximal end of the stimulating catheter are electrically exposed. The catheter has a proximal end **63**, a distal tip **65**, and a body **61**. The catheter has means to convey electric impulse from the proximal end **63** to the distal tip **65**. Any electric current sent through the proximal end **63** will only travel axially through the body **61** and exit from the distal end **65**. This allows for precise placement of the catheter tip next to a target nerve. The catheter cover sheath **68** is made of thin clear plastic and is attached to the distal hub **67** and the proximal hub **62** as shown in **Fig. 3**. The sheath **68** is attached to periphery of hubs **67** and **62** in a sealed and secured way to maintain the sterility of the catheter **61**.

[021] Referring to **Fig. 3**, the sheath **68** is manufactured of adequate length as to when fully expanded, to cover the catheter **61** over its length beginning adjacent to the needle **12** and continuing until just before the proximal end **63** of the catheter **61** which is placed inside a catheter adaptor. The distal hub **67** is attached to an entry hub **18** of the plunger **6**. This attachment may be permanent or, preferably releasable but secured, like a Luer fitting, or a male-female connection, or any other way known to prior art. It is important that this connection does not come apart accidentally during the catheter placement procedure, which may render the catheter **61** exposed and subject to outside contamination.

[022] Alternatively, as explained earlier, the catheter **61** can be a non-stimulating catheter. In embodiments assembled using a non-stimulating catheter, the proximal end **63** of the catheter **61** may be maintained by a catheter adaptor attached to a proximal hub **62**, or, alternatively, it may be left free inside the catheter sheath **68**. This is because electrical stimulation of the catheter, during catheter placement, is not needed when a non-stimulating catheter is used. The catheter adaptor can be attached/reattached to the catheter's **61** proximal end **63** after the catheter **61** is placed correctly and the needle is removed from the patient's body.

[023] Referring to **Figs. 4A** and **4B**, a generic catheter adaptor **71** is shown. These adaptors generally have a first part **72** and a second part **74**. The first part **72** has a front end **76** and rear end **78**. The front end **76** has space in it to accept and firmly grasp the proximal end **63** of the catheter **61**. This provides for an electrical connection between the catheter **61** and the catheter adaptor **71**, and provides for fluid communication with the catheter **61**. **Fig. 4A** shows the catheter adaptor **71** in the released position. In **Fig. 4B**, part **74** has moved in relation to part **72**, which puts the catheter adaptor **71** in the locked position, which locks the proximal end **63** of the catheter in place. The rear end **78** of the catheter adaptor **71** is shaped to accept syringes of local anesthetics or infusion pumps for purposes of injecting liquid medicine through the catheter adaptor **71** into catheter lumen.

[024] The rear end **78** of the catheter adaptor **71** is covered by a removable protective cap to maintain sterility. The catheter adaptor 71 depicted in **Figs. 4A** and **4B** has a stimulating wire **73** and a connecting plug **75**. The connecting plug **75** is used to connect the catheter adaptor **71** to an electric supply source. The front end **76** of the adaptor **71** is connected securely, but

releasably, to the proximal hub **62** of the sheath **68**. This can be done, for example, with Luer fitting connections or any similar manner known to prior art. Accidental disconnection of the adaptor **71** from the proximal hub **62** during catheter placement can render the catheter **61** contaminated.

[025] Referring to **Fig. 5**, an embodiment of the catheter system is shown fully assembled. A protective cap (not shown) should cover the distal end **20**. The protective cap needs to be removed just prior to needle insertion. A second cap (not shown) should cover the rear end **78** of the catheter adaptor **71**. This should be removed in order to introduce local anesthetics into the catheter adaptor **71** and into the catheter lumen. As shown in **Fig. 5**, no areas of either the catheter or the needle are exposed.

[026] By preloading the catheter and placing the parts of the catheter system in protective sheaths, the anesthesia provider can touch and operate the entire catheter system unit without the need to wear sterile gloves or use extensive protective draping; a simple preparation of the insertion site will suffice. A pair of clean gloves will be needed to cover the anesthesia provider's hands. The provider will join the connection plug **75** to a nerve stimulator (not shown here), then he/she will place the distal end **20** of the housing **10** against the insertion site.

[027] Referring to **Fig. 5**, the needle **11** is advanced toward the targeted nerve by advancing the plunger **6** through the housing **10**. Advancing the plunger 6 fully inside the housing 10 will cause the needle **11** to protrude out of the distal end **20** of the housing **10** the same length as similar commercially available needles. The anesthesia provider can operate the nerve stimulator simultaneously with the catheter system. The catheter is manipulated until its tip **15** comes in contact with the electrically conducting interior lumen of the needle **11**. This will electrically couple the nerve stimulator to the needle tip **15**. When the needle tip **15** is verified to be adequately close to the target nerve, the catheter **61** is grasped through the catheter sheath **68** and advanced inside the needle **11**.

[028] Marks on the catheter **61** will show the practitioner when the catheter tip **65** exits out of the needle tip **15** and loses electric contact with it. A satisfactory muscle twitch observed after this point in time is the result of direct stimulation of the target nerve by the catheter tip

65, which means correct placement of the catheter tip **65** within the nerve sheath. When an adequate length of the catheter **61** is placed adjacent to the nerve, the proximal end **63** of the catheter **61** is released from the adaptor **71**. This allows the catheter end to move freely inside the sheath **68**. The catheter **61** is then further fed through the plunger hub **18**, while the needle **11** is simultaneously removed from the patient.

[029] Care must be taken not to withdraw the catheter **61** while the needle **11** is being removed. When the needle tip **15** is out of the patient, the catheter **61** is held by the hand at a point distal to the needle tip **15**. The proximal portion of catheter **61** is then pulled out of the sheath **68** and the needle **11**. Care should be taken not to touch and contaminate the proximal end **63** of the catheter **61**, and the front end **76** of the catheter adaptor **71**. These two portions need to be reconnected in a sterile manner.

[030] In some embodiments of the present invention, marks may be placed along the catheter **61** at a distance that is almost one inch away from the proximal end **63** to warn the practitioner of the eminent exit of the proximal end **63** out of the needle **11**, so accidental contamination of the catheter end **63** can be avoided. The adaptor **71** at this point is released from the proximal hub **62** and reconnected to the proximal end **63**. Next, the needle **11** is pulled completely into the housing **10** and is disposed of safely. Lastly, the catheter **61** is secured to the patient properly.

[031] In an alternative embodiment, a first electric impulse is sent from a source of electricity to the needle tip **15** using the needle's stimulating wire **14**. The needle tip **15** is positioned next to the nerve and the catheter **61** is then advanced, through the catheter sheath **68** and through the needle **11**, to a point beyond the needle **11** tip. When the catheter **61** has been advanced to a point beyond the needle **11** tip, a second electric impulse is sent to the catheter tip **65** using the stimulating wire **73** of the catheter adaptor **71** to verify correct catheter placement. Then, the catheter proximal end **63** is freed from catheter adaptor, the needle **11** is removed, and the catheter's **61** proximal end is reattached to catheter adaptor.

[032] In one embodiment, the invention is made the same way as described above, but instead of a stimulating catheter **61**, a non-stimulating one is preloaded inside the needle **11** lumen and covered by a protective cover sheath **68**. The proximal end of the catheter **61** may

be grasped by a catheter adaptor, or it may be left free inside catheter sheath **68**. In this embodiment, an electric impulse is sent to the needle **11** tip using the needle's **11** stimulating wire **14**, the needle **11** tip is then positioned near the target nerve, and the catheter **61** is then advanced through the catheter sheath **68** and through the needle **11**, to a point beyond the needle's **11** tip. The needle **11** is removed and catheter adaptor is attached/reattached to the catheter's **61** proximal end. Correct positioning of the catheter tip can be verified by visualizing the catheter tip, using an ultrasound device, or by injecting doses of local anesthetics into the catheter lumen and around the nerve and confirming the occurrence of a nerve block.

[033] In another embodiment, the needle **11** is manufactured as a hollow shaft metal needle without insulating covering over the outside surface and without a stimulating wire **14**. A non-stimulating catheter **61** is preloaded inside the needle **11** and covered with a protective sheath **68**, in the same way as in other embodiments. The catheter's **61** proximal end **63** may be grasped by a catheter adaptor or it may be left free inside the catheter sheath **68**.

[034] In various embodiments, an ultrasound device may be used to visualize the target nerve and the needle **11** as the needle **11** travels through the patient's skin and into the body, and to place needle tip **15** in a position that is close to that target nerve. In embodiment described above, using ultrasound device, the needle tip 15 is placed next to a nerve, then the catheter **61** is advanced through the catheter sheath **68** and through the needle **11**, and extrudes through and beyond the needle tip **15**. The needle **11** is removed from the patient's body and the catheter adaptor **71** is attached/reattached to the catheter's proximal end **63**. Correct positioning of the catheter tip **65** can be verified by visualizing the catheter **61** through the use of an ultrasound device, or by injecting doses of local anesthetics into the catheter lumen and around the target nerve and confirming the occurrence of a nerve block.

[035] In an embodiment of the invention assembled using a non-stimulating catheter **61**, a non-stimulating catheter adaptor **71** may be used. While a stimulating catheter adaptor **71** is comprised of components that allow a nerve stimulator device to be connected to the catheter's proximal end **63** to send electrical impulses to the catheter **61**, a non-stimulating catheter adaptor **71** is devoid of such components. However, similar to a stimulating catheter

61, a non-stimulating catheter **61** will tightly grasp the catheter's proximal end **63** and provide for fluid access into the catheter lumen.

[036] In other embodiments, one or more orifices may be provided along the section 2 of the needle **11**. Space should exist between this portion of the needle **11** and the interior lumen of the plunger **6**. The plunger **6** should be made of clear plastic. In this embodiment, if accidental intravascular entry happens, blood will enter into the open space inside the plunger **6** and can be seen by the anesthesia provider. Exit holes may be placed, preferably on the proximal end of the plunger **6**, to allow air to exit as blood flows in. In this embodiment, it is necessary that the catheter tip **65** be placed proximal to the orifices so as not to block the flow of blood if intravascular entry happens.

[037] In the embodiment depicted in **Fig. 6**, the invention may include a stylet **50**. A stylet **50** is comprised of an elongated body made of metal or preferably plastic. The stylet **50** may be removably placed inside a hollow needle. Stylets are designed to facilitate insertion of a needle into a patient's body and also prevent skin or other tissue materials from plugging the needle's relatively large bore. In **Fig. 6**, the plunger **6** is comprised of a proximal portion **6a**, a middle portion **6b**, and a distal portion **6c**. The section 2 of the needle **11** also has a proximal portion **2a** and a distal portion **2b**.

[038] Needle portions **2a** and **2b** are connected by a metal plate **6b(p)**, which runs through the middle portion **6b** of the plunger **6**. The middle portion **6b** of the plunger **6** is an enlarged space that is in fluid communication with needle portions **2a** and **2b**. The middle portion **6b** of the plunger **6** not only allows for the insertion or withdrawal of the stylet **50**, it will also allow blood to freely flow into the plunger **6** in case the needle **11** accidentally pierces a vein or artery when the stylet **50** is removed. The internal diameters of portions **2a** and **2b** are the same as the internal diameter of the entire needle **11**. The needle **11** again is electrically insulated on its outer surface, except its tip **15** and proximal end **16**. The proximal end **16** may be connected to a stimulating wire **14**.

[039] Any electric current coming through needle portion **2a**, either through the wire **14** or by way of contact with the catheter tip **65**, will exit only from the tip **15**. The middle portion **6b** of the plunger **6** also has a slot **6b(s)**. This slot 6b(s) is designed to allow insertion of the

stylet **50**. **Fig. 6B** depicts a stylet **50** designed to fit the embodiment shown in **Fig. 6**. It has a body **52**, a tip **58** and a knob **54** and a plug **56**. The stylet **50** can be inserted and withdrawn through slot **6b(s)** of the middle portion **6b**. The plug **56** is sized to fit snugly into slot **6b(s)** and the knob **54** can be grabbed by the practitioner so the stylet **50** can be inserted or withdrawn. When fully advanced, the stylet tip **58** will reach the needle tip **15** and will be flush with the needle tip **15**.

[040] In one embodiment shown in **Figs. 7** through **7B**, the housing **10** is provided with a longitudinal side slot **21**. The side slot **21** runs on the side of the housing **10**, from the proximal end **23** to just above the conduit **22**. It is sized to fit the needle **11**. In this embodiment, the proximal end **23** of the needle **11** is curved and faces outward as is shown in **Fig. 7A**. This curve allows the needle hub **18** to maintain its position just next to and out of the housing **10**. This positioning allows the practitioner to grab the hub **18** in order to advance the needle **11** through the housing **10** by way of sliding the needle alongside the slot **21**. An annular ring **8** is placed around needle **11** at a place between the curved and straight portions of the needle **11**. As in the other embodiment of the invention shown in **Fig. 5**, the catheter **61** is preloaded inside needle **11** and is covered with the sheath **68**. The distal hub **67** is attached to the hub **18** as it is in other embodiments of the invention. As can be seen in **Fig. 7B**, by providing a slot **21**, the needle **11** and the catheter system can be made much shorter than other embodiments without sacrificing the actual needle length available to penetrate the patient's body.

[041] In an alternative embodiment shown in **Fig. 8**, the invention comprises a switch pad 30. While the switch pad 30 can be any size and shape, the switch pad 30 is preferably similar in size, shape and structure to a regular ECG pad. An electric impulse is sent to the needle **11** by way of contact with catheter tip **65**. Alternatively, the needle **11** can be connected to the nerve stimulator directly using a needle wire **14** and then the catheter is connected to the nerve stimulator by disconnecting the nerve stimulator from the needle and attaching it to catheter **61** through the catheter adaptor **71**.

[042] The switch pad **30** allows the task of electrically stimulating the needle 11 and/or the catheter 61 quickly and/or single-handedly. The switch pad **30** is made of soft plastic or a similar non-conductive material. The switch pad **30** has a top surface **30a** and a bottom surface **30b**. The bottom surface **30b** is covered with a layer of adhesive material which

enables the switch pad **30** to be temporarily attached to the patient's body. A knob **31** is affixed into the switch pad 30. The knob **31** is constructed of a conductive material. The knob **31** has a cylindrical top portion **31a** and a disc-shaped bottom portion **31b**. The knob **31** is positioned into the switch pad **30** in such a way that the cylindrical top portion **31a** sits perpendicularly on the top surface **30a** while the disc-shaped bottom portion **31b** is attached to and is substantially flush with the bottom surface **30b** of the switch pad **30**. The **31b** portion is covered with a layer of conductive gel to facilitate its electric connection to the patient's body.

[043] Attaching the switch pad **30** to a patient's body will provide an electrical connection between the patient's skin and the knob **31**. The knob **31** will function as a ground connection between the patient body and a nerve stimulator device. The switch pad **30** is further comprised of knobs **33** and **35**. These knobs **33**, **35** are made of conductive material, but they are electrically isolated in such way that no connection exits between the two knobs **33**, **35**, or between the two knobs **33**, **35** and the bottom surface **30b**.

[044] The stimulating wire **14** of the needle **11** and the wire **73** of the catheter adaptor **71** can be attached to the knobs **33**, **35** using standard alligator clips. As is shown in **Fig. 8**, a metal pivot **37** is provided on the top surface **30a**. A metal bar **39** is attached to the pivot **37** in such a way that it can move between the two knobs **33**, **35**. The metal bar **39** maintains a constant electrical connection to the pivot **37**. A dent or slot may be provided on the side of knobs **33**, **35** to hold the metal bar **39** snugly in position in order to provide a reliable electrical connection. As is shown in **Fig. 8**, wires from the nerve stimulator can be connected to the knob **31** and the pivot **37** using alligator clips.

[045] Referring to **Fig. 8**, at the beginning of the catheter placement procedure, wires **14** and **73** are connected to knobs **33** and **35**. The needle **11** is electrically stimulated. Thereafter, when the catheter **61** is advanced through the needle **11** and placed into position near the target nerve, the anesthesia provider can then switch to catheter stimulation by moving the metal bar **39** from its position against knob **33** to a position against knob **35**. Alternatively, the switch pad **30** may only have knob **37** and knob **31**. Knob **31** provides a grounding connection. The second wire of the nerve stimulator is attached to the knob **37** using an alligator clip. Then the anesthesia provider can switch from needle stimulation to

catheter stimulation and vise versa by attaching wires **14** and **73** to the knob **37** in an alternating fashion.

[046] Other embodiments of the invention comprise a sealing diaphragm around catheter **61**. The sealing diaphragm may be needed if the anesthesia provider wishes to inject liquids like normal saline into the catheter **61**, before the catheter **61** is advanced through the needle **11**, to facilitate catheter **61** advancement within the nerve sheath. In this embodiment, a sealing diaphragm may be provided around the catheter **61** at the level of the hub **67** or the hub **18**. The function of the sealing diaphragm is to prevent liquid from flowing back inside the sheath **68**. The catheter tip is advanced to the position of the needle tip **15**, then liquid is injected into catheter **61** through catheter adaptor to exit from catheter tip and be deposited in the nerve sheath.

Claims:

I claim:

1. A medical device for the placement of regional anesthesia catheters, said device comprising:

(a) a hollow needle comprising a shaft, a proximal end and a distal tip;

(b) a plunger attached to or around said proximal end of said needle, said plunger comprising a hub, said hub providing access to the interior lumen of said needle;

(c) a housing having a proximal end and a distal end, said housing being dimensioned to allow said plunger to move inside of said housing with friction;

(d) a regional anesthesia catheter comprising a hollow body, a proximal end and a distal tip, said distal tip being pre-loaded inside said needle; and

(e) a clear, flexible sheath comprising a proximal hub and a distal hub, said distal hub being attached to said hub of said plunger, and said sheath covering said catheter.

2. The medical device of claim **1**, further comprising a catheter adaptor, wherein said catheter adaptor is attached to said proximal hub of said sheath.

3. The medical device of claim **2**, wherein said catheter adaptor comprises a means for conveying an electric impulse from an electric supply source to said proximal end of said catheter.

4. The medical device of claim **1**, wherein said catheter further comprises a means for conveying an electric impulse from said proximal end of said catheter to said distal tip of said catheter.

5. The medical device of claim **4**, wherein said catheter tip is in contact with the interior lumen of said needle such that an electric current sent through said catheter is conveyed to said needle's distal tip.

6. The medical device of claim **1**, wherein said needle is able to convey electric impulses from said proximal end of said needle to said distal tip of said needle, and said needle further comprising an outer surface that is covered with an insulating material.

7. The medical device of claim **6**, wherein said needle further comprises a stimulating wire, said wire comprising a first end attached to said proximal end of said needle and a second end adapted to connect to an electric supply source.

8. The medical device of claim **1**, wherein said housing further comprises a conduit at said distal end of said housing, said conduit being dimensioned in such a way as to guide said needle out of said housing.

9. The medical device of claim **8**, wherein said conduit is made of a flexible material such that compressing said conduit will lock said needle into position and releasing compression will free said needle from its locked position.

10. The medical device of claim **1**, wherein said distal end of said housing is beveled.

11. The medical device of claim **1**, wherein said catheter comprises marking to show the position of said catheter in relation to said needle.

12. The medical device of claim **1**, further comprising a sealing diaphragm positioned around said catheter at a point distal to said distal end of said sheath.

13. The medical device of claim **1**, wherein said needle comprises at least one orifice on said shaft of said needle for allowing the visible flow of blood out of said needle.

14. The medical device of claim 1, further comprising a plurality of markings that show the depth of penetration of said needle into a patient's body.

15. The medical device of claim **1**, further comprising a stylet.

16. The medical device of claim 1, further comprising a switch pad, said switch pad comprising a top surface and a bottom surface, said bottom surface being covered with layer of adhesive material, said switch pad further comprising at least two knobs for connecting to an electric supply source, one of said knobs being able to contact with a patient's body and providing for ground connection between the patient's body and said electric supply source, said switch pad further comprising a means for connecting said electric supply source to said needle through said needle's stimulating wire and to said catheter through said catheter adaptor.

17. A medical device for the placement of regional anesthesia catheters, said device comprising;

(a) a hollow needle comprising a straight shaft, a curved proximal end, a proximal hub, and a distal tip;

(b) an annular ring placed around said needle;

(c) a housing comprising a proximal end, a distal end, and a side longitudinal slot, said slot being sized to fit said curved portion of said needle, said housing dimensioned to allow said annular ring to move inside said housing with friction, said needle placed inside said housing with said curved portion placed inside said slot;

(d) a regional anesthesia catheter comprising a hollow body, a proximal end

and a distal tip, said distal tip being pre-loaded inside said needle; and

(e) a clear, flexible sheath comprising a proximal hub and a distal hub, said distal hub being attached to said proximal hub of said needle, and said sheath covering said catheter.

18. The medical device of claim **17**, further comprising a catheter adaptor, wherein said catheter adaptor is attached to said proximal hub of said sheath.

19. The medical device of claim **17**, wherein said catheter adaptor comprises a means for conveying an electric impulse from an electric supply source to said proximal end of said catheter.

20. The medical device of claim **17**, wherein said catheter further comprises a means for conveying an electric impulse from said proximal end of said catheter to said distal tip of said catheter.

21. The medical device of claim **20**, wherein said catheter tip is in contact with the interior lumen of said needle such that an electric current sent through said catheter is conveyed to said needle's distal tip.

22. The medical device of claim **17**, wherein said needle is able to convey electric impulses from said proximal end of said needle to said distal tip of said needle, and said needle further comprising an outer surface that is covered with an insulating material.

23. The medical device of claim **22**, wherein said needle further comprises a stimulating wire, said wire comprising a first end attached to said proximal end of said needle and a second end adapted to connect to an electric supply source.

24. The medical device of claim **17**, wherein said housing further comprises a conduit at said distal end of said housing, said conduit being dimensioned in such a way as to guide said needle out of said housing.

25. The medical device of claim **24**, wherein said conduit is made of a flexible material such that compressing said conduit will lock said needle into position and releasing compression will free said needle from its locked position.

26. The medical device of claim **17**, wherein said distal end of said housing is beveled.

27. The medical device of claim **17**, wherein said catheter comprises marking to show the position of said catheter in relation to said needle.

28. The medical device of claim **17**, further comprising a sealing diaphragm positioned around said catheter at a point distal to said distal end of said sheath.

29. The medical device of claim **17**, wherein said needle comprises at least one orifice on said shaft of said needle for allowing the visible flow of blood out of said needle.

30. The medical device of claim **17**, further comprising a plurality of markings that show the depth of penetration of said needle into a patient's body.

31. The medical device of claim **17**, further comprising a switch pad, said switch pad comprising a top surface and a bottom surface, said bottom surface being covered with layer of adhesive material, said switch pad further comprising at least two knobs for connecting to an electric supply source, one of said knobs being able to contact with a patient's body and providing for ground connection between the patient's body and said electric supply source, said switch pad further comprising a means for connecting said electric supply source to said needle through said needle's stimulating wire and to said catheter through said catheter adaptor.

32. A method of placing a regional anesthesia catheter inside an organism, said method comprising the steps of:

(a) attaching a medical device to a source of electricity, said medical device comprising a housing, said housing having a proximal end and a distal end, a

hollow metal needle, said needle having a shaft, a proximal end and a distal tip, said shaft being electrically insulated on outer surface, a plunger attached to the proximal end of said needle, a catheter, said catheter having a proximal end and a distal tip, said distal tip being placed inside said needle, said catheter comprising a means for conveying electric impulses from said proximal end to said distal tip, a catheter adaptor, said catheter adaptor comprising a means for conveying electric impulses from an electric supply source to said proximal end of said catheter, and a sheath covering said catheter;

(b) placing said distal end of said housing on a patient's skin directly over a target nerve;

(c) inserting said needle into said patient's skin by advancing said plunger through said housing and advancing the tip of said needle towards said target nerve;

(d) sending an electric impulse from said electricity source through said catheter to said catheter's distal tip;

(e) manipulating said distal tip of said catheter to bring said distal tip into contact with a conducting interior lumen of said needle so that said electric impulse is conveyed to said needle tip;

(f) advancing said needle tip toward said target nerve, thereby eliciting a desired muscle contraction;

(g) confirming proximity of said needle tip to target nerve;

(h) advancing catheter tip beyond said distal tip of said needle by gripping said catheter through said sheath and feeding said catheter through said needle;

(i) verifying the correct placement of said catheter by eliciting specific muscle contraction through the use of specified low intensity impulses sent through said catheter tip toward said target nerve;

(j) releasing the proximal end of said catheter from said catheter adaptor;

(k) removing said needle out of said patient's body while maintaining said catheter in place by simultaneously feeding said catheter through said needle while withdrawing said needle out of said patient's body;

(l) reattaching said catheter adaptor to the proximal end of said catheter;

(m) withdrawing said needle completely inside said housing and disposing of said needle; and

(n) securing said catheter to said patient's body and administering local anesthetic into said catheter by attaching syringes of local anesthetics to said catheter adaptor.

33. The method of claim **32**, further comprising the step of:

(a) attaching one end of a stimulating wire to the proximal end of said needle and the other end of the stimulating wire to a electric supply source;

(b) sending a first electric impulse to said needle tip using said stimulating wire;

(c) verifying correct positioning of said needle tip next to a target nerve and then advancing said catheter tip beyond said needle tip;

(d) sending a second electric impulse to said catheter using said catheter adaptor to verify correct positioning of said catheter tip next to target nerve.

34. The method of claim **33**, further comprising the steps of;

(a) providing a switch pad, said switch pad comprising a top surface and a bottom surface, said bottom surface being covered with layer of adhesive material, said switch pad further comprising at least two knobs for connecting to said electric supply source, one of said knobs being able to contact with a patient's body and providing a ground connection between said patient's body and said electric supply source, said switch pad further comprising a means for alternatively coupling said electric supply source to said needle through said needle's stimulating wire or to said catheter through said catheter adaptor;

(b) attaching said switch pad to said patient's body;

(c) attaching said electric supply source to said switch pad; and

(d) using said switch pad to alternatively sending a first electric impulse to said needle and a second electric impulse to said catheter.

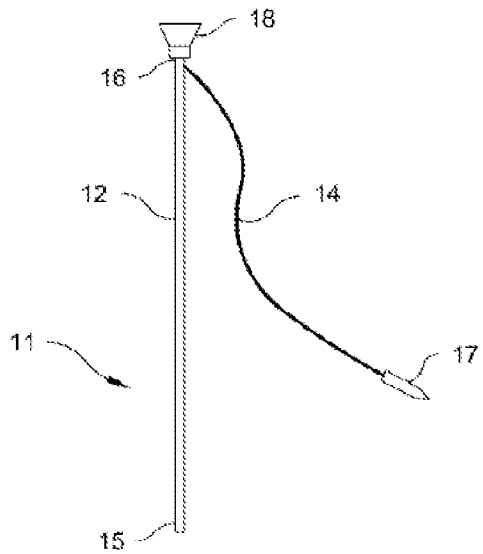

Fig. 1
(Prior Art)

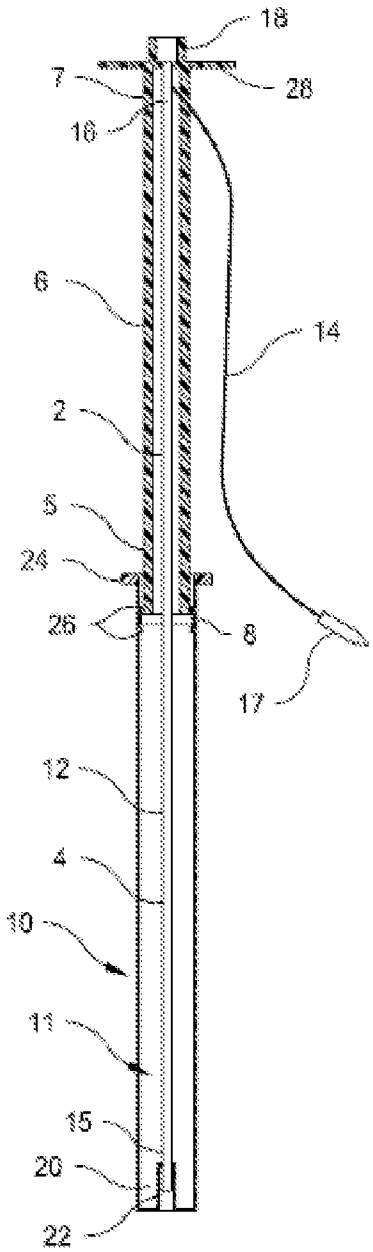

Fig. 2

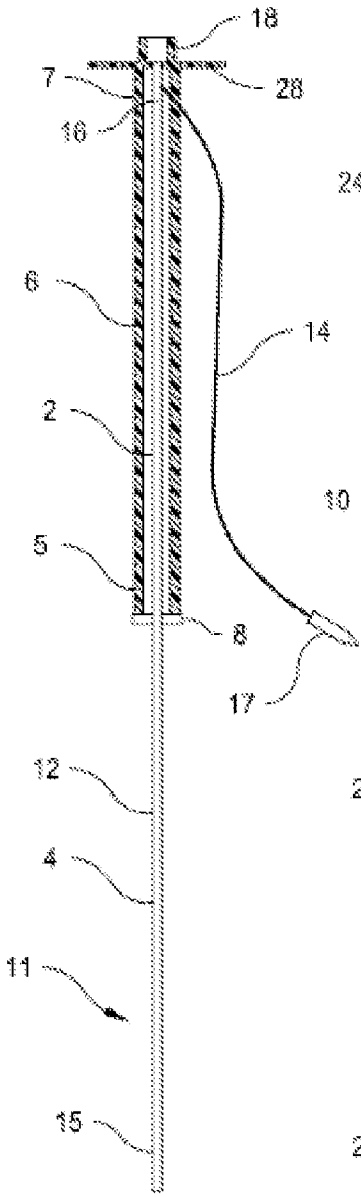

Fig. 2A

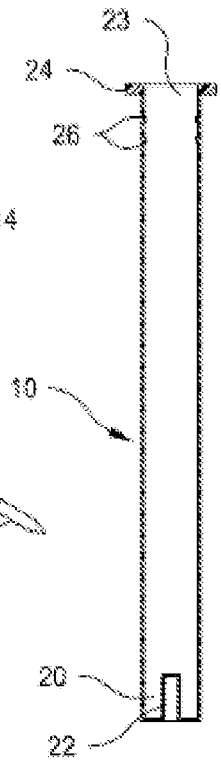

Fig. 2B

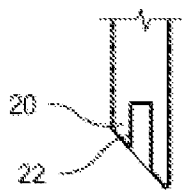

Fig. 2C

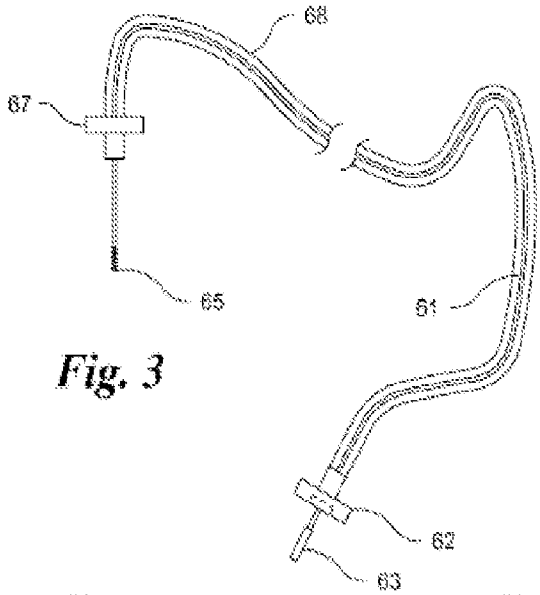

Fig. 3

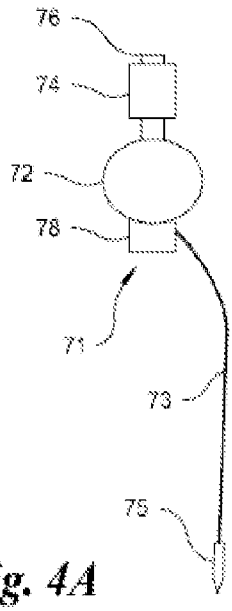

Fig. 4A

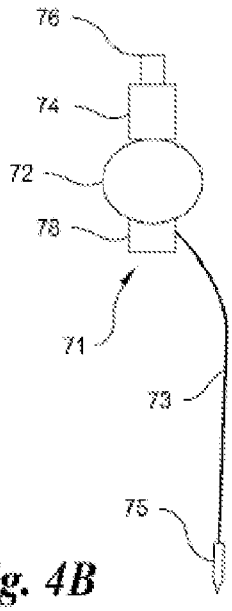

Fig. 4B

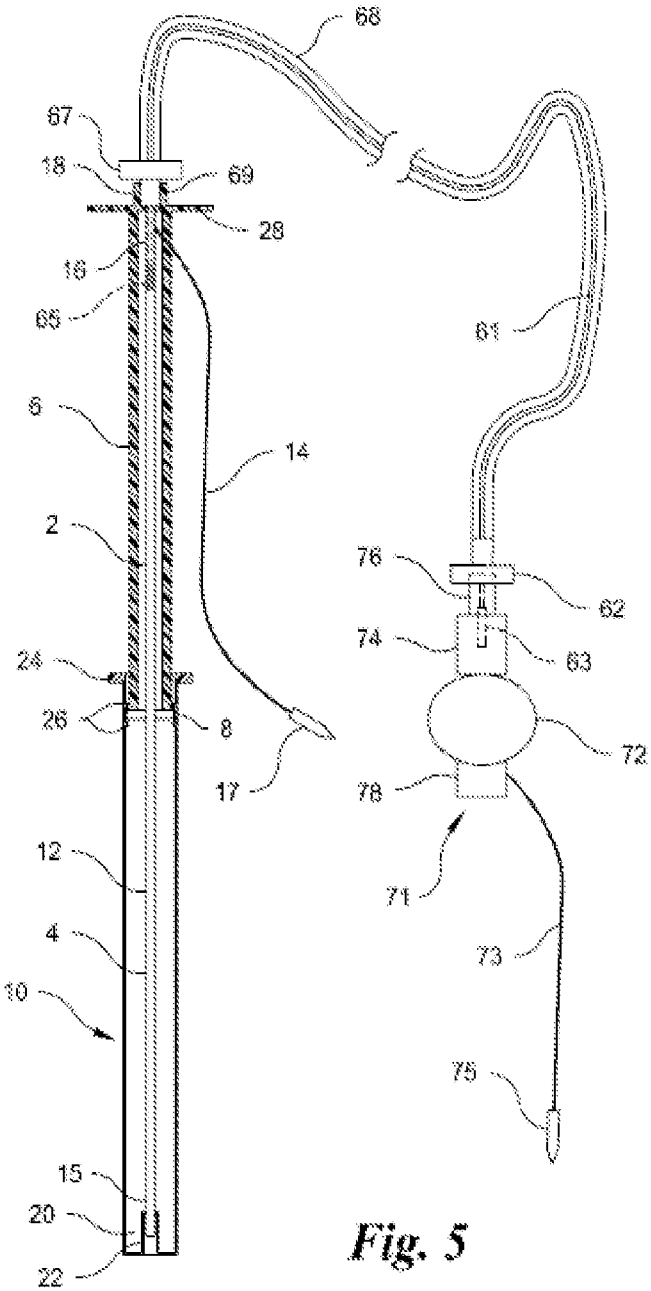
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Fig. 5

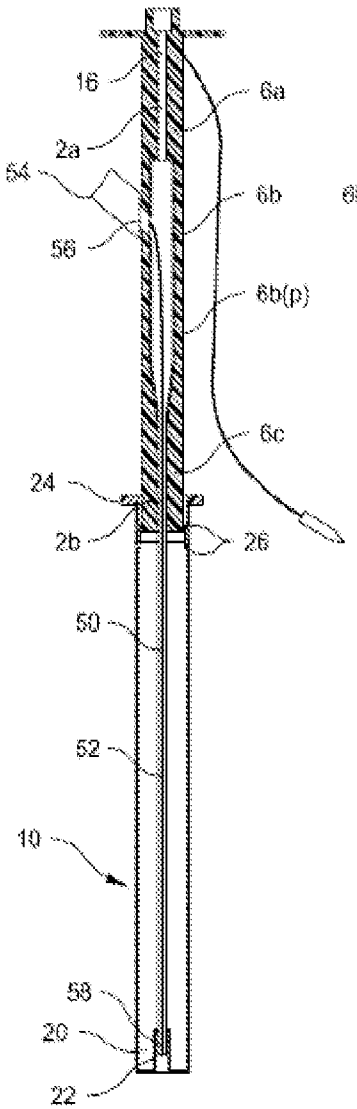

Fig. 6

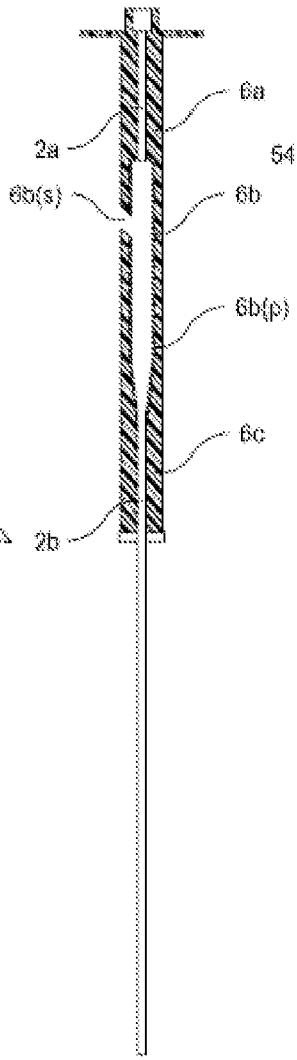

Fig. 6A

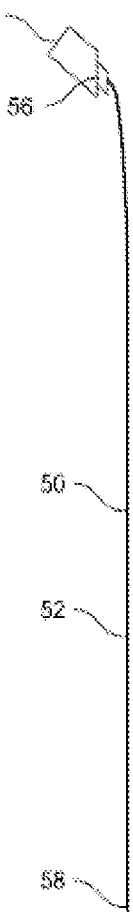

Fig. 6B

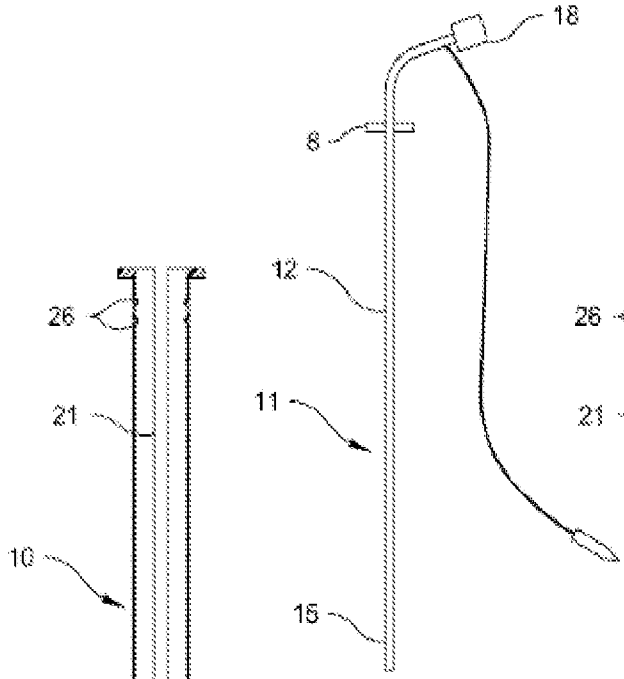

Fig. 7A

Fig. 7

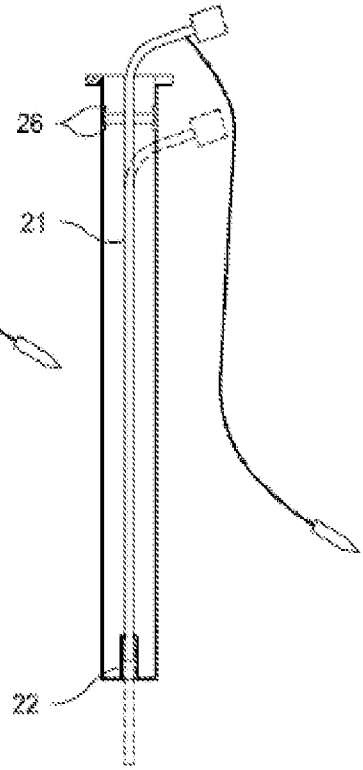

Fig. 7B

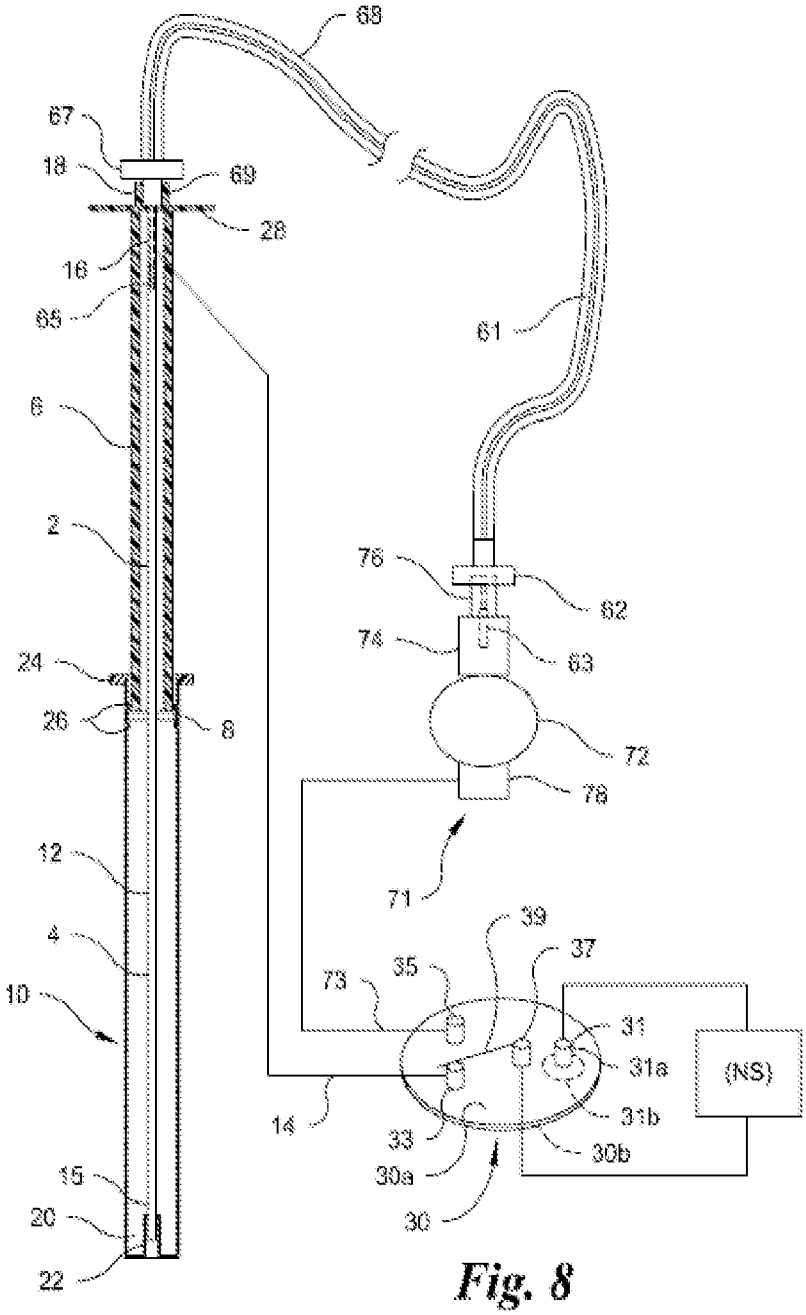
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Fig. 8

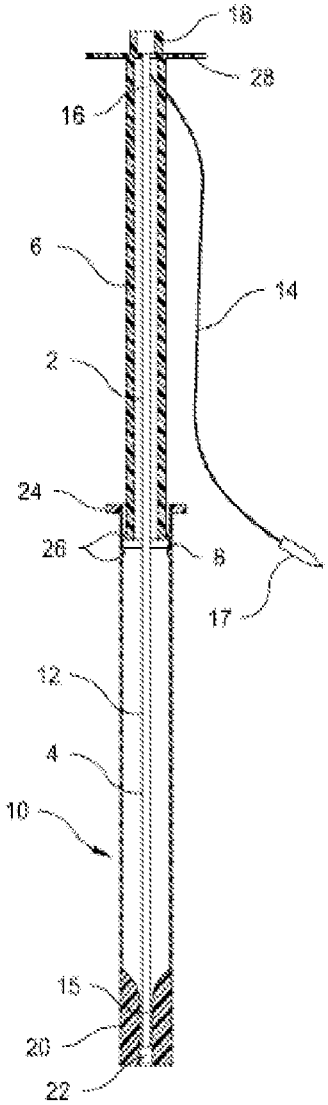
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Fig. 9A

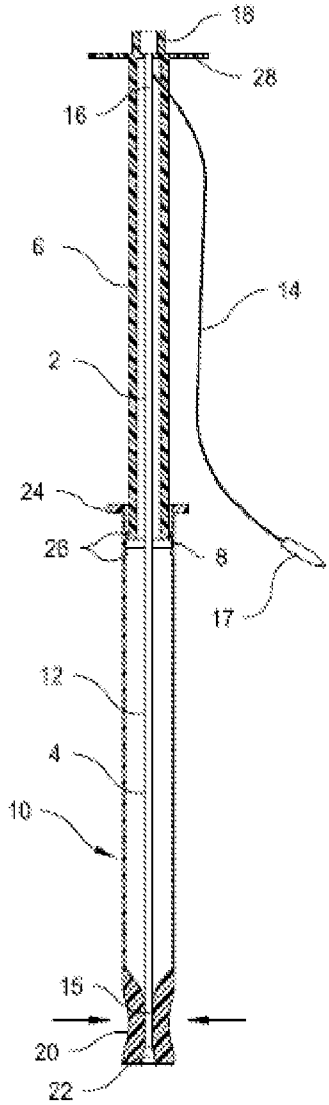
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Fig. 9B