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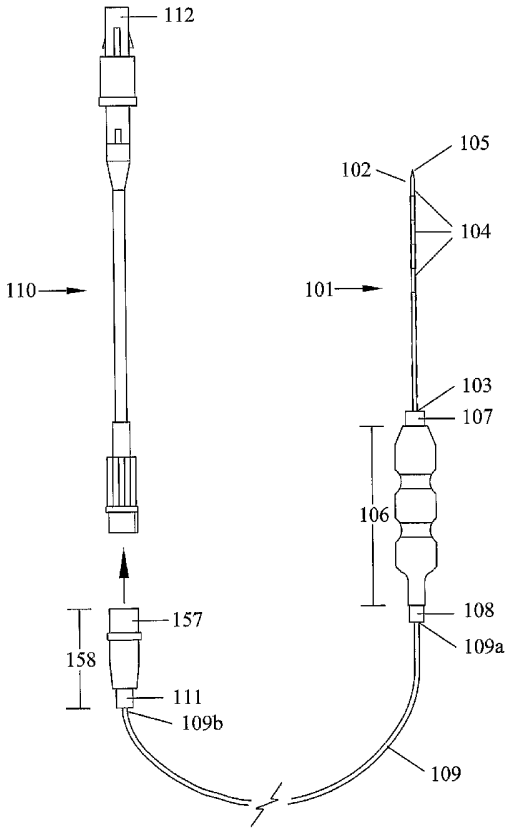
(54) Title: PERCUTANEOUS ELECTRICAL NERVE STIMULATION THERAPY



(57) Abstract: An improved method and apparatus for the treatment of chronic pain in discrete areas through the use of electrical pulses. In particular the present invention provides an electrical stimulation device comprising a probe for delivering a subcutaneous electrical stimulus in a subject and a generator for generating a stimulus output source for hyperpolarising A-Beta fibres in the presence of allodynia and hyperalgesia.

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PERCUTANEOUS ELECTRICAL NERVE STIMULATION THERAPY

Field of the Invention

The present invention relates to the field of alleviating pain in patients through the use of electrical pulses. This invention in particular relates to an apparatus and a method for delivering electrical impulses to treat chronic peripheral neuropathic pain and specifically discrete areas of allodynia and hyperalgesia.

Background to the Invention

Chronic pain is a well known and world wide problem, in some instances chronic pain can be a debilitating disease. The persistence and intensity of chronic pain may be affected by environmental and psychological factors and in some cases chronic pain cannot be alleviated by the known medical treatments. Common chronic pain complaints include, for example, headache, back pain, pain induced by other conditions such as cancer, arthritis, shingles and such like, neurogenic pain and psycogenic pain.

The goal of pain management is to make pain tolerable and to improve functionality. Pain management includes multiple therapies categorised into pharmacological, non-pharmacological, and surgical [32] Generally, a treatment progresses from therapies that are less invasive and have minor side effects to those that are more invasive. [33] Often, multiple medications for pain relief will be combined and used with non-pharmacological therapies.

Neuropathic pain begins or is caused by damage or dysfunction to the nervous system. [1;4] and is extremely difficult to manage. People are considered to have chronic pain if their symptoms persist for at least 6 months or if they have symptoms that last longer than expected for tissue healing or resolution of an underlying disease [1;6]. Chronic pain is an emotional, social, and economic burden for those living with it. Depression, reduced quality of life, absenteeism

from work, and a lower household income are positively correlated with chronic pain. [6]

The prevalence of neuropathic pain has been estimated at about 1.5% of the population of the United States and 1% of the population in the United Kingdom. [1;2] and it is extremely difficult to manage. Patients with neuropathic pain typically present with hyperalgesia (an increased response to a stimulus that is normally painful) and allodynia (pain due to a stimulus that does not normally provoke pain). [8]. Research into the area of alleviating and in some case treating the symptom of chronic pain through the use of electrical pulses has resulted in methods of treatment that are accepted by the medical community for example Transcutaneous Electrical Nerve Stimulation (TENS) can be used to stimulate peripheral inhibitory fibres in patients with nociceptive pain where the pain messages travel from the periphery via C Fibres to Rexed Lamina 1 & 2 and from there via the spinal thalamic tract to terminate in the sensory cortex resulting in a reduction of pain to the affected body area. Transcutaneous Electrical Nerve Stimulation (TENS) is a patient controlled method of treatment that is accepted by the medical community for the stimulation of peripheral inhibitory fibres in patients with nociceptive pain. TENS is a small portable battery operated electronic device used to treat pain. It allows for patient control of stimulation settings. Electrical pulses are transferred to the patient through electrode pads that attach to the skin near the painful part of the body [5]. The electrical pulses pass through the skin and stimulate nerves and nerve endings in body tissues under the skin in the region of the electrodes. In general TENS is more effective for acute pain control than for chronic pain or when pain is superficial, well localised, and not severe. In the case of peripheral neuropathic pain and specifically areas of allodynia or hyperalgesia, a subset of patients have increased pain in the presence of TENS therapy. Studies have shown that in this group of patients C-fibre termination at Rexed Lamina 1 & 2 ceases as a result of peripheral nerve damage and is replaced at Rexed Lamina 1 & 2 by Aβ-fibres. In a patient with neuropathic pain the Aβ-fibres projecting into Rexed Lamina 1 & 2

cause an exaggerated nociceptive response to what are normally innocuous stimuli. For this reason no evidence exists to support the use of TENS for the treatment of hyperalgesia or persistent allodynia.

TENS involves the application of electrical pulses to the body via electrode pads disposed on the surface of the skin. The electrical pulses pass through the skin and stimulate nerves and nerve endings in body tissues under the skin in the region of the electrodes. This has proved to be effective in alleviating pain such as back pain and pain associated with pregnancy and child birth. However, in the case of peripheral neuropathic pain a subset of patients have increased pain in the presence of TENS therapy. Studies have shown that in this group of patients C fibre termination at Rexed Lamina 1 & 2 ceases as a result of peripheral nerve damage and is replaced at Rexed Lamina 1 & 2 by A beta fibres. In a patient with neuropathic pain the A beta fibres projecting into Rexed Lamina 1 & 2 cause an exaggerated nociceptive response to what are normally innocuous stimuli.

In addition, TENS therapy can be expensive in terms of the amount of equipment used per patient which will vary depending on the size and location of the area(s) to be treated. As the treatment is a continuous therapy it is not possible to utilise the same piece of equipment with more than one patient during a course of treatment.

Gracely et al [31] reported that a patient's abnormal pain sensation (allodynia and / or hyperalgesia) would be eliminated completely if a temporary local anaesthetic block of a painful foci could be extended indefinitely. Although the actual number is unknown, a proportion of people with chronic neuropathic pain fail to obtain pain relief from pharmacological therapies despite adequate and reasonable efforts to use them. These people are said to have intractable neuropathic pain and they are the target population for Spinal Cord Stimulation (SCS).

Another electrical nerve stimulation treatment is known as spinal cord stimulation (SCS) also known as dorsal column stimulation (DCS). This involves the application of electrical pulses directly to the spinal cord via the epidural space and cerebrospinal fluid. Electrodes may be surgically implanted close to the spinal cord, for example in the epidural space and even touching dura mater surrounding the spinal cord. This is acknowleged to be an effective method for providing pain relief. However, implanting the electrodes, for example by accessing the epidural space, requires significant invasive surgery. This procedure therefore carries with it the risk of infection and damage to the spinal cord. SCS / DCS also tends to provide paresthesia in a relatively large region of the body, which is not always desirable. SCS is a form of electrical stimulation commonly referred to as Neuromodualtion. It is a reversible pain therapy that uses low-voltage electrical pulses to manage chronic, intractable neuropathic pain of the trunk and limbs. [13;14] SCS involves the application of electrical pulses directly to the spinal cord via the epidural space and cerebrospinal fluid. Electrodes may be surgically implanted close to the spinal cord, for example in the epidural space and even touching dura mater surrounding the spinal cord. This is acknowledged to be an effective method for providing pain relief. However, implanting the electrodes, for example by accessing the epidural space, requires significant invasive surgery. This procedure therefore carries with it the risk of infection and damage to the spinal cord. SCS also tends to provide paresthesia in a relatively large region of the body, which is not always desirable. Moreover, discrete areas of hyperalgesia very often persist post-SCS implant.

More recently SCS electrodes have been implanted in the subcutaneous tissue, the term Subcutaneous Electrical Nerve Stimulation (SENS) has been used to describe this method. This method has proved more effective for the treatment of persistent allodynia and hyperalgesia than conventional SCS, [37;38] although it is limited by the design characteristics of SCS technology. Permanent implantation is restricted in many instances by the insufficient length of an

electrode array (typically 4-7cm). Where a treatment area is large, multiple electrode leads are required, multiple leads require multiple power sources (IPG's) and this becomes impractical in terms of patient comfort and cost. A further restriction of the SCS technology is that the IPG is too big to implant at the extremities and the tunnelling of a lead from an extremity to a suitable IPG implant site is not practical. Although the SENS method remains a surgical prodecure with the related surgical risks, generally the risks associated with SENS are less than those associated with SCS.

A further electrical nerve stimulation treatment known as peripheral nerve stimulation (PNS) has also been developed. This involves the application of electrical pulses directly to major nerves extending away from the spinal cord, such as the sciatic nerve of the leg, which are generally known as "peripheral nerves". This can provide pain relief more localised than that of SCS. However, PNS still requires significant invasive surgery for the electrodes to be put in place. Indeed, as the precise location of the peripheral nerves varies from patient to patient, the surgeon may well need to cut away a significant amount of tissue to locate the desired nerve during electrode implantation. This can cause significant trauma and nerve damage to the patient and is clearly undesirable.

SCS, SENS and PNS technology consists of 3 fully implantable components; a pulse generator (IPG), an extension lead, and an electrode lead. The IPG is the power source for the spinal cord stimulator. It generates low-voltage (up to 12.5 Volts) electrical pulses. The extension lead connects the IPG to the electrode lead. The electrode lead is a small wire with a series of electrodes at the distal end. A programmer is used to set the stimulation output parameters. The programmer is a hand-held device with parameter adjuster keys and a display screen.

Pain in localised regions of the body and in particular parts of the trunk, cannot be successfully targeted using SCS.

A further electrical nerve stimulation treatment known as peripheral nerve stimulation (PNS) has also been developed. This involves the application of electrical pulses directly to major nerves extending away from the spinal cord, such as the sciatic nerve of the leg, which are generally known as "peripheral nerves". This can provide pain relief more localised than that of SCS. However, PNS still requires significant invasive surgery for the electrodes to be put in place. Indeed, as the precise location of the peripheral nerves varies from patient to patient, the surgeon may well need to cut away a significant amount of tissue to locate the desired nerve during electrode implantation. This can cause significant trauma and nerve damage to the patient and is clearly undesirable.

Electrodes for both SCS / DCS and PNS are usually implanted whilst the patient is either under general anaesthesia or heavily sedated. The implantation is therefore an inpatient procedure and is expensive in terms of operating room time and bed occupancy. It also utilises resources such as fluoroscopic equipment, which have multiple other uses.

US 2003/0153960 (Chornenky *et al*) describes an apparatus and method for minimally invasive treatment of deep subcutaneous fat deposits. Two or more needle electrodes are used to create an electric field to kill subcutaneous fat cells utilising electroporation techniques, and requires a high voltage electroporation pulse generator. The apparatus uses one or two needles which are pushed into deep subcutaneous fat deposits. Needle electrode diameters are described as falling within the range of about 0.3 mm to about 1.0 mm. The apparatus described is not suitable for delivering the pain relief therapies of the present invention. Furthermore the apparatus is not suitable for delivering an electrical stimulus beneath a sensitive are such as an area of sensitive or painful to touch skin.

WO 03/02673 (Firlik) describes a system which requires surgical incision for implantation of two electrodes in a patient's body, for example on opposing sides of a wound. The electrodes are connected to a pulse system for delivery of an electrical pulse. The electrodes are in general flexible dieletric (electrically insulating) materials with internal lumens and on which are provided spaced apart conductive contacts. Alternative embodiments include a solid core wire in part covered with a dielectric material which may, according to Firlik have "sufficient pushability" to allow it to be advanced through tissue volume, though in some embodiments a trocar is used. It is not clear to the present inventor how the solid core wire system could be implanted – it appears it will not move with the patient's movements and is thus likely to cause damage internally. This is particularly so as it will have a sharp tip.

WO 01/39829 (Bishay *et al*) describes a system for administering percutaneous electrical therapy. Essentially the system utilises a series of acupuncture needles which are inserted into the skin through individual housings for each needle. The housing is attached to the skin of the patient. As recognised by Bishay *et al* the acupuncture needles tend to bend or buckle upon insertion. The housing provides axial support against such buckling. The electrodes are inserted at right angles to the skin and to a depth of 3cm through the housing which is held to the skin with adhesive. A 32-gauge stainless steel needle is described.

GB 1,291,868 (Wellcome Foundation Limited) discloses a hypodermic syringe needle which has electrodes for applying an electrical stimulus to a patient and is in the form of two co-axial tubes. The needle is used to identify a nerve and for injection into that nerve. The needle has an open tip and is bevelled to pierce the skin.

Furthermore in most of the documents described above, all are for delivering an electrical stimulus into subcutaneous tissue by pushing the needle etc. straight through the skin and into the target area.

Therefore there is a need for a method of alleviating pain in discrete locations in patients through the use of electrical pulses that does not entail major surgery and can be administered quickly, easily and cheaply.

Object of the Invention

It is an object of the present invention to provide a method and apparatus for the treatment of chronic pain in discrete areas (such as allodynia and hyperalgesia typically present in chronic peripheral neuropathic pain) through the use of electrical pulses.

Summary of the Invention

Percutaneous Electrical Nerve Stimulation therapy (PENSt) is a a method which allows percutaneous electrical nerve stimulation (PENS) of the sensory nerves and nerve endings contained within the subcutaneous tissue regardless of the location of any major peripheral nerves. A specific combination of electrical impulses are delivered via a specifically designed PENSt probe. The present invention provides a suitable PENS therapy probe which may be inserted (and tunneled) into subcutaneous tissue under the skin of a subject. The probe of the present invention may be suitable for delivering an electrical stimulus to the subcutaneous tissue, the probe comprising:

(i) an electrically conductive elongate body having a first free end, a second end and at least one stimulus delivery portion between the first and second ends for delivering the electrical stimulus into the subcutaneous tissue; the first end having a sharp tip for piercing the skin to allow for insertion into the subcutaneous

tissue at least so far as to locate the stimulus delivery portion in the subcutaneous tissue; and

(ii) a connector located at the second end for connecting the probe externally to the body of the subject to a means for providing electrical impulses and for transferring the electrical impulses to at least the stimulus delivery portion of the body.

It is desirable that the body (which will generally be manufactured as a straight piece) be easily manipulated (usually bent) to a desired shape by hand without any breaking or kinking. It is also desirable that the body retains its manipulated shape. It is yet further desirable, that the body retains sufficient rigidity to be inserted into a body to be treated in its manipulated shape – again without kinking or breaking and additionally while substantially retaining the required shape.

As far as the present inventor is aware there is no other system which can offer all three advantages above apart from the present invention. With the present invention a shaped probe can be provided that is free of sharp edges along the probe body, which can be shaped as desired and which is easily inserted (by pushing through the skin or tissue and without any guide or introduction device). In this way the present invention allows the probe body to be inserted and tunnelled underneath the skin for example at a substantially constant depth. Furthermore it allows a user to shape the insertion path of the probe. Alternatively the probe can come pre-shaped to match a desired (non-linear). insertion path.

The elongate body may be from about 5 cm to about 25 cm long. It may have a thickness (diameter) of between about 0.255 mm to about 1.449 m, for example 0.5mm to about 1.1mm more especially 0.6mm to about 1.0mm such as 0.65 to about 0.95mm, e.g. 0.7 to about 0.9 mm such as about 0.8mm

The length of the probe or probe and cannula may vary and are typically in the region of 10 mm to 300mm long, such as 10mm to 200mm long such as 25mm to 170mm long, for example 50mm to 200mm long more especially 50mm to 150mm or 200mm long. The gauge (thickness or outside diameter) of the probe or probe and cannular may also vary but may typically be in the region of 15 to 30 gauge (0.305mm to 1.82 mm), such as 18 to 25 gauge (0.51mm to 1.24mm) for example 20 to 22 gauge (0.71mm to 0.89mm) for instance 21 gauge (0.81mm). Suitably the elongate body has a thickness in the range from about 0.75 to about 0.85 mm. The length and gauge of the probe and probe with cannula may be selected by the end user and will correspond with the size of the area to be treated.

Generally the material chosen for the conductive body will be a metallic material. It is desirable (for example by choosing these thicknesses) that the body is easily bent to a desired shape by hand, but without snapping or kinking. There is a balance therefore to be struck between the rigidity and strength of the elongate body which is sufficiently rigid for insertion but on the other hand the need for flexibility to allow such manipulation by a user.

Desirably, the connector may be connected to a specifically designed generator such as a PENSt NeuroStimulator adapted to generate electrical impulses having balanced biphasic form with negative leading pulse and electrical impulses having square form to deliver electrical impulses to treat discrete areas of allodynia and hyperalgesia. The impulses may induce an analgesic effect. Preferably, the electrical impulses may have an alternating combination of low and high frequency pulses, and a square wave positive voltage pulse for the user set time value, changing immediately to a square wave negative pulse of the same voltage for the user set time value again, with a short sloping trailing edge and square wave positive voltage pulse for the user set time value, followed by a brief pause, followed by an immediate negative voltage pulse of lower amplitude, with an immediate long sloping trailing edge.

In one embodiment, the connector may comprise an intermediate cable as a means of connecting the second end of the probe cable to the NeuroStimulator. Preferably, the intermediate cable is a dual intermediate cable.

The present invention also provides a probe for inserting into the subcutaneous tissue of a subject and for delivering an electrical stimulus to the subcutaneous tissue, the probe comprising: an electrically conductive elongate body having a first free end, a second end and at least one stimulus delivery portion between the first and second ends for delivering the electrical stimulus into the subcutaneous tissue; the first end having a sharp tip for piercing the skin to allow for insertion into the subcutaneous tissue at least so far as to locate the stimulus delivery portion in the subcutaneous tissue; the electrically conductive elongate body being sufficiently pliable to allow it to be bent to a desired shape without kinking to allow it to follow a curved insertion path while sufficiently rigid to allow it to retain its desired shape during and after insertion.

And an apparatus for use in PENS therapy comprising a probe described above and a generator for generating the electrical stimulus operably coupled to the probe.

PENSt may be used in treating, for example, post mastectomy pain, neuropathic chest wall pain, chronic post surgical pain, post surgical wound pain, complex regional pain syndrome, reflex sympathetic dystrophy, neuropathic head and/or neck pain and/or facial pain, neuropathic foot pain, penile pain, scrotal pain, testicular pain, post inguinal hernia repair pain, neuropathic abdominal wall pain, neuropathic failed back surgery syndrome (FBSS) pain, migraine pain, post traumatic cervical neuropathic pain, vulvadynia, coccydynia, mastectomy lymphedema and combinations thereof.

It is suggested that PENS therapy when applied to the area of primary hyperalgesia, may cause hyperpolarisation of A-Beta Fibres in the presence of

neuropathic pain (nociceptive input) thus blocking peripheral allodynia and hyperalgesia and thus causing significant regional pain reduction [37;38]. Furthermore, it has been suggested that subcutaneously stimulation of an area of primary hyperalgesia, regardless of the location of any major peripheral nerve using alternating low / high frequency pulses, may (completely) eliminate the abnormal pain sensation (hyperalgesia / allodynia). In addition normalised central processing could be sustained for a period that is substantially longer than previously achieved via a local anaesthetic block. [37;38]

In this respect, PENSt differs from the prior art methods of pain relief for example by:

1. an absence of pain (induced analgesia) may be created (achieved) rather than paresthesia as a result of hyperpolarisation of A-Beta fibres (compared with the paresthesia experienced with TENS, SCS and Electro Actupuncture (EA));
2. It is not a permanently implanted device such as SCS and is thus less invasive to the patient;
3. it is not a continuously administered therapy and;
4. it is not administered directly onto the painful areas such as might occur with a TENS system (in contrast with TENS, the probe may be inserted at a location peripheral to the area of hyperalgesia / allodynia and from there tunneled subcutaneously until the probe is located in the area to be treated).

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Figure 1a, 2a and 3a are front elevations of 50mm long probes in accordance with the present invention;

Figure 1b, 2b and 3b are front elevations of 100mm long probes in accordance with the present invention;

Figure 1c, 2c and 3c are front elevations of 150mm long probes in accordance with the present invention;

Figure 4 is a detailed drawing of a connector;

Figure 5 is a front elevation of a 100mm probe without the detachable cannula;

Figure 6a, 6b and 6c are front elevations of 100mm cannula in accordance with the present invention;

Figure 7 is a schematic representation of an area to be treated in accordance with the present invention;

Figure 8 is a schematic representation of a probe located in the target area (area to be treated);

Figure 9 is a schematic representation of two probes located in the target area (area to be treated);

Figure 10 and 10a is a perspective view of a PENSt NeuroStimulator in accordance with the present invention;

Figure 11a, 12a and 13a are front elevations of 50mm long probes in accordance with the present invention;

Figure 11b, 12b and 13b are front elevations of 100mm long probes in accordance with the present invention;

Figure 11c, 12c and 13c are front elevations of 150mm long probes in accordance with the present invention;

Figure 11d, 12d and 13d are front elevations of 200mm long probes in accordance with the present invention;

Figure 14 is a schematic representation of a dual intermediate cable in accordance with the present invention;

Figure 15 is a schematic representation of an area to be treated in accordance with the present invention;

Figure 16 is a schematic representation of a probe located in the target area (area to be treated);

Figure 17 is a schematic representation of two probes located in the target area (area to be treated);

Figure 18 is a schematic representation of a return electrode cable in accordance with the present invention;

Figure 19 is a front elevation of any of probes 1, 2 or 3 demonstrating the flexibility of the body of the probe in accordance with the embodiments as shown in figures 1-21;

Figure 20 and 20a is a perspective view of a PENSt NeuroStimulator in accordance with the present invention;

Figure 21a is a schematic of a program A wave form produced by the NeuroStimulator of the present invention;

Figure 21b is a schematic of a program B wave form produced by the NeuroStimulator of the present invention; and

Figure 22 a to c illustrate known nerve activity. Figure 22a illustrates spontaneous activity in primary afferents can produce peripheral sensitisation in injured and uninjured adjacent neurons. Partial denervation increases relative concentrations of neuron growth factor for intact calls. Figure 22b illustrates that after nerve injury C-fibre terminals atrophy and A-fibre terminals sprout into the superficial dorsal horn. Figure 22c illustrates normal compared with injured nerve tissue.

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Detailed Description of the Drawings

One embodiment of the invention will be described with reference to the embodiment shown in figures 1-9. Probe assembly units are shown in Figures 1a, 2a, 3a, 1b, 2b, 3b, 1c, 2c and 3c, where a probe 1 comprises an electrically conductive elongate body with a first end 2 and a handle assembly 6 which

retains a second end 3 and a stimulus delivery portion 4 between the first 2 and second 3 ends. In one embodiment the first end 2 of the probe 1 comprises a sharp tip 5 to assist in piercing the skin when inserting the probe 1 percutaneously into the target area 21 so that at least the stimulus delivery portion 4 is located in the target area 21. In one embodiment the first end is closed and the sharp tip 5 is formed by tapering the end 2. The handle assembly 6 further comprises a probe retaining portion 7 and a first cable-retaining portion 8. A cable 9 comprising a first end 9a and a second end 9b is connected to the probe 1 through its first end 9a, which is located in the cable retaining portion 8 of the handle 6. The second end 9b is retained in a connector 10. The connector 10 comprises a second cable-retaining portion 11 and a NeuroStimulator engaging portion 12.

The probe 1 has an elongate body and is preferably substantially cylindrical in shape however it is also possible to have probes of different shapes for example a fork-shaped probe with a plurality of tines or a probe shaped in accordance with the topology of the nerves to be treated for example the probe may comprise at least one branch and the branch(es) may be curved and of different lengths and shapes. The probe(s) 1 is made from an electrical conductive material so that an electrical current can travel from the NeuroStimulator 22 through the cable 2 and along the probe 1. It is desirable that the probe(s) 1 are substantially rigid so that they can be easily manipulated. An example of a suitable material is stainless steel although other suitable materials will be readily apparent to a person skilled in the art. The length of the probe(s) 1 will vary depending on the area to be treated for example for a treatment area wherein the largest dimension is about 6cm, an about 5cm long probe can be employed. Typically the length of the probe(s) 1 will be between about 1cm to about 25cm for example about 3cm to about 20cm, such as about 5cm to about 15cm. However, when the target area 21 is large it is possible to insert more than one probe 1 into the target area 21 to obtain the desired effect (see Figure 9). The NeuroStimulator can accommodate either 1 or 2 probes at the same time through probe connector port(s) 38.

The probe retaining portion 7 acts to securely retain the probe 1 in the handle assembly 6. Typically the probe retaining portion 7 comprises the connection assembly where the strands from within the cable 9 connect to the probe 1. Desirably the probe retaining portion 7 is constructed from a non-electrical conducting material such as a hard plastic material. The probe retaining portion 7 abuts the first cable retaining portion 8 to make up the handle assembly 6. The first cable retaining portion 8 is desirably constructed from a non-electrical conducting material such as a hard plastic material. The first cable retaining portion 8 and the probe retaining portion 7 lie adjacently to make up the handle and connection assembly 6. Preferably the handle assembly 6 is substantially rigid [hard plastic] so that it can withstand the external forces applied to it when the probe 1 is inserted into the target area 21. Desirably the handle assembly 6 has a non-slip grip to assist the end user when inserting the probe. Typically the handle assembly 6 will be constructed so that it is easy to hold and manipulate the position of the probe 1.

The cable 2 connects the probe 1 to a NeuroStimulator 22 (see Figures 10 and 10a). The second end of the cable 9b is housed in the second cable retaining portion 11 where the conductive strands 9c running through the cable 2 are connected to the pins 12b in the NeuroStimulator engaging portion 12 as in Figure 4. The pins 12b in the NeuroStimulator engaging portion 12 mate with the holes in the probe connector port(s) 38 of the NeuroStimulator 22. To further secure the attachment of the NeuroStimulator engaging portion 12 to the probe connector port(s) 38 there is a snap lock mechanism 12a built into the NeuroStimulator engaging portion 12. The second cable retaining portion 11 is desirably constructed from a non-electrical conducting material such as a hard plastic material. Typically, the cable 2 is approximately about 2m to about 0.5m long such as about 1.5m to about 0.7m long for example about 1.2m to about 1m long to facilitate maintaining a sterile field at the patient while being connected to the NeuroStimulator 22 through the NeuroStimulator engaging portion 12. The

NeuroStimulator engaging portion 12 is preferably a plug wherein the external surface comprises a non-electrical conducting material such as a hard plastics material and the internal dimensions of the NeuroStimulator engaging portion 12 are configured to mate with the corresponding area of the NeuroStimulator 22 for example like a plug and socket. The interior of the NeuroStimulator engaging portion 12 comprises an electrical conducting means so that the electricity can be transferred from the NeuroStimulator 22 to the probe 1. The exterior of the NeuroStimulator engaging portion 12 includes a "snap-lock" type mechanism 12a which secures the NeuroStimulator engaging portion 12 into the probe connector port(s) 38. The NeuroStimulator engaging portion 12 is adjacent to the second cable engaging portion 11 [detail of 10 above].

Figure 6 showing 6a, 6b and 6c illustrate a non-electrically conductive cannula 14 that has a first end (un-insulated) 16, a second end 17 (insulated in 6a and 6b, un-insulated in 6c) and at least one stimulus delivery portion 18 between the first 16 and second 17 ends. The first end 16 of the cannula 14 desirably has a sharp tip 19 to facilitate insertion of the cannula 14 percutaneously. In one embodiment the sharp tip is closed and is formed by tapering the first end 16 of the cannula body 15. The cannula body 15 is elongate (substantially cylindrical) and dimensioned so that it can be placed over the probe 13 show in Figure 5 (like a sleeve). Therefore the shape of the cannula 14 is intimately linked with the shape of the probe 13, for example if the probe 13 is fork shaped, the cannula 14 will also be fork shaped. The internal dimensions of the cannula 14 are shaped to compliment the dimensions of the probe 13. The cannula 14 is constructed from a conductive material such as stainless steel and is insulated in part, in 6a and 6b with a Teflon® type material in example 6c the cannula 14 is not insulated at all and is thereby one long stimulus delivery area 18. The cannula body 15 comprises at least one stimulus delivery portion 18, whereby the stimulus delivery portion 18 is defined by the lack of insulation with a Teflon type material of the cannula 14. According to the present invention there may be one stimulus delivery portion 18 for example the embodiment of Figure 6b and 6c alternatively

there may be a plurality of stimulus delivery portions 18 substantially extending along the length of the cannula 14 for example the embodiment of Figure 6a. In use the NeuroStimulator engaging portion 12 is inserted into the probe connector port(s) 38 of the NeuroStimulator 22 and an electrical current can be created by the NeuroStimulator 22 which will pass from the NeuroStimulator 22, along the cable 2 and through the probe 13 and the cannula 14. The stimulus deliver portion 18 of the cannula 14 acts to transmit electrical current from the NeuroStimulator 22 to stimulate subcutaneous and cutaneous nerves and nerve ends in the tissue in the target area 21, no electrical impulse will pass through areas of the cannula 14 that are insulated with a Teflon® type material. The cannula has a cap 20 that is preferably made from a plastics material. Alternatively, the cap may be made from the same material as the cannula body 15. The cannula cap 20 provides an area in which the end user can touch the cannula 14 to ensure that it is secured over the probe 13 without contaminating the working area (body) of the cannula.

The length of the probe 1 or probe 13 and cannula 14 can vary and are typically in the region of about 10mm to about 200mm long such as about 25mm to about 170mm long, for example about 50mm to about 150mm long and the gauge in the region of about 15 to about 30 gauge, such as about 18 to about 25 gauge for example about 20 to about 22 gauge. The length and gauge of the probe 1 and probe 13 with cannula 14 will be selected by the end user and will correspond with the size of the area to be treated.

In one embodiment of the present invention illustrated in Figures 1, 2 and 3 the cannula and probe 1, and cable 2 are permanently connected to form one disposable device. Whereas in a further embodiment such as that illustrated in Figures 5 and 6, the cannula 14 is a separate sleeve which may be releasably attached to the probe 13. This embodiment allows the cannula 14 to be replaced in instances where it would not be desirable to reintroduce the cannula 14 into the target area 21 such as when the treatment area is located on the scalp of a

patient where the risk of transferring infection into the target area 21 is high. In the device of this embodiment the probe 13 is reusable only in that when covered by the cannula 14 it can be inserted into multiple treatment sites, each time with a new sterile cannula 14, in the same or different target areas 21 but always on the same patient as the probe 13 itself may not be sterilised.

In use, the probe 1 is introduced subcutaneously along a previously determined target area 21. The NeuroStimulator engaging portion 12 is connected to the NeuroStimulator 22 via the probe connector port(s) 38, the treatment parameters are selected and the NeuroStimulator 22 set accordingly and the therapy is administered. The therapy may be administered a number of times.

Figures 10 and 10a illustrate a specific embodiment of the front, base and side view of a PENSt NeuroStimulator 22 in which the control panel 24 is a membrane keypad which may be accessed intra operatively using a transparent sterile disposable cover much like Op-Site known by a person skilled in the art (not shown). The PENSt NeuroStimulator 22 may have a casing 23 with dimensions of approximately about 240mm W x about 200mm H x about 50mm D with a stand 43 inset into the underside of the casing 23 so that the NeuroStimulator 22 can be angled at approximately about 45 degrees making the control panel 24 easy to operate and monitor. Non-slip padding 42 is built into the stand 43 to secure the NeuroStimulator 22 in position while in use. On the side of the NeuroStimulator 22 would be an inset ON/OFF switch 40 and a mains port 41

The control panel 24 has digital display windows 25, 26, 27, 29 and 30 which display the treatment parameters which parameters are selected using the keypads 31, 32, 33, 35 and 37 to customise the therapy to the indication being treated. The start/stop key 36 initiates a treatment session and is backlit while a therapy is being administered. The test key 34 is backlit when the NeuroStimulator is performing a system integrity test. The system mode digital display window 28 displays the current status of the NeuroStimulator 22, for

example, while performing an integrity test it will display "Test Mode", while delivering a therapy it will display "In Use mode", when ready to begin a therapy it will display "Ready Mode" and while resetting to default it will display "- - -" The end user can select the wave form using the wave form selector keys 31, the duration of the therapy through the timer keys 35 (the default is about 120 seconds and the time is increased or decreased in increments of about 10 seconds), the voltage through the voltage adjuster keys 37 (the default is about 2 Volts) and frequency through the Pulse Rate adjuster 33 keys (the default is about 2Hz) and Pulse Width adjuster keys 32 A typical treatment session may include a first session with a specific set of parameters and a second session with a different set of parameter and a typical treatment would include a first session using one wave form and a second session using the other wave form so that a complete treatment session included stimulation using both wave forms.

In use, Therapy selection would include:

(i) either a "balanced biphasic with negative leading pulse" and / or a "square wave form";

(ii) a pulse rate of either about 2, about 5, about 10, about 40, about 50 or about 70Hz;

(iii) a duration of the therapy, normally from about 60 to about 600 seconds

(iv) a pulse width of either about 1.0mSec or about 2.0mSec

(v) a voltage of about 0.00 to about 3.00 volts. Typically about 2.00 volts. Adjusts in increments of about 0.1 volts

In use, the target allodynic area 21 is mapped by using a combination of cotton wool stimuli to the affected area with a comparator normal body part and to the hyperalgesic area using pin prick stimuli in the same manner. This method will identify the areas of greatest allodynia and hyperalgesia.

The area 21 is then covered with a transdermal local anaesthetic such as Emla and 30 minutes is allowed for local anaesthetic to take effect.

A suitable PENSt Probe(s) 1 or 13 with attached cannula 14 is selected based on the size of the identified target treatment area 21. Larger areas may require the use of 2 probes simultaneously as described in Figure 9. The probe(s) 1 or 13 with 14 is then placed on the skin over the target area 21 and the probe entry point (X in Figures 8) is marked such that stimulus deliver portions 4 or 18 fall within the target area 21 when the probe(s) 1 or 13 with 14 is inserted into the tissue up to 3 as in Figures 1, 2 and 3 or 17 as in Figure 6.

The PENSt probe(s) 1 or 13 with 14 is introduced percutaneously at the marked entry point (X) and tunnelled subcutaneously along the centre of the previously mapped target area 21.

The connector assembly of a Diathermy Pad (standard item not shown) is connected to the PENSt NeuroStimulator 22 via the return port 39 and then placed on the patients skin an appropriate distance from the treatment area 21. The cable 2 extending from the probe(s) 1 or 13 with 14 is attached to the PENSt NeuroStimulator 22 through the NeuroStimulator engaging portion 12 and the probe connector port(s) 38 and the desired parameters are set to begin the therapy session. The Start Key 36 is disabled until the NeuroStimulator 22 has successfully performed a system integrity test.

Once the desired parameters have been selected and the probe(s) 1 or 13 with 14 is positioned, the test key 34 is pressed. The NeuroStimulator 22 performs a system integrity test to ensure a complete circuit, at this time the System Mode digital display window 28 will display "Test Mode" and all other keys are disabled. Once the test has been successfully completed (just a few seconds) the System Mode digital display window 28 will display "Ready Mode". If the test fails due to a broken circuit etc. the system mode digital display window 28 will display "Test Failed" and all connections will have to be checked. The start key 36 will not be enabled until a successful test has been done completed prior to each new

session. Pressing start/stop key 36 begins the therapy. Start/stop Key 36 will light up indicating therapy delivery and the System Mode digital display window 28 will display "In Use" and all treatment parameter keys are disabled. The Timer digital display window 29 will count down from the preset time to zero and then automatically stop. The backlight on Start/stop key 36 will go off when the timer display window 29 displays "000". The System Mode digital display window 28 will then briefly display " - - - " during which time all keys are disabled. It will then display "Ready Mode". Pressing the start/stop key 36 at any time during therapy delivery will stop the therapy session. The System Mode window 28 will display "Aborted" for a few seconds and then "Ready". An aborted therapy session can not be re-started midway. A new session would be delivered. A few seconds after a therapy session has been completed the control panel 24 will reset to the default settings.

Typically, therapy continues for a period of about 2 to about 10 minutes and uses a frequency in the range from about 2Hz to about 70Hz and a selected wave form, depending on the indication. Once the therapy has completed the probe(s) 1 or 13 with 14 is removed. A steristrip closes the needle entry point and the patient goes home. This therapy is repeated at intervals based on patient response.

The successful patient will report significant if not total pain relief for a period. This period varies from patient to patient and could be months, future treatment sessions are based on the outcome of the initial session.

Further embodiments of the invention are now described with reference to figures 11-19. With reference to the probe assembly units in Figures 11a, 12a, 13a, 11b, 12b, 13b, 11c, 12c 13c, 11d, 12d and 13d where a probe 101 comprises an electrically conductive elongate body with a first end 102 and a handle assembly 106 which retains a second end 103 and a stimulus delivery portion 104 between the first 102 and second 103 ends. In one embodiment the first end 102 of the

probe 101 comprises a sharp tip 105 to assist in piercing the skin when inserting the probe 101 percutaneously into the target area 121 so that at least the stimulus delivery portion 104 is located in the target area 121. In some embodiments the sharp tip 105 will be a closed end. The handle assembly 106 further comprises a probe retaining portion 107 and a first cable-retaining portion 108. A cable 109 comprising a first end 109a and a second end 109b is connected to the probe 101 through its first end 109a, which is located in the cable retaining portion 108 of the handle 106. The second end 109b is retained in a connector 110. The connector 110 comprises a second cable-retaining portion 111 and a dual intermediate cable 10 engaging portion 157. The engaging portion 157 and second cable retaining portion 111 form the second end 158 of the probe cable 109. The engaging portion 157 fits into the dual intermediate cable 110 as shown by the arrow.

The probe 101 has an elongate body and is preferably substantially cylindrical in shape however it is also possible to have probes of different shapes for example a fork-shaped probe with a plurality of tines or a probe shaped in accordance with the topology of the nerves to be treated for example the probe may comprise at least one branch and the branch(es) may be curved and of different lengths and shapes. The probe(s) 101 is made from an electrical conductive material so that an electrical current can travel from the NeuroStimulator 122 through the dual intermediate cable 110 and the probe cable 109 and along the probe(s) 101. It is desirable that the body of the probe(s) 101 are substantially rigid so that they can be easily manipulated and inserted through the skin. The probe(s) 101 body is also substantially flexible so that the probe can be manipulated to contour different anatomical sites without affecting (altering) the functionality of the probe(s) 101. The body of the probe 101 is flexible enough so that the probe is rigid enough to penetrate the skin and subcutaneous tissue of a subject whilst having enough pliability to tunnel and turn into and through the subcutaneous tissue to the desired location. In use, the handle assembly 106 of the probe is retained in the palm of the users hand with the users fingers gripping the handle

assembly 106 such that the finger tips abut the palm of the hand. Insertion and tunneling of the probe 101 into the subject/patient is effected by the wrist movement of the user.

Figure 19 illustrates the flexibility of the various embodiments of the probes of the invention; for example 1, 101. A probe is normally in a substantially vertical alignment (figure 19a). The body of the probe 1, 101 is constructed by a material that is pliable enough for the body of the probe to be bent in a desired configuration using manual strength (figure 19b dotted line). The body of the probe 1, 101 is made of a resiliently deformable material such that the body remains in the bent orientation (permanently bent) (reversibly fixed disposition) (figure 19c). In use the probe 1, 101 body is bent into the desired configuration prior to insertion into a subject. An example of a suitable material for the probe(s) 1, 101 body is stainless steel. It will be apparent to a person skilled in the art however that alternative materials possessing the desired characteristics (strength, flexibility, electrically conductive and the like) may also be used in the construction of the probe(s) 1, 101 body.

The length of the probe(s) 101 will vary depending on the area to be treated for example for a treatment area wherein the largest dimension is about 6cm, an about 5cm long probe can be employed. Typically the length of the probe(s) 101 will be between about 1cm to about 30cm or about 1cm to about 25cm for example about 3cm to about 25cm or about 3cm to about 20cm, such as about 5cm to about 20cm or about 5cm to about 15cm. However, when the target area 121 is large it is possible to insert more than one probe 101 into the target area (area to be treated) 121 to obtain the desired effect. The NeuroStimulator can accommodate either 1 or 2 probes at the same time through probe connector port(s) 138. In one embodiment the NeuroStimulator can accommodate 1 or more probes 101 for example two or three probes at the same time through the probe connector ports 138.

The probe retaining portion 107 acts to securely retain the probe 101 in the handle assembly 106. Typically the probe retaining portion 107 or the handle assembly 106 comprises a connection assembly between the probe 101 and the cable 109 such as at the position where the strands from within the cable 109 connect to the probe 101. Desirably the probe retaining portion 107 is constructed from a non-electrical conducting material such as a hard plastic material. In an alternative embodiment, the probe retaining portion 107 is constructed from an electrical conducting material such as stainless steel or the like. Preferably, the probe retaining portion 107 is constructed from the same material as the probe body. The probe retaining portion 107 abuts the handle assemble 106 which in turn abuts the first cable retaining portion 108. The handle assembly 106 is desirably constructed from a non-electrical conducting material such as a hard plastics material. The first cable retaining portion 108 is desirably constructed from a non-electrical conducting material such as a plastic material (for example hard or soft plastics) or rubber material. The first cable retaining portion 108 and the probe retaining portion 107 lie adjacently to the connection assembly 106. Preferably the handle assembly 106 is substantially rigid [hard plastic] so that it can withstand the external forces applied to it when the probe 101 is inserted into the target area 121. Desirably the handle assembly 106 has a non-slip grip to assist the end user when inserting the probe 101. Typically the handle assembly 106 will be constructed so that it is easy to hold and manipulate the position of the probe 101.

The cable 109 connects the probe 101 to the dual intermediate cable 110 which in turn connects to the NeuroStimulator 122 through the neurostimulator engaging portion 112 The second end of the cable 9b is housed in the second cable retaining portion 111. The second cable retaining portion forms part of the connector 116 where the conductive strands run through the cable 109 and are connected to the pins 112b in the NeuroStimulator engaging portion 112. The pins 112b in the NeuroStimulator engaging portion 112 mate with the holes in the probe connector port(s) 138 of the NeuroStimulator 122. In an alternative

embodiment, the second cable retaining portion 111 forms part of the connector 116 where the conductive strands running through the cable 109 terminate in a three pin engaging portion 112 of the connector 116. A three pin connector 110a in the dual intermediate cable 110 mates with the engaging portion 112 of connector 116. The dual intermediate cable 110 has a second end 110b. The second end 110b has a four pin connector which mates with the probe connector port(s)

To further secure the attachment of the NeuroStimulator engaging portion 110b to the probe connector port(s) 138 there is a snap lock mechanism 110c built into the NeuroStimulator engaging portion 110b. In one embodiment the snap lock mechanism may be built into the NeuroStimulator engaging portion 110b of the dual intermediate cable 110. The second cable retaining portion 11 is desirably constructed from a non-electrical conducting material such as a hard or soft plastic or rubber material. Typically, the cable 109 is approximately about 2m to about 0.5m long such as about 1.5m to about 0.7m long for example about 1.2m to about 1m long to facilitate maintaining a sterile field at the patient while being connected to the NeuroStimulator 122 through the NeuroStimulator engaging portion 112 or dual intermediate cable 110. The NeuroStimulator engaging portion 110c is preferably a plug wherein the external surface comprises a non-electrical conducting material such as a hard plastics material and the internal dimensions (of the NeuroStimulator engaging portion 112) are configured to mate with the corresponding area (probe connector ports 138) of the NeuroStimulator 122 for example like a plug and socket. The interior of the NeuroStimulator engaging portion 110b comprises an electrical conducting means so that the electricity can be transferred from the NeuroStimulator 122 to the probe 101. The exterior of the NeuroStimulator engaging portion 112 includes a "snap-lock" type mechanism 112a which secures the NeuroStimulator engaging portion 110c into the probe connector port(s) 138. The NeuroStimulator engaging portion 112 is adjacent to the second cable engaging portion 110a.

The length of the probe 1 or probe 13 and cannula 14 can vary and are typically in the region of about 10 mm to about 300mm long, such as about 10mm to about 200mm long such as about 25mm to about 170mm long, for example about 50mm to about 200mm long more especially about 50mm to about 150mm or about 200mm long. The gauge (thickness or outside diameter) of the probe may be in the region of about 15 to about 30 gauge (about 0.305mm to about 1.82 mm), such as about 18 to about 25 gauge (about 0.51mm to about 1.24mm) for example about 20 to about 22 gauge (about 0.71mm to about 0.89mm) for instance about 21 gauge (about 0.81mm). Suitably the elongate body has a thickness in the range from about 0.75 to about 0.85 mm. The length and gauge of the probe 1, 101 and probe 13 with cannula 14 will be selected by the end user and will correspond with the size of the area to be treated.

The return electrode cable 147 has a return electrode pad connector end 148, a NeuroStimulator connector end 146 and a cable 152. Cable 152 has a first end 152a and a second end 152b. First end 152a is connected to the electrode pad connector end 148 through the cable retaining portion 151. Second end 152b is connected to the NeuroStimulator connector end 146 through the cable retaining portion 150. The Electrode pad connector end 148 has a universal crocodile clip for attaching an industry standard return electrode pad. The NeuroStimulator engaging portion 120 is connected to the NeuroStimulator 122 via the return electrode connector port 139.

In use, the probe 101 is introduced subcutaneously along a previously determined target area 121. The NeuroStimulator engaging portion 112 or the NeuroStimulator engaging portion 110c of the dual intermediate cable 110 is connected to the NeuroStimulator 122 via the probe connector port(s) 138, and to the probe(s) 101 via the second cable retaining portion 110a. The NeuroStimulator engaging portion 120 of the return electrode cable 147 is connected to the NeuroStimulator 122 via the return electrode port 139. The return electrode pad connector 148 is attached to a return electrode (not shown)

and the return electrode pad is placed at the appropriate site on the patient. The treatment parameters are selected and the NeuroStimulator 122 (set accordingly) and the therapy is administered. The therapy may be administered a number of times.

The NeuroStimulator is a transportable desktop device which may be moved from one location to another between periods of use. The user interface controls and displays the stimulation parameters.

Figures 20 and 20a illustrate a specific embodiment of the front, base and side view of a PENSt NeuroStimulator 122 in which the control panel 124 is a PCB based, backlit membrane keypad which may be accessed intra operatively using a transparent sterile disposable cover much like Op-Site known by a person skilled in the art (not shown). The PENSt NeuroStimulator 122 may have a casing 123 with dimensions of approximately about 302mm or about 240mm W x about 125mm or about 200mm H x about 272mm or about 50mm D. In one embodiment, a stand 143 may be inset into the underside of the casing 123 so that the NeuroStimulator 122 can be angled at approximately about 45 or about 20 degrees making the control panel 24 easy to operate and monitor. Non slip padding 142 is built into the stand 143 to secure the NeuroStimulator 122 in position while in use. On the side or rear panel of the NeuroStimulator 122 would be an inset ON/OFF switch 140 and/or a mains port 141 and/or a printer port 156.

The control panel 124 has digital display windows 125, 126, 127, 129 and 130 which display the treatment parameters which parameters are selected using the keypads 131, 132, 133, 135 and 137 to customise the therapy to the indication being treated. The start/stop key 136 initiates a treatment session and is backlit yellow while a therapy is being administered. The test key 134 is backlit yellow when the NeuroStimulator is performing a system integrity test. The system mode digital display window 128 displays the current status of the

NeuroStimulator 122, for example, while performing an integrity test it will display "Test Mode", test error messages displayed are "Test Failed Internal Fault" and "Test Failed External Connections", while delivering a therapy it will display "In Use mode" or "In Use" and if a fault is detected during stimulus delivery the messages "ABORTED External Connection Failed" or "ABORTED Max Current Exceeded" will be displayed, if the stimulus delivery is interrupted by the user "ABORTED" will be displayed. When ready to begin a therapy it will display "Ready Mode" or "Ready Initiate Test" and while resetting to default it will display "- - -". When prompting for a print report "Print Duplicate START/STOP to Print TEST to Continue" will be displayed. The end user can select the wave form/program using the wave form/program selector keys 131. There are three program options A, B and C, program C is the default program. The duration of the therapy is set through the timer keys 135 (the default is about 120 to about 240 seconds and the time is increased or decreased in increments of about 10 seconds). Program A and B duration range is from about 10 to about 1800 seconds. Program C is set at about 1200 seconds and can not be altered by the user. Therapy duration for programs A or B is increased or decreased in increments of about 1 seconds by pressing either of the left or right arrow keys 135 and ramps continuously if pressed for longer than about 1 second. The voltage is selected through the voltage adjuster keys 37 (the default is about 2 Volts). The range for program A and B is about 0.2 to about 3 Volts. Program C is set at about 2 Volts. The voltage is increased or decreased for programs A or B in increments of about 0.1 volts by pressing either of the keys 137 and ramps continuously if pressed for more than about 1 second. The frequency is selected through the Pulse Rate adjuster keys 133 (the default is about 2Hz). Program A and B range from about 2Hz to about 100Hz and is increased or decreased in increments of about 1Hz by pressing either of the keys 133 and ramps continuously if pressed for longer than about one second. Program C automatically alternates between about 2 to about 100Hz. The Pulse Width is selected through the adjuster keys 132. The pulse width range for program A is about 0.2mSec to about 0.25mSec. The default is set at about 0.2mSec. The

pulse width range for program B is about 1.0mSec to about 0.2mSec. The default for program B is set at about 0.1mSec. Program C has a pulse width that alternates between about 0.2mSec and about 1.0mSec. A typical treatment session may include a first session with a specific set of parameters for example program A and a second session with a different set of parameters for example program B and a typical treatment session would include a first session using one wave form such as program A and a second session using the other wave form such as program B or program C so that a complete treatment session included stimulation using both wave forms such as programs A and B, or program C only.

Modes of Operation

Parameter	User Range	Default
Program A - Constant High or Low Frequency Programme		
Wave Form: Square wave positive voltage pulse for the user set time value, followed by a brief pause, followed by an immediate negative voltage pulse of lower amplitude, with an immediate long sloping trailing edge		
Timer	10 — 1800seconds	240sec
Pulse Duration	0.20, 0.25mSec	0.20mSec
Pulse Rate	2 — 100Hz	100Hz
Voltage	0.2 — 3Volts	2V
Program B - Constant High or Low Frequency Programme		
Wave Form: Square wave positive voltage pulse for the user set time value, changing immediately to a square wave negative pulse of the same voltage for the user set time value again, with a short sloping trailing edge		
Timer	10 — 1800seconds	240sec
Pulse Duration	1.0, 2.0mSec	1.0mSec
Pulse Rate	2 — 100Hz	2Hz
Voltage	0.2 — 3Volts	2V

Program C – A continuous alternating of 2 sets of parameters. Lock out on user adjustable settings.		
Wave Form: Cycle A) Square wave positive voltage pulse for the user set time value, followed by a brief pause, followed by an immediate negative voltage pulse of lower amplitude, with an immediate long sloping trailing edge alternating at about 3 second intervals with, Cycle B) Square wave positive voltage pulse for the user set time value, changing immediately to a square wave negative pulse of the same voltage for the user set time value again, with a short sloping trailing edge.		
	Cycle A	**Cycle B**
Timer	3 Sec (alternating with Cycle B for a total of 1200 seconds)	3 Sec (alternating with Cycle A for a total of 1200 seconds)
Pulse Duration	0.20mSec	1.0mSec
Pulse Rate	100Hz	2Hz
Voltage	2V	2V

In use, Therapy selection would include:

(vi) either a "balanced biphasic with negative leading pulse" and / or a "square wave form";

(vii) a pulse rate of either about 2, about 5, about 10, about 40, about 50 or about 70Hz;

(viii) a duration of the therapy, normally from about 60 to about 600 seconds

(ix) a pulse width of either about 1.0mSec or about 2.0mSec

(x) a voltage of about 0.00 to about 3.00 volts. Typically about 2.00 volts. Adjusts in increments of about 0.1 volts

Such as:

either program A — having a square wave positive voltage pulse for the user set time value, followed by a brief pause, followed by an immediate negative voltage pulse of lower amplitude, with an immediate long sloping trailing edge having as [?] (Figure 11a); a pulse rate with a user range of between about 2 and about 100Hz, default being about 100Hz; a duration of the therapy with a user range from about 10 to about 1800 seconds, default being about 1200 seconds; a pulse width with a user range of either about 0.2mSec or about 0.25mSec, default being about 0.2mSec; a voltage with a user range from about 0.2 to about 3Volts, default being about 2Volts;

(i) Program B — having a square wave positive voltage pulse for the user set time value, changing immediately to a square wave negative pulse of the same voltage for the user set time value again, with a short sloping trailing edge (see Figure 11b) having a pulse rate with a user range of between either about 2 to and about 5, about 10, about 40, about 50 or about 1070Hz, default being about about 2Hz; a duration of the therapy with a user range , normally from about 610 to about 1800 seconds; default being about 1200 seconds; a pulse width with a user range of either about 1.0mSec or, or about 2.0mSec, about 0.2mSec or about 0.25mSec, default being about 1.0mSec; or

(ii) a voltage with a user range of about 0.200 to about 3.00 vVolts, default being typically about 2.00 vVolts. Adjusts in increments of about 0.1 volts; or

(iii) Program C – which is the default program and it has no user adjustable ranges. Program C is the continuous alternating / cycling between Program A at the default settings with and Program B at the default settings. Program A and Program B Cycling / alternating every about 3 seconds for a total therapy duration of about 1200 seconds.

In use, the target allodynic area 121 is mapped by using a combination of cotton wool stimuli to the affected area with a comparator normal body part and to the hyperalgesic area using pin prick stimuli in the same manner. This method will identify the areas of greatest (primary) allodynia and hyperalgesia.

The area 121 is then covered with a transdermal local anaesthetic such as Emla and 30 minutes is allowed for local anaesthetic to take effect or alternatively a small amount of local anesthetic is injected into the probe entry site.

A suitable PENSt Probe(s) 101 is selected based on the size of the identified target treatment area 121. Larger areas may require the use of 2 probes simultaneously as described in Figure 17. The probe(s) 101 is then placed on the skin over the target area 21 and the probe entry point (X in Figures 15-17) is marked such that stimulus deliver portions 104 fall within the target area 121 when the probe(s) 101 is inserted into the tissue up to 103 as in Figures 11, 12 and 13 or 117 as in Figure 16.

The PENSt probe(s) 101 is introduced percutaneously at the marked entry point (X) and tunnelled subcutaneously along the centre of the previously mapped target area 121.

The connector assembly 113 of a Diathermy Pad (standard item not shown) or return electrode cable 147 is connected to the PENSt NeuroStimulator 122 via the return port 139. In the embodiment with the return electrode cable 147, the return electrode cable 147 has a second end 148 which is a universal clip for attaching to a return electrode pad (standard item not shown) which is then placed on the patients skin an appropriate distance from the treatment area 121. The engaging portion 112 of the cable 109 extending from the probe(s) 101 is attached to the PENSt NeuroStimulator 122 through the NeuroStimulator engaging portion 112 and the probe connector port(s) 138 or the dual

intermediate cable 110 through the engaging portion 110a which in turn is attached to the PENSt Neurostimulator 122 through the NeuroStimulator engaging portion 110c and the probe connector ports 138. The desired parameters are set to begin the therapy session. The Start/Stop Key 136 is disabled until the NeuroStimulator 122 has successfully performed a system integrity test.

Once the desired parameters (program and program parameters) have been selected and the probe(s) 101 or 113 with 114 is positioned, the system mode window 128 displays "ready initiate test". The test key 134 is pressed and the NeuroStimulator 122 performs a system integrity test to ensure a complete circuit, at this time the System Mode digital display window 128 will display "Test Mode" and all other keys are disabled. Once the test has been successfully completed (just a few seconds) the System Mode digital display window 128 will display "Ready Mode" or "Ready Start Treatment". If the test fails (due to a broken circuit etc.) the system mode digital display window 128 will display "Test Failed" or "test failed internal fault" or "test failed external connections". All connections will have to be checked. The start/stop key 136 will not be enabled until a successful test has been completed prior to (at the start of) each new session. Pressing the start/stop key 136 begins the therapy. Start/stop Key 136 will light up (illuminate) indicating therapy delivery or stimulus output and the System Mode digital display window 128 will display "In Use" and all treatment parameter keys are disabled at this time. The Timer digital display window 129 will count down from the preset time to zero and then automatically stop (terminate stimulus delivery). If the printer (optional, not shown) is connected via the printer port 156, the NeuroStimulator 122 will send the printer an automatic print command. The System Mode window will display "Print Duplicate Start/Stop to Print Test to continue", additional printouts may be requested at this time only. Additionally the printout indicates the therapy parameters delivered.

The backlight on the Start/stop key 136 will go off (out) when the timer display window 129 displays "000". The System Mode digital display window 128 will then briefly display " - - - " while resetting to default during which time all keys are disabled. It will then display "Ready Mode" or "ready initiate test". Pressing the start/stop key 136 at any time during therapy delivery (stimulus output) will stop the therapy session (immediately terminate stimulus output). An automatic printout is also printed at this time indicating the parameters actually delivered for the interrupted session. The System Mode window 128 will display "Aborted" for a few seconds and then "Ready" or "ready initiate test". An aborted therapy session can not be re-started (re-initiated) midway. A new therapy session would be delivered (initiated). A few seconds after a therapy session has been completed the control panel 124 will reset to the default settings.

Typically, therapy continues for a period of about 2 to about 10 or about 4 to about 30 minutes and uses a frequency in the range from about 2Hz to about 70Hz or about 100Hz or alternating frequencies and a selected wave form (Figures 21a and 21b), depending on the indication. Once the therapy has completed the probe(s) 101 or 113 with 114 is removed. A steristrip closes the needle entry point and the patient goes home (as directed by the physician). This therapy is repeated at intervals based on patient response.

The successful patient will report significant if not total pain relief for a period. This period varies from patient to patient and could be months, future treatment sessions are based on the outcome of the initial session.

Examples

The invention will be more clearly understood with reference to the following Examples:

EXAMPLE 1 - Post Mastectomy Pain

The most commonly cited theory of chronic postoperative pain in breast cancer patients is the intentional sacrificing of the intercostobrachial nerves. These sensory nerves exit through the muscles of the chest wall, and provide sensation predominantly to the shoulder and upper arm. Because these nerves usually run through the packet of lymph nodes in the armpit, they are commonly cut by the surgeon in the process of removing the lymph nodes.

Symptoms are described as burning, tingling, itching, or frank lancinating pain. In a small percentage of patients, chronic pain results, and the painful symptoms persist. The symptoms may be present almost continually, or they may occur in response to changes in physical activity or temperature. They may also be exacerbated by physical contact with the affected area i.e. the surgical scar, chest wall, breast, axilla and or ipsilateral upper extremity.

The incidence of chronic pain syndromes following breast cancer treatment has been estimated to occur in about 20-25% of patients undergoing axillary (armpit) dissection, with or without mastectomy. Additional factors linked to breast cancer-associated chronic pain syndromes include polyneuropathies caused by chemotherapy and radiation therapy, which may be additive to impairments caused by surgery.

It is well known that a percentage of post mastectomy patients present with areas of hyperalgesia and allodynia .

The treatment area

The area of greatest (primary) hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. We map out the areas of greatest (primary) hyperalgesia or when the areas of primary hyperalgesia have been identified, the

Probe is placed in the middle of that field such that the electrically conductive portion of the probe lies across the middle of the identified area.

In the case of Post Mastectomy pain the area of primary hyperalgesia is usually associated with the surgical scar, in this case the probe is positioned just above or below the scar in a manner such that it is parallel to the scar. If the scar not a straight line the probe is manually manipulated to mimic the shape of the scar and then inserted to follow this line.

Current treatment options

Anti-inflammatory agents (e.g., ibuprofen, naproxen, and other *NSAIDs*), low doses of antidepressant medications (e.g., Elavil, Pamelor, and the SSRI-class of drugs, including Zoloft) can often be very helpful, although these agents must be taken consistently for several weeks to attain the greatest benefit. Unfortunately, narcotics are relatively ineffective against established chronic neuropathic pain, and the risk of narcotic dependency is very high when used in this setting. Topical counterirritants, such as capsaicin and mentholated creams, are useful in some cases, although their overall efficacy has been rather poor in most studies. Patients with longstanding and severe chronic postoperative pain syndromes, and patients with RSD following surgery in particular, present a very difficult dilemma for both patient and physician. Many such patients eventually become dependent on ever-increasing doses of narcotics to control their symptoms, and occasionally with tragic results. For patients with these very refractory and debilitating chronic pain syndromes, a combination of interventions may provide at least some relief from symptoms. Thoracic sympathectomy may provide relief, although there are some significant risks involved with such procedures. Intermittent or continuous injections of anaesthetic and/or corticosteroids into the space around the spinal cord may also be effective. Medication e.g. amitriptylene, gabapentin, carbamazepine, clonodine, opioids, a pain management program and cognitive behaviour therapy.

PENSt

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 2 to about 10 or about 20 minutes of stimulation at a typical frequency of about 2Hz using program A or B selected by the user although a therapeutic treatment range could vary from about 2Hz to about 70Hz or about 100Hz or use Program C. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good (>50%) but did not extend beyond about 2 or about 4 weeks would be offered alternative treatment options such as a permennantly implanted continuous stimulation therapy. The PENSt procedure in this instance acts as the diagnostic tool.

Our patients (patients audited to date) report 80% -100% pain relief for periods of between about 1 and > about 90 days.

EXAMPLE 2 - Neuropathic Chest Wall Pain

Description of the condition

Chronic pain post surgery or an existing medical condition i.e. infection, cystic fibrosis etc. causes pain and second respiratory function reduction

The treatment area

Area of greatest (primary) hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. We map out the areas of greatest hyperalgesia. Once the area of greatest hyperalgesia has been identified we place the Probe in the middle of that field such that the electrically conductive portion of the probe lies across the middle of the identified area.

In the case of Post Surgical pain the area of greatest hyperalgesia is usually associated with the surgical scar, in this case the probe is positioned just above or below the scar in a manner such that it is parallel to the scar. If the scar not a straight line the probe is manually manipulated to mimic the shape of the scar and then inserted to follow this line.

Current treatment options

Medication e.g. amitriptylene, gabapentin, carbamazepine, clonodine, a pain management program and cognitive behaviour therapy. Opioids are not an option as may interfere with respiratory function

PENSt

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two

electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Our patients (patients audited to date) report 80% -100% pain relief for periods of between 1 and >90 days.

EXAMPLE 3 - Chronic Post Surgical Pain

Description of the condition

Pain which developed after a surgical procedure and is still present in excess of about 2 months post surgery

The treatment area

Area of greatest (primary) hyperalgesia, normally associated with the scar of surgery (surgical scar), or the site of a drain used at surgery. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. We map out the areas of greatest hyperalgesia (once the area of greatest hyperalgesia has been identified) and place the Probe in the middle of that field such that the electrically conductive portion of the probe lies across the middle of the identified area.

In the case of Post Surgical pain the area of greatest hyperalgesia is usually associated with the surgical scar, in this case the probe is positioned just above or below the scar in a manner such that it is parallel to the scar. If the scar not a straight line the probe is manually manipulated to mimic the shape of the scar and then inserted to follow this line.

Current treatment options

Local Anaesthetic infiltration, local nerve blockade, amitriptylene, gabapentin, carbamazepine, clonodine, a pain management program and cognitive behaviour therapy.

PENSt

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about about 2Hz to about 100Hz.

In other aspects of the invention a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool.

Our patients (Patients audited to date) report 80% -100% pain relief for periods of between 1 and >90 days.

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EXAMPLE 4 - Complex Regional Pain Syndrome (CRPS)/ Reflex Sympathetic Dystrophy (RSD)

Description of the condition

Post traumatic sensory or mixed nerve neuropathic pain, post trauma / surgery / myocardial infarct.

Complex Regional Pain Syndrome (CRPS) is a chronic pain condition. A patient with CRPS has pain as well as changes in blood flow, sweating, and swelling in the painful area. Sometimes the condition leads to changes in the skin, bones and other tissues. It may also become hard for a patient with CRPS to move the painful body part. The patient's arms or legs are usually involved, but CRPS may affect any part of the body, such as the face or trunk. In some patients, many different areas of the body are affected. CRPS can be progressive. CRPS usually develops after an injury. The injury may be to the skin, bone, joints or tissue. This type of CRPS has been called reflex sympathetic dystrophy. CRPS can also develop after any type of injury to major nerves. This type has been called causalgia. The injury that leads to CRPS may be only minor, and sometimes a patient cannot remember any injury or event that caused CRPS to start.

The treatment area

The Probe is placed in the area of primary hyperalgesia on the affected limb. The present invention accordingly provides a method of mapping the allodynic area using "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of primary hyperalgesia has been identified the Probe may be positioned such that the electrically conductive portion of the probe lies across the middle of the identified area. In non-mutually exclusive alternative

embodiments of the invention, the probe is placed in the area of greatest hyperalgesia on the affected limb.

Current treatment options

Anti-inflammatory drugs, corticosteroids, antidepressants, anticonvulsants, calcitonin, or opioids. Patients may have to take several different drugs together to get the best pain relief. Sympathetic nerve blocks - include stellate ganglion nerve blocks, lumbar sympathetic nerve blocks and Bier blocks. Phentolamine infusion, thought to have a similar effect as a sympathetic nerve block.

Some patients with CRPS have good pain relief from sympathetic nerve blocks, but the pain relief does not last long. For these patients, doctors might suggest a sympathectomy (killing the sympathetic nerves leading to the painful body part, either by using surgery or chemicals). Some patients get longer pain relief after the sympathectomy, but others do not. Also, there is the slight chance that patients who get a sympathectomy for CRPS of the leg might develop a new pain syndrome, called post-sympathectomy syndrome.

Acupuncture, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation, or dorsal column stimulation. Intraspinal infusion - morphine, can be given in low doses through the catheter.

Physical and occupational therapists can help patients with CRPS begin a program of stretching, strengthening, and aerobic conditioning. The goal of this program is to help the patient get back range of motion, strength and motor control. Physical and occupational therapists might also try treatments like warm and cold baths, ultrasound, or electric stimulation.

"Desensitization" is another important treatment that can be used to help with allodynia the patient's painful skin is rubbed with different materials, starting with soft, light textures and proceeding to rough, irritating surfaces. Gradually, the painful skin gets used to the rough textures, until the patient can easily deal with the touch of clothing, bed sheets, towels, etc.

PENS therapy

Many RSD patients get significant pain relief from SCS although there are instances where discrete areas of hyperalgesia / allodynia persist. These patients would have both an SCS implant and PENSt therapy.

Post SCS implant:

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between about 1 and > about 90 days.

In alternative embodiments of the invention (such as those shown in figures 1-9), a treatment session is about about 2 to about about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about about 2Hz to about about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool.Our patients report 80% -100% pain relief.

EXAMPLE 5 - Neuropathic Head, Neck and Facial Pain

Description of the condition

Hyperalgesic / alloynic area on head or neck

The treatment area

The Probe is placed in the area of primary hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of greatest hyperalgesia has

been identified the Probe can be positioned such that the electrically conductive portion of the probe lies across the middle of the identified area.

It may be that a combination of a) the identified area and b) access to this area, would require the probe to be manually manipulated into a shape which would allow the probe to mimic the specific anatomical contours while maintaining an appropriate probe entry point.

An alternative embodiment of the invention (for example, those shown in figures 1-9) comprises a method of mapping the allodynic area using "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. The areas of greatest hyperalgesia are mapped out and the Probe placed in the middle of that field.

Current treatment options

The treatment / management of neuropathic pain is multidisciplinary and includes a psychological assessment that is often crucial in developing strategies for pain management. Psychological variables include distress, depression, expectations of treatment, motivation to improve, and background environmental factors. Drug regimens utilise tricyclic antidepressants, anticonvulsants, and topical applications of capsaicin for intraoral pain.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm,

such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between about 1 and > about 90 days.

In alternative embodiments of the invention (such as those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool.

Patients report 80% -100% pain relief.

EXAMPLE 6 - Neuropathic Foot Pain

Description of the condition

Discreet area of pain in a distribution of a sensory nerve in the foot

The treatment area

Area of primary hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. We map out the areas of greatest hyperalgesia and place the Probe in the middle of that field. Once the area of greatest hyperalgesia has been identified the Probe can be positioned such that the electrically conductive portion of the probe lies across the middle of the identified area.

It may be that a combination of a) the identified area and b) access to this area, would require the probe to be manually manipulated into a shape which would allow the probe to mimic the specific anatomical contours while maintaining an appropriate probe entry point.

In non-mutually exclusive alternative embodiments of the invention (for example, those shown in figures 1-9), the probe is placed in the area of greatest hyperalgesia on the affected limb.

Current treatment options

Medication e.g. amitriptylene, gabapentin, carbamazepine, clonodine, a pain management program and cognitive behaviour therapy. Sympathetic nerve block, local nerve block, SCS – max 50% pain relief

PENS therapy

Some patients get significant pain relief from SCS although there are many instances where discrete areas of hyperalgesia / allodynia persist. These patients would have both an SCS implant and PENS therapy. In patients where the treatment area is discrete only PENS therapy would be used.

PENS therapy Pre or Post SCS implant:

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative

treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acting as the diagnostic tool. Patients report 80% -100% pain relief.

EXAMPLE 7 - Penile / Scrotal / Testicular Pain

Description of the condition

Focal neuropathic pain at either site

The treatment area

The Probe is positioned subcutaneously over the inguinal canal such that the electrically conductive portion of the probe is closest to the site

Current treatment options

Medication e.g. amitriptylene, gabapentin, carbamazepine, clonodine, opioids, a pain management program and cognitive behaviour therapy. Nerve Blocks.

PENS t herapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool.

Patients report 80% -100% pain relief.

EXAMPLE 8 - Post Inguinal Hernia Repair Pain

Description of the condition

Focal neuropathic pain at the site

The treatment area

The Probe is positioned subcutaneously over the inguinal canal such that the electrically conductive portion of the probe is closest to the site.

Current treatment options

Medication e.g. amitriptylene, gabapentin, carbamazepine, clonodine, opioids, a pain management program and cognitive behaviour therapy. Nerve Blocks.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and

tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In non-mutually exclusive alternative embodiments of the invention (for example, those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks

would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool. Patients report 80% -100% pain relief.

EXAMPLE 9 - Neuropathic Abdominal Wall pain

Description of the condition

It has been proposed that cutaneous nerve roots can become injured where they pass through the abdominal wall, perhaps by the stretching or compression of the nerve root along its course through the abdominal fascia. In some instances, a tight belt or other poorly fitted clothing can cause nerve root irritation, especially in physically unfit persons with protuberant abdomens. Pain also can occur in or around the abdominal wall where muscles insert on bones or cartilage. For example, the pain can occur where the rectus abdominis muscles insert on the lower ribs or where the lower ribs connect through cartilage. The xiphoid cartilage is sometimes a specific focus of pain.

Most commonly, abdominal wall pain is related to cutaneous nerve root irritation or myofascial irritation. The pain can also result from structural conditions, such as localized endometriosis or rectus sheath haematoma, or from incisional or other abdominal wall hernias. If hernia or structural disease is excluded, injection of a local anaesthetic with or without a corticosteroid into the pain trigger point can be diagnostic and therapeutic.

Pain that is the same or increased when the abdominal wall is tensed generally indicates an origin in the abdominal wall.

The mechanism for the pain may involve the development of an area of hyperalgesia as a result of myofascial stretch injury.

The treatment area

Area of primary hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of primary hyperalgesia has been identified we and position the Probe such that the electrically conductive portion of the probe lies across the middle of the identified area.

It may be that a combination of a) the identified area and b) access to this area, would require the probe to be manually manipulated into a shape which would allow the probe to mimic the specific anatomical contours while maintaining an appropriate probe entry point.

In alternative embodiments of the invention (for example, those shown in figures 1-9), the areas of greatest hyperalgesia are mapped out and the Probe placed in the middle of that field.

Current treatment options

The trigger point for abdominal wall pain can be treated with injection of a small volume of local anaesthetic. Local Anaesthetic and Steroid for more permanent relief of pain, it is often useful to inject a mixture of local anaesthetic and corticosteroid. Steroids presumably reduce inflammation or result in the thinning of connective tissue around painful nerve roots. If the correct spot is injected, the pain should be relieved immediately, but it may return in a few hours when the effects of the lidocaine wear off. Triamcinolone may take effect slowly over a day or two and then provide long-term relief. More than one injection may be required, given the hit-or-miss nature of this treatment. If reasonable care is taken, the risks associated with the injections should be minimal. Repeated injections or larger doses of the corticosteroid can cause thinning of the fascia and result in a hernia. For this reason, depot-type steroids should not be used in

the fascia. A trial of acupuncture or other alternative treatment might be considered.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool. Patients report 80% -100% pain relief.

EXAMPLE 10 - Neuropathic FBSS pain

Description of the condition

Neuropathic low back pain following back surgery e.g. post spinal fushion, discectomy

The treatment area

Area of primary hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of primary hyperalgesia has been identified we and position the Probe such that the electrically conductive portion of the probe lies across the middle of the identified area.

In the case of FBSS the area of greatest hyperalgesia is often associated with the surgical scar, in this case the probe is positioned just above or below the scar in a manner such that it is parallel to the scar. If the scar not a straight line the

probe is manually manipulated to mimic the shape of the scar and then inserted to follow this line.

In alternative embodiments of the invention (for example, those shown in figures 1-9), the areas of greatest hyperalgesia are mapped out and Probe placed in the middle of that field.

Current treatment options

Epidurals, nerve blocks, medication e.g. amitriptylene, gabapentin, carbamazepine, clonodine, opioids, a pain management program and cognitive behaviour therapy medication, SCS, Intrathecal opioids are delivered via a fully implantable device and deliver very small amounts of prescribed medication such as morphine directly into the intrathecal space, which is a protective space containing spinal fluid which bathes the spinal cord.

PENS therapy

Many patients get significant pain relief from SCS although there are instances where discrete areas of hyperalgesia / allodynia persist. These patients would have both an SCS system implanted and PENS therapy.

PENS therapy Pre or Post SCS implant:
PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of

primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool. Patients audited to date report 50% - 80% pain relief for periods between 1 and >30 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool.

Patients report 50% - 80% pain relief.

EXAMPLE 11 - Migraine

Description of the condition

Recurring intense headaches preceded by a sensory warning sign (aura), such as flashes of light, blind spots or tingling in your arm or leg. Migraines are also often accompanied by other symptoms, such as nausea, vomiting and extreme sensitivity to light and sound. Migraine pain can be excruciating and may incapacitate the sufferer for hours or even days.

The treatment area

The area of primary hyperalgesia in the occipital scalp. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of primary hyperalgesia has been identified we and position the Probe such that the electrically conductive portion of the probe lies across the middle of the identified area.

It may be that a combination of a) the identified area and b) access to this area, would require the probe to be manually manipulated into a shape which would allow the probe to mimic the specific anatomical contours while maintaining an appropriate probe entry point.

In alternative embodiments of the invention (for example, those shown in figures 1-9), the areas of greatest hyperalgesia are mapped out and the Probe placed in the middle of that field.

Current treatment options

Treatment of chronic migraine may include certain antidepressants, anti-seizure medications or cardiovascular drugs. However, even with such treatment, migraines may persist. Currently there is no cure. Medications can help reduce the frequency of migraines and stop the pain once it has started. The right medicines combined with self-help remedies and changes in lifestyle.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool. Patients report 80% -100% pain relief.

EXAMPLE 12 - Post Traumatic Cervical Neuropathic Pain

Description of the condition

Cervical neuropathic pain in the area of discrete nerve distribution

The treatment area

Area of primary hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of primary hyperalgesia has been identified we and position the Probe such that the electrically conductive portion of the probe lies across the middle of the identified area.

It may be that a combination of a) the identified area and b) access to this area, would require the probe to be manually manipulated into a shape which would allow the probe to mimic the specific anatomical contours while maintaining an appropriate probe entry point.

In an alternative embodiment of the invention (for example, those shown in figures 1-9) one method of mapping the allodynic area is to use "cotton wool"

stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. We map out the areas of greatest hyperalgesia and place the Probe in the middle of that field.

Current treatment options

Diagnostic facet joint block, nerve root block, dorsal root ganglion block, medication e.g. amitriptylene, gabapentin, carbamazepine, clonodine, opioids, a pain management program and cognitive behaviour therapy.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9), a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool. Patients report 80% - 100% pain relief.

EXAMPLE 13 - Vulvadynia

Description of the condition

Vulvadynia / Vestibulitis is pain or discomfort of the female genitalia or surrounding area. Complaints may be of pain, burning, stinging, irritation, itching, inflammation or rawness. The discomfort can be constant or intermittent. Some women will only have pain when pressure is applied to the area surrounding the entrance of the vagina or the vestibule area, caused by trauma, surgery, child birth.

The treatment area

The Probe is positioned subcutaneously over the inguinal canal such that the electrically conductive portion of the probe is closest to the site

Current treatment options

Avoidance of vulvar irritants, diet, use of oral and topical medicines, vulvar injections, and surgery although treatment of some aspects remains controversial.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9) a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool. Patients report 80% - 100% pain relief.

EXAMPLE 14 - Coccydynia

Description of the condition

Pain in the area of the coccyx (tailbone) is called coccydynia or coccygodynia. Coccydynia can be anything from discomfort to acute pain, varying between people and varying with time in any individual. The name describes a pattern of symptoms (pain brought on or aggravated by sitting), so it is really a collection of conditions which can have different causes and need different treatments.

Coccydynia can follow after falls, childbirth, repetitive strain or surgery. In some cases the cause is unknown. The pain can disappear by itself or with treatment,

or it can continue for years, and may get worse. It is five times more common in women than men, probably because the female pelvis leaves the coccyx more exposed. It appears that in most cases the pain is caused by an unstable coccyx, which causes chronic inflammation.

The treatment area

Area of primary hyperalgesia. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of primary hyperalgesia has been identified we and position the Probe such that the electrically conductive portion of the probe lies across the middle of the identified area.

It may be that a combination of a) the identified area and b) access to this area, would require the probe to be manually manipulated into a shape which would allow the probe to mimic the specific anatomical contours while maintaining an appropriate probe entry point.

In alternative embodiments of the invention (for example, those shown in figures 1-9) one method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. We map out the areas of greatest hyperalgesia and place the Probe in the middle of that field.

Current treatment options

Standard treatment is injection of an anti-inflammatory drug around the coccyx.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is about 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days.

In alternative embodiments of the invention (for example, those shown in figures 1-9) a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from

about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond about 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool. Patients report 80% - 100% pain relief.

EXAMPLE 15 - Lymphedema (post mastectomy)

Description of the condition

Whenever the normal drainage pattern in the lymph nodes is disturbed or damaged (often during surgery to remove the lymph nodes), swelling of the arm may occur. Radiation and chemotherapy may also cause swelling of the arm. This swelling of the arm, caused by an abnormal collection of too much fluid, is called lymphedema.

When the lymph nodes under the arm have been removed, a woman is at higher risk of lymphedema. Lymphedema may occur immediately following surgery, or months or years later. Not every woman who has a mastectomy will experience lymphedema.

There are several types of lymphedema. The acute, temporary, and mild type of lymphedema occurs within a few days after surgery and usually lasts a short period of time. The acute and more painful type of lymphedema can occur about 4 to about 6 weeks following surgery. However, the most common type of lymphedema is slow and painless and may occur about 18 to about 24 months after surgery.

The main symptom of lymphedema is swelling of the affected arm. The degree of swelling may vary. Some people may experience severe swelling (edema) - with the affected arm being several inches larger than the other arm, while others will

experience a milder form of edema - with the affected arm being slightly larger than the other arm.

In addition to swelling of the affected arm, the following are the most common symptoms of lymphedema. However, each individual may experience symptoms differently.

Symptoms may include:

- feeling of fullness or tightness in the affected arm
- aching or pain in the affected arm
- swelling in the hand (may be evidenced by rings that no longer fit)
- weakness in the affected arm

The treatment area

The area of primary hyperalgesia in affected arm. Our current method of mapping the allodynic area is to use "cotton wool" stimulation of the affected area with a comparator normal body part, and the hyperalgesic area using "pin prick" stimulation in the same manner. Once the area of primary hyperalgesia has been identified we and position the Probe such that the electrically conductive portion of the probe lies across the middle of the identified area.

It may be that a combination of a) the identified area and b) access to this area, would require the probe to be manually manipulated into a shape which would allow the probe to mimic the specific anatomical contours while maintaining an appropriate probe entry point.

In alternative embodiments of the invention (for example, those shown in figures 1-9), the invention is directed towards an affected arm showing an area of greatest hyperalgesia.

Current treatment options

Treatment for lymphedema depends on the severity and extent of the condition. Prevention and controlling lymphedema play an important role with this condition since there is no cure.

PENS therapy

PENS therapy is performed by a trained physician in a clinical setting only.

The generated current is delivered to the nerves and nerve endings contained within the subcutaneous tissue of a patient through the use of either one or two electrically conductive about 21 gauge disposable probe/s. The probe is percutaneously introduced from a point outside of the identified target area and tunnelled subcutaneously, at a depth ranging between about 0.5 and about 3cm, such that the electrically conductive portion of the probe crosses the major axis of the identified target area. This method enables electrical stimulation of an area of primary hyperalgesia without causing discomfort to the patient through direct penetration of this area.

In most instances, stimulation to the area can be achieved through the use of a single probe, reducing trauma to the patient, and the risks associated with multiple skin punctures.

A typical treatment session is 20 minutes of stimulation using Program C although a treatment range could be selected by the user through either Program A or B with a pulse rate range from about 2Hz to about 100Hz.

This procedure is used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was >50% but did not extend beyond about 4 weeks, would be offered alternative treatment options such as a permanently implanted, continuous stimulation

therapy. The PENS therapy procedure in this instance is an inexpensive diagnostic tool.

Patients audited to date have reported 80% -100% pain relief for periods of between 1 and >90 days and a significant reduction in swelling.

In alternative embodiments of the invention (for example, those shown in figures 1-9) a treatment session is about 2 to about 10 minutes of stimulation at a typical frequency of about 2Hz although a therapeutic treatment range could vary from about 2Hz to about 70Hz. This procedure is non-invasive and inexpensive and would be used as either a diagnostic tool or as a therapy in itself to be repeated at intervals. Unsuccessful patients i.e. responders where pain relief was good but did not extend beyond 2 weeks would be offered alternative treatment options. The PENSt procedure in this instance acts as the diagnostic tool. Patients report 80% - 100% pain relief and a significant reduction in swelling.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

The words "comprises/comprising" and the words "having/including" when used herein with reference to the present invention are used to specify the presence of stated features, integers, steps or components but does not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

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Claims

1. A probe for inserting into the subcutaneous tissue of a subject and for delivering an electrical stimulus to the subcutaneous tissue, the probe comprising:

   (i) an electrically conductive elongate body having a first free end, a second end and at least one stimulus delivery portion between the first and second ends for delivering the electrical stimulus into the subcutaneous tissue; the first end having a sharp tip for piercing the skin to allow for insertion into the subcutaneous tissue at least so far as to locate the stimulus delivery portion in the subcutaneous tissue; and

   (ii) a connector located at the second end for connecting the probe externally to the body of the subject to a means for providing electrical impulses and for transferring the electrical impulses to at least the stimulus delivery portion of the body.

2. A probe for inserting into the subcutaneous tissue of a subject and for delivering an electrical stimulus to the subcutaneous tissue, the probe comprising:

   (i) an electrically conductive elongate body having a first free end, a second end and at least one stimulus delivery portion between the first and second ends for delivering the electrical stimulus into the subcutaneous tissue; the first end having a sharp tip for piercing the skin to allow for insertion into the subcutaneous tissue at least so far as to locate the stimulus delivery portion in the subcutaneous tissue; and

   (ii) a connector located at the second end for connecting the probe externally to the body of the subject to a means for providing

electrical impulses and for transferring the electrical impulses to at least the stimulus delivery portion of the body;

the elongate body having a thickness of about 0.7 to about 0.9mm.

3. A probe as claimed in claim 1 or 2 further comprising a handle assembly for manipulating the probe.

4. A probe as claimed in claim 3 wherein the handle assembly is located at the second end of the probe and the connector extends from the handle.

5. A probe as claimed in any one of the preceding claims wherein at least one non-electrically conductive portion is provided on the body to insulate tissue in contact with the non-electrically conductive portion from the electrical stimulus.

6. A probe as claimed in any one of the preceding claims further comprising a plurality of non-electrically conductive portions spaced along the length of the probe between the first and second ends.

7. A probe as claimed in any one of the preceding claims further characterised in that the stimulus delivery portion is provided by at least two discrete portions of the body which are between insulated portions of the body which are for insulating tissue in contact with the body of the probe.

8. A probe as claimed in any one of the preceding claims wherein the stimulus delivering portion runs from the tip toward the second end for a distance greater than about 0.4 cm from the tip and for a distance of at least about 2 cm.

9. A probe as claimed in any one of the preceding claims wherein at least one non-electrically conductive portion is located at the second end.

10. A probe as claimed in any one of the preceding claims wherein the body has a plurality of sharp tips.

11. A probe as claimed in any one of the preceding claims for delivering a subcutaneous electrical stimulus in a subject for hyperpolarizing A-Beta fibres optionally in the presence of allodynia and hyperalgesia.

12. A probe according to any one of the preceding claims wherein the probe body is shaped to follow a non-linear path for example curved.

13. A probe according to any preceding claim wherein the elongate body is from about 5 cm to about 30 cm in length.

14. An electrical stimulation device comprising

a probe according to any preceding claim, operably connected to a generator for generating the electrical stimulus.

15. An electrical generator for generating an output for electrical stimulation of subcutaneous tissue and adapted to generate electrical pulses including a square wave positive voltage pulse; and a square wave negative pulse of the same voltage .

16. An electrical generator according to claim 15 having both a square wave positive voltage pulse for a user set time value, changing immediately to a square wave negative pulse of the same voltage for the user set time value, with a short sloping trailing edge and square wave positive voltage pulse for the user set time value, followed by a brief pause, followed by an immediate negative voltage pulse of lower amplitude, with an immediate long sloping trailing edge, and using alternating low and high frequency pulses.

17. An electrical generator according to Claim 15 or 16, the generator being adapted for connection to at least two probes for delivering the electrical stimulus.

18. An electrical generator according to any one of Claims 15 to 17 adapted to wherein the pulse rate is selected from about 2 to about 100 Hz.

19. An electrical generator according to any one of Claims 15 to 18 wherein the pulse rate is selected from about 0.5 to about 80 Hz.

20. An electrical generator according to any one of Claims 15 to 19 according to anyone of Claims 15 to 20 wherein the pulse width is from about 0.2mSec to about 2.0mSec.

21. An electrical generator according to any one of Claims 15 to 20 wherein the voltage ranges from about 0.2 to about 3.00 volts.

22. An electrical stimulation device comprising a probe as claimed in any one of the claims 1 to 13 and a generator as claimed in any one of claims 15 to 21 which are operably connected.

23. An electrical stimulation device comprising a probe for delivering a subcutaneous electrical stimulus in a subject operably couplable to a generator for generating an electronic stimulus the stimulus for facilitating the release of certain neuropeptides in the Central Nervous System through the use of the alternating low and high frequency stimulation and/or for hyperpolarising A-Beta fibres optionally in the presence of allodynia and hyperalgesia

24. A method of alleviating pain in a human or animal body comprising the step of delivering percutaneously to subcutaneous tissue of the body via a curved probe, an electrical stimulus to treat pain.

25. A method of alleviating pain in a human or animal body comprising the step of delivering percutaneously to subcutaneous tissue of the body, an electrical stimulus that facilitates the release of certain neuropeptides in the Central Nervous System through the use of the alternating low and

high frequency stimulation and/or causes hyperpolarisation of A-Beta fibres.

26. A method according to claim 25 wherein the electrical stimulus is delivered by a probe inserted percutaneously.

27. A method according to claim 26 wherein the electrical stimulus is delivered by a probe inserted percutaneously and along a subcutaneous path.

28. A method according to Claim 26 or 27 wherein the probe is as claimed in any one of Claims 1 to 13.

29. A method according to Claim 26 wherein the probe is inserted at an angle of less than about 45° to the body.

30. A method according to Claim 26 wherein the probe is inserted at an angle of less than about 30° to the body.

31. A method according to Claim 26 wherein the probe is inserted at an angle of less than about 25° to the body.

32. A method according to Claim 26 wherein the probe comprises a stimulus delivery portion and the probe is inserted so that the stimulus delivery portion is located within the subcutaneous tissue.

33. A method according to any one of claims 20 to 28 wherein the electrical stimulus is from a generator according to any one of Claims 15 to 21.

34. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is pulsed at a rate of between about 1 and about 110 Hz.

35. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is pulsed at a rate of between about 2 and about 100 Hz.

36. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is pulsed at a rate of about 5Hz.

37. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is pulsed at a rate of about 10Hz.

38. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is pulsed at a rate of about 40Hz.

39. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is pulsed at a rate of about 50Hz.

40. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is provided at a voltage of up to about 3.00 Volts.

41. A method according to any one of claims 24 to 33 wherein the electrical stimulus is provided for a time between about 1 and about 60 minutes.

42. A method according to any one of Claims 24 to 33 wherein the electrical stimulus is provided for a time between about 1 and about 30 minutes.

43. A method of reversibly inserting a probe into the subcutaneous tissue of a subject at an acute angle so that the probe tunnels under the skin comprising the steps:

(i) mapping the area to be treated;
(ii) covering the area to be treated with anaesthetic;
(iii) selecting a probe of suitable dimensions for the area to be treated
(iv) manually manipulating the probe to a desired curved shape
(v) marking the location of entry of the probe;
(vi) percutaneously introducing the probe at the marked entry point and tunnelling the probe subcutaneously to the area to be treated.

44. The method as claimed in claim 43, further comprising the steps of:

(vi) connecting the probe to the electrical stimulation device as claimed in any one of claims 12 to 19;

(vii) selecting the treatment parameters for the therapy; and

(viii) initiating the electrical stimulus from the electrical stimulation device.

45. The method as claimed in claim 42 or claim 43 wherein the step of mapping the area to be treated comprises pin prick or cotton wool stimulation.

46. The method as claimed in any one of Claims 42 to 44 wherein the probe is inserted into an area of hyperalgesia or allodynia.

47. The method as claimed in any one of Claims 24 to 45 wherein the indications to be treated are selected from the group comprising: post mastectomy pain; neuropathic chest wall pain; chronic post surgical pain; post surgical wound pain complex regional pain syndrome; reflex sympathetic dystrophy; neuropathic head pain; neuropathic neck pain; neuropathic facial pain; neuropathic foot pain; penile pain; scrotal pain; testicular pain; post inguinal hernia repair pain; neuropathic abdominal wall pain; neuropathic failed back surgery syndrome pain; migraine; post traumatic cervical neuropathic pain; vulvadynia; coccydynia; post mastectomy lymphedema; and combinations thereof.

48. An apparatus comprising a probe for insertion percutaneously into subcutaneous tissue and a generator for operable connection to the probe for delivering an electric signal thereto adapted to carry out a method according to any one of Claims 24 to 46.

49. A probe for inserting into the subcutaneous tissue of a subject and for delivering an electrical stimulus to the subcutaneous tissue, the probe comprising: an electrically conductive elongate body having a first free end, a second end and at least one stimulus delivery portion between the first and second ends for delivering the electrical stimulus into the subcutaneous tissue; the first end having a sharp tip for piercing the skin to allow for insertion into the subcutaneous tissue at least so far as to locate the stimulus delivery portion in the subcutaneous tissue; the electrically conductive elongate body being sufficiently pliable to allow it to be bent to a desired shape without kinking to allow it to follow a curved insertion path while sufficiently rigid to allow it to retain its desired shape during and after insertion.

50. An apparatus for use in PENS therapy comprising a probe according to Claim 49 and a generator for generating the electrical stimulus operably coupled to the probe.

51. A probe as described herein and/or with reference to Figures 1 to 9 and 19 of the drawings.

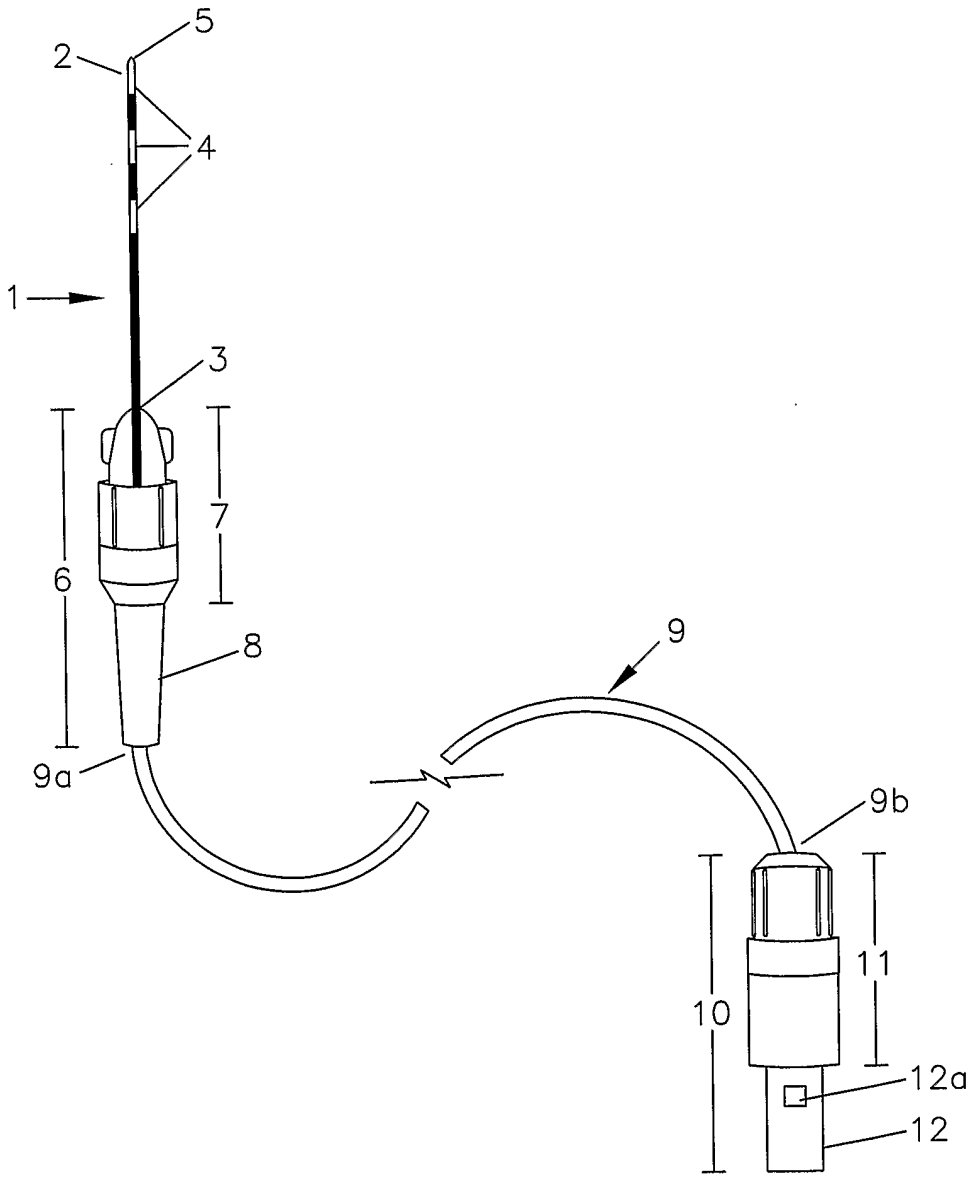
52. A probe as described herein and/or with reference to Figures 11 to 13 and 19 of the drawings.

53. An electrical generator as described herein and/or with reference to Figures 10 and 10a of the drawings.

54. An electrical generator as described herein and/or with reference to Figures 20 and 20a of the drawings.

55. A method of reversibly inserting a probe as described herein.

56. A method of alleviating pain as described herein and / or with reference to the Examples.



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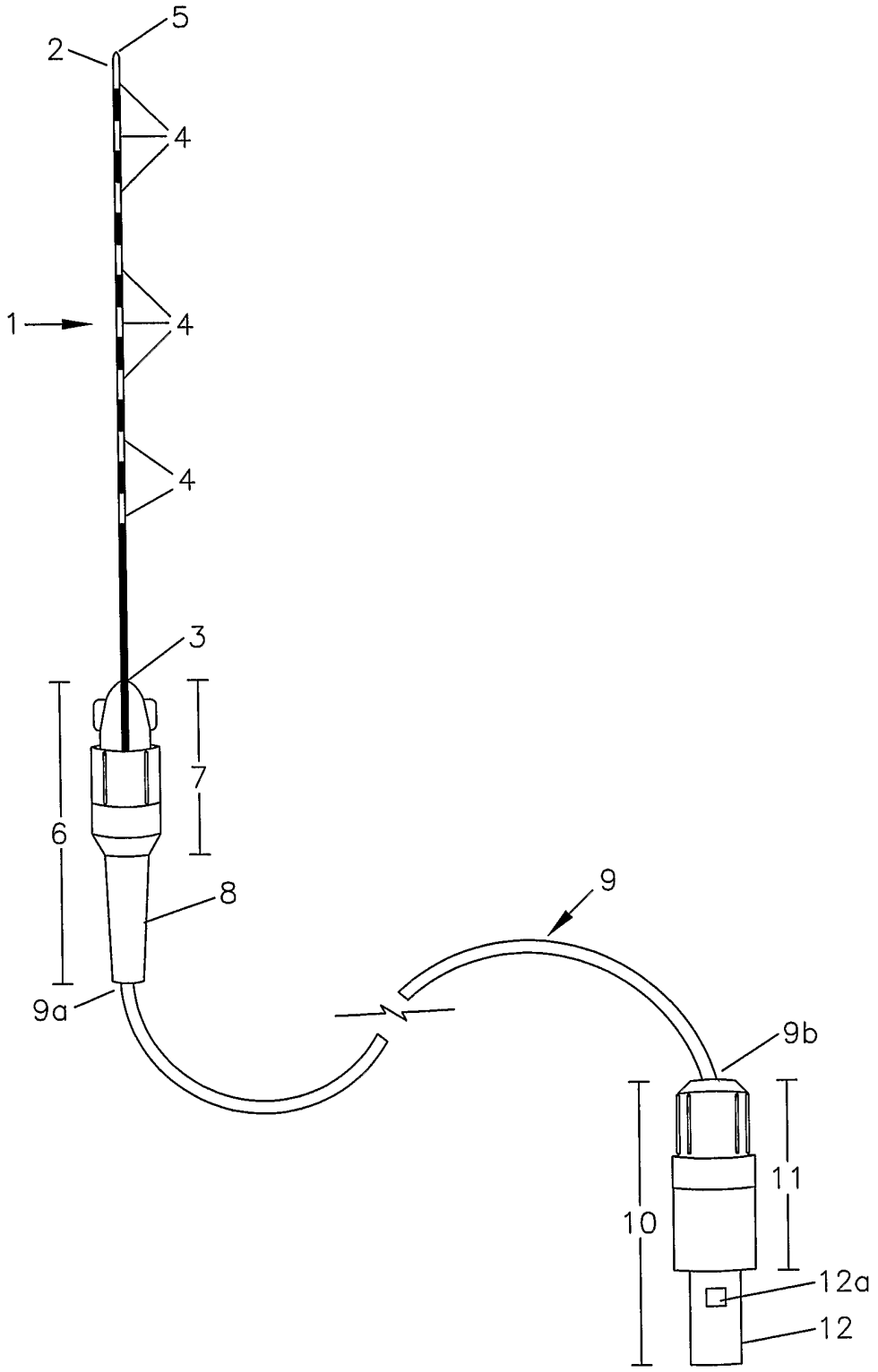


Figure 1b

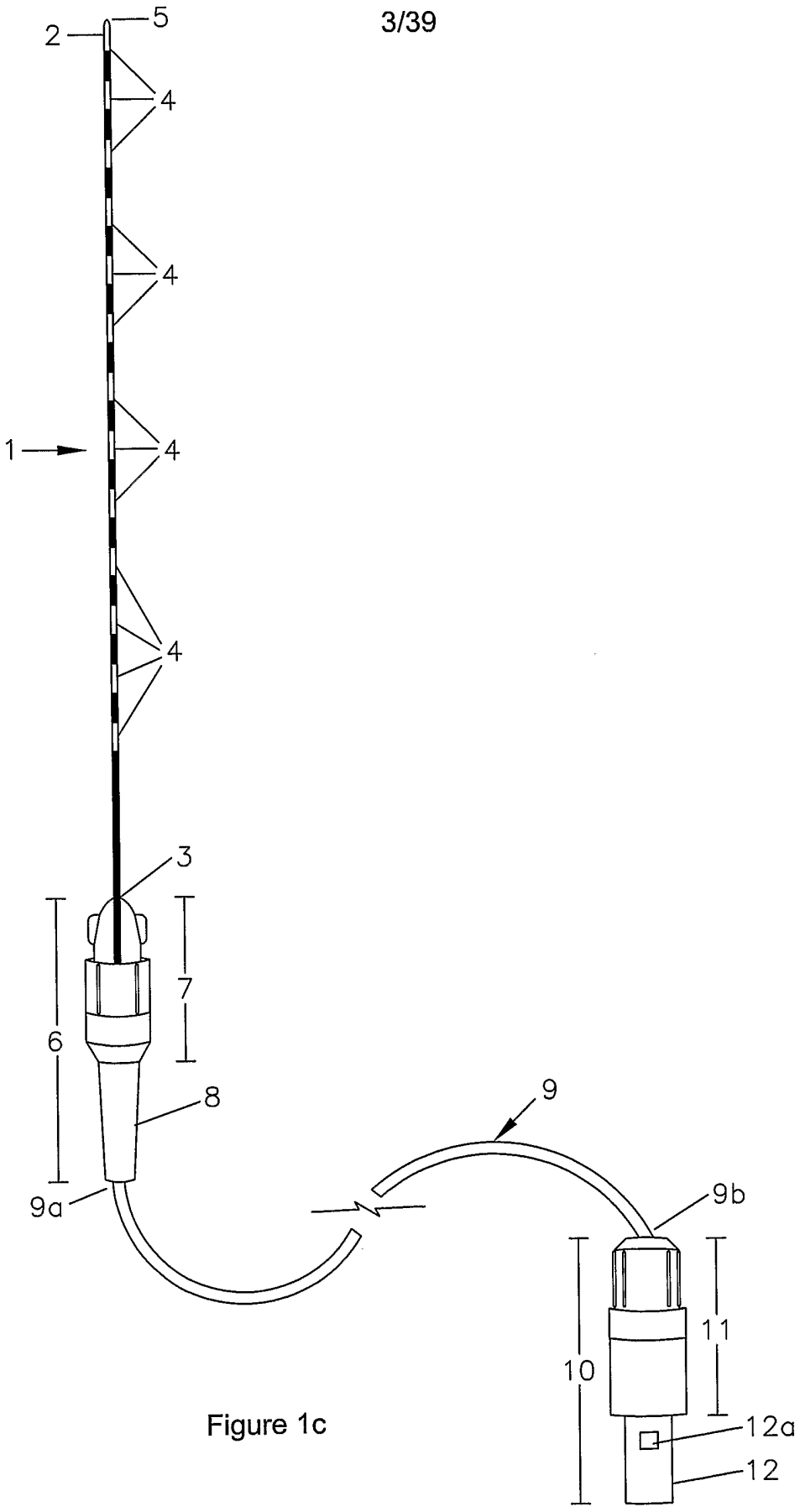


Figure 1c

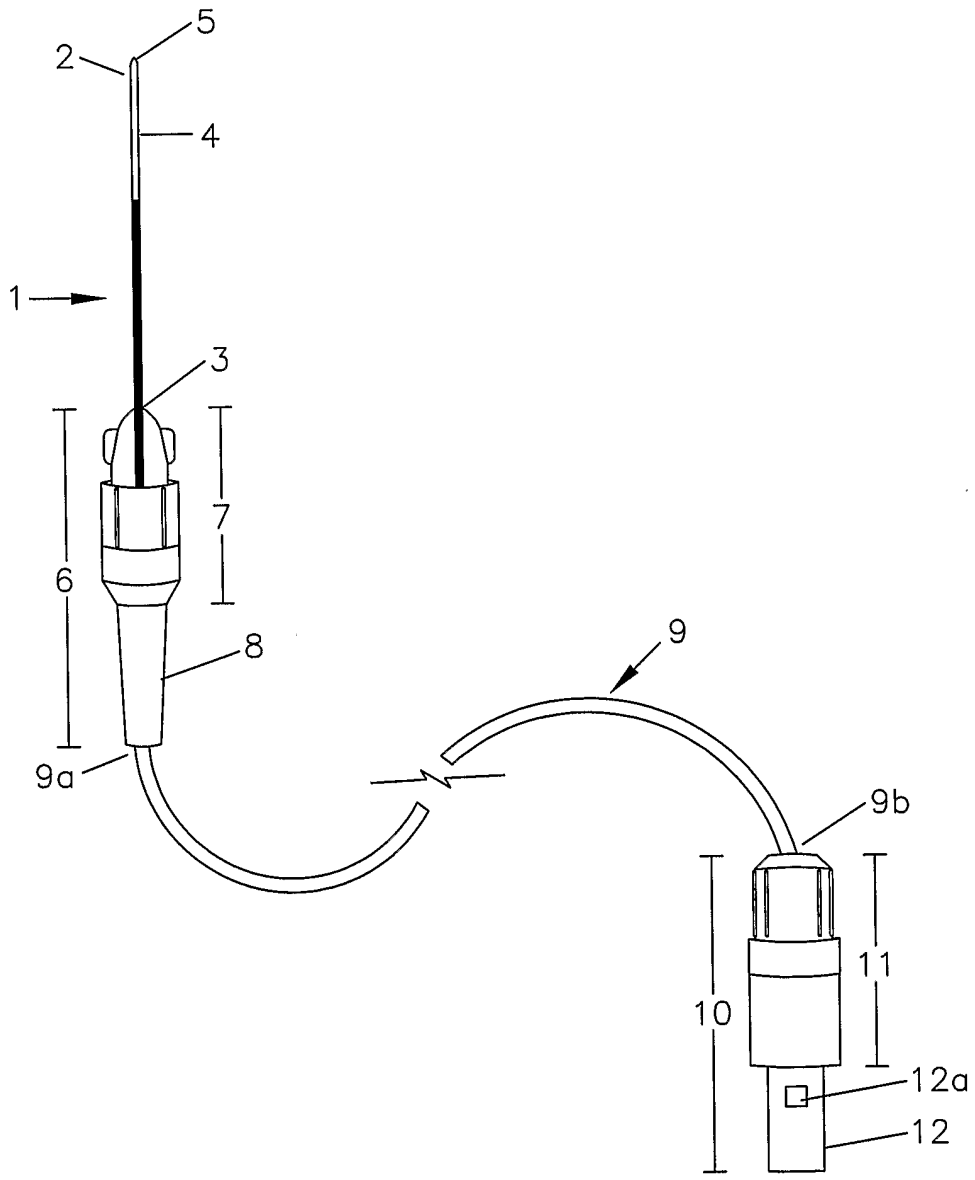


Figure 2a

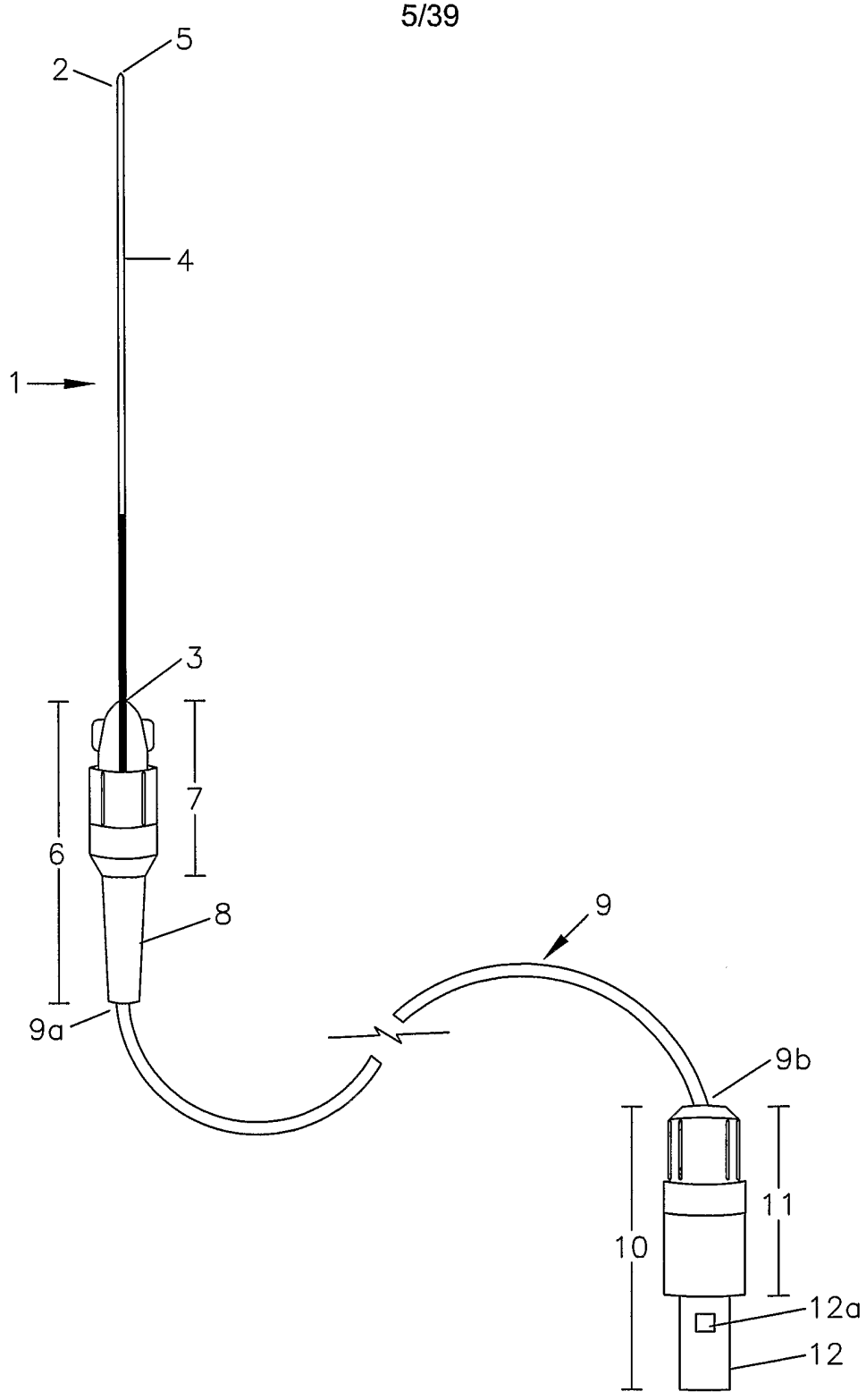
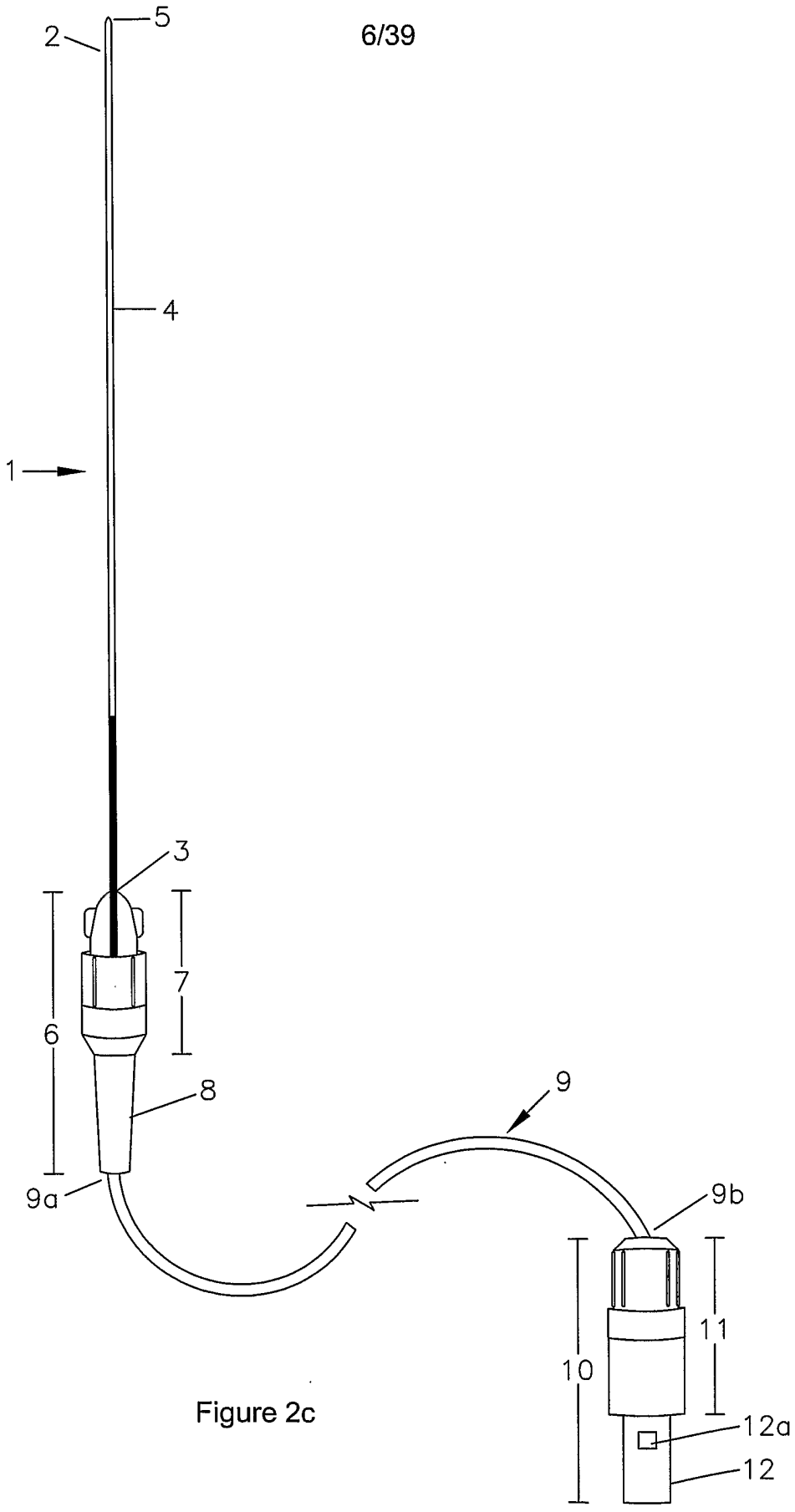


Figure 2b



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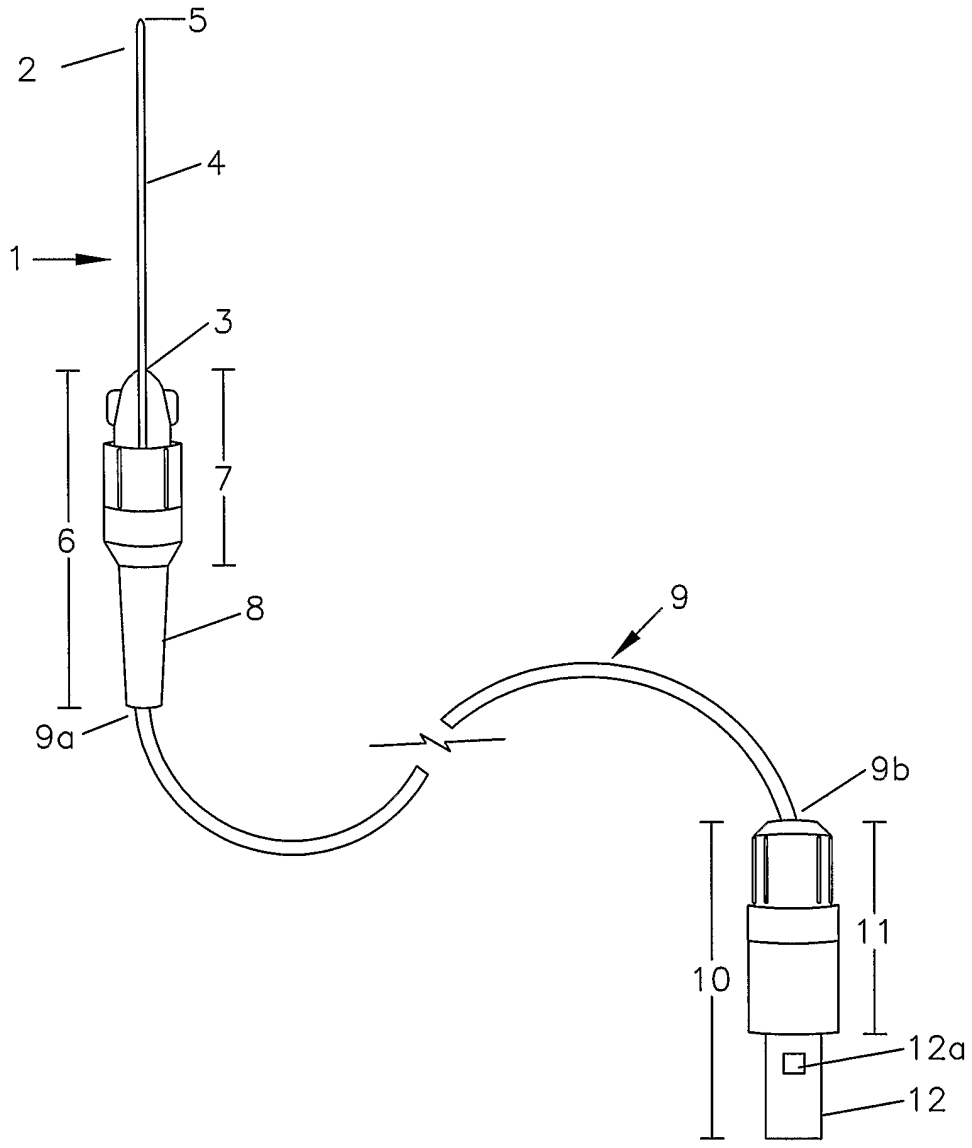
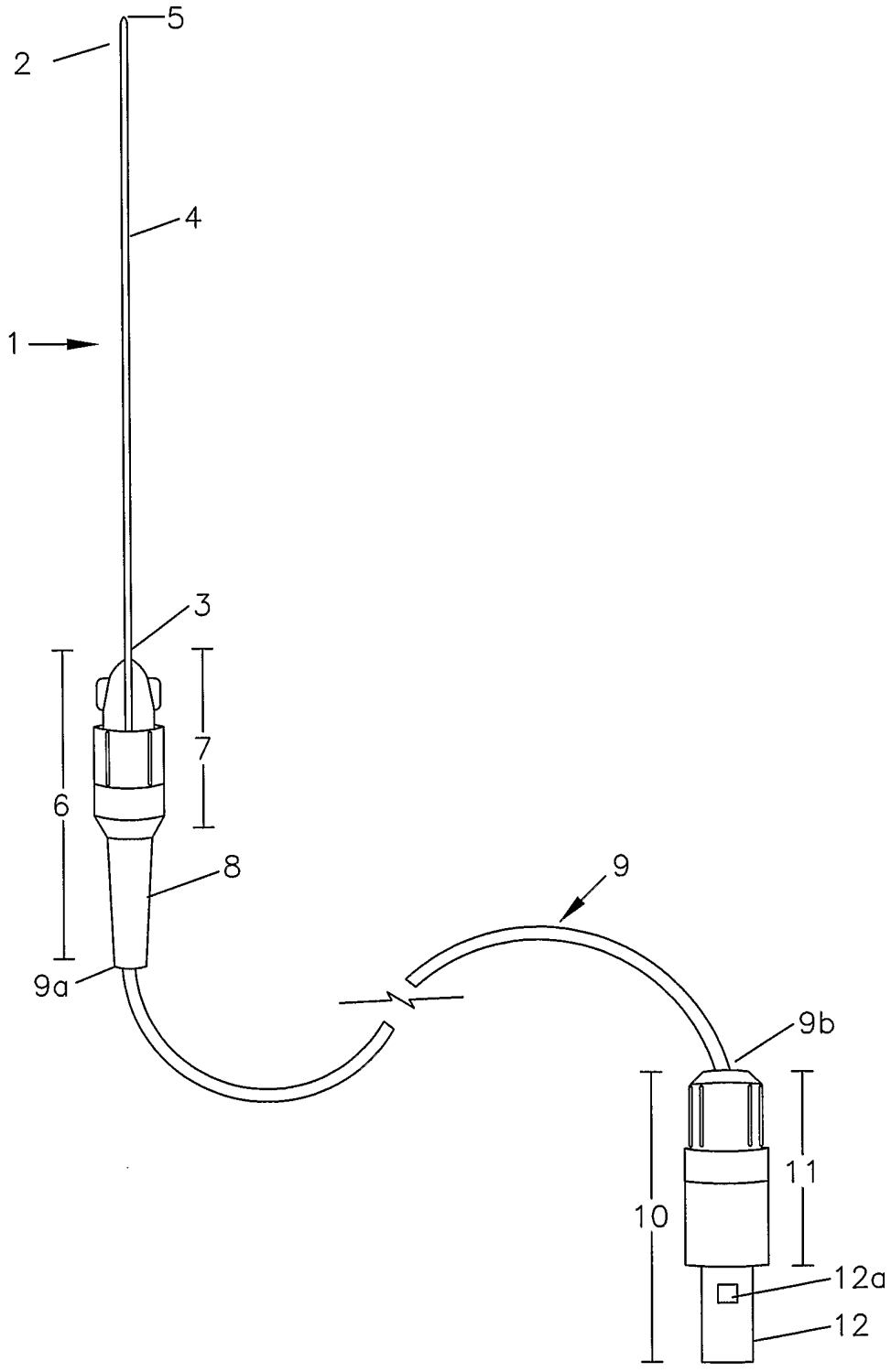


Figure 3a



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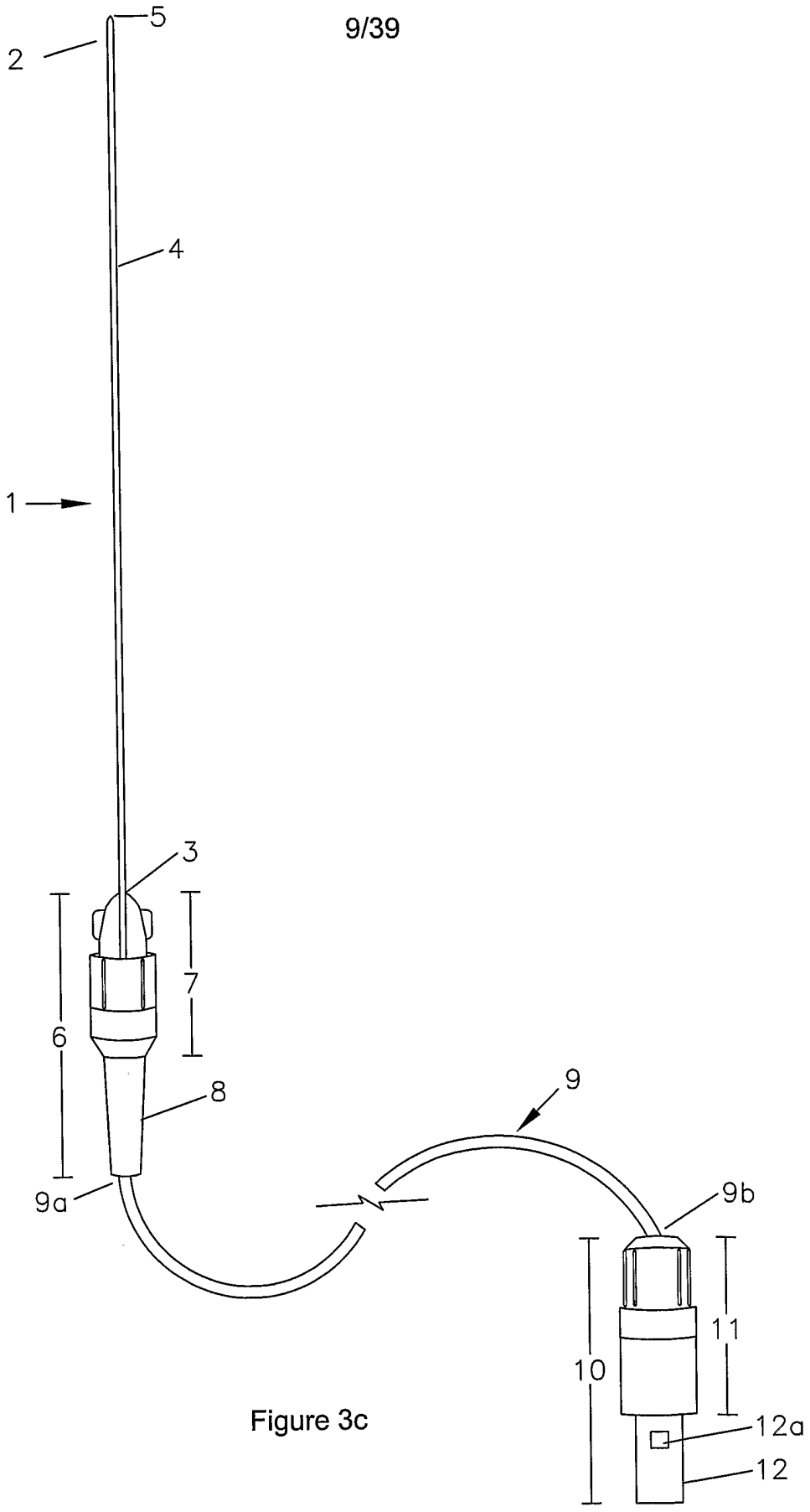

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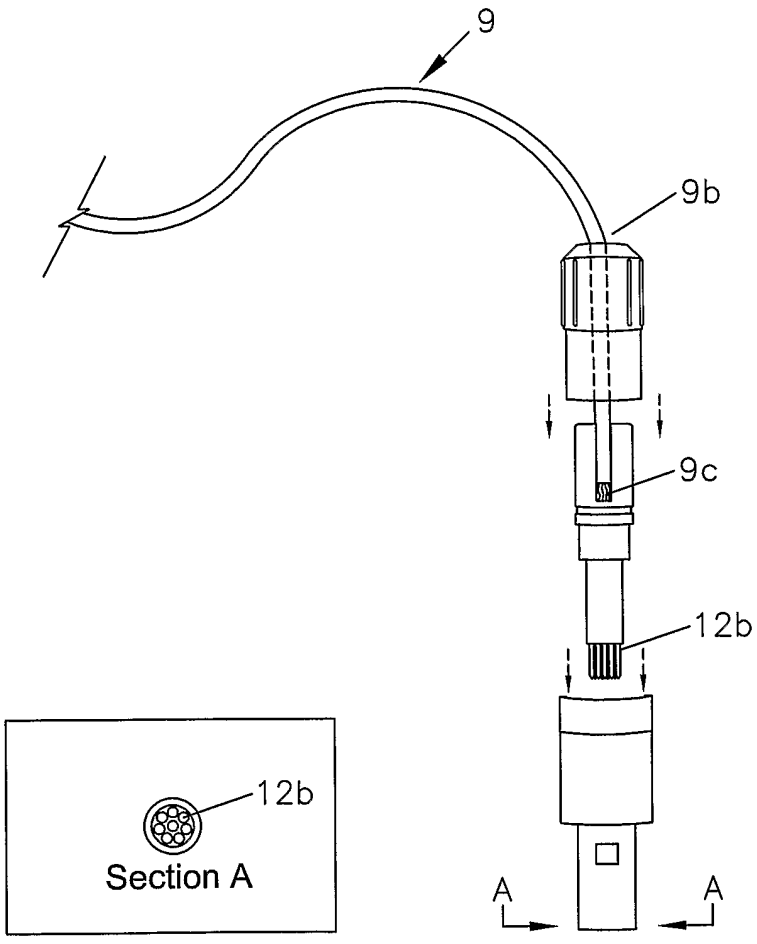

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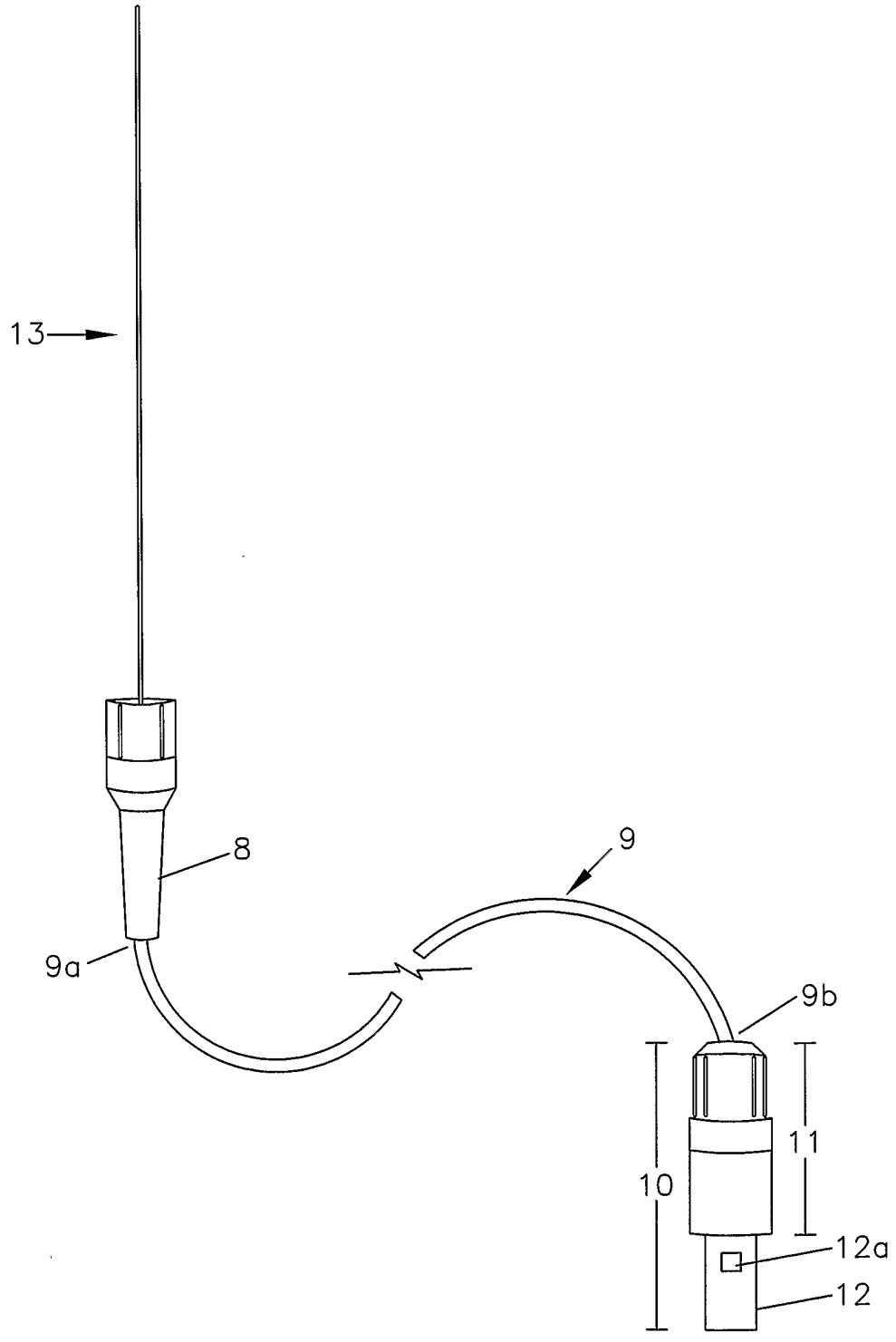

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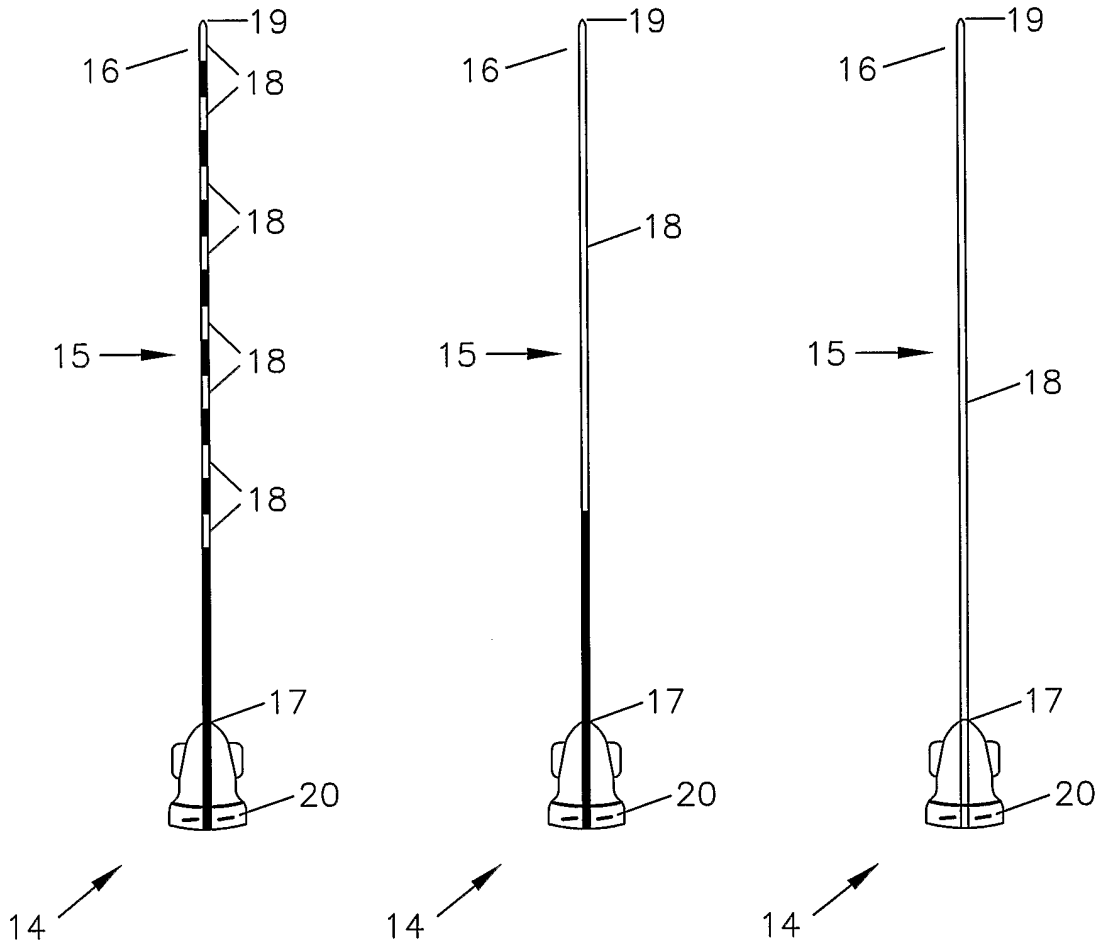

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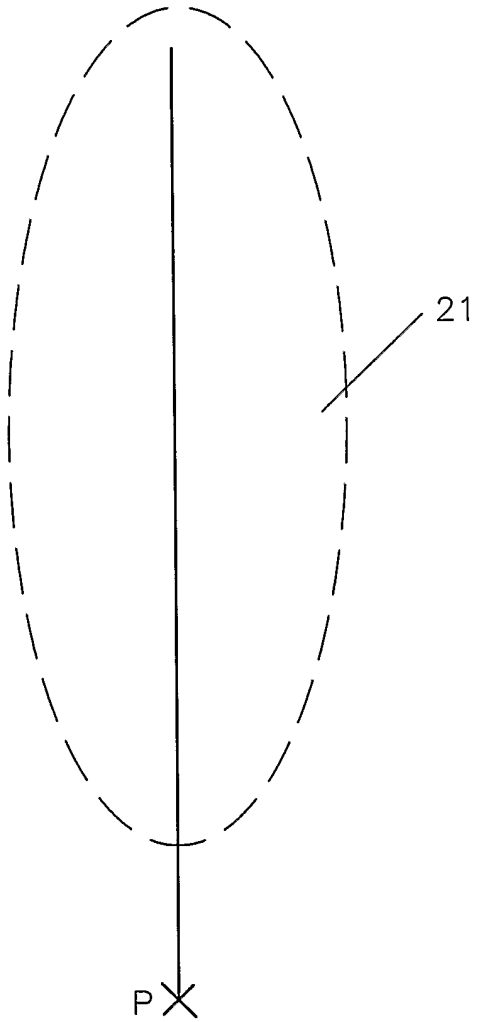
Figure 6



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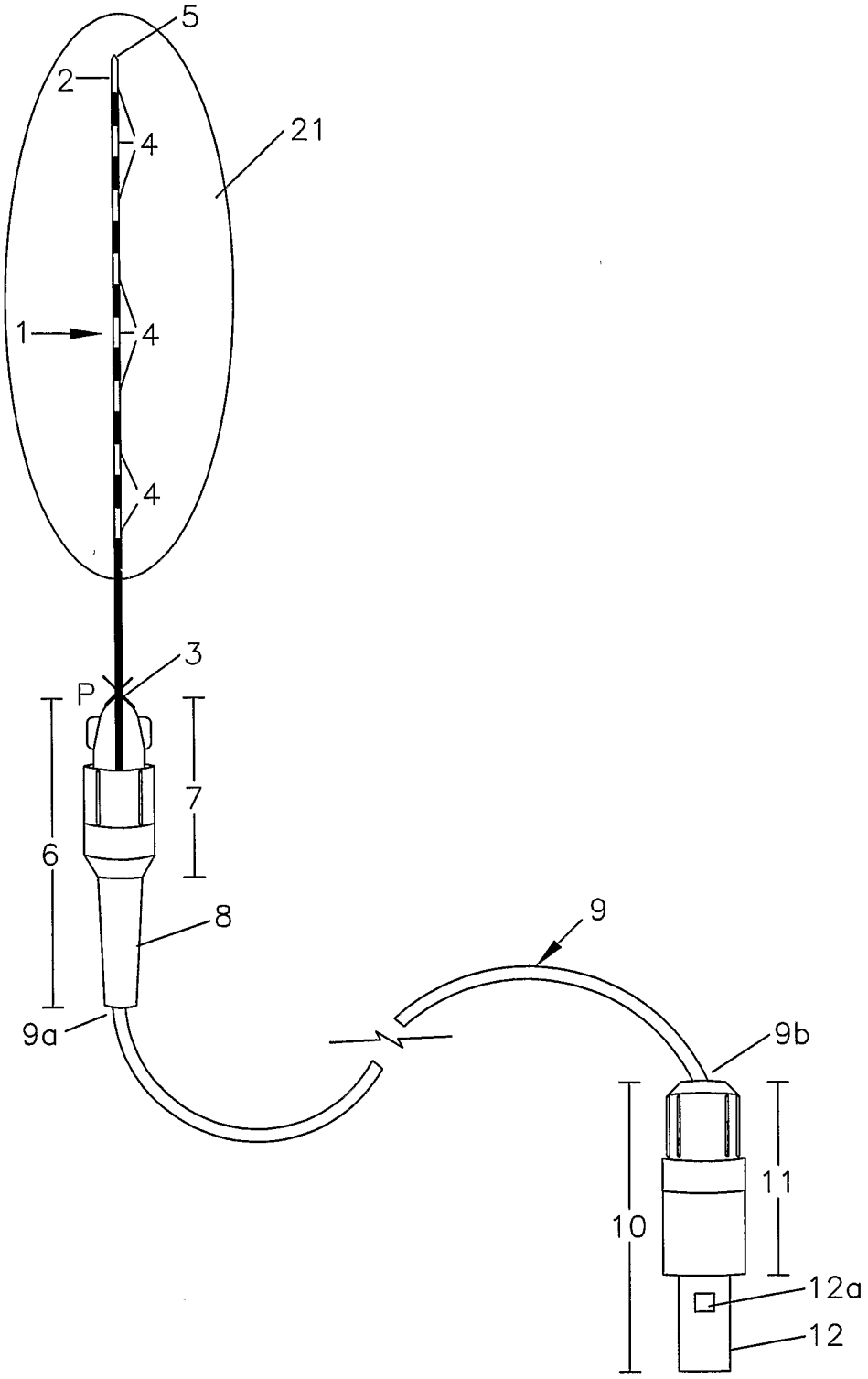

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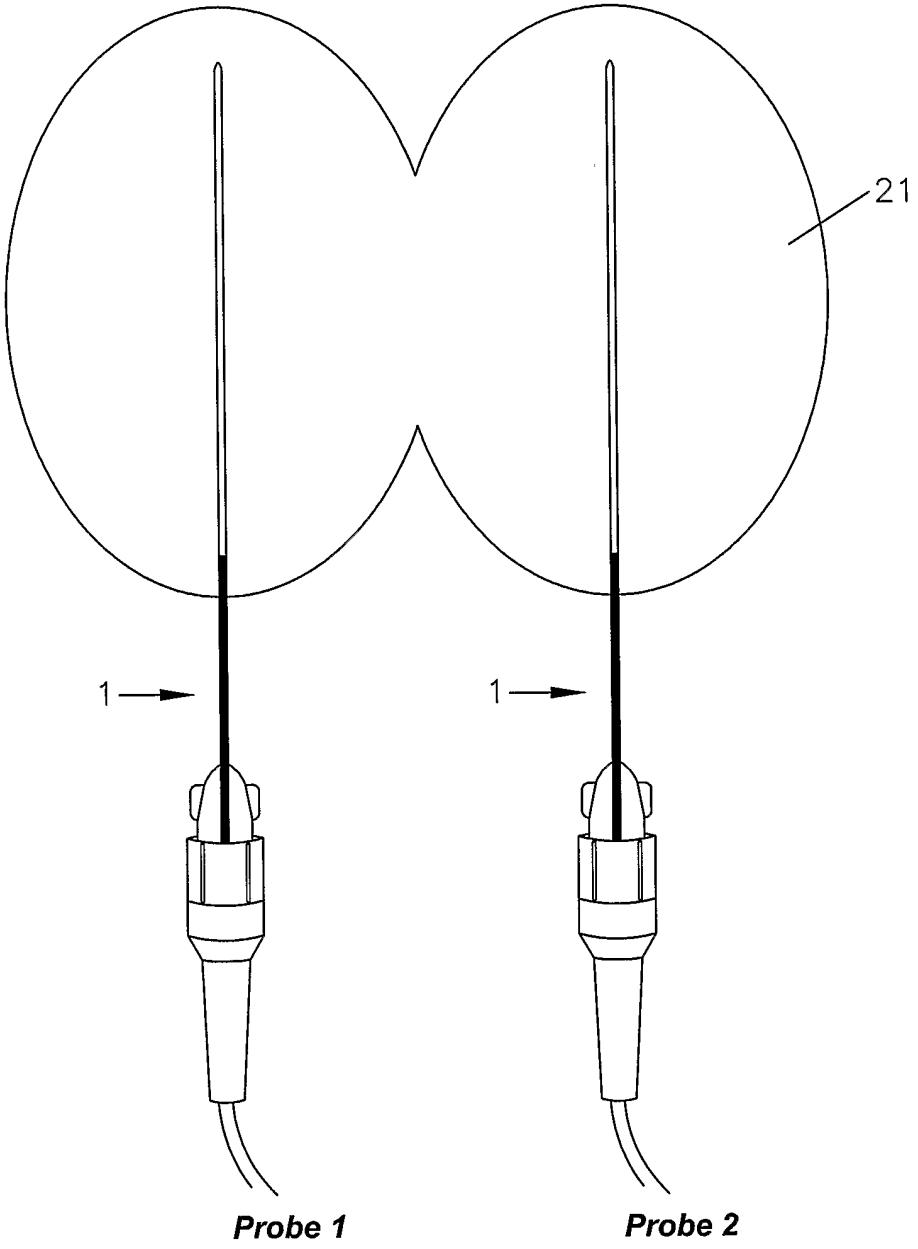

Figure 9

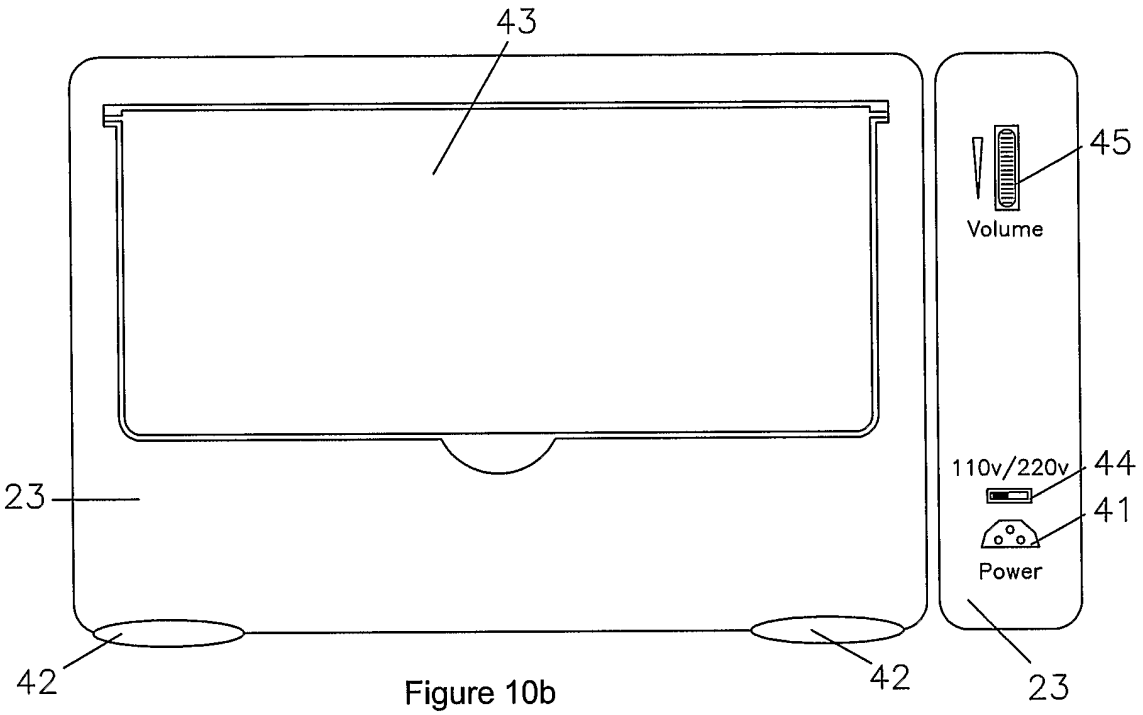

Figure 10b

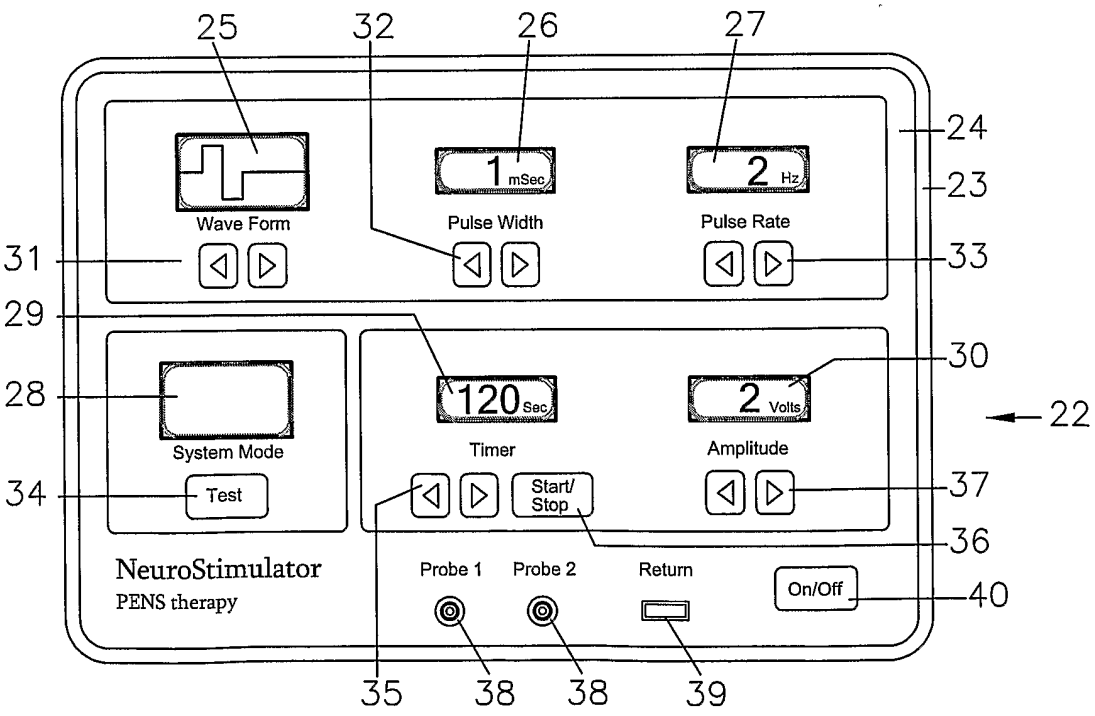

Figure 10c

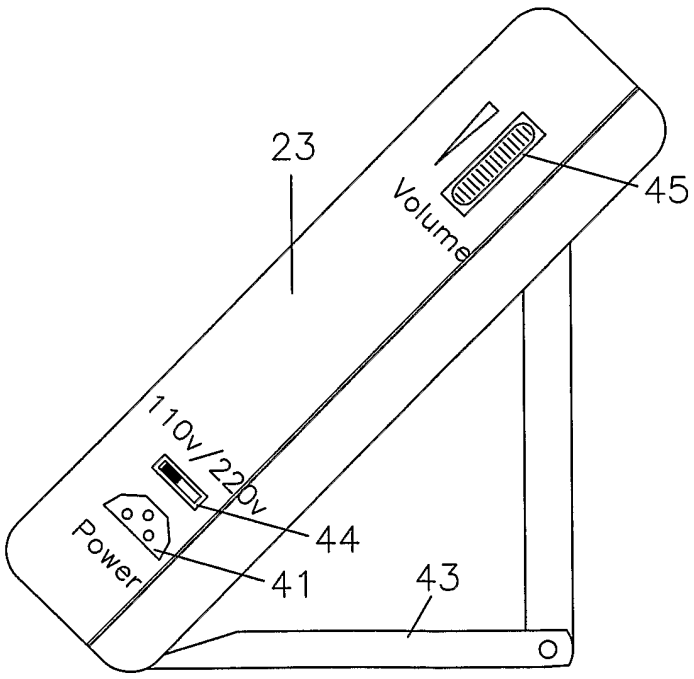

Figure 10a

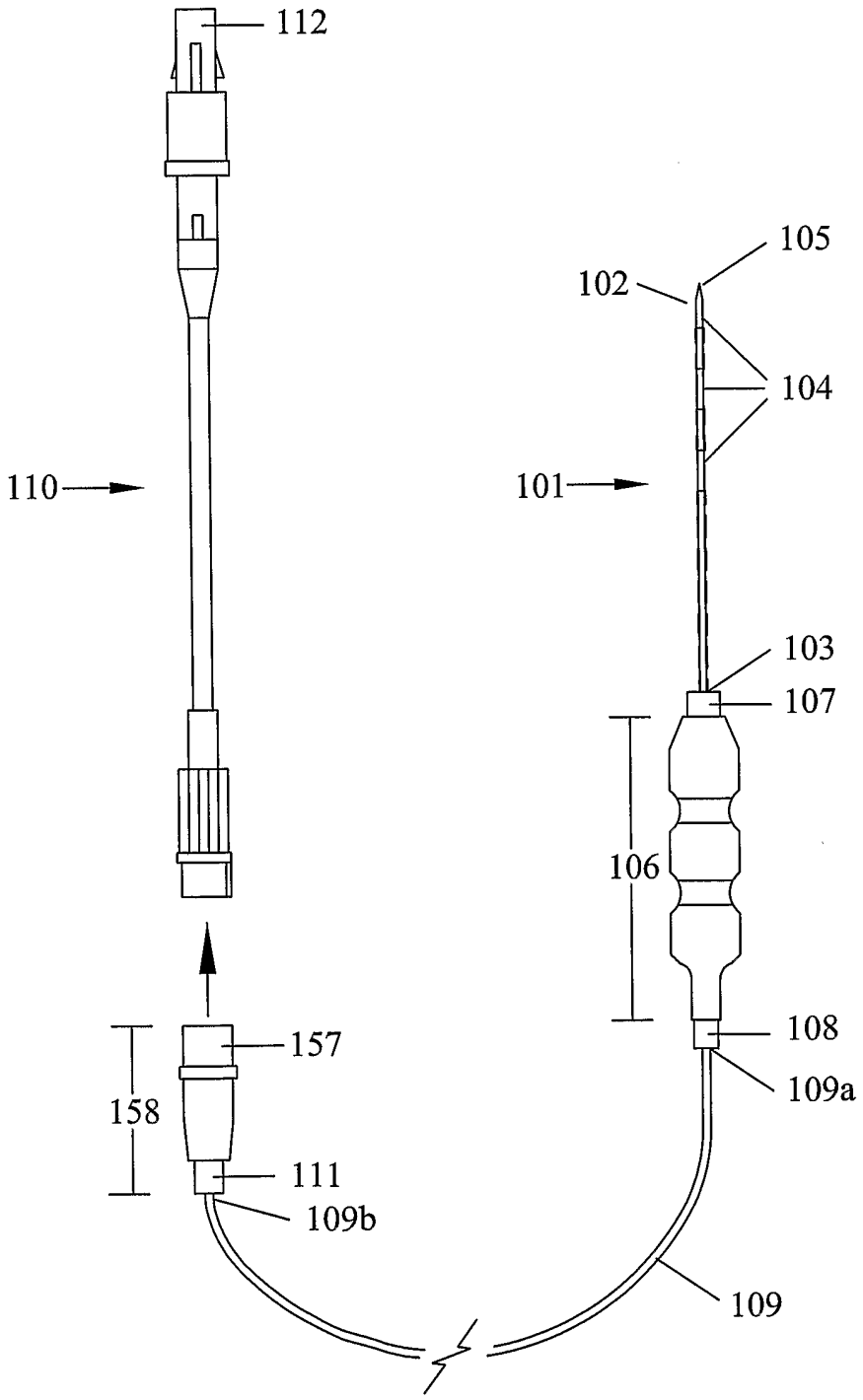
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Figure 11a

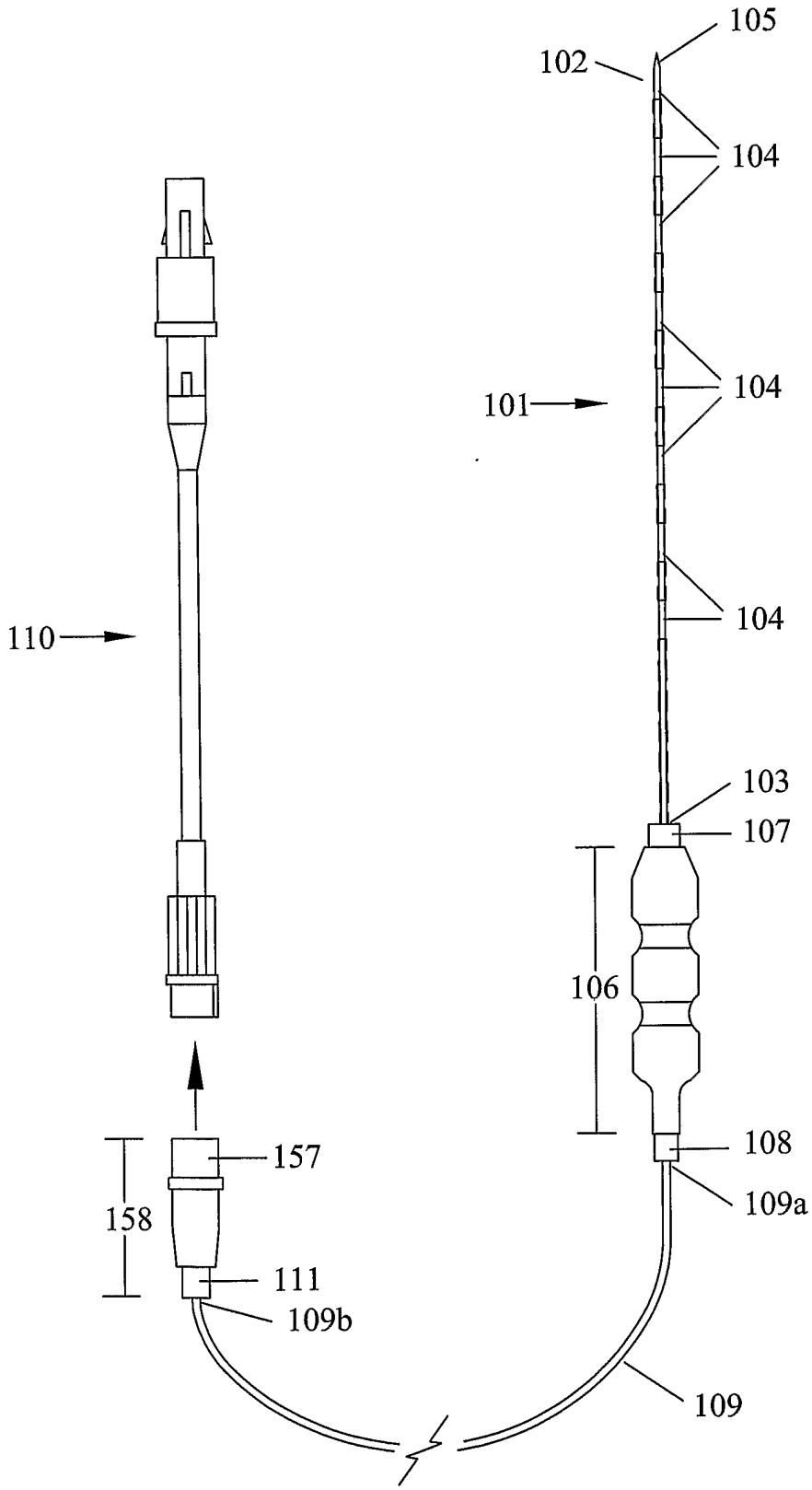
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Figure 11b

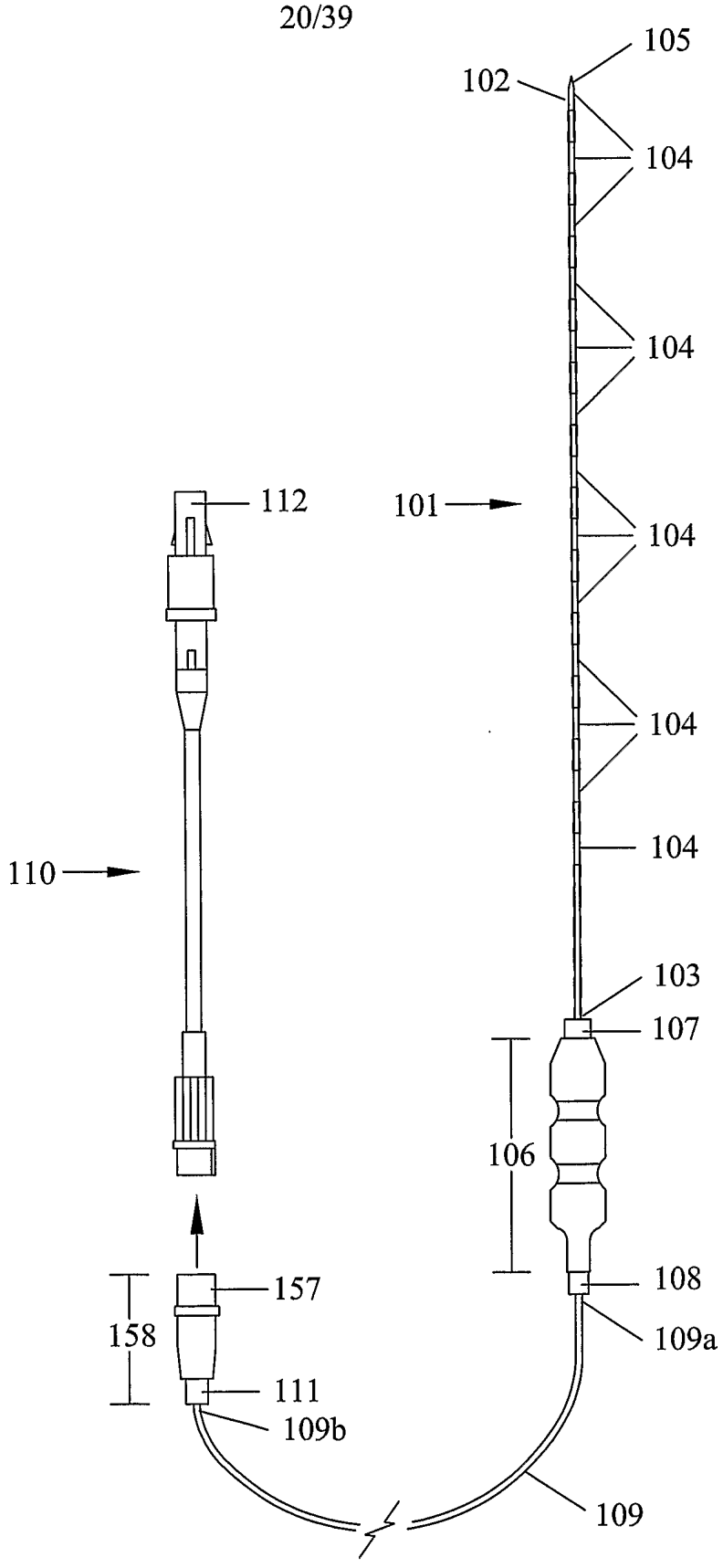
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Figure 11c

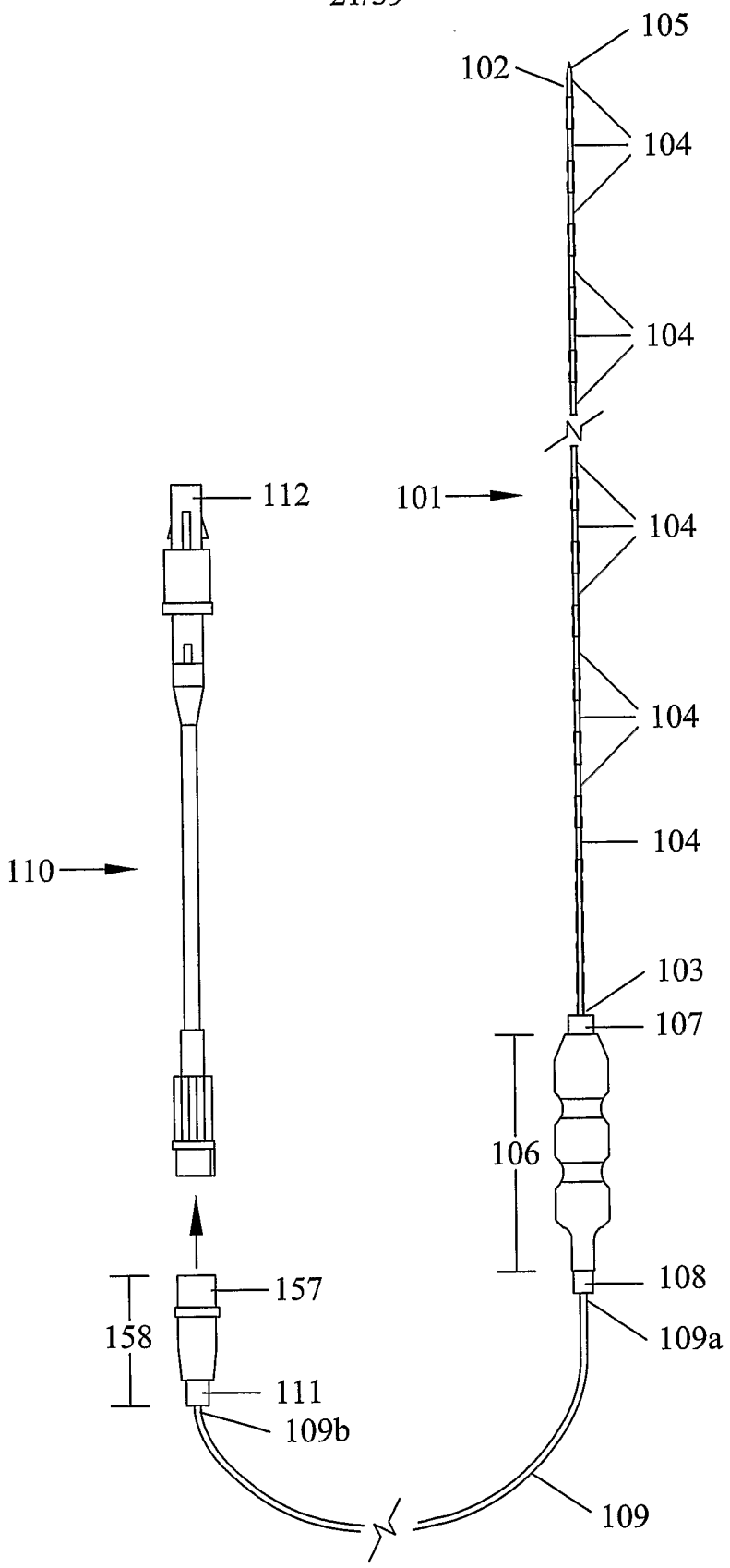
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Figure 11d

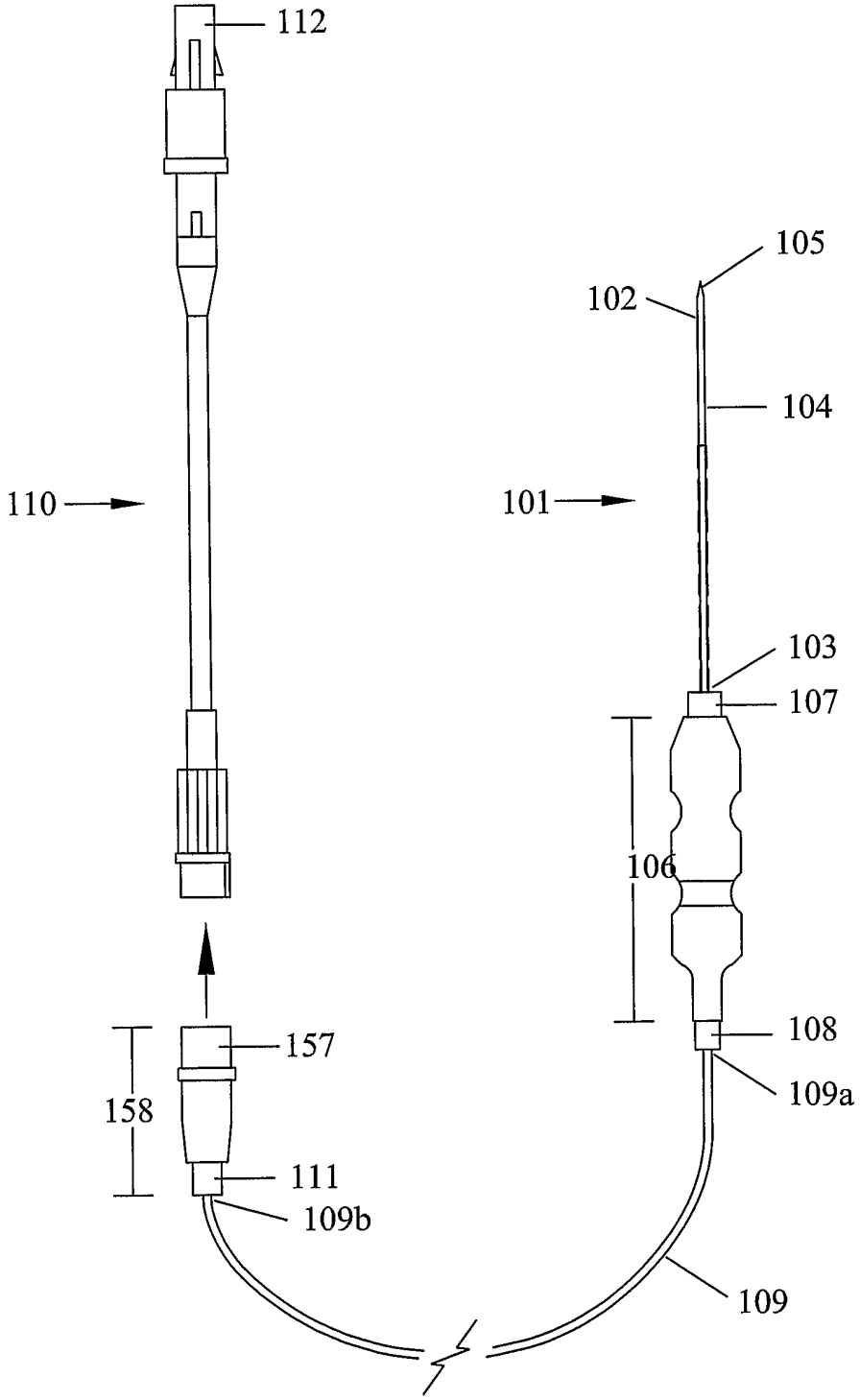
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Figure 12a

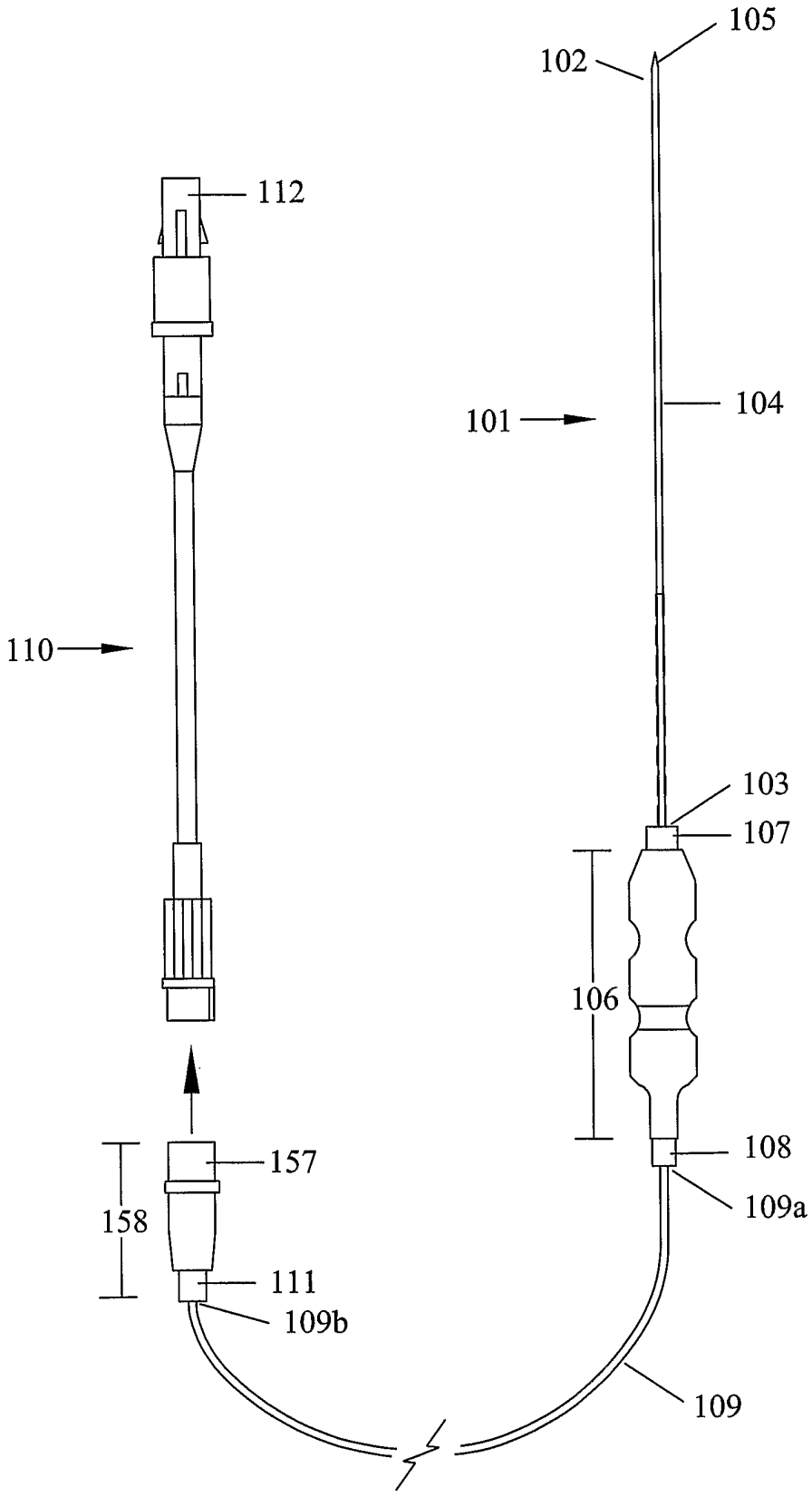
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Figure 12b

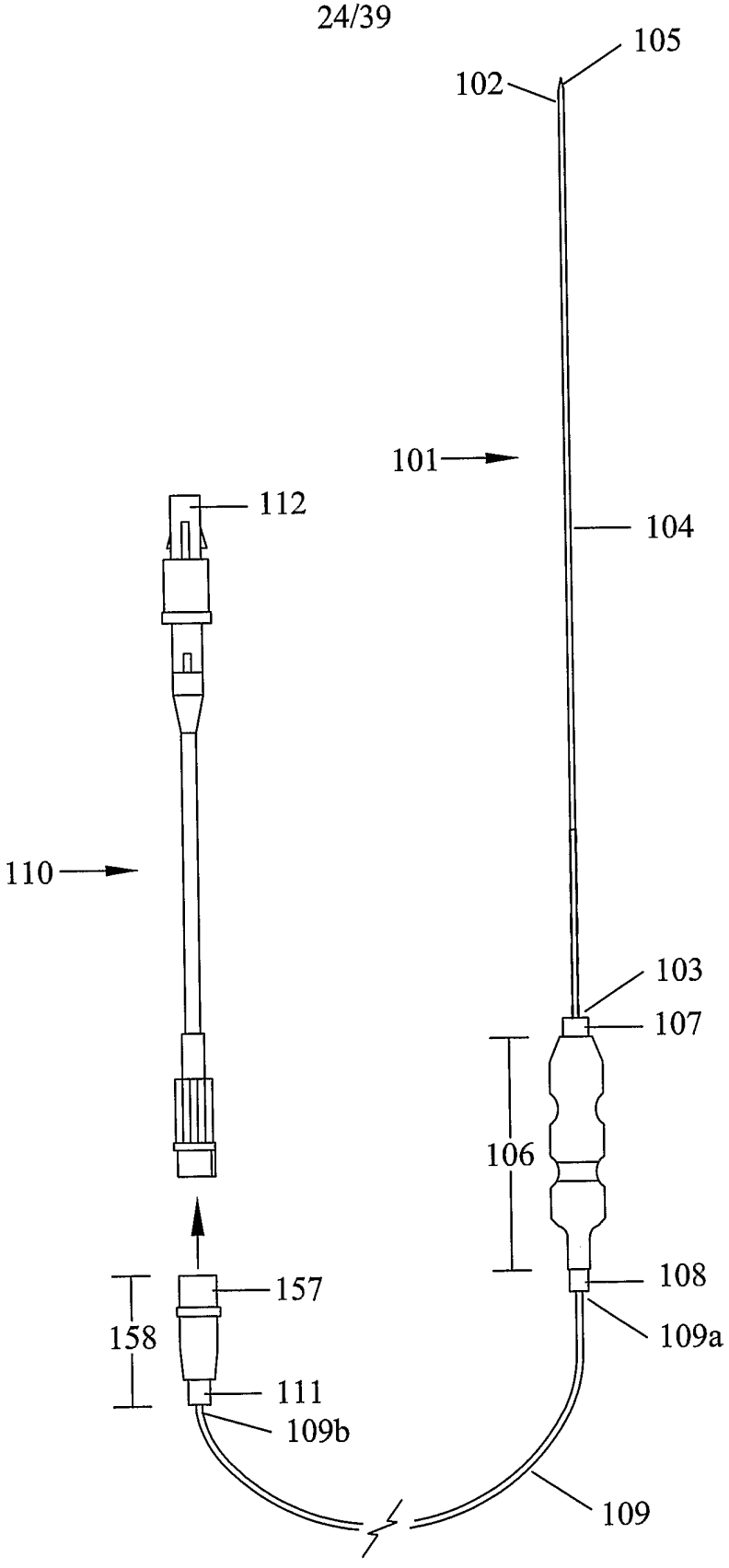
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Figure 12c

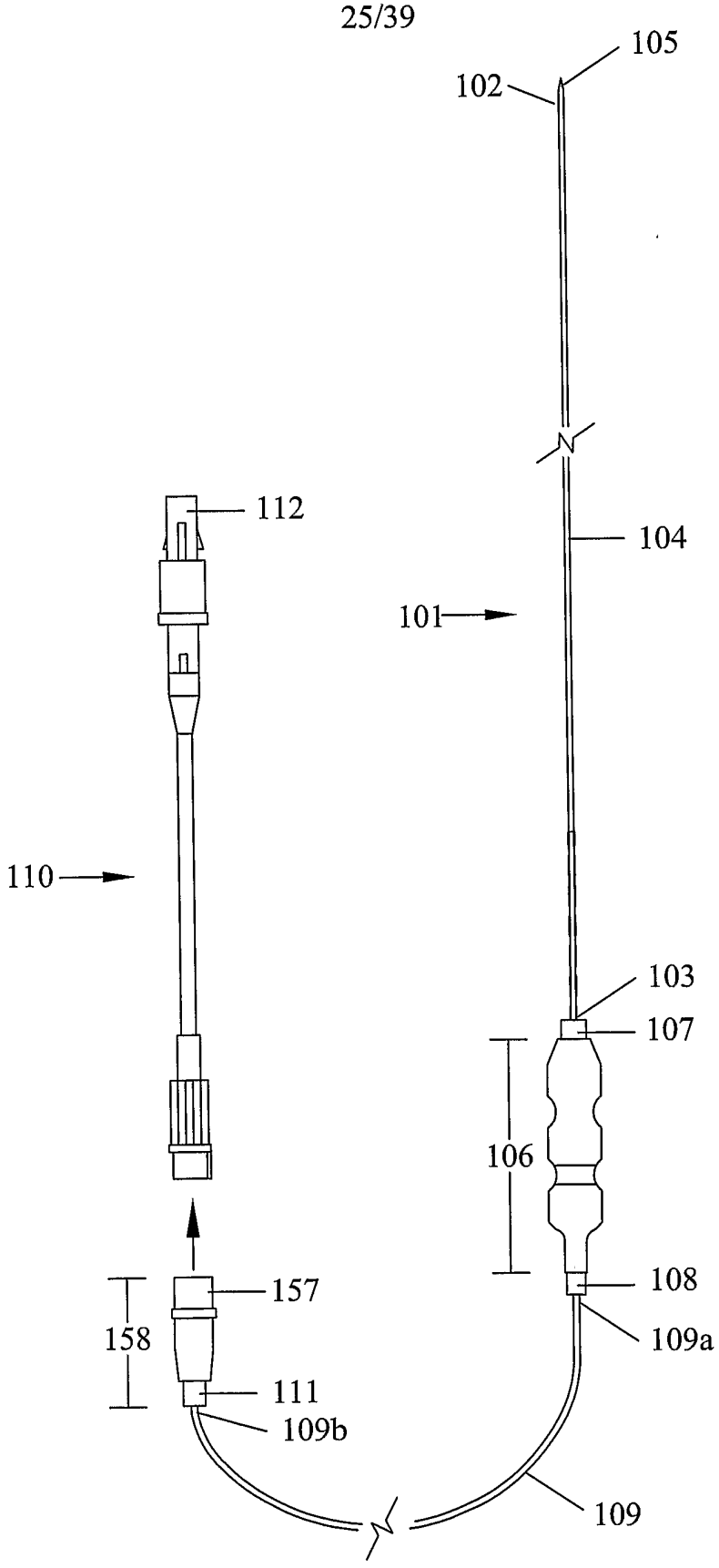
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Figure 12d

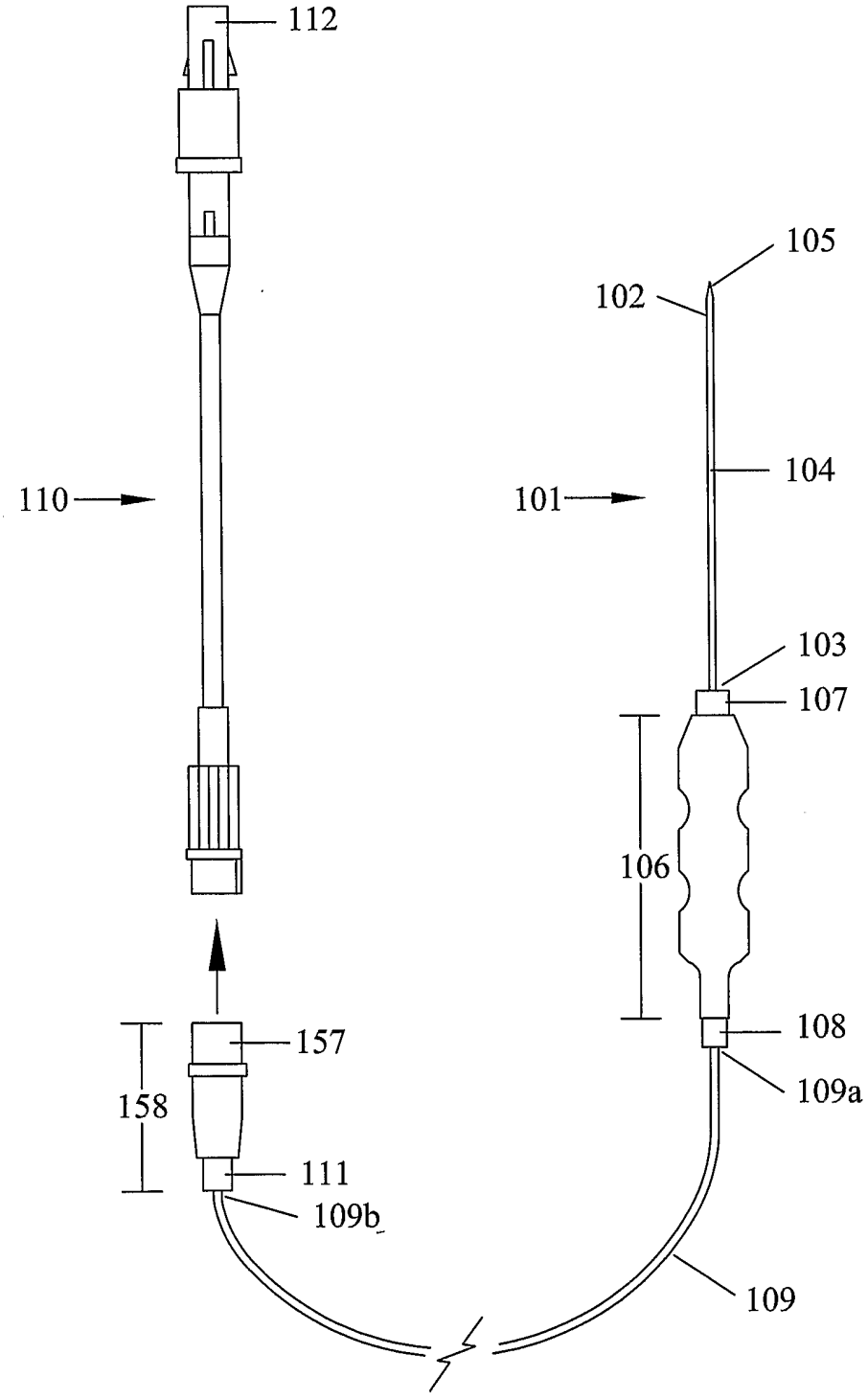
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Figure 13a

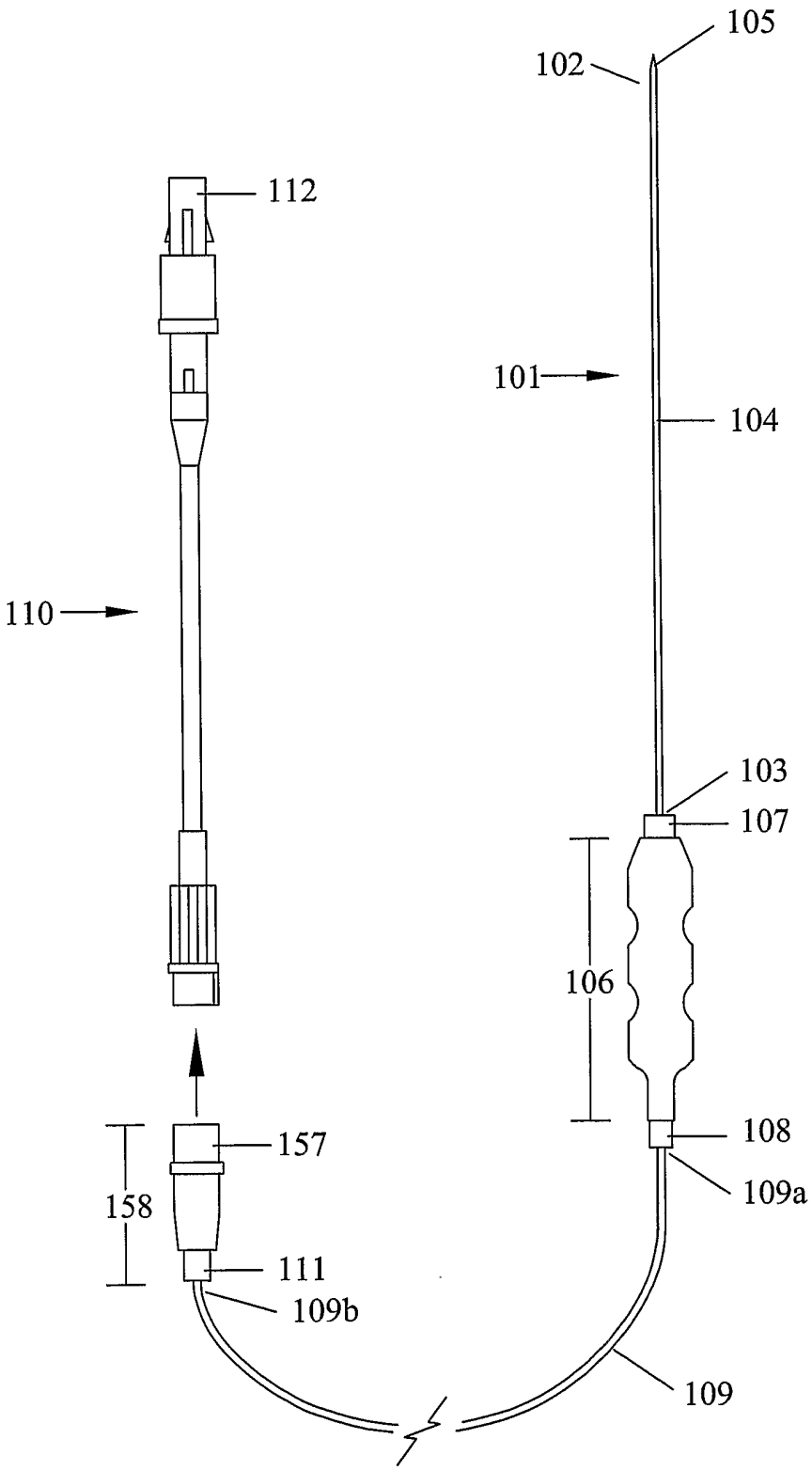
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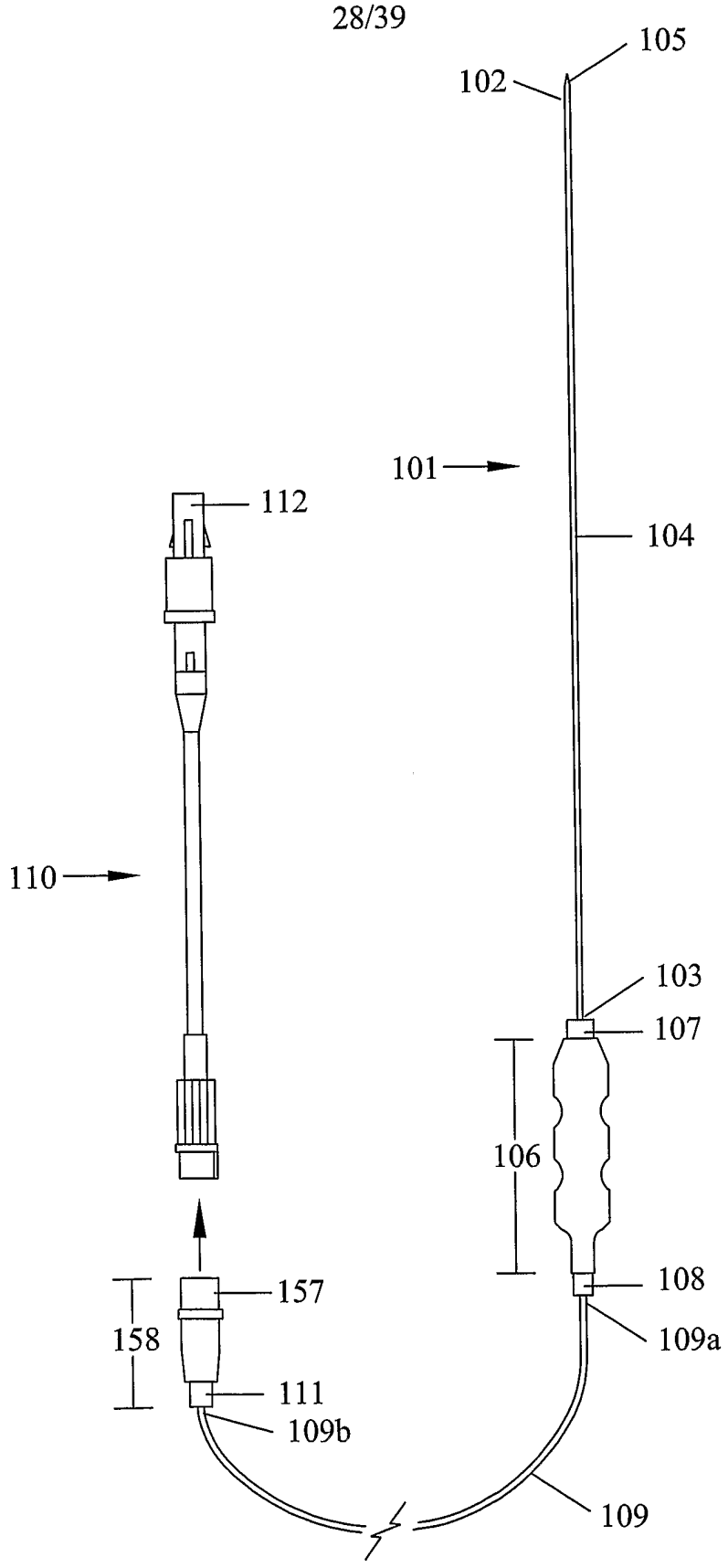
Figure 13b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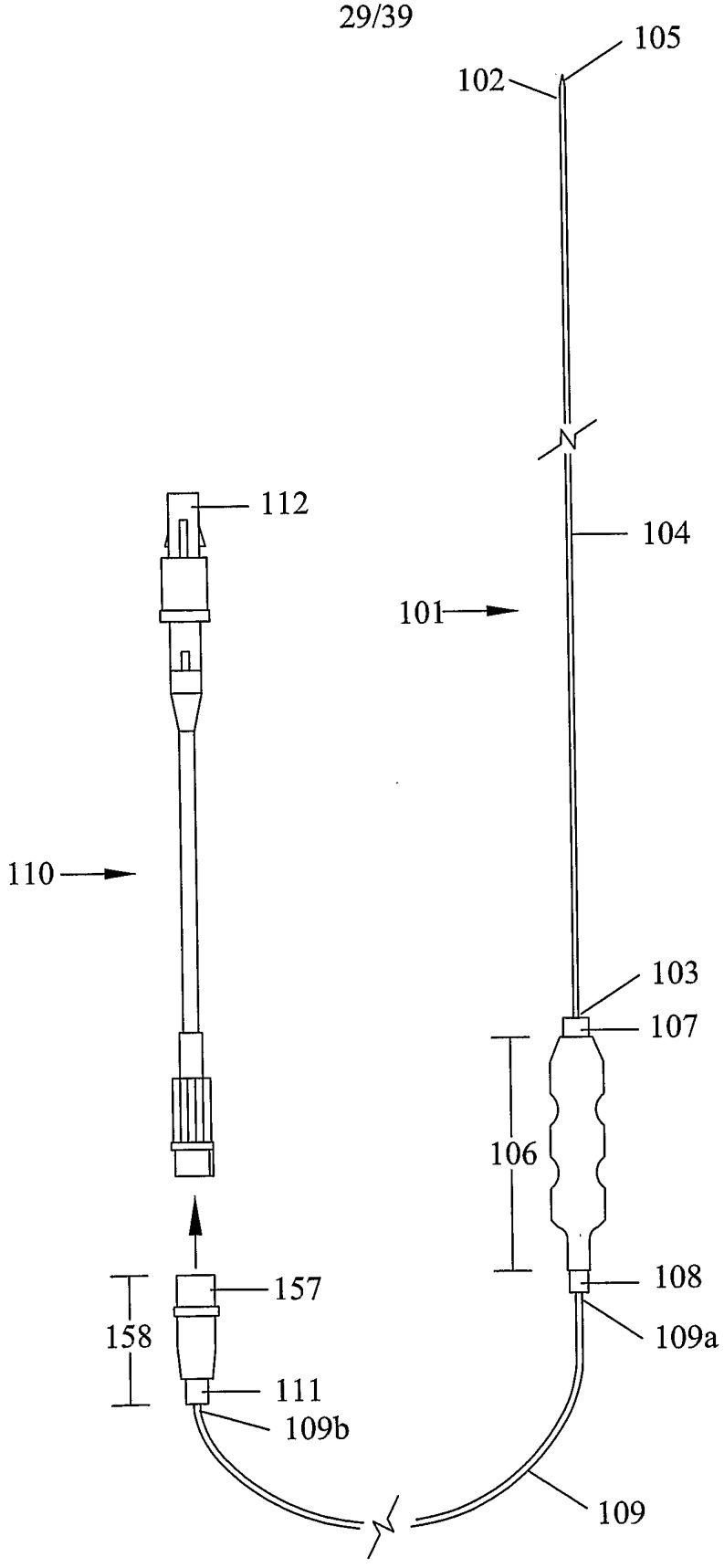
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Figure 13d

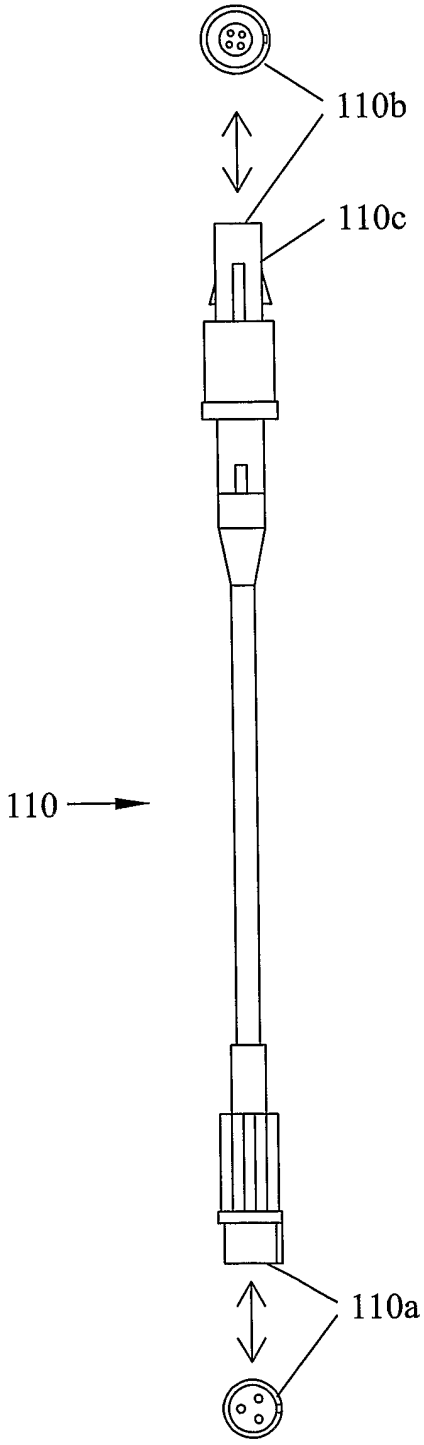


Figure 14

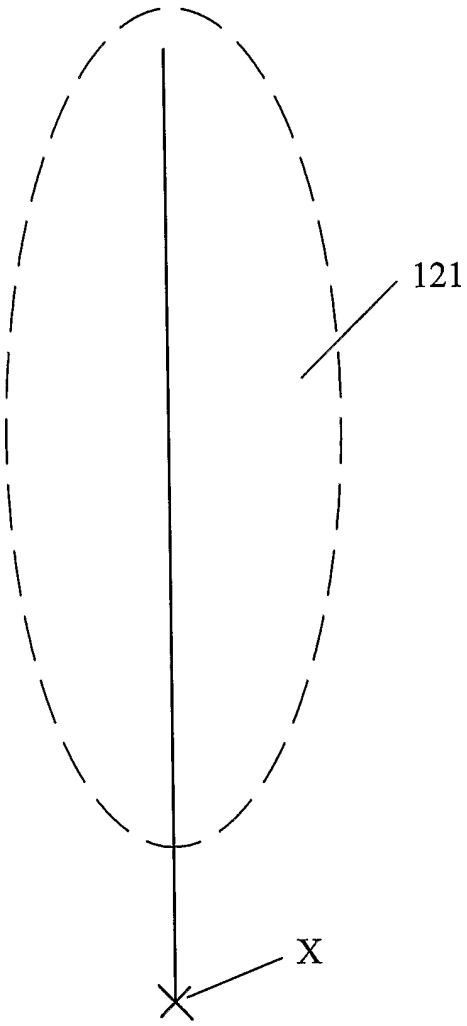
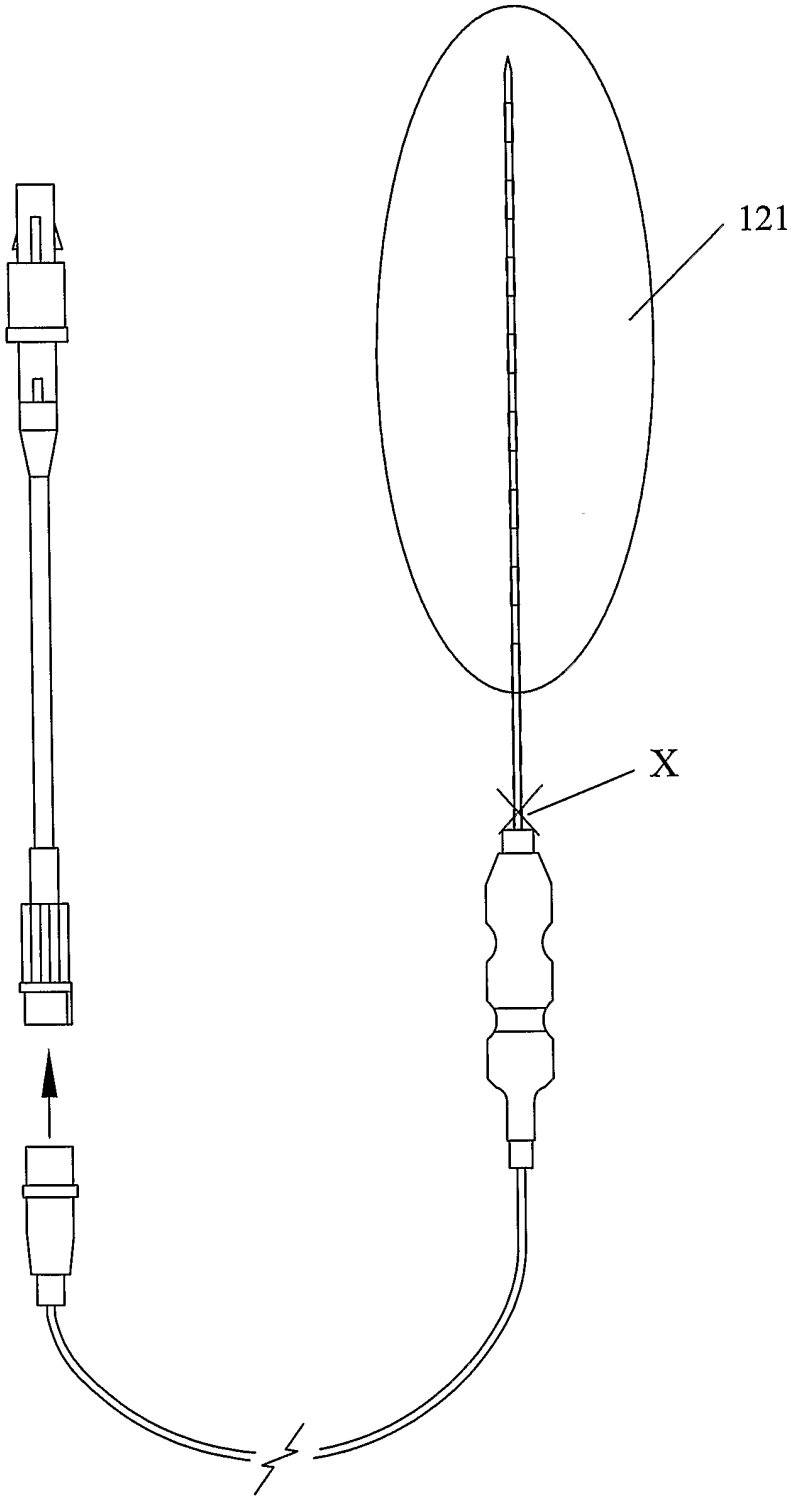


Figure 15



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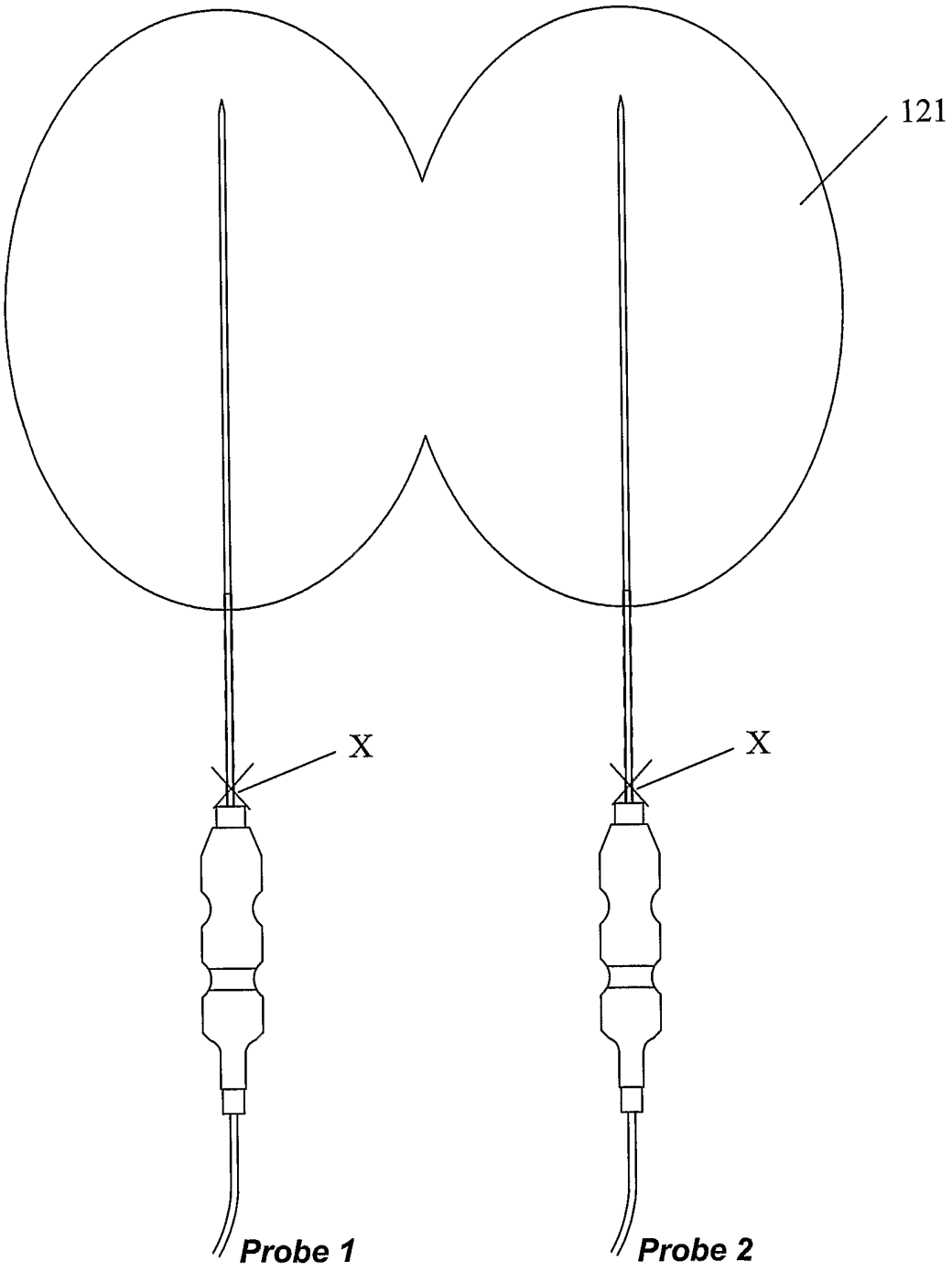

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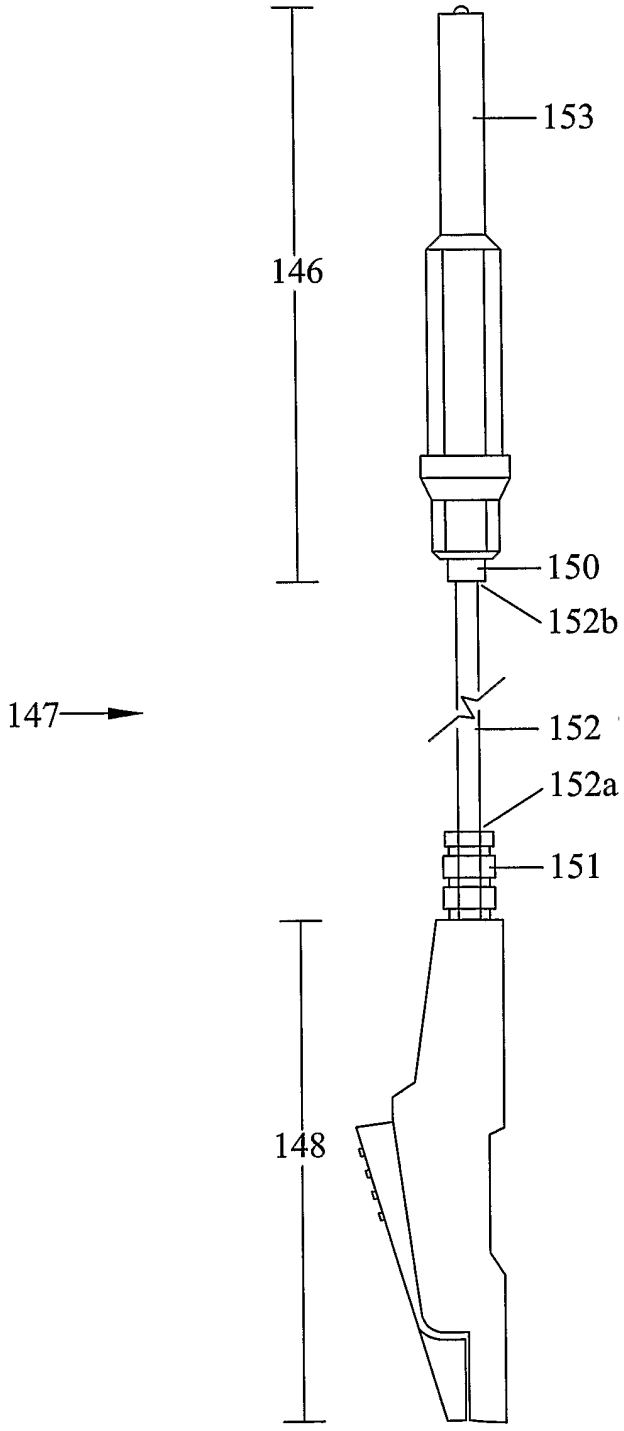
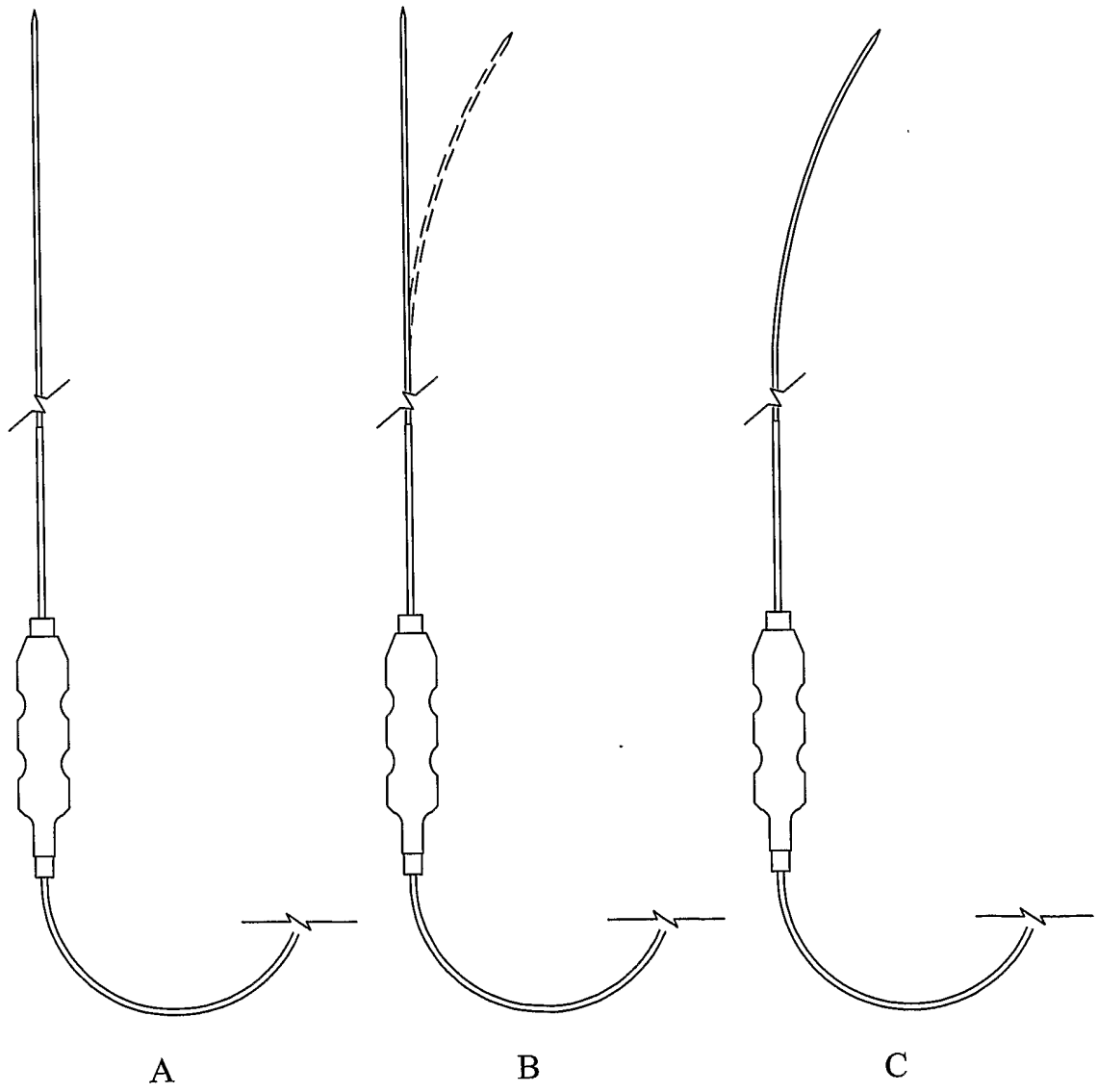


Figure 18



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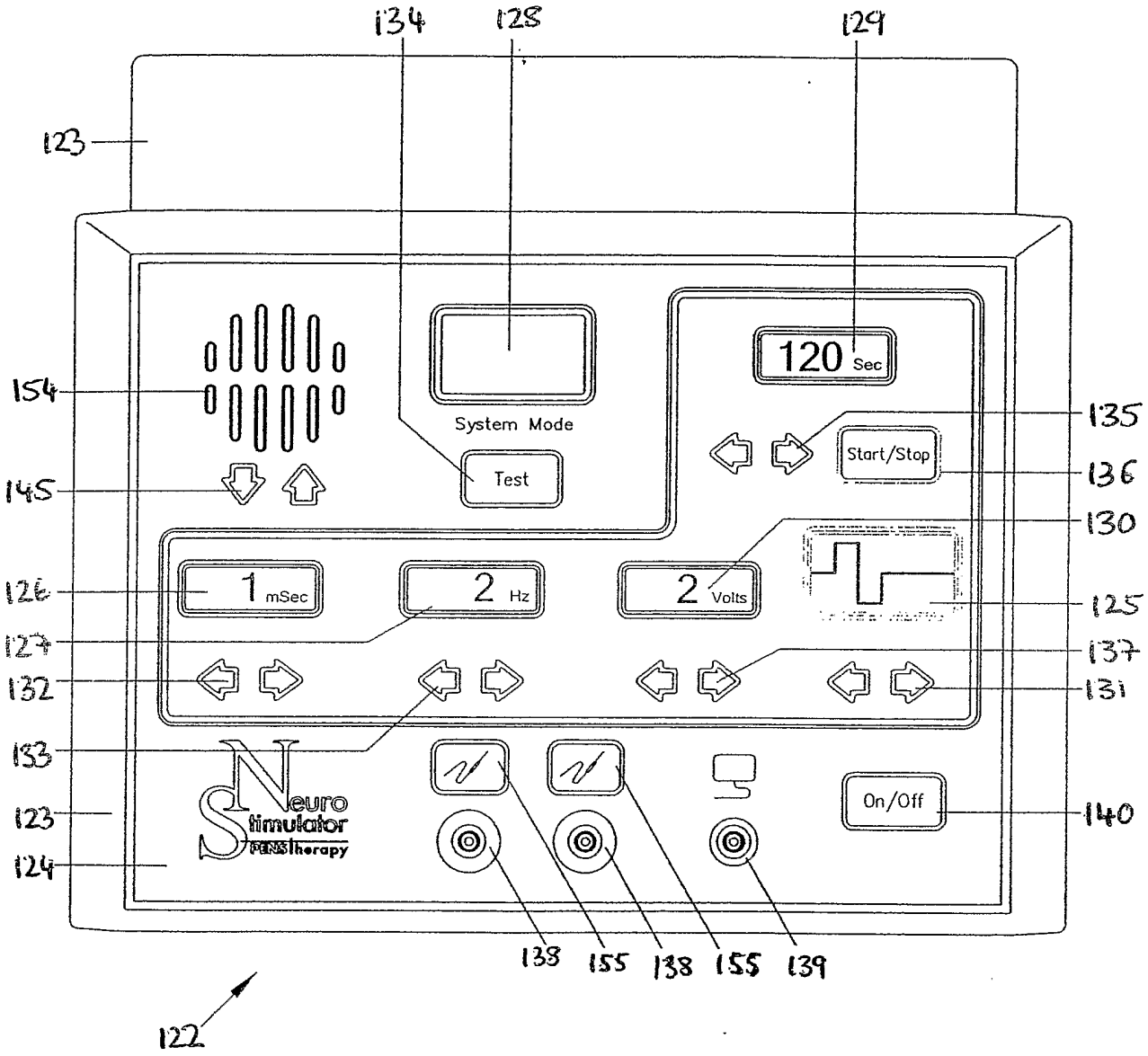
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Neuro Stimulator
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Figure 20

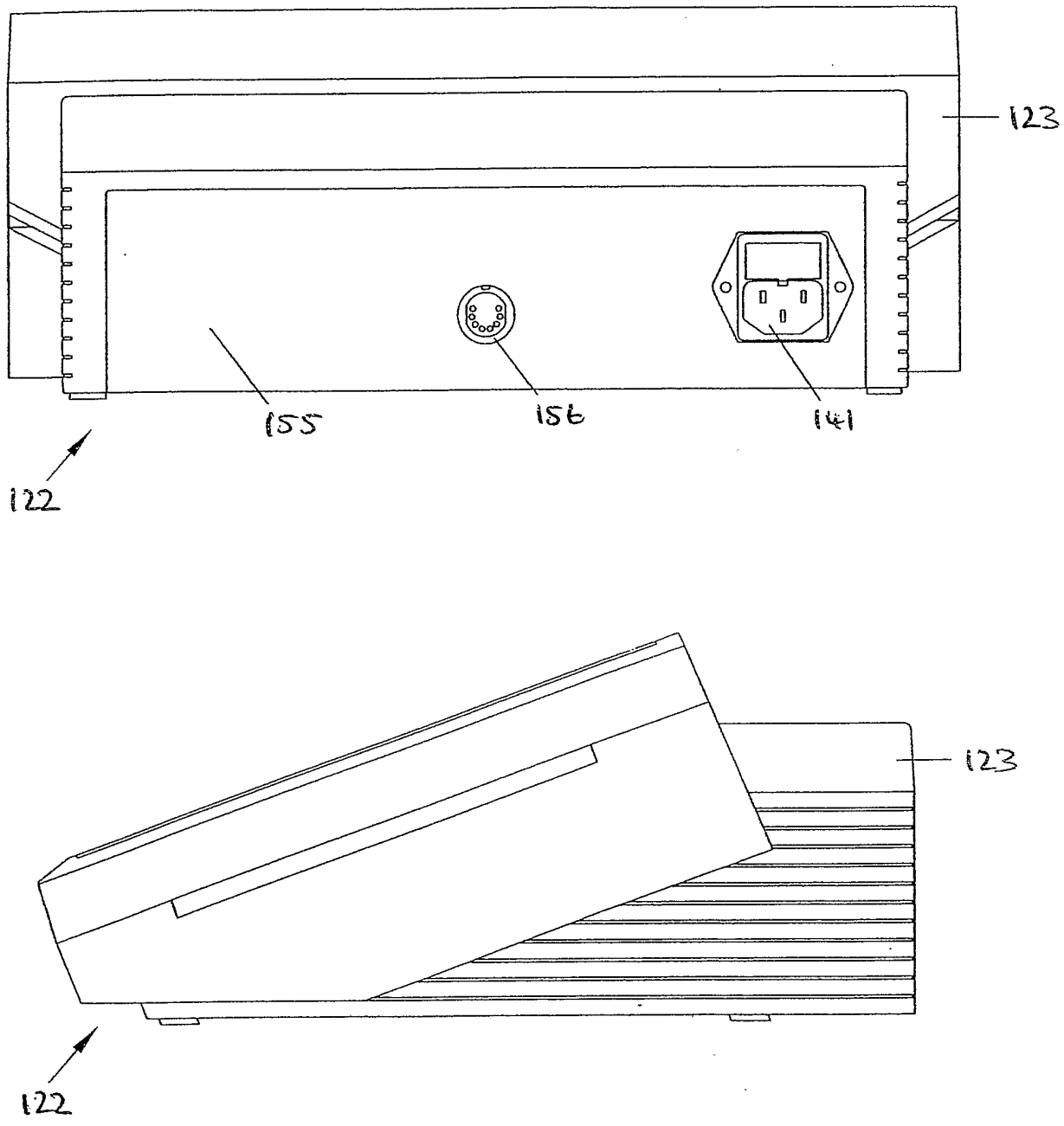
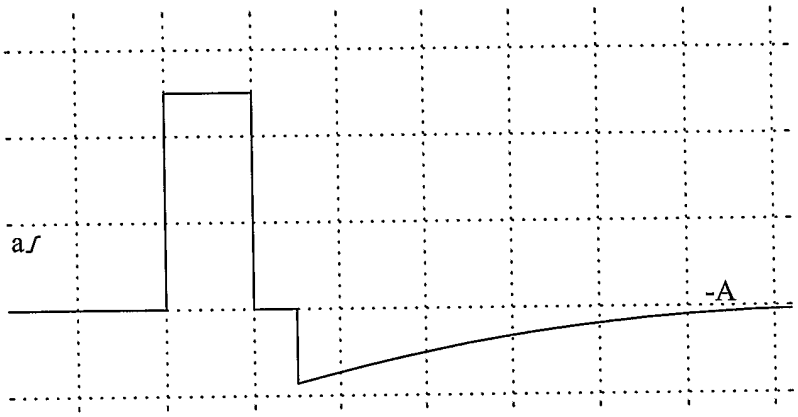
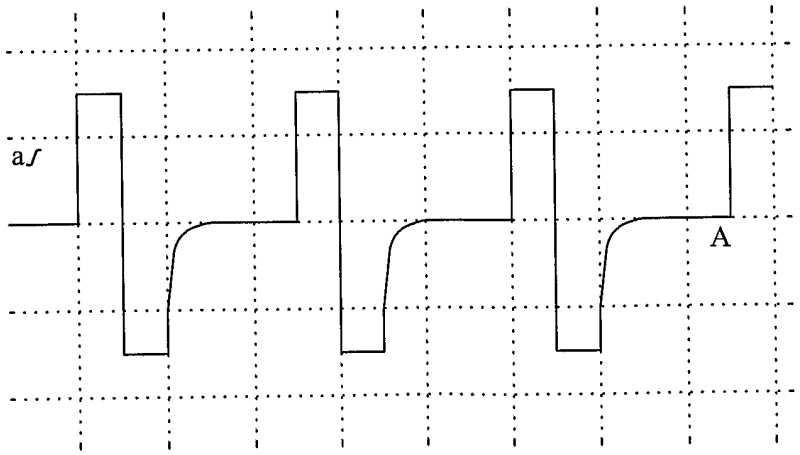


Figure 20a



Program A wave form

Figure 21b



Program A wave form

Figure 21b

Spontaneous activity in primary afferents can produce peripheral sensitisation in injured and uninjured adjacent neurons. Partial debervation increases relative concentrations of neuron growth factor for intact cells.

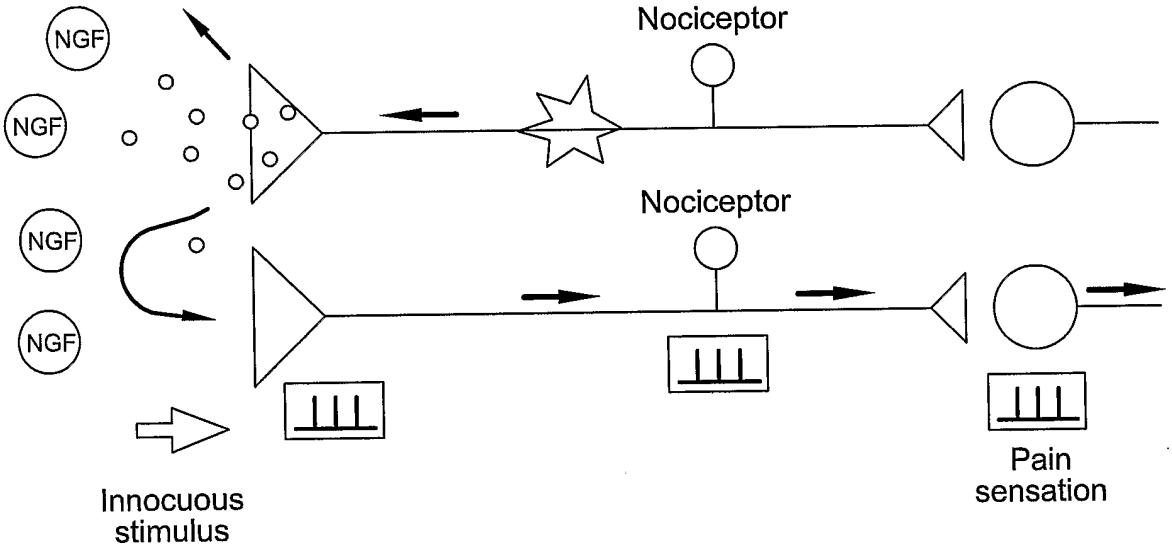
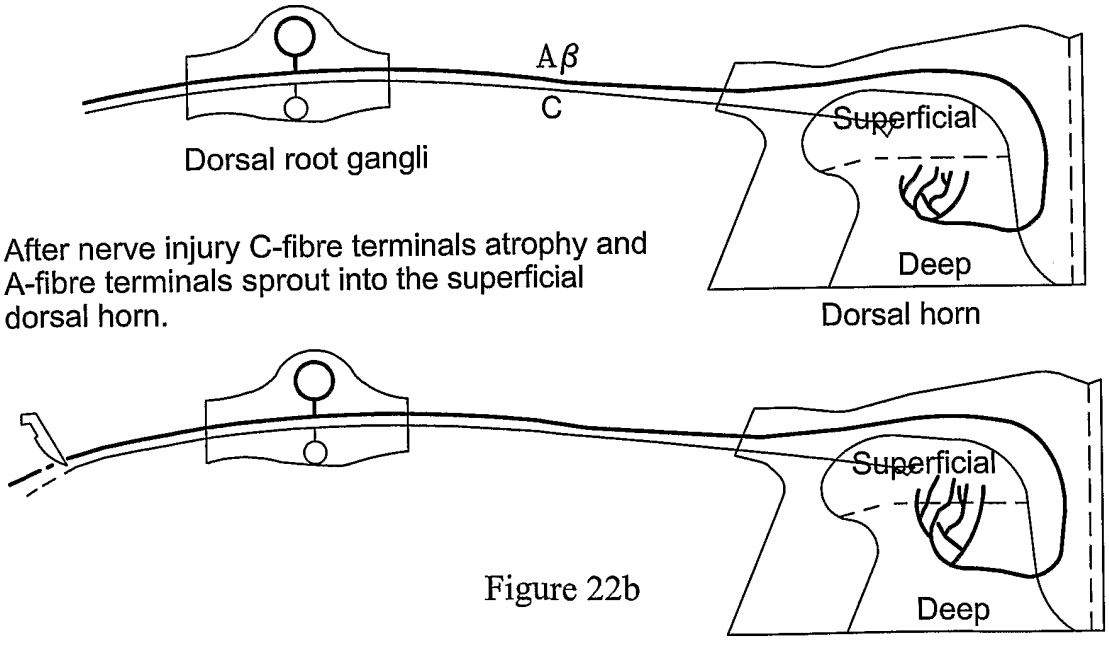


Figure 22a



After nerve injury C-fibre terminals atrophy and A-fibre terminals sprout into the superficial dorsal horn.

Figure 22b