

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 August 2008 (21.08.2008)

PCT

(10) International Publication Number
WO 2008/100841 A1

(51) International Patent Classification:
A61N 1/05 (2006.01)

[US/US]; 6384 Forestview Lane, Maple Grove, MN 55369 (US).

(21) International Application Number:
PCT/US2008/053543

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(22) International Filing Date:
11 February 2008 (11.02.2008)

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

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/706,146 14 February 2007 (14.02.2007) US

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(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,

[Continued on next page]

(54) Title: IMPLANTABLE MEDICAL LEAD INCLUDING A DIRECTIONAL ELECTRODE AND FIXATION ELEMENTS ALONG AN INTERIOR SURFACE

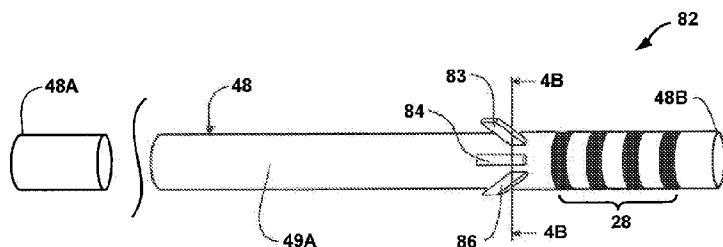


FIG. 5A

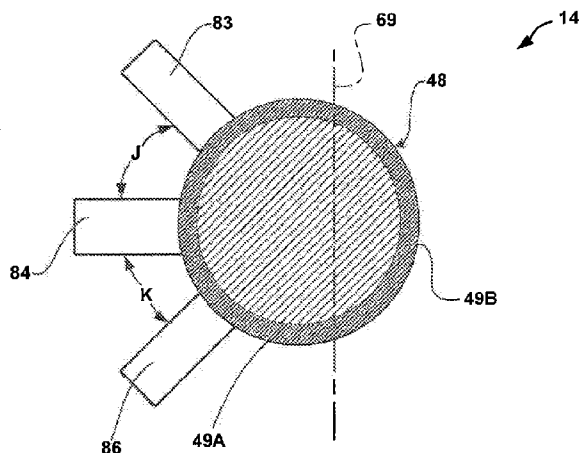


FIG. 5B

(57) Abstract: An implantable medical elongated member includes a first outer surface portion and a second outer surface portion extending around at least ten percent of an outer perimeter of the elongated member. A fixation element extends a distance from the first outer surface portion of the implantable medical elongated member. A longitudinally-extending section of the second outer surface portion proximate to a distal end of the elongated member is substantially devoid of any fixation elements that extend the distance from second outer surface portion. In some embodiments, the longitudinally-extending section of the second outer surface portion is substantially devoid of any exposed electrodes.



ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

IMPLANTABLE MEDICAL LEAD INCLUDING A DIRECTIONAL ELECTRODE AND FIXATION ELEMENTS ALONG AN INTERIOR SURFACE

5 TECHNICAL FIELD

The invention relates to medical device systems and, more particularly, to elongated members in medical device systems.

BACKGROUND

10 Electrical stimulation systems may be used to deliver electrical stimulation therapy to patients to treat a variety of symptoms or conditions such as chronic pain, tremor, Parkinson's disease, multiple sclerosis, spinal cord injury, cerebral palsy, amyotrophic lateral sclerosis, dystonia, torticollis, epilepsy, pelvic floor disorders, gastroparesis, muscle stimulation (e.g., functional electrical stimulation (FES) of muscles) or obesity. An
15 electrical stimulation system typically includes one or more implantable medical leads coupled to an electrical stimulator.

The implantable medical lead may be percutaneously or surgically implanted in a patient on a temporary or permanent basis such that at least one stimulation electrode is positioned proximate to a target stimulation site. The target stimulation site may be, for
20 example, a nerve or other tissue site, such as a spinal cord, pelvic nerve, pudendal nerve, stomach, bladder, or within a brain or other organ of a patient, or within a muscle or muscle group of a patient. The one or more electrodes located proximate to the target stimulation site may deliver electrical stimulation therapy to the target stimulation site in the form electrical signals.

25 Electrical stimulation of a sacral nerve may eliminate or reduce some pelvic floor disorders by influencing the behavior of the relevant structures, such as the bladder, sphincter and pelvic floor muscles. Pelvic floor disorders include urinary incontinence, urinary urge/frequency, urinary retention, pelvic pain, bowel dysfunction, and male and female sexual dysfunction. The organs involved in bladder, bowel, and sexual function
30 receive much of their control via the second, third, and fourth sacral nerves, commonly referred to as S2, S3 and S4 respectively. Thus, in order to deliver electrical stimulation to

at least one of the S2, S3, or S4 sacral nerves, an implantable medical lead is implanted proximate to the sacral nerve(s).

Electrical stimulation of a peripheral nerve, such as stimulation of an occipital nerve, may be used to mask a patient's feeling of pain with a tingling sensation, referred to as paresthesia. Occipital nerves, such as a lesser occipital nerve, greater occipital nerve or third occipital nerve, exit the spinal cord at the cervical region, extend upward and toward the sides of the head, and pass through muscle and fascia to the scalp. Pain caused by an occipital nerve, e.g. occipital neuralgia, may be treated by implanting a lead proximate to the occipital nerve to deliver stimulation therapy.

In many electrical stimulation applications, it is desirable for a stimulation lead to resist migration following implantation. For example, it may be desirable for the electrodes disposed at a distal end of the implantable medical lead to remain proximate to a target stimulation site in order to provide adequate and reliable stimulation of the target stimulation site. In some applications, it may also be desirable for the electrodes to remain substantially fixed in order to maintain a minimum distance between the electrode and a nerve in order to help prevent inflammation to the nerve and in some cases, unintended nerve damage. Securing the implantable medical lead at the target stimulation site may minimize lead migration.

SUMMARY

In general, the invention is directed toward an implantable medical elongated member that includes one or more fixation elements along an interior surface of the elongated member, as well as a method for implanting the elongated member in a patient. The elongated member is configured to be coupled to a medical device to deliver a therapy from the medical device to target therapy delivery site in a patient. The therapy may be electrical stimulation, drug delivery, or both.

An "interior" surface of the elongated member is a portion of an outer surface of the elongated member that generally faces away from an epidermis layer of a patient (or a scalp of the patient, depending on the particular application of the elongated member) when implanted in subcutaneous tissue of the patient. Accordingly, an "exterior" side of the elongated member generally faces toward the epidermis of the patient when the elongated member is implanted in subcutaneous tissue of a patient. The elongated

member may be implanted so that the fixation elements face inward away from an integumentary layer of the patient (e.g., the epidermis, dermis, or scalp), rather than outward so as to avoid damage to the integumentary layer or irritation to the patient from engagement of a fixation member with the integumentary layer. In one embodiment, the elongated member is fixed at one or more points that are distributed about less than a full outer perimeter of the elongated member in order to minimize or eliminate points of stress between the one or more fixation elements and the epidermis or scalp of a patient.

In accordance with one embodiment of the invention, at least a section of the exterior surface of the elongated member near a distal end of the elongated member is devoid of any fixation elements in order to help minimize or prevent stress points between the elongated member and an integumentary layer of the patient. In other embodiments, the exterior surface includes fixation elements that are sized to minimize any interference with the epidermis or scalp of the patient.

In one embodiment, the elongated member is an implantable medical lead that is coupled to an implantable or external electrical stimulator, which is configured to deliver electrical stimulation therapy to a target stimulation site in a patient via the lead, and more specifically, via at least one electrode disposed adjacent to a distal end of a lead body of the lead. The lead may be, for example, a cylindrical lead or a paddle lead. In another embodiment, the elongated member is a catheter configured to deliver a fluid, such as pharmaceutical agents, insulin, pain relieving agents, gene therapy agents, or the like from an implantable or external fluid reservoir and/or pump to a target tissue site in a patient.

The fixation element may be any suitable fixation element that helps substantially fix a position of the elongated member to (e.g., at or near) the target therapy delivery site, thereby reducing migration of the elongated member when the elongated member is implanted in a patient.

In one embodiment, the invention is directed to an apparatus comprising an implantable medical elongated member configured to couple to a medical device to deliver a therapy from the medical device to a target therapy delivery site in a patient. The elongated member extends between a proximal end and a distal end and defines an outer surface comprising a first outer surface portion, and a second outer surface portion extending around at least ten percent of an outer perimeter of the elongated member. The apparatus further comprises a fixation element extending a distance from the first outer

surface portion of the implantable medical elongated member. A longitudinally-extending section of the second outer surface portion proximate to the distal end of the elongated member and extending around at least ten percent of the outer perimeter of the elongated member is substantially devoid of any fixation elements that extend the distance from
5 second outer surface portion.

In another embodiment, the invention is directed to a system including a medical device and an elongated member. The implantable medical elongated member is configured to couple to the medical device to deliver a therapy from the medical device to a target therapy delivery site in a patient. The elongated member extends between a
10 proximal end and a distal end and defines an outer surface comprising a first outer surface portion, and a second outer surface portion extending around at least ten percent of an outer perimeter of the elongated member. The apparatus further comprises a fixation element extending a distance from the first outer surface portion of the implantable medical elongated member. A longitudinally-extending section of the second outer surface
15 portion proximate to the distal end of the elongated member and extending around at least ten percent of the outer perimeter of the elongated member is devoid of any fixation elements that extend the distance from second outer surface portion.

In yet another embodiment, the invention is directed toward an implantable medical lead comprising a lead body, one or more electrodes carried by the lead body, and
20 one or more fixation elements extending from an outer surface of the lead body. At least a circumferential sub-section of the outer surface extending over at least ten degrees is substantially devoid of the fixation elements.

In yet another embodiment, the invention is directed to method for implanting an elongated member in a patient. The method comprises introducing the elongated member
25 a body of a patient. The elongated member extends between a proximal end and a distal end and defines an outer surface comprising a first outer surface portion and a second outer surface portion extending around at least ten percent of an outer perimeter of the elongated member. The elongated member further comprises a fixation element extending a distance from the first outer surface portion of the implantable medical elongated
30 member. A longitudinally-extending section of the second outer surface portion proximate to the distal end of the elongated member and extending around at least ten percent of the outer perimeter of the elongated member is substantially devoid of any fixation elements

that extend the distance from second outer surface portion. The method further comprises orienting the elongated member so that the second outer surface portion faces a superficial direction and advancing the elongated member through the introducer to a target therapy delivery site to deploy the fixation member into tissue of the patient, wherein the fixation
5 element engages with surrounding tissue to substantially fix a position of the elongated member proximate to the target therapy delivery site.

In another embodiment, the invention is directed to an implantable medical lead comprising a lead body defining an outer surface comprising a first outer surface portion and a second outer surface portion extending around at least ten percent of an outer
10 perimeter of the lead body. The implantable medical lead further comprises a fixation element extending a distance from the first outer surface portion and at least one electrode coupled to the lead body. A longitudinally-extending section of the second outer surface portion proximate to a distal end of the lead body is substantially devoid of any fixation elements that extend the distance from the second outer surface portion. The
15 longitudinally-extending section of the second outer surface portion is substantially devoid of any exposed electrodes.

In another embodiment, the invention is directed toward an implantable medical lead comprising a substantially cylindrical lead body defining an outer surface comprising a first outer surface portion, and a second outer surface portion extending around at least
20 ten percent of an outer perimeter of the lead body. The implantable medical lead further comprises a fixation element extending a distance from the first outer surface portion and at least one electrode coupled to the lead body. A longitudinally-extending section of the second outer surface portion proximate to a distal end of the lead body is substantially devoid of any fixation elements that extend the distance from the second outer surface
25 portion. The at least one electrode is configured to limit delivery of electrical stimulation to directions radially outward from the first outer surface portion.

In yet another embodiment, the invention is directed to method for implanting an
30 medical lead in a patient. The method comprises introducing the medical lead into a body of the patient and advancing the medical lead to a target therapy delivery site within the body of the patient. The medical lead defines an outer surface comprising a first outer surface portion and a second outer surface portion extending around at least approximately ten percent of an outer perimeter of the medical lead. A longitudinally-extending section

of the second outer surface portion proximate to a distal end of the medical lead is substantially devoid of any fixation elements that extend the distance from the second outer surface portion. The medical lead further comprises at least one electrode coupled to the medical lead and a fixation element extending a distance from the first outer surface
5 portion. The second outer surface portion is substantially devoid of any exposed electrodes.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from
10 the claims.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 illustrates the implantation of a therapy system, which includes an electrical stimulator coupled to an implantable medical lead, at a location proximate to an occipital
15 nerve.

FIG. 2 is a block diagram illustrating various components of the electrical stimulator and implantable lead of the therapy system of FIG. 1.

FIG. 3A is a perspective view of the implantable medical lead of FIG. 1 implanted in subcutaneous tissue.

FIG. 3B is a schematic cross-sectional view of the implantable medical lead of
20 FIGS. 1-3A.

FIG. 3C is a schematic cross-sectional view of the introducer taken along line 3C-3C in FIG. 1.

FIGS. 4A-4B are schematic cross-sectional views of alternate embodiments of
25 implantable medical leads including fixation elements along a first outer surface portion of the lead body.

FIGS. 5A-8 illustrate alternate arrangements of fixation elements on a lead body.

FIG. 9 is a perspective view of a lead including fixation elements extending radially outward from a lead body at approximately 90° with respect to a first outer surface
30 portion of the lead body.

FIGS. 10A and 10B are a perspective view and schematic cross-sectional view, respectively, of a lead including a fixation element extending around a first outer surface portion of a lead body.

FIG. 11 is a schematic cross-sectional view of a lead including a fixation element
5 extending around less than a full first outer surface portion of a lead body.

FIG. 12A is a side view of a paddle lead including fixation elements along a first outer surface portion.

FIG. 12B is a schematic cross-sectional view of the lead body taken along line 12B-12B in FIG. 12A.

FIGS. 13A and 13B are side views of alternate embodiments of a paddle lead
10 including fixation elements along both the first outer surface portion and the second outer surface portion.

FIG. 14 is a flow diagram illustrating one example method for implanting a lead including fixation members along a first outer surface portion in accordance with an
15 embodiment of the present invention.

FIG. 15A is a perspective view of one embodiment of a lead including directional electrodes and fixation elements along a first outer surface portion of a lead body.

FIG. 15B is a schematic cross-sectional view of the lead of FIG. 15A taken along line 15B-15B in FIG. 15A.

FIG. 15C a cross-sectional view of another embodiment of the lead shown in
20 FIG. 15B, which includes an electrically insulating mask covering at least a portion of an electrode.

FIG. 16A is a perspective view of a lead and a sheath disposed over full ring electrodes to electrically insulate a subsection of the electrodes.

FIG. 16B is a schematic cross-sectional view of the lead of FIG. 16A taken along
25 line 16B-16B in FIG. 16A.

FIG. 17 is a schematic cross-sectional view of another embodiment of a lead, which includes an electrode with an electrically conductive section along an entire first outer surface portion of the lead body.

FIG. 18 is a perspective view of an embodiment of a lead including segmented
30 electrodes, as well as fixation elements along a first outer surface portion of a lead body.

FIG. 19A is a perspective view of another embodiment of a lead including directional electrodes and fixation elements along a first outer surface portion of a lead body.

FIG. 19B is a schematic cross-sectional view of the lead of FIG. 19A taken along
5 line 18B-18B in FIG. 19A.

DETAILED DESCRIPTION

The present invention relates to an implantable medical elongated member including one or more fixation elements disposed about an outer surface of the elongated
10 member in an arrangement that minimizes or eliminates points of stress between the fixation elements and an integumentary layer (e.g., an epidermis layer, dermis or scalp) of a patient. For example, the elongated member may include fixation elements that radially extend from less than a full outer circumference of a lead body or fixation elements disposed along one outer surface portion of the elongated member. Due to the
15 arrangement of the fixation elements about the outer surface of the elongated member, the elongated member may be implanted so that the fixation elements do not interfere with the epidermis, dermis, or scalp of the patient. For example, the elongated member may be implanted such that the fixation elements may face away from the epidermis, dermis, or scalp of the patient.

The elongated member is configured to be coupled to a medical device to deliver a
20 therapy from the medical device to target tissue in a patient. Various embodiments of the elongated member may be applicable to different therapeutic applications. For example, the elongated member may be a stimulation lead or a lead extension that is used to deliver electrical stimulation to a target stimulation site and/or sense parameters (e.g., blood
25 pressure, temperature or electrical activity) of a patient. In another embodiment, the elongated member may be a catheter that is placed to deliver a fluid, such as pharmaceutical agents, insulin, pain relieving agents, gene therapy agents or the like from a fluid delivery device (e.g., a fluid reservoir and/or pump) to a target tissue site in a patient. The invention is applicable to any configuration or type of implantable elongated
30 member that is used to deliver therapy to a site in a patient. For purposes of illustration, however, the disclosure will refer to a neurostimulation lead.

FIG. 1 a schematic perspective view of a therapy system 10, which includes an electrical stimulator 12 coupled to implantable medical lead 14. Lead 14 is aligned to be introduced into introducer needle 16, which is positioned proximate to target stimulation site 18 of patient 20. In particular, lead 14 is aligned to be implanted and anchored or
5 fixated with fixation elements proximate to target stimulation site 18 within patient 20 for stimulation of one or more occipital nerves. In the example shown in FIG. 1, target stimulation site 18 is proximate to at least one of lesser occipital nerve 22, greater occipital nerve 24 or third occipital nerve 26. In alternate embodiments, lead 14 may be positioned proximate to one or more other peripheral nerves proximate to occipital nerves 22, 24,
10 and 26 of patient 20, such as nerves branching from occipital nerves 22, 24 or 26. In addition, therapy system 10 may be used to provide stimulation therapy to any other suitable nerves within patient 20, such as, but not limited to, trigeminal nerves, branches of trigeminal nerves or nerves within a brain, stomach or spinal cord of patient 20.

In the embodiment shown in FIG. 1, electrical stimulator 12 is a neurostimulator
15 that is either implantable or external. For example, neurostimulator 12 may be subcutaneously implanted in the body of a patient (e.g., in a chest cavity, lower back, lower abdomen, or buttocks of patient 20). Neurostimulator 12 provides a programmable stimulation signal (e.g., in the form of electrical pulses or substantially continuous-time signals) that is delivered to target stimulation site 18 by implantable medical lead 14, and
20 more particularly, via one or more stimulation electrodes 28 carried by lead 14. In some embodiments, neurostimulator 12 may be coupled to two or more leads, e.g., for bilateral or multi-lateral stimulation. Stimulation of occipital nerves 22, 24, and 26 may help alleviate pain associated with, for example, chronic migraines, cervicogenic headaches, occipital neuralgia or trigeminal neuralgia. Neurostimulator 12 may also be referred to as
25 a pulse generator. In some embodiments, lead 14 may also carry one or more sense electrodes to permit neurostimulator 12 to sense electrical signals from target stimulation site 18.

Proximal end 14A of lead 14 may be both electrically and mechanically coupled to connector 13 of neurostimulator 12 either directly or indirectly (e.g., via a lead extension).
30 In particular, conductors disposed within a lead body of lead 14 electrically connect stimulation electrodes 28 (and sense electrodes, if present) located adjacent to distal end 14B of lead 14 to neurostimulator 12.

As described in further detail below, lead 14 further includes one or more one fixation elements (not shown in FIG. 1) extending from an interior portion of an outer surface of lead 14 to help substantially fix lead 14 proximate to target stimulation site 18. In the embodiment shown in FIG. 1, an interior portion of the outer surface of lead 14 faces away from scalp 30 of patient 20. By including one or more fixation elements that face away from scalp 30, and including substantially no fixation elements on a side facing scalp 30, the possibility of a fixation element (which may protrude from lead 14) extending into or through scalp 30 is minimized or eliminated. At the same time, however, the inward-facing fixation elements are effective in resisting displacement of lead 14, and particularly electrodes 28, from the stimulation site. In one embodiment, an exterior portion of the outer surface of lead (i.e., a portion that faces scalp 30 when lead 14 is implanted in patient 20) is devoid of any fixation elements, which may contribute to the comfort of patient 20 and avoidance of tissue erosion or damage when lead 14 is implanted in patient 20.

In the application of therapy system 10 shown in FIG. 1, implantation of lead 14 may involve the subcutaneous placement of lead 14 transversely across one or more occipital nerves 22, 24, and/or 26 that are causing patient 20 to experience pain. Where treating occipital neuralgia, patient 30 may be placed in a lateral position or in a prone position during implantation of lead 14.

In order to locate the specific occipital nerve causing pain, a clinician may palpate the area of pain. In addition, some embodiments, a screening lead may be used prior to implanting lead 14 to develop optimal stimulation parameters (e.g., various electrode combinations, amplitude, pulse width or rate).

In one example method of implanting lead 14 proximate to one or more occipital nerves 22, 24, and/or 26, a vertical skin incision 33 approximately two centimeters in length is made in the neck of patient 20 lateral to the midline of the spine at the level of the C1 vertebra. Fluoroscopy may be used to identify the location of the C1 vertebra. Typically, local anesthetic is used during the implantation procedure. The length of vertical skin incision 33 may vary depending on the particular patient. At this location, the patient's skin and muscle are separated by a band of connective tissue referred to as fascia. Introducer needle 16, which may be a Tuohy needle, is introduced into the subcutaneous tissue, superficial to the fascia and muscle layer but below the skin. In some

embodiments, introducer needle 16 may be manually curved by the clinician to conform to the contour of the body of patient 20 proximate to the peripheral nerve, and in the embodiment shown in FIG. 1, the clinician may conform introducer needle 16 to the contour of the neck of patient 20.

5 Occipital nerves 22, 24, and 26 are located within the cervical musculature and overlying fascia, and as a result, introducer needle 16, and eventually lead 14, are inserted superior to occipital nerves 22, 24, and 26. That is, in one embodiment, introducer needle 16 is introduced into the fascia layer of patient 20 such that introducer needle 16 is between the skin of patient 20 and the occipital nerve 22, 24, and/or 26 to be stimulated.

10 Introducer needle 16 may be guided transversely from incision 33 across the midline of the spine of patient 16. Fluoroscopic observation may aid the clinician in identifying the trunk of the occipital nerve.

 Once introducer needle 16 is fully inserted, a needle stylet may be removed from the introducer needle, if introducer needle 16 includes a stylet. Lead 14 may then be
15 advanced through introducer needle 16 and positioned to allow stimulation of the lesser occipital nerve 22, greater occipital nerve 24, third occipital nerve 26, and/or other peripheral nerves proximate to an occipital nerve. The position of lead 14 may be verified via fluoroscopy or another suitable technique. In addition, the clinician may confirm that the electrodes proximate to distal end 14A of lead 14 are properly placed with respect to
20 the particular occipital nerve. For example, the clinician may provide electrical signals to the electrodes and patient 30 may provide feedback relating to the paresthesia coverage. Upon placement of lead 14, introducer needle 16 may be removed (either before or after confirming the placement of the electrodes). As described below, in one embodiment, upon removal of introducer needle 16, the one or more fixation elements of lead 14 engage
25 with surrounding tissue to substantially fix a position of lead 14 proximate to target stimulation site 18. In another embodiment, the one or more fixation elements of lead 14 adhere to surrounding tissue to substantially fix a position of lead 14.

 Accurate lead placement may affect the success of occipital nerve stimulation, as well as any other nerve stimulation application of therapy system 10. If lead 14 is located
30 too deep, i.e. anterior, in the subcutaneous tissue, patient 20 may experience muscle contractions, grabbing sensations, or burning. Such problems may additionally occur if lead 14 migrates after implantation. Furthermore, due to the location of implanted lead 14

on the back of the neck of patient 20, lead 14 may be subjected to pulling and stretching that may increase the chances of lead migration. For these reasons, fixating lead 14 may be advantageous.

Although occipital nerve stimulation is shown in FIG. 1, therapy system 10 is
5 useful in other neurostimulation applications. In alternate applications of lead 14, target stimulation site 18 may be a location proximate to other nerves, organs, muscles, muscle groups or other tissue sites in patient 20, which may be selected based on, for example, a therapy program selected for a particular patient 20. For example, therapy system 10 may be used to deliver neurostimulation therapy to a sacral nerve, a pudendal nerve, a perineal
10 nerve or other areas of the nervous system, in which cases, lead 14 would be implanted and substantially fixed proximate to the respective nerve. As further examples, lead 14 may be positioned for temporary or chronic spinal cord stimulation for the treatment of pain, for peripheral neuropathy or post-operative pain mitigation, ilioinguinal nerve stimulation, intercostal nerve stimulation, gastric stimulation for the treatment of gastric
15 mobility disorders and obesity, muscle stimulation (e.g., functional electrical stimulation (FES) of muscles), for mitigation of other peripheral and localized pain (e.g., leg pain or back pain), or for deep brain stimulation to treat movement disorders and other neurological disorders. Accordingly, although patient 20 and target stimulation site 18 of
20 FIG. 1 are referenced throughout the remainder of the disclosure for purposes of illustration, a neurostimulation lead 14 in accordance with the invention may be adapted for use in a variety of electrical stimulation applications.

Therapy system 10 may also include clinician programmer 32 and patient programmer 34. Clinician programmer 32 may be a handheld computing device that permits a clinician to program neurostimulation therapy for patient 20, e.g., using input
25 keys and a display. For example, using clinician programmer 32, the clinician may specify neurostimulation parameters for use in delivery of neurostimulation therapy. Clinician programmer 32 supports telemetry (e.g., radio frequency (RF) telemetry) with neurostimulator 12 to download neurostimulation parameters and, optionally, upload operational or physiological data stored by neurostimulator 12. In this manner, the
30 clinician may periodically interrogate neurostimulator 12 to evaluate efficacy and, if necessary, modify the stimulation parameters.

Like clinician programmer 32, patient programmer 34 may be a handheld computing device. Patient programmer 34 may also include a display and input keys to allow patient 20 to interact with patient programmer 34 and neurostimulator 12. In this manner, patient programmer 34 provides patient 20 with an interface for control of neurostimulation therapy by neurostimulator 12. For example, patient 20 may use patient programmer 34 to start, stop or adjust neurostimulation therapy. In particular, patient programmer 34 may permit patient 20 to adjust stimulation parameters such as duration, amplitude, pulse width and pulse rate, within an adjustment range specified by the clinician via clinician programmer 34, or select from a library of stored stimulation therapy programs.

Neurostimulator 12, clinician programmer 32, and patient programmer 34 may communicate via cables or a wireless communication, as shown in FIG. 1. Clinician programmer 32 and patient programmer 34 may, for example, communicate via wireless communication with neurostimulator 12 using RF telemetry techniques known in the art. Clinician programmer 32 and patient programmer 34 also may communicate with each other using any of a variety of local wireless communication techniques, such as RF communication according to the 802.11 or Bluetooth specification sets, infrared communication, e.g., according to the IrDA standard, or other standard or proprietary telemetry protocols.

FIG. 2 is a block diagram illustrating various components of neurostimulator 12 and an implantable medical lead 14. Neurostimulator 12 includes therapy delivery module 40, processor 42, memory 44, telemetry module 46, and power source 47. In some embodiments, neurostimulator 12 may also include a sensing circuit (not shown in FIG. 2). Implantable medical lead 14 includes lead body 48 extending between proximal end 48A and distal end 48B. In the embodiment of FIG. 2, lead body 48 is cylindrical and defines an outer surface including a first portion 49A, which is facing away from the plane of the image of FIG. 2. The outer surface of lead body 48 further defines a second portion 49B (not shown in FIG. 2) that faces into the plane of the image of FIG. 2. In other embodiments, lead body 48 may be paddle-shaped (i.e., a "paddle" lead), in which case lead body 48 would define two opposing surfaces, as shown in FIG. 11 with respect to lead 142.

Electrodes 28A, 28B, 28C, and 28D (collectively "electrodes 28") are disposed on lead body 48 adjacent to distal end 48B of lead body 48. In some embodiments, electrodes 28 may be ring electrodes. In other embodiments, electrodes 28 may be segmented or partial ring electrodes, each of which extends along an arc less than 360 degrees (°) (e.g., 90-120 degrees) around the circumference of lead body 48. The configuration, type, and number of electrodes 28 illustrated in FIG. 2 are merely exemplary.

In embodiments in which lead 14 is a paddle lead, electrodes 28 may extend along one side of lead body 48. Electrodes 28 extending around a portion of the circumference of lead body 48 or along one side of a paddle lead may be useful for providing an electrical stimulation field in a particular direction/targeting a particular therapy delivery site. For example, in the electrical stimulation application shown in FIG. 1, electrodes 28 may be disposed along lead body 48 such that the electrodes face toward occipital nerves 22, 24, and/or 26, or otherwise away from scalp 30. This may be an efficient use of stimulation because electrical stimulation of scalp 30 may not provide any or very minimal useful therapy to patient 20. In addition, the use of segmented or partial ring electrodes 28 may also reduce the overall power delivered to electrodes 28 by neurostimulator 12 because of the efficient delivery of stimulation to occipital nerves 22, 24, and/or 26 (or other target stimulation site) by eliminating or minimizing the delivery of stimulation to unwanted or unnecessary regions within patient 20.

In embodiments in which electrodes 28 extend around a portion of the circumference of lead body 48 or along one side of a paddle lead, lead 14 may include one or more orientation markers 45 proximate to proximal end 14A that indicate the relative location of electrodes 28. Orientation marker 45 may be a printed marking on lead body 48, an indentation in lead body 48, a radiographic marker, or another type of marker that is visible or otherwise detectable (e.g., detectable by a radiographic device) by a clinician. Orientation marker 45 may help a clinician properly orient lead 14 such that electrodes 28 face the desired direction (e.g., toward occipital nerves 22, 24, and/or 26) within patient 20. For example, orientation marker 45 may also extend around the same portion of the circumference of lead body 48 or along the side of the paddle lead as electrodes 28. In this way, orientation marker 45 faces the same direction as electrodes,

thus indicating the orientation of electrodes 28 to the clinician. When the clinician implants lead 14 in patient 20, orientation marker 45 may remain visible to the clinician.

Neurostimulator 12 delivers stimulation therapy via electrodes 28 of lead 14. In particular, electrodes 28 are electrically coupled to a therapy delivery module 40 of neurostimulator 12 via conductors within lead body 48. In one embodiment, an implantable signal generator or other stimulation circuitry within therapy delivery module 40 delivers electrical signals (e.g., pulses or substantially continuous-time signals, such as sinusoidal signals) to targets stimulation site 18 (FIG. 1A) via at least some of electrodes 28 under the control of a processor 42. The implantable signal generator may be coupled to power source 47. Power source 47 may take the form of a small, rechargeable or non-rechargeable battery, or an inductive power interface that transcutaneously receives inductively coupled energy. In the case of a rechargeable battery, power source 47 similarly may include an inductive power interface for transcutaneous transfer of recharge power.

The stimulation energy generated by therapy delivery module 40 may be formulated as neurostimulation energy, e.g., for treatment of any of a variety of neurological disorders, or disorders influenced by patient neurological response. The signals may be delivered from therapy delivery module 40 to electrodes 28 via a switch matrix and conductors carried by lead 14 and electrically coupled to respective electrodes 28.

Processor 42 may include a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or the like. Processor 42 controls the implantable signal generator within therapy delivery module 40 to deliver neurostimulation therapy according to selected stimulation parameters. Specifically, processor 42 controls therapy delivery module 40 to deliver electrical signals with selected amplitudes, pulse widths (if applicable), and rates specified by the programs. In addition, processor 42 may also control therapy delivery module 40 to deliver the neurostimulation signals via selected subsets of electrodes 28 with selected polarities. For example, electrodes 28 may be combined in various bipolar or multi-polar combinations to deliver stimulation energy to selected sites, such as nerve sites adjacent the spinal column, pelvic floor nerve sites, or cranial nerve sites.

Processor 42 may also control therapy delivery module 40 to deliver each stimulation signal according to a different program, thereby interleaving programs to simultaneously treat different symptoms or provide a combined therapeutic effect. For example, in addition to treatment of one symptom such as sexual dysfunction, neurostimulator 12 may be configured to deliver neurostimulation therapy to treat other symptoms such as pain or incontinence.

Memory 44 of neurostimulator 12 may include any volatile or non-volatile media, such as a RAM, ROM, NVRAM, EEPROM, flash memory, and the like. In some embodiments, memory 44 of neurostimulator 12 may store multiple sets of stimulation parameters that are available to be selected by patient 20 via patient programmer 34 (FIG. 1) or a clinician via clinician programmer 32 (FIG. 1) for delivery of neurostimulation therapy. For example, memory 44 may store stimulation parameters transmitted by clinician programmer 32 (FIG. 1). Memory 44 also stores program instructions that, when executed by processor 42, cause neurostimulator 12 to deliver neurostimulation therapy. Accordingly, computer-readable media storing instructions may be provided to cause processor 42 to provide functionality as described herein.

In particular, processor 42 controls telemetry module 46 to exchange information with an external programmer, such as clinician programmer 32 and/or patient programmer 34 (FIG. 1), by wireless telemetry. In addition, in some embodiments, telemetry module 46 supports wireless communication with one or more wireless sensors that sense physiological signals and transmit the signals to neurostimulator 12.

As previously discussed, migration of lead 14 following implantation may be undesirable, and may have detrimental effects on the quality of therapy delivered to a patient 20. For example, with respect to the occipital nerve stimulation application shown in FIG. 1, migration of lead 14 may cause displacement of electrodes 28 carried adjacent to distal end 14B of lead 14 with respect to target stimulation site 18. In such a situation, the electrodes may not be properly positioned to deliver therapy to target stimulation site 18, resulting in reduced electrical coupling, and possibly undermining therapeutic efficacy of the neurostimulation therapy from system 10.

Substantially fixing lead 14 to surrounding tissue may help prevent lead 14 from migrating from target stimulation site 18 following implantation, which may ultimately help avoid harmful effects that may result from a migrating lead 14. However, while it

may be desirable to fix lead 14 such that electrodes 28 remain proximate to target stimulation site 18 (FIG. 1), in some situations, it may also be desirable to minimize discomfort to patient 20 from lead 14. For example, when lead 14 is implanted in a dermis or subcutaneous tissue of patient 20 (FIG. 1), such as in the occipital nerve stimulation application shown in FIG. 1, patient 20 may be more aware of lead 14 due to the location of lead 14 near an epidermis, scalp 30 or another integumentary layer of patient 20.

To that end, lead 14 includes fixation elements 50, 52, and 54 (not shown in FIG. 3A) along a first portion 49A of outer surface 49 of lead body 48 to minimize migration of lead 14 and substantially fix a position of electrodes 28 proximate to target stimulation site 18. When lead 14 is implanted proximate to target stimulation site 18, lead body 48 may be oriented such that first portion 49A ("first outer surface portion") of outer surface 49 generally faces away from the scalp 30 of patient and in an inward, deep direction and a majority of second portion 49B ("second outer surface portion") (shown in FIG. 3B) faces outward in a superficial direction. In this way, first portion 49A of outer surface 49 may also be referred to as an "interior surface" of lead body 48 and second portion 49B may also be referred to as an "exterior surface" of lead body 48. During implantation, the caregiver will take note of the interior and exterior surfaces 49A, 49B of lead body 48 and appropriately position lead 14 so that the interior and exterior surfaces face inward and outward, respectively.

Fixation elements 50, 52, and 54 engage with surrounding tissue at target stimulation site 18 to fix a position of lead 14. When lead 14 is implanted in patient 20 such that first outer surface portion 49A of lead body 48 faces away from scalp 30 (or another integumentary layer) of patient 20, fixation elements 50 and 54 extend substantially parallel to scalp 30 and fixation element 52 extends away from scalp 30. In the embodiment of lead 14 shown in FIG. 2, second portion 49B of outer surface 49 of lead body 48 is devoid of any fixation elements. As a result, lead 14 does not include any fixation elements that may extend into scalp 30, and possibly protrude through scalp 30, thereby resulting in an implantable medical lead 14 that is more comfortable to patient 20 and reduces the possibility of erosion or damage to subcutaneous tissue.

Although lead 14 includes three fixation elements 50, 52, and 54 in the embodiment shown in FIG. 2, lead 14 may include any suitable number of fixation elements 50, 52, and 54. Furthermore, fixation elements 50, 52, and 54 need not be

protrusions that extend from lead 14. Fixation elements 50, 52, and 54 may be any suitable actively or passively deployed fixation element that helps prevent migration of lead 14 when lead 14 is implanted in patient 20, such as, but not limited to, one or more tines, barbs, hooks, wire-like elements, adhesives (e.g., surgical adhesives), balloon-like
5 fixation elements, pinning fixation elements, collapsible or expandable fixation structures, and so forth. Fixation elements 50, 52, and 54 may be composed of any suitable biocompatible material, including, but not limited to, polymers, titanium, stainless steel, Nitinol, other shape memory materials, hydrogel or combinations thereof.

Fixation elements 50, 52, and 54 may be any suitable size, which may depend on
10 the particular application of lead 14. In particular, it may be desirable to select the size of or otherwise configure fixation elements 50, 52, and 54 to fix lead 14 to a particular region of the patient proximate to the target stimulation site (e.g., a peripheral nerve stimulation site), which may involve selecting the size of fixation elements 50, 52, and 54 to
15 accommodate the specific anatomical configuration of a region of the patient proximate to the peripheral nerve.

Furthermore, fixation elements 50, 54, and 54 may not be attached directly to lead 14, but may be carried by another apparatus that is attached to the elongated member, such as a sleeve or mounting band. An example of a mounting band is described in commonly-assigned U.S. Patent No. 6,999,819, entitled "IMPLANTABLE MEDICAL
20 ELECTRICAL STIMULATION LEAD FIXATION METHOD AND APPARATUS" and issued on February 14, 2006.

Examples of suitable hydrogel fixation elements are described in commonly assigned U.S. Patent Application Publication No. 2006/0095077, entitled
"EXPANDABLE FIXATION STRUCTURES, filed on October 29, 2004; U.S. Patent
25 Application Publication No. 2006/0095078, entitled "EXPANDABLE FIXATION MECHANISM", filed on October 29, 2004; and U.S. Patent Application Serial No. 11/591,174 by Martin T. Gerber, entitled "IMPLANTABLE MEDICAL ELONGATED MEMBER INCLUDING EXPANDABLE FIXATION MEMBER", filed on October 31, 2006.

30 Other suitable fixation elements may include wire-like fixation elements as described in commonly assigned U.S. Patent Application Publication No. 2005/0096718, entitled "IMPLANTABLE STIMULATION LEAD WITH FIXATION MECHANISM",

filed on October 31, 2003 and commonly-assigned U.S. Patent Application Serial No. 11/591,282 by Martin T. Gerber, entitled "IMPLANTABLE STIMULATION LEAD INCLUDING WIRE-LIKE FIXATION ELEMENTS" filed on October 31, 2006. An example of tine fixation elements is described in U.S. Patent No. 6,999,819, entitled
5 "IMPLANTABLE MEDICAL ELECTRICAL STIMULATION LEAD FIXATION METHOD AND APPARATUS".

An example of a suitable lead including a tissue-receiving cavity is described in commonly-assigned U.S. Patent Application Serial No. 11/591,294 by Martin T. Gerber, entitled "IMPLANTABLE MEDICAL ELONGATED MEMBER INCLUDING A
10 TISSUE RECEIVING CAVITY", filed on October 31, 2006. An example of a suitable in situ formed fixation element is described in commonly-assigned U.S. Patent Application Serial No. 11/591,433 by Martin T. Gerber, entitled "IMPLANTABLE MEDICAL ELONGATED MEMBER WITH IN SITU FORMED FIXATION ELEMENT" filed on October 31, 2006. An example of suitable balloon-like fixation elements are described in
15 commonly-assigned U.S. Patent Application Serial No. 11/591,447 by Martin T. Gerber, entitled, "IMPLANTABLE STIMULATION LEAD INCLUDING BALLOON FIXATION ELEMENT".

Each of the aforementioned patents and patent applications relating to suitable fixation elements are herein incorporated by reference in their entirety.

20 FIG. 3A illustrates a schematic cross-sectional view of skin 61 of patient 20, which includes epidermis 62, dermis 64, and subcutaneous tissue 66, as well as a portion of a nerve 68. FIG. 3A further shows a perspective view of implantable medical lead 14 of FIGS. 1 and 2 implanted in a subcutaneous tissue 66 proximate to nerve 68. FIG. 3B illustrates a schematic cross-sectional view of lead 14 taken along line 3B-3B in FIG. 3A.

25 Distal end 48B of lead body 48 is shown in FIG. 3A. Proximal end 48A of lead body 48, which contains contacts (not shown in FIGS. 3A and 3B) to electrically couple lead 14 (and in particular, electrodes 28) to a lead extension or a neurostimulator (e.g., neurostimulator 12 in FIG. 1). Skin 61 and nerve 68 are general representations of a region of patient 20 and are shown to aid in the description of the invention, and thus, are
30 not necessarily specific to a specific nerve of patient 20, nor drawn to any particular scale.

If neurostimulator 12 (FIGS. 1 and 2) is implanted in patient 20, the entire length of lead 14 is typically implanted in patient 20. On the other hand, if neurostimulator 12 is

external, lead 14 may be partially implanted within patient 20 and lead 14 (or a lead extension to which proximal end 14A (shown in FIG. 1) is coupled) may extend through epidermis layer 62 via a percutaneous port.

As previously discussed, lead body 48 defines outer surface 49, which includes first ("interior") outer surface portion 49A and second ("exterior") outer surface portion 49B, which are demarcated by line 69 in FIG. 3A. In general, first outer surface portion 49A and second outer surface portion 49B do not overlap and have center points 70 and 72 that are generally opposite each other. Center points 70 and 72 are shown in FIG. 3B and referred to herein as reference points to aid in the description of the invention. Fixation elements 50, 52, and 54 (shown in FIG. 3B) are distributed about less than a full outer perimeter of lead body 48 because first outer surface portion 49A extends around less than a full outer perimeter of lead body 48. The outer perimeter of lead body 48 is the outer circumference of lead body 48. In embodiments in which a lead includes a noncircular cross-section, the outer perimeter of the lead body is defined by the outermost edge of a cross-section of the lead body.

In the embodiment shown in FIG. 3A, first outer surface portion 49A has a larger size (i.e. measured in terms of surface area) than second outer surface portion 49B. In particular, in the embodiment shown in FIGS. 3A-B, second outer surface portion 49B extends around less than or equal to about 50 percent (%) of the outer perimeter of lead body 48. In one embodiment, second outer surface portion 49B extends around at least 10% of the outer perimeter of lead body 48, while second outer surface portion 49A extends around about 50% to about 90% of the outer perimeter of lead body 48. In the embodiment shown in FIGS. 3A-B, first outer surface portion 49A extends around approximately 75% of the outer perimeter of lead body 48. Therefore, fixation elements 50, 52, and 54 are distributed about approximately 75% of the outer perimeter of lead body 48. In some embodiments, first and second portions 49A and 49B may be the same size. For example, demarcation line 69 may extend through a center of lead body 48, such that first and second outer surface portions 49A and 49B each define a half of lead body 48. Alternatively, demarcation line 69 may be moved toward center point 70 of first portion 49A to define a second portion 49B that is a greater (i.e., has a greater surface area) than first portion 49A.

In embodiments in which lead body 48 has a circular cross-section, the percentages given above can be translated to a percentage of a circle. For example, in the embodiment shown in FIGS. 3A-B, first outer surface portion 49A extends around approximately 75% of the outer perimeter of lead body 48, or alternatively, extends over about 270°.

5 Regardless of the respective sizes of first and second outer surface portions 49A and 49B, lead 14 may be oriented and implanted in patient such that first outer surface portion 49A (particularly center point 70) generally faces a deep direction 67A (i.e., faces away from epidermis 62), while a majority of second outer surface portion 49B (particularly center point 72) faces a superficial direction 67B (i.e., faces toward
10 epidermis 62). Of course, due to the cylindrical shape of lead body 48 in the example of FIGS. 3A and 3B, at least some of first outer surface portion 49A neither faces toward nor away from epidermis 62, but rather faces a direction 63 (shown in FIG. 3B) that is generally parallel to epidermis 62. Only a small percentage of second outer surface portion 49B faces direction 63, and thus, it can be said that the “majority” of second outer
15 surface portion 49B faces a superficial direction.

 Lead 14 may include a visible marker 65 (shown in FIG. 2 in phantom) on the proximal end 48A of lead body 48. Visible marker 65 may provide a reference point for a clinician during implantation of lead 14 in patient 20. For example, the clinician may use visible marker 65 to orient lead 14 such that first outer surface portion 49A faces a deep
20 direction when lead 14 is implanted in patient 20. Visible marker 65 may be a printed marking on lead body 48, an indentation in lead body 48, a radiographic marker, or another type of marker that is visible or otherwise detectable (e.g., detectable by a radiographic device) by a clinician. In FIG. 2, visible marker 65 is shown in phantom because visible marker 65 is located on second outer surface portion 49B of lead body 48,
25 which is facing into the plane of the image of FIG. 2. Alternatively, visible marker 65 may be on first outer surface portion 49A. In other embodiments, visible marker 65 may be any suitable configuration (e.g., another shape, size, etc.).

 In addition to or instead of visible marker 65, introducer 16 (FIG. 1) may have orientation marks to properly orient fixation elements 50, 52, and 54 of lead 14 with
30 respect to epidermis 62 of patient 20. For example, proximal end 16A of introducer 16 may include printed markings for aligning with visible marker 65 of lead 14 to orient lead 14 such that first outer surface portion 49A faces away from epidermis 62 when lead

14 is implanted in patient 20. In some embodiments, visible marker 65 and orientation marker 45 may overlap and may effectively be a single marker.

FIG. 3C is a schematic cross-sectional view of introducer 16 taken along line 3C-3C in FIG. 1. In embodiments in which fixation elements 50, 52, and 54 protrude from lead body 48 during an implantation procedure, introducer 16 may be keyed to receive lead 14 in a certain orientation. In the embodiment shown in FIG. 3C, introducer 16 defines lumen 79 for receiving lead body 48, where lumen 79 defines channels 80A-C that are sized and otherwise configured to receive fixation elements 50, 52, and 54, respectively, so that lead 14 may be introduced into introducer 16 in a limited number of orientations. In this way, once introducer 16 is properly oriented with respect to epidermis 62 of patient, introducer 16 may be used to force proper orientation of lead 14 with respect to epidermis 62. Introducer 16 may be properly oriented with respect to epidermis 62 via any suitable means, such as, for example, visible or radiographic marker 81 on introducer 16. For example, when the clinician is introducing introducer 16 into patient 20, the clinician may orient introducer 16 such that visible or radiographic marker 81 is facing the clinician or facing a particular direction in order to properly orient channels 80A-C with respect to epidermis 62. In addition, channels 80A-C defined by lumen 79 of introducer 16 may help minimize the overall diameter of introducer 16, which may help minimize the invasiveness of an implantation procedure.

In addition to or instead of visible marker 65 on lead body 48 or orienting features of introducer 16, a keyed stylet may be used to guide lead 14 into an orientation that results in fixation elements 50, 52, and 54 facing away from epidermis 62. For example, just as introducer 16 is shown in FIG. 3C to be configured to receive lead 14 in one orientation, a stylet may be keyed to receive lead 14 in one orientation.

At least a longitudinally-extending section (i.e., extending in the direction between proximal end 48A and distal end 48B of lead body 48) of second outer surface portion 49B near electrodes 28 is devoid of any fixation elements or of any fixation elements that may extend into epidermis layer 62 when lead 14 is implanted in subcutaneous tissue 66. For example, in the embodiment shown in FIG. 3A, the entire second outer surface portion 49B is devoid of any fixation elements. However, in other embodiments, second outer surface portion 49B may include fixation elements sized to engage with subcutaneous tissue 66, but not epidermis 62 or dermis 64, or fixation

elements to engage with dermis 64, but not epidermis 62. In another embodiment, a portion of second outer surface portion 49B other than the portion proximate to electrodes 28 may include fixation members that are the same size or greater than fixation elements 50, 52, and 54.

5 Fixation elements 50, 52, and 54 are angled toward proximal end 48A of lead body 48, which may help distal end 48B of lead body 48 resist the pulling force from proximal end 48A. However, in some applications, it may also be desirable for lead 14 to resist pulling forces from distal end 48B. Accordingly, the invention contemplates configurations of fixation elements 50, 52, and 54 that are angled both toward and away
10 from proximal end 48A of lead body 48 (e.g., as shown in FIG. 8).

 Fixation elements 50, 52, and 54 radially extend from lead body 48 at an acute angle with respect to first portion 49A. However, in other embodiments, fixation elements 50, 52, and 54 radially extend from lead body 48 at a 90° angle (e.g., as shown with respect to fixation elements 126, 128, and 130 in FIG. 9). Extending from lead
15 body 48 at an acute angle enables fixation elements 50, 52, and 54 to engage with surrounding tissue to prevent both axial and radial movement of lead body 48.

 FIG. 3B is a schematic cross-sectional view of lead 14 taken along line 3B-3B in FIG. 3A. Lead body 48 carries a plurality of conductors 74 (shown in FIG. 3B as a single conductive center of lead body 48 for clarity of illustration) for electrically coupling
20 electrodes 28 (FIG. 3A) to therapy delivery module 40 of neurostimulator 12 (FIG. 2). Typically, a separate conductor electrically couples each electrode 28A-D to therapy delivery module 40. Separate conductors permit independent selection of individual electrodes 28A-D. Furthermore, each of the conductors electrically coupled to separate electrodes 28A-D are electrically insulated from each other. Insulating layer 76 surrounds
25 conductors 74 in order to electrically insulate conductors 74 from subcutaneous tissue 66 when lead 14 is implanted in patient 20 and to help protect a clinician who may be handling lead 14 from shock.

 As previously described, each of fixation elements 50, 52 or 54 may be directly coupled to lead body 48, as shown in FIG. 3B, or indirectly coupled to lead body 48 (e.g.,
30 carried by a fixation sleeve). In the embodiment shown in FIG. 3B, fixation elements 50, 52 or 54 are each attached to lead body 48 with an adhesive. For example, adhesive 78 is disposed between fixation element 54 and lead body 48.

As FIGS. 3A and 3B illustrate, when lead 14 is implanted in subcutaneous tissue 66, fixation elements 50 and 54 extend from lead body 48 substantially parallel to epidermis layer 62, while fixation element 52 extends away from epidermis layer 62. Implanting lead 14 within subcutaneous tissue 66 such that one or more fixation elements 50, 52 or 54 extended through dermis layer 64 or even epidermis layer 66 may increase discomfort to patient 20. In addition, one or more fixation elements 50, 52 or 54 may be visible (e.g., a protrusion may be seen protruding into epidermis 62). Discomfort to patient 20 may be attributable to the one or more fixation elements 50, 52 or 54 causing stress points at the interface between the one or more fixation elements 50, 52 or 54 and dermis layer 64, or even epidermis layer 62. In addition, fixation elements 50, 52 or 54 may rub against dermis layer 64 and/or even epidermis layer 62, which may lead to erosion of and possible damage to dermis layer 64 and/or epidermis layer 62. As discussed, in the embodiment of lead 14 shown in FIGS. 3A-3B, second outer surface portion 49B is devoid of fixation elements. As a result, second outer surface portion 49B provides a relatively smooth surface for interfacing with epidermis layer 62 or dermis layer 64. Thus, in some applications, such as when lead 14 is implanted in subcutaneous tissue 66, it may be desirable for lead 14 to be implanted in a specific orientation.

In some embodiments, second outer surface portion 49B may include structural fixation elements that also engage with surrounding tissue to prevent migration of lead 14. However, these fixation elements do not extend as far from second outer surface portion 49B as fixation elements 50, 52 or 54 extend from first portion 49A in order to minimize the extent to which the fixation elements on second portion 49B engage with epidermis layer 62 or dermis layer 64. FIG. 4A is a schematic cross-sectional view of lead 55 including fixation element 56 extending from second outer surface portion 49B of lead body 48. As FIG. 4A illustrates, fixation element 56 is relatively small compared to fixation elements 50, 52, and 54. Fixation element 56 does not extend as far from lead body 48 as fixation elements 50, 52, and 54. In particular, in the embodiment shown in FIG. 4A, fixation element 56 extends a distance A from outer surface 49 of lead body 48, while fixation element 52 (as well as fixation elements 50 and 54) extend a distance B from outer surface 49 of lead body 48. Distance B of fixation element 56 may be selected such that fixation element 56 engages with subcutaneous tissue 66, rather than epidermis layer 62 or dermis layer 64, when lead 55 is implanted in subcutaneous tissue 66 of patient

20 and oriented such that first outer surface portion 49A faces away from epidermis layer 66.

Also shown in FIG. 4A are lines 57A and 57B, which are shown to demonstrate that lead body 48 defines four quadrants 58A-D. Rather than describing the arrangement of fixation elements 50, 52, 54, and 56 about lead body 48 with respect to first and second outer surface portions 49A and 49B (FIG. 3B), respectively, the arrangement of fixation elements 50, 52, 54, and 56 may also be described with respect to quadrants 58A-D of lead body 48. In the embodiment of lead 55 shown in FIG. 4A, fixation element 50 extends from first quadrant 58A of lead body 48, fixation element 52 extends from second quadrant 58B, third fixation element 54 extends from third quadrant 58C, and fixation element 56 extends from fourth quadrant 58D. Fixation element 56 extending from fourth quadrant has a smaller cross-sectional profile than fixation elements 50, 52, and 54.

Lead body 48 also defines quadrants 58A-D in each of the schematic cross-sectional views shown in FIGS. 3B, 4B, 5B, 6B, 10B, and 11. However, for clarity of illustration and description, quadrants are not labeled in FIGS. 3B, 4B, 5B, 6B, 10B, and 11. Each of the leads shown in FIGS. 3B, 4B, 5B, 6B, 10B, and 11 may be described with respect to quadrants 58A-D. For example, lead 14 shown in FIG. 3B includes fixation element 50 extends from first quadrant 58A of lead body 48, fixation element 52 extends from second quadrant 58B, and third fixation element 54 extends from third quadrant 58C, while fourth quadrant 58D is devoid of any fixation elements:

In yet another embodiment, second outer surface portion 49B may include a non-structural fixation element, such as a surgical adhesive. FIG. 4B is a schematic cross-sectional view of lead 58 including adhesive layer 59 along second outer surface portion 49B of lead body 48, and fixation elements 51, 52, and 54 along first outer surface portion 49A. As FIG. 4B illustrates, adhesive layer 59 does not protrude from second portion 49B of adhesive layer to the extend fixation elements 50, 52, and 54 protrude from first portion 49A. In another embodiment, an adhesive may be embedded in second portion 49B of lead body 48, rather than being a separate adhesive layer 59. Regardless of the type of fixation element, if any, carried by second outer surface portion 49B, it is desirable to minimize the extent to which the fixation element along second outer surface portion 49B engages with and protrudes into epidermis layer 62 or dermis layer 64 in order to increase the comfort to patient 20.

Adhesive layer 59 may be, for example, surgical adhesive elements disposed on or embedded with second outer surface portion 49B of lead body 48. Examples of suitable adhesive elements are discussed in commonly assigned U.S. Patent Application Serial No. 11/591,443 by Martin T. Gerber, entitled "IMPLANTABLE MEDICAL ELONGATED

5 MEMBER WITH ADHESIVE ELEMENTS", filed on October 31, 2006. The adhesive properties of adhesive layer 59 may be activated by any suitable means, including exposure to fluids, a certain temperature, or by activating agents. For example, adhesive layer 59 may be separated from surrounding tissue by a sheath until lead 14 reaches a targets stimulation site, at which time a clinician may withdraw the sheath to expose

10 adhesive layer 59 to surrounding tissue, which may activate adhesive layer 59 via moisture, temperature or otherwise.

Fixation element 51 of lead 58 is disposed on first outer surface portion 49A, but extends in a superficial direction toward epidermis 62 when lead 58 is implanted in patient such that first outer surface portion 49A faces a deep direction. Although fixation

15 element 51 extends toward epidermis 62, fixation element 51 does not contact epidermis 62 because of its placement on first outer surface portion 49A. In particular, fixation element 51 does not extend as far demarcation line 69 separating first and second outer surface portions 49A and 49B, respectively.

While lead 14 includes three fixation elements 50, 52, and 54 spaced about 90°

20 with respect to each other about lead body 48, and particularly, on first outer surface portion 49A, in other embodiments, a lead may include any suitable number of fixation elements in any suitable arrangement about the lead body. These and other embodiments of leads including alternate numbers and/or arrangements of fixation elements are shown in FIGS. 5A-13B and described in reference thereto. For clarity of description, like

25 numbered reference numbers designate substantially similar elements throughout FIGS. 2-12. In FIGS. 1-13B, the components of the leads, as well as any other components that may be illustrated, are not necessarily drawn to scale. For example, each of the hydrogel fixation members 50, 52, and 54 shown in FIGS. 2-4B are not necessarily drawn in correct proportion to the length or diameter of lead body 48.

30 FIGS. 5A and 5B are a perspective view and schematic cross-sectional view, respectively, of lead 82, which includes fixation elements 83, 84, and 86 disposed between proximal end 48A and electrodes 28 for fixing lead 82 proximate to target stimulation

site 18. As previously described, proximal end 48A of lead body typically includes contacts (not shown in FIG. 5A), for electrically connecting electrodes 28 of lead 82 with a neurostimulator (e.g., neurostimulator 12 in FIG. 1A), a lead extension or other medical device. Fixation elements 83, 84, and 86 are coupled to first outer surface portion 49A of
5 outer surface 49 of lead body 48. In FIG. 5A, first outer surface portion 49A is shown, while second outer surface portion 49B faces into the plane of the image of FIG. 5A. In FIG. 5B, line 69 indicates the demarcation between first outer surface portion 49A and second outer surface portion 49B.

As FIG. 5B illustrates, fixation elements 83 and 84 are spaced about angle J with
10 respect to each other about the outer perimeter of lead body 48, while fixation elements 84 and 86 are spaced about angle K with respect to each other. Angles J and K may, but need not be equal. In contrast to fixation elements 50, 52, and 54 of lead 14 (FIGS. 2-4B), fixation elements 83, 84, and 86 are spaced less than about 90° with respect to each other about first portion 49A of lead body 48. For example, angles J and K may each be
15 about 45°. As a result of the arrangement of fixation elements 83, 84, and 86 about first outer surface portion 49A of lead body 48, when lead 82 is implanted in subcutaneous tissue 66 (FIG. 3A), fixation elements 83, 84, and 86 extend away from epidermis layer 62. Thus, neither fixation element 83, 84 or 86 radially extend from first
20 portion 49A lead body 48 in a direction that results in fixation element 83, 84 or 86 that are substantially parallel to epidermis layer 62, as with fixation elements 50 and 54 of lead 14 (FIGS. 2-3B).

First outer surface portion 49A of the lead body 48 of each of leads 14 and 82 both include one set of fixation elements (i.e., a group of fixation elements that substantially share an axial position with respect to lead body 48) located proximal to electrodes 28. In
25 other embodiments, a lead may include more than one set of fixation elements, and the fixation elements may be otherwise arranged, such as between electrodes 28, distal to electrodes 28, or combinations thereof. Examples of these embodiments are shown in FIGS. 6A-8.

FIGS. 6A and 6B are a perspective view and schematic cross-sectional view of
30 lead 90, which includes two sets 92 and 94 of fixation elements on first outer surface portion 49A that are axially displaced from each other with respect to lead body 48. First set 92 include fixation elements 95-97, and second set 94 includes fixation

elements 98-102. As shown in FIG. 6B, in the cross-sectional view of lead 90, the fixation elements 95-102 do not overlap. Thus, fixation elements 95-97 of first set 92 each have different radial locations about first outer surface portion 49A than fixation elements 98-102 of second set 94. Accordingly, fixation elements 95-102 each extend
5 from first outer surface portion 49A of lead body 48 in different radial directions.

First and second sets 92 and 94 of fixation elements are shown proximate to electrode 50. However, as shown in FIG. 7, lead 106 may include first set 108 of fixation elements separated from second set 110 of fixation elements by electrodes 28. First and second sets 108 and 110 of fixation elements are each disposed along first outer surface
10 portion 49A of lead body 48. In the embodiment of lead 106 shown in FIG. 7, first and second sets 108 and 110 of fixation elements, which may each include any suitable number of fixation elements, may be located proximate and distally, respectively, with respect to electrodes 28. While both leads 14 (FIGS. 3A-3) and 106 include fixation elements for fixing leads 14 and 106, respectively, to target stimulation site 18 (FIG. 1),
15 which may be within subcutaneous tissue 66 (FIG. 3A), lead 106 may be useful for locally fixing distal end 48B of lead body 48. In some applications of therapy system 10 (FIGS. 1 and 2), such as when therapy system 10 is used to stimulate a pudendal nerve, it may be desirable to locally fix distal end 48B of lead body 48.

FIG. 8 is a perspective view of yet another embodiment of lead 112 in accordance
20 with the invention. In addition to first and second sets 108 and 110 of fixation elements along first outer surface portion 49A of lead body 48, lead 112 includes third set 114 of fixation elements between electrodes 28B and 28C. Third set 114 includes fixation elements 116, 118, 120, and 122. In other embodiments, lead 112 may include a set of fixation elements between all of electrodes 28 or between any other combination of
25 electrodes (e.g., between electrodes 28A and 28B).

While each of leads 14, 82, 90, and 106 of FIGS. 3A, 5A, 6A, and 7 include fixation elements angled toward proximal end 48A of lead body 48, in other embodiments, the fixation elements may also be angled toward distal end 48B of lead body 48. For example, fixation elements 116 and 122 of third set 114 of fixation elements of lead 112
30 shown in FIG. 8 are angled toward proximal end 48A of lead body 48, while fixation elements 118 and 120 are angled toward distal end 48B.

Fixation elements 116, 118, 120, and 122 each extend from lead body 48 at an acute angle with respect to first portion 49A of lead body 48. As previously discussed, fixation elements of a lead in accordance with the invention may also extend radially outward at about 90° with respect to first portion 49A of lead body 48. An embodiment of such a lead is shown in FIG. 9, which is a perspective view of lead 124 including fixation elements 126, 128, and 130 that extend radially outward at approximately 90° with respect to first outer surface portion 49A of lead body 48.

While tine-shaped fixation elements are shown in FIGS. 2-9 above, a fixation element may have any suitable shape. FIGS. 10A and 10B are a perspective view and cross-sectional view, respectively, of lead 134, which includes fixation element 136 that extends around first outer surface portion 49A of lead body 48. Although fixation element 136 is shown in FIGS. 10A and 10B as expanding radially outward without an angular component (i.e. at 90° with respect to first outer surface portion 49A), in alternate embodiments, fixation element 136 may extend from lead body 48 at an angle with respect to first portion 49A.

As shown in FIGS. 10A and 10B, a single fixation element 136 is disposed between electrodes 28 and proximal end 48A of lead body 48. In alternate embodiments, lead 134 may include any suitable number of fixation elements that extend around first outer surface portion 49A of lead body 48 and/or fixation element 134 may be used in combination with tine-like or other fixation members that do not extend around first outer surface portion 49A of lead body 48. For example, in another embodiment, fixation member 136 may extend around 25 %, 50% or 75% of the outer perimeter of first outer surface portion 49A of lead body 48. For example, FIG. 11 shows a schematic cross-sectional view of lead 138, which includes fixation element 140 extending around about 75% of first outer surface portion 49A of lead body 48.

In each of leads 14, 82, 90, 106, 112, 124, 134 of FIGS. 3A, 5A, 6A, 7-9, respectively, lead body 48 is cylindrical and defines first outer surface portion 49A carrying fixation elements, while second outer surface portion 49B is devoid of any fixation elements or includes one or more fixation elements that do not engage with epidermis 62 (FIG. 3A) when lead 14 is implanted in subcutaneous tissue 66. In another embodiment, a lead may include a paddle shape (i.e. a paddle lead) and may include fixation elements along one surface of the paddle lead, to thereby define a paddle lead

including interior fixation when the paddle lead is implanted in subcutaneous tissue 66 (FIG. 2) of patient 20 or near occipital region 29 (FIG. 1) of patient 20.

FIGS. 12A and 12B are a side view and a schematic cross-sectional view of paddle lead 142, respectively, which includes substantially flat, paddle-like shaped lead body 144 coupled to distal end 146A of lead body connector 146. A proximal end (not shown in FIG. 12A) of lead body connector 146 may be mechanically coupled to a neurostimulator (e.g., neurostimulator 12 of FIGS. 1 and 2) or another medical device. Lead body 144 defines a "paddle" like shape, including first surface 144A and second surface 144B, which is opposite first surface 144A. As shown in FIG. 12B, which is a schematic cross-sectional view of lead body 144 taken along line 12B-12B in FIG. 12A, lead body 144 defines an outer perimeter 145 (shown in phantom lines). Line 147 demarcates first and second surfaces 144A and 144B, respectively, which each extend around about fifty percent of outer perimeter 145 of lead body 144.

In the embodiment shown in FIG. 12A, electrodes 148 are carried by first surface 144A of lead body 144. In another embodiment, paddle lead 142 may also include electrodes along second surface 144B of lead body 144. Each of electrodes 148 may be electrically coupled to the neurostimulator, lead extension or other medical device via electrical conductors disposed within lead body connector 146. A proximal end (not shown in FIG. 12A) of lead body connector 146 may include electrical contacts for electrically connecting the electrical conductors within lead body connector 146 with the neurostimulator.

First surface 144A of lead body 144 includes fixation elements 149A-E, while second surface 144B is devoid of any fixation elements. In the embodiment shown in FIG. 12A, fixation elements 149A-D are tine-like structures that are angled toward lead body connector 146. In other embodiments, fixation elements 149A-D on first surface 144A of paddle lead body 144 may be any suitable shape or type of fixation element, and may extend from first surface 144A at any suitable angle (e.g., radially outward or away from lead body connector 146).

When paddle lead 142 is implanted in patient 20, lead 142 may be oriented such that first surface 144A, and accordingly fixation elements 149A-D, faces away from epidermis 62, scalp 30 or another integumentary layer of patient 20 in order to help minimize or eliminate any discomfort or irritation to patient attributable to fixation

elements 149A-D. Second surface 144B of lead body 144 provides a relatively smooth surface for interfacing with epidermis 62 (FIG. 2) or scalp 30 of patient 20 because second surface 144B does not have any fixation elements that may engage with epidermis 62 or scalp 30 to create points of stress.

5 FIG. 13A is a side view of another embodiment of paddle lead 150, which includes substantially flat, paddle-like shaped lead body 144 coupled to distal end 146A of lead body connector 146 and electrodes on first surface 144A of lead body 144. In addition to fixation elements 149A-D on first surface 144A of lead body 144, lead 150 includes
10 fixation element 152 on second surface 144B of lead body 144. In particular, fixation element 152 is a layer of surgical adhesive that helps prevent migration of lead 150 following implantation in patient 20. Alternatively, surgical adhesive layer 152 may be adhesive elements disposed on or embedded with second surface 144B of lead body, as discussed by commonly assigned U.S. Patent Application Serial No. 11/591,443 by Martin T. Gerber, entitled "IMPLANTABLE MEDICAL ELONGATED MEMBER WITH
15 ADHESIVE ELEMENTS", filed on October 31, 2006.

 FIG. 13B is a side view of another embodiment of paddle lead 154, which includes fixation elements 156A-D along second surface 144B of lead body 144. Fixation elements 149A-D as well as fixation elements 156A-D may engage with surrounding tissue to help substantially fix a position of lead 154 proximate to target stimulation
20 site 18. In the embodiment shown in FIG. 13B, fixation elements 156A-D are tine-like structures that are angled toward lead body connector 146. In other embodiments, fixation elements 156A-D on second surface 144B of paddle lead body 144 may be any suitable shape or type of fixation element (e.g., one or more balloon fixation elements) and may extend from second surface 144B at any suitable angle (e.g., radially outward or away
25 from lead body connector 146).

 Fixation elements 156A-D do not extend from second surface 144B of lead body 144 to the extent that fixation elements 149A-D extend from first surface 144A of lead body 144. That is, in FIG. 13A, dimension E, which is the overall distance each of fixation elements 149A-D extend from first surface 144A of lead body 144 is greater than
30 dimension F, which is the overall distance each of fixation elements 156A-D extend from second surface 144B. Dimension F is selected such that fixation elements 156A-D do not engage with and protrude into an integumentary layer (e.g., epidermis layer 62 (and in

some cases, dermis layer 64) or scalp 30 (FIG. 1)) of patient 20 when lead 154 is implanted in patient 20 such that first surface 144A of lead body 144 faces away from the integumentary layer. The selective sizing of fixation elements 156A-D may thus help minimize any discomfort to patient 20 that is attributable to fixation elements 156A-D.

5 FIG. 14 is a flow diagram of process 160 for implanting a lead 14 (FIGS. 1-3B) including fixation elements along first surface 49A of lead body 48 in accordance with the invention. While lead 14 is referenced in the description of FIG. 14, it should be understood that process 160 may be used to implant any of leads 82, 90, 106, 112, 124, 134, and 138 of FIGS. 5A, 6A, 7, 8, 9, 10A, and 11, respectively, or any other lead
10 including fixation elements disposed along a portion (e.g., first portion 49A) of an outer surface of lead body 48 in accordance with the invention. Furthermore, while implantation of lead 14 into subcutaneous tissue 66 (FIG. 3A) of patient 20 is described, in other embodiments, lead 14 may be implanted proximate to any suitable target therapy delivery site in patient 20.

15 A lead introducer, such as an introducer needle, is introduced into epidermis layer 62 (FIG. 3A) of patient 20 (FIG. 1) and a distal end of the introducer is guided into subcutaneous tissue 66 proximate to nerve 68 (162). The introducer needle may be inserted into the patient percutaneously or via an incision (e.g., incision 33 in FIG. 1) in epidermis layer 62. Lead 14 is introduced into a lumen of the introducer (164). In
20 particular, distal end 14B of lead 14 is introduced into the lumen before proximal end 14A.

 Lead 14 is advanced through the lumen until electrodes 28 adjacent to distal end 48B of lead body 48B of lead 14 are positioned proximate to nerve 68 (166). For example, distal end 14B of lead 14 may be advanced through the lumen of the introducer until at least distal end 14B protrudes past the lumen and into tissue of patient 20 and
25 fixation elements 50, 52, and 54 are deployed from the introducer (i.e., are advanced past a distal end of the introducer). Alternatively, fixation elements 50, 52, and 54 may be deployed from the introducer by withdrawing the introducer or another sheath separating fixation elements 50, 52, and 54 from tissue of patient 20, thereby exposing lead 14.

 If necessary, lead 14 is oriented (e.g., rotated) such that first outer surface
30 portion 49A of lead body 48 faces away from epidermis layer 62 (168). Lead 14 may be oriented prior to or subsequent to positioning electrodes 28 proximate to nerve 68 (166). Positioning of the introducer and/or orientation and positioning of lead 14 may be aided by

imaging techniques, such as by fluoroscopy using markers (e.g. radio-opaque or otherwise visible) on lead body 48. The markers may help indicate a location of fixation elements 50, 52, and 54 with respect to the introducer needle. Alternatively, lead 14 may be oriented using visible marker 65 (FIG. 2) and/or a stylet or introducer 16 may include features (e.g., channels for receiving fixation elements 50, 52, and 54) for orienting lead 14 such that first outer surface portion 49A of lead body 48 faces away from epidermis 62 when lead 14 is implanted in patient 20.

Upon deployment into body tissue, fixation elements 50, 52, and 54 engage with surrounding subcutaneous tissue 66 to substantially fix electrodes 28 within subcutaneous tissue 66 proximate to nerve 68. After lead 14 is positioned, the lead introducer is withdrawn from patient 20 (170). If an adhesive is also used to help prevent migration of lead 14 after implantation in patient 20 (e.g., an adhesive disposed along second outer surface portion 49B of lead body 48), the adhesive may begin reacting with surrounding tissue or otherwise activating upon deployment into body tissue.

As described above, a lead comprising one or more fixation elements arranged on lead body 48 to minimize interference with epidermis 62, scalp 30 or another integumentary layer of patient 20 may include one or more directional electrodes. A “directional” electrode is an electrode that provides electrical stimulation in specific directions, rather than in all directions away from lead body 48. A directional electrode is an electrode that is exposed around less than the full outer perimeter of the lead body (i.e., circumference in the case of a cylindrical lead body 48). An exposed part of an electrode is not electrically insulated or otherwise inhibited from providing electrical stimulation to surrounding tissue when the lead is implanted within patient 20 (FIG. 1). More specifically, a directional electrode may include one or more exposed sections that together subtend less than about 359° of the outer circumference of lead body 48 in embodiments in which lead body 48 is cylindrical. For example, a directional electrode may include one or more electrode segments (i.e., one or more partial ring electrodes) that define the exposed parts of the electrode. As another example, a directional electrode may be a full ring electrode that is shielded by an electrically nonconductive (i.e., electrically insulating) material. In general, a directional electrode is any electrode that is configured to provide electrical stimulation in limited directions.

Electrodes extending around a portion of the circumference of lead body 48 or along one side of a paddle lead may be useful for providing an electrical stimulation field in a particular direction/targeting a particular therapy delivery site. For example, in the electrical stimulation application shown in FIG. 1, directing electrical stimulation toward occipital nerves 22, 24, and/or 26, or otherwise away from scalp 30 may be an efficient use of stimulation (as compared to full ring electrodes which would transmit energy toward the occipital nerves and toward the scalp). The increased efficiency may help reduce the overall power delivered to the electrodes of the lead by neurostimulator 12 by eliminating or minimizing the delivery of stimulation to unwanted or unnecessary regions within patient 20. Reducing the amount of overall power delivered to the electrodes of the lead helps conserve the power (e.g., battery) resources of neurostimulator 12, which are typically limited.

In some embodiments of leads including directional electrodes and one or more fixation elements that radially extend from less than a full outer perimeter of lead body 48, the electrodes (or exposed sections of the electrodes) may extend around the same portion of outer surface 49 of lead body 48 as the fixation elements. That is, in some embodiments, exposed sections of electrodes reside within first outer surface portion 49A of lead body 48, while second outer surface portion 49B is substantially devoid of any exposed electrodes and in some embodiments, second outer surface portion 49B is substantially devoid of any electrodes.

FIG. 15A is a perspective view of one embodiment of lead 172 including directional electrodes 174A-D (collectively "electrodes 174"), as well as first set 176 of fixation elements and second set 178 of fixation elements along first outer surface portion 49A of lead body 48. First and second sets 176 and 178 of fixation elements are located proximally and distally, respectively, to electrodes 174. In other words, electrodes 174 reside between the more proximal first set 176 of fixation elements and the more distal second set 178 of fixation elements. First set 176 of fixation elements comprises fixation elements 180-182 and second set 178 includes fixation elements 183-185. Fixation elements 180-185 are positioned along first outer surface portion 49A of lead body 48. Fixation elements 180-182 of first set are substantially axially aligned with each other, while fixation elements 183-185 of second set 178 are substantially axially aligned with each other and are axially displaced from first set 176.

In other embodiments, fixation elements 180-185 within each set 176, 178 may be axially displaced from each other.

In the embodiment shown in FIG. 15A, second outer surface portion 49B of lead body 48 is substantially devoid of any fixation elements, e.g., to avoid protrusion of
5 fixation elements into epidermis 62, scalp 30 or another integumentary layer of patient 20. However, as described above, in other embodiments, second outer surface portion 49B of lead body 48 may include fixation elements that do not protrude from lead body 48 as far as fixation elements 180-185.

FIG. 15B is a schematic cross-sectional end view of lead 172 taken along line 15B-
10 15B in FIG. 15A, where cross-sections of conductors 74 and insulating layer 76 (shown in FIG. 3B) have been removed from FIG. 15B to simplify the illustration. Directional electrode 174A is also shown in FIG. 15B. Electrodes 174A-D are substantially similar, and accordingly, a description of electrode 174A is also applicable to electrodes 174B-D.

In the embodiment shown in FIG. 15B, directional electrode 174A is a partial ring
15 electrode (i.e., a single electrode segment) that extends around less than the full outer perimeter of lead body 48. Directional electrode 174A subtends angle L, where angle L may be any angle less than 360°, and in the embodiment shown in FIG. 15B angle L is between about 30° and 270°. In FIG. 15B, the entire directional electrode 174A is exposed. However, in other embodiments, electrical insulation may cover a part of
20 electrode 174A to expose a subsection of electrode 174A, rather than the entire electrode 174A. An embodiment including electrical insulation covering a part of an electrode is shown in FIGS. 15C and 16.

Directional electrode 174A resides within first outer surface portion 49A of lead body 48. Electrode 174A, however, does not span the entire first outer surface
25 portion 49A, but rather, electrode 174A extends along substantially the same circumferential subsection occupied by fixation elements 180-182 and extends between the outermost (in a circumferential direction) fixation elements 180 and 182 of first set 176. In this way, the circumferential size of electrode 174A substantially matches the area of first outer surface portion 49A occupied by fixation elements 180-182. Second
30 set 178 of fixation elements is substantially symmetrical to first set 176, and accordingly, electrode 174A also extends between the outermost fixation elements 183 and 185 of second set 178.

In other embodiments, such as the embodiment shown in FIG. 17, a circumferential size of each electrode 174 may be greater than the circumferential subsection occupied by fixation elements 180-182. That is, each electrode 174 may extend past outermost fixation elements 180 and 182 of first set 176. Alternatively, a
5 circumferential size of each electrode 174 may be less than the circumferential subsection occupied by fixation elements 180-182. That is, each electrode 174 may not extend completely between outermost fixation elements 180 and 182 of first set 176.

In some cases, it may be desirable to direct electrical stimulation in the same direction in which fixation elements 180-182 extend. For example, if lead 172 is
10 implanted in subcutaneous region 66 (shown in FIG. 2) of patient 20, such as in occipital or trigeminal nerve stimulation applications of lead 172, it may be desirable to direct electrical stimulation in a deep direction as well as implant lead 172 such that fixation elements 180-182 extend in a deep direction so as not to irritate or cause damage to epidermis 62 or dermis 64 (shown in FIG. 2).

When lead 172 is implanted within patient 20 (FIG. 1) and neurostimulator 12
15 (FIG. 1) provides electrical stimulation therapy to surrounding tissue via directional electrode 174A (which may be coupled to neurostimulator 12 via an electrical conductor disposed within lead body 48), electrical stimulation is provided in directions radially outward (in the case of a cylindrical lead body 48) from first outer surface portion 49A of
20 lead body 48 because directional electrode 174A is only located within first outer surface portion 49A. Because second outer surface portion 49B is devoid of any electrodes or any exposed electrodes, electrode 174A is configured to limit stimulation in directions radially outward from first outer surface portion 49A, and prevent stimulation in directions radially outward from second outer surface portion 49B.

25 Second outer surface portion 49B is devoid of any exposed electrodes, and furthermore, second outer surface portion 49B is devoid of any electrodes in the embodiment of lead 172 shown in FIG. 15B. However, in some embodiments, such as when lead 172 and electrodes 174 deliver electrical stimulation to sacral nerves, it may be desirable for electrodes 174 to also extend at least partially into second outer surface
30 portion 49B of lead body 48.

FIG. 15C is a schematic cross-sectional view of lead 186, which is substantially similar to lead 172, except that lead 186 includes one or more electrodes 188 that are full

ring (i.e., a cylindrical) electrodes that each extend around an entire outer perimeter of lead body 48, rather than electrodes 174 that extend around less than the full outer perimeter of lead body 48. Full ring electrode 188 subtends about 360° of the outer circumference of lead body 48. In order to define a directional electrode from full ring electrode 188 that is
5 configured to provide focused stimulation in limited directions radially outward from at least a part of first outer surface portion 49A, a nonconductive coating 190 may be applied to cover a subsection of electrode 188. The placement of nonconductive coating 190 over at least a subsection of electrode 188 residing within second outer surface portion 49B results in electrode 188 that includes an exposed portion that resides within first outer
10 surface portion 49A. In this way, electrical stimulation may be provided in directions limited to those directions radially outward from first outer surface portion 49A.

Nonconductive coating 190 may also be applied to cover a corresponding part of the other electrodes of lead 186, or the other electrodes may include separate nonconductive coatings to define directional electrodes. Nonconductive coating 190 may
15 be any suitable biocompatible and electrically insulating material, such as, but not limited to, silicone rubber or polyurethane. Nonconductive coating 190 may also be used to electrically insulate a subsection of a partial ring electrode.

Nonconductive coating 190 may be any suitable form of electrical insulation that helps block electrical stimulation from electrode 188. One or more separate (i.e.,
20 noncontiguous) electrical insulation pieces may be used to cover a single electrode 188. For example, one piece may cover a subsection of electrode 188 residing within second outer surface portion 49B, while another piece may cover a subsection of electrode 188 residing within first outer surface portion 49A (if a part of electrode 188 within first outer surface portion 49A is covered). In other embodiments, the nonconductive coating 190
25 may not be a coating, but rather a separate member that is attached to lead body 48 to cover a subsection of one or more electrodes 188 in order to define directional electrodes. The electrically insulating member may be adhered, crimped, or otherwise mechanically held in place relative to lead body 48.

In the embodiment shown in FIG. 15C, section 188A of electrode 188 along first
30 outer surface portion 49A and section of electrode 188B along second outer surface portion 49B are masked by coating 190. In this way, coating 190 exposes section 188C of electrode 188 that substantially “matches” the arrangement of fixation elements 180-182.

As previously mentioned, it may be desirable in some embodiments to direct electrical stimulation in the same direction in which fixation elements 180-182 extend. In other embodiments, coating 190 may be applied to only second outer surface portion 49B to define a directional electrode that includes an exposed section that spans the entire first
5 outer surface portion 49A or coating 190 may be applied to only a part of second outer surface portion 49B to define a directional electrode that includes an exposed part (or section) that spans a part of second outer surface portion 49B. The amount of coating 190 and the electrode area covered by coating 190 may vary depending on the particular application of lead 186 and the desired electrical stimulation field that is to be provided by
10 electrode 188.

Nonconductive coating 190 directs electrical stimulation from ring electrode 188 toward a target stimulation site by masking certain sections of electrode 188 to define one or more exposed electrode sections. For example, when lead 186 is implanted in patient 20 (FIG. 1), lead 186 may be oriented such that coating 190 faces toward scalp 30
15 and the electrically conductive sections of each electrode 188 faces a deep direction and toward occipital nerves 22, 24, 26 or a trigeminal nerve. In some cases, by electrically insulating some sections of electrode 188, coating 190 also helps to direction electrical stimulation away from certain sites within the patient, such as sites in which electrical stimulation provides little to no effective therapy or sites in which electrical stimulation
20 may be otherwise undesirable or harmful.

FIG. 16A is a perspective view of lead 192 and sheath 194 disposed over full ring electrodes 188 to electrically insulate a subsection of electrodes 174 and expose a subsection of electrodes 188 residing within first outer surface portion 49A of lead body 48. FIG. 16B is a schematic cross-sectional view of lead 192 taken along
25 line 16B-16B in FIG. 16A, where first and second sets 176, 178 of fixation elements have been removed for clarity of illustration.

Inner surface 194A (FIG. 16B) of sheath 194 is sized and shaped to receive lead body 48. Sheath 194 may be secured to lead body 48 using any suitable technique. For example, in some embodiments, sheath 194 is friction fit around lead body 48. Sheath 194
30 may also be adhered to lead body 48 in addition to or instead of being friction fit around lead body 48. In some embodiments, sheath 194 is a complete ring (in cross-section) and is introduced around lead body 48 from a longitudinal direction (i.e., lead 192 is fed

through sheath 194 from proximal end 48A or distal end 48B of lead body 48). In other embodiments, sheath 194 has a partial ring cross-section and may be introduced around lead body 48 from an axial direction or a longitudinal direction.

In FIGS. 16A and 16B, the relative sizes of sheath 194 and lead body 48 are not drawn to any particular scale. It may be desirable to limit a thickness T_s (measured between inner surface 194A and outer surface 194B) of sheath 194 in order to limit the overall profile of lead 192. Minimizing the overall profile of lead 192 may generally limit the invasiveness of the implantation of lead 192 in patient 20.

In the embodiment shown in FIG. 16A, sheath 194 only axially extends across a portion of lead body 48. In other embodiments, sheath 194 may substantially extend from proximal end 48A to distal end 48B of lead body 48, or any other percentage thereof, so long as sheath 194 is substantially aligned with electrodes 188.

Sheath 194 includes an electrically insulating portion 196 and electrically conductive portion 198. In order to define a directional electrode from full ring electrode 188 that is configured to provide focused stimulation in limited directions, electrically conductive portion 198 is aligned with the subsection of ring electrode 188 that is to be exposed. That is, electrically conductive portion 198 is aligned with sections of ring electrode 188 that provides stimulation in desired directions. As a result, electrically insulating portion 196 of sheath 190 is aligned with the sections of electrode 188 that faces directions in which it is desirable to limit stimulation. In FIGS. 16A and 16B, electrically conductive portion 198 of sheath 194 is aligned with first outer surface portion 49A of lead body 48 in order to define an electrically exposed section of electrode 188 that substantially resides within first outer surface portion 49A of lead body 48. In the embodiment shown in FIGS. 16A-B, electrically conductive portion 198 of sheath 194 subtends angle L of the outer perimeter of lead body 48.

FIG. 17 is schematic cross-sectional view of another embodiment of a lead 200, which is similar to lead 172 of FIGS. 15A-B, but includes one or more partial ring electrodes 202 that do not match the arrangement of fixation elements 180-182. That is, electrode 202 extends past outermost fixation elements 180 and 182 of first set 176. The entire electrode 202 is exposed in the embodiment shown in FIG. 17. Directional electrode 202 subtends angle M, where angle M may be any angle less than 360° , and in the embodiment shown in FIG. 15B angle M is about 180° . In other embodiments,

electrodes 202 may extend up to or slightly past demarcation line 69 between first and second outer surface portions 49A, 49B.

In the embodiment shown in FIG. 17, partial ring electrode 202 defines one electrically conductive section that remains within first outer surface portion 49A of lead
5 body 48. In other embodiments, an electrically nonconductive coating may be applied to partial ring electrode 202 to define one or more electrically conductive sections.

While a lead including continuous directional electrodes 174, 188, and 202 are shown in the embodiments shown in FIGS. 15A-15C, 16, and 17, in other embodiments, a lead may include two or more substantially axially aligned segmented electrodes that
10 define a directional electrode that is substantially noncontinuous over first outer surface portion 49A of lead body 48, as shown in FIG. 18. FIG. 18 is a perspective view of lead 204, which includes groups 206-209 of directional electrode segments, as well as first set 176 of fixation elements and second set 178 of fixation elements along first outer surface portion 49A of lead body 48. First and second sets 176 and 178 of fixation
15 elements are located proximally and distally, respectively, to groups 206-209 of segmented directional electrodes. Lead 204 is substantially similar to lead 172 shown in FIG. 15A except that lead 204 includes segmented electrodes rather than partial ring electrodes 174.

Each group 206-209 comprises two or more segmented electrodes that are substantially axially aligned relative to lead body 48. Group 206 comprises segmented
20 electrodes 206A-B, group 207 comprises segmented electrodes 207A-C, group 208 comprises segmented electrodes 208A-B, and group 209 comprises segmented electrodes 209A-C. Segmented electrodes 206A-B, 207A-C, 208A-B, and 209A-C are electrodes that do not extend around the full outer circumference of lead body 48 and may each subtend about 1° to about 359° of the outer circumference of lead body 48.

25 Segmented electrodes 206A-B, 207A-C, 208A-B, and 209A-C reside within first outer surface portion 49A of lead body 48, while second outer surface portion 49B of lead body 48 is devoid of any electrodes. Accordingly, all exposed subsections of electrodes 206A-B, 207A-C, 208A-B, and 209A-C are located within first outer surface portion 49A of lead body 48.

30 Each segmented electrode 206A-B, 207A-C, 208A-B, and 209A-C may be electrically coupled to a separate electrical conductor, which electrically couples the respective segmented electrode 206A-B, 207A-C, 208A-B, and 209A-C to

neurostimulator 12 (FIGS. 1 and 2). A switch matrix disposed within neurostimulator 12 may be used to select various segmented electrode 206A-B, 207A-C, 208A-B, and 209A-C with which to deliver stimulation signals to patient 20 (FIG. 1). The electrode segments may be selected individually or in various combinations to form a wide variety of unipolar, bipolar, and multipolar electrode combinations over a variety of spatial positions and patterns.

As described above, segmented electrodes are useful for achieving targeted stimulation and may also provide an efficient use of stimulation energy. For example, for occipital nerve or trigeminal nerve stimulation, it may be desirable to stimulate on only one side of lead body 48 while avoiding stimulation on the other side. In other stimulation applications, it may be desirable to stimulate in a first direction under certain conditions and other directions under different conditions or at a different time. In such a case, it may be useful to include multiple electrode segments within each group 206-209 (i.e., multiple electrodes that share an axial position), where each electrode segment extends less than 360° of the outer circumference of lead body 48 (e.g., 30, 60, 90 or 120 degrees). In addition, the arrangement of segmented electrodes to define multiple “columns” (extending in an axial direction) and “rows” (extending in a circumferential direction substantially perpendicular to the columns) shown in FIG. 18 may be useful for achieving different electrical fields by activating different combinations of electrode segments 206A-B, 207A-C, 208A-B, and 209A-C. In the embodiment shown in FIG. 18, electrodes 206A and 208A are circumferentially aligned to define a column, electrodes 207A and 209A are circumferentially aligned to define another column, electrodes 207B and 209B are circumferentially aligned to define yet another column, and so forth, while each group 206-209 defines a separate row of electrodes.

FIG. 19A is a perspective view of lead 210 including fixation elements 212, 213, and 214 proximal to directional electrodes 216A-D. FIG. 19B is a cross-sectional view of lead 210 taken along line 19B-19B in FIG. 19A. Lead 210 is an embodiment of a lead including electrodes 216A-D that are each electrically conductive along the entire first outer surface portion 49A of lead body 48. As FIG. 19B illustrates, electrode 216A (which is representative of each of electrodes 216A-D) is exposed along first outer surface portion 49A from fixation element 98 to opposing fixation element 102. Electrodes 216A-D may be each any suitable electrode that includes an exposed section that is isolated on

first outer surface portion 49A of lead body 48. For example, electrodes 216A-D may each be partial ring (or segmented) electrodes (as shown in FIGS. 15A-B, 17 or 18) or full ring electrodes covered by electrical insulation along at least second outer surface portion 49B (as shown in FIGS. 15C and 16).

5 A lead including a one or more fixation elements along an interior surface may be useful for various electrical stimulation systems. For example, the lead may be used to deliver electrical stimulation therapy to patients to treat a variety of symptoms or conditions such as chronic pain, tremor, Parkinson's disease, multiple sclerosis, spinal cord injury, cerebral palsy, amyotrophic lateral sclerosis, dystonia, torticollis, epilepsy, pelvic
10 floor disorders, gastroparesis, muscle stimulation (e.g., functional electrical stimulation (FES) of muscles) or obesity. In addition, the fixation element arrangement described herein with respect to leads 14, 82, 90, 106, 112, 124, 134, and 138 may also be useful for fixing a catheter, such as a drug deliver catheter, proximate to a target drug delivery site.

 Various embodiments of the invention have been described. These and other
15 embodiments are within the scope of the following claims.

CLAIMS:

1. An implantable medical lead comprising:
a lead body defining an outer surface comprising:
5 a first outer surface portion; and
a second outer surface portion extending around at least ten percent of an outer
perimeter of the lead body;
a fixation element extending a distance from the first outer surface portion, wherein a
longitudinally-extending section of the second outer surface portion proximate to a distal
10 end of the lead body is substantially devoid of any fixation elements that extend the
distance from the second outer surface portion; and
at least one electrode coupled to the lead body, wherein the longitudinally-extending
section of the second outer surface portion is substantially devoid of any exposed
electrodes.
15
2. The implantable medical lead of claim 1, wherein the at least one electrode
comprises a ring electrode extending around the outer perimeter of the lead body, and the
implantable medical lead further comprises electrical insulation covering a subsection of
the at least one electrode residing within the longitudinally-extending section of the
20 second outer surface portion.
3. The implantable medical lead of claim 2, wherein the subsection of the at
least one electrode is a first subsection and the electrical insulation comprises a first piece
of electrical insulation, and the implantable medical lead further comprises a second piece
25 of electrical insulation covering a second subsection of the at least one electrode residing
within the first outer surface portion of the lead body.
4. The implantable medical lead of claim 3, wherein the first and second
pieces of electrical insulation are substantially contiguous.
30
5. The implantable medical lead of claim 2, wherein the electrical insulation
comprises an electrically insulating mask.

6. The implantable medical lead of claim 2, further comprising a sheath configured to receive the lead body, wherein the sheath comprises the electrical insulation.

5 7. The implantable medical lead of claim 1, wherein the at least one electrode comprises at least one electrode segment extending around less than one hundred percent of the outer perimeter of the lead body.

8. The implantable medical lead of claim 7, wherein the at least one electrode
10 comprises at least two substantially axially aligned electrode segments.

9. The implantable medical lead of claim 1, wherein the longitudinally-
extending section of the second outer surface portion is substantially devoid of any
electrodes.

15 10. The implantable medical lead of claim 1, wherein the at least one electrode is exposed along the entire first outer surface portion of the lead body.

11. The implantable medical lead of claim 1, wherein the fixation element is a
20 first fixation element and the implantable medical lead further comprises a second fixation element substantially axially aligned with the first fixation element, wherein the at least one electrode is exposed along the first outer surface portion of the lead body between the first fixation element and the second fixation element.

25 12. The implantable medical lead of claim 1, wherein the fixation element is a first fixation element extending a first distance from the first outer surface portion of the implantable medical lead, and the apparatus further comprises a second fixation element extending a second distance from the second outer surface portion of the implantable medical lead, wherein the first distance is greater than the second distance.

30 13. The implantable medical lead of claim 1, wherein the distance is a first distance, and the apparatus further comprises an adhesive along at least a subsection of the

second outer surface portion of the implantable medical lead, the adhesive extending a second distance from the second outer surface portion of the implantable medical lead, and the second distance being less than the first distance.

5 14. The implantable medical lead of claim 1, wherein the longitudinally-extending section of the second outer surface portion proximate to the distal end of the lead body is substantially devoid of any fixation elements.

 15. The implantable medical lead of claim 1, wherein the first and second outer
10 surface portions have substantially equal sizes.

 16. The implantable medical lead of claim 1, wherein the lead body has a circular cross-section defining a first quadrant of the outer surface, a second quadrant of the outer surface, a third quadrant of the outer surface, and a fourth quadrant of the outer
15 surface, and the fixation element extends from at least one of the first, second or third quadrants, and the fourth quadrant of the outer surface is devoid of any fixation elements that extend the distance from the outer surface.

 17. The implantable medical lead of claim 16, wherein the at least one
20 electrode is exposed within at least one of the first, second or third quadrants of the outer surface, and the fourth quadrant is devoid of any exposed electrodes.

 18. The implantable medical lead of claim 16, wherein the fixation element comprises a first fixation element extending a first distance from at least one of the first,
25 second or third quadrants of the outer surface of the implantable medical lead, and the implantable medical lead further comprises a second fixation element extending a second distance from the fourth quadrant of the outer surface, wherein the first distance is greater than the second distance.

30 19. The implantable medical lead of claim 18, further comprising a third fixation element and a fourth fixation element, wherein the first fixation element extends from the first quadrant of the outer surface, the third fixation element extends from the

second quadrant of the outer surface, and the fourth fixation element extends from the third quadrant of the outer surface.

20. The implantable medical lead of claim 1, wherein the second outer surface
5 portion extends around at least twenty-five percent of the outer perimeter of the lead body.

21. The implantable medical lead of claim 1, wherein the fixation element
comprises at least one of a tine, a barb, a hook, an adhesive element, a flange, a balloon or
a wire-like element.

10

22. The implantable medical lead of claim 1, wherein the fixation element
comprises at least a first fixation element located between the at least one electrode and a
proximal end of the lead body and the implantable medical lead further comprises a
second fixation element located between the at least one electrode and the distal end of the
15 lead body.

23. The implantable medical lead of claim 1, wherein the at least one electrode
comprises an array of electrodes and the fixation element is disposed between two
electrodes of the array of electrodes.

20

24. The implantable medical lead of claim 1, wherein the longitudinally-
extending section of the second outer surface portion extends from the distal end of the
lead body to a proximal side of the at least one electrode.

25. The implantable medical lead of claim 1, wherein the lead body is a paddle
lead body, the first outer surface portion is a first side of the paddle lead body and the
second outer surface portion is a second side of the paddle lead body opposite the first
side.

26. The implantable medical lead of claim 1, further comprising a visible
marker on the lead body to orient the fixation element with respect to an epidermis of the
patient or an introducer.

30

27. An implantable medical lead comprising:
a substantially cylindrical lead body defining an outer surface comprising:
a first outer surface portion; and
5 a second outer surface portion extending around at least ten percent of an outer
perimeter of the lead body;
a fixation element extending a distance from the first outer surface portion; and
at least one electrode coupled to the lead body,
wherein a longitudinally-extending section of the second outer surface portion proximate
10 to a distal end of the lead body is substantially devoid of any fixation elements that extend
the distance from the second outer surface portion, and
wherein the at least one electrode is configured to limit delivery of electrical stimulation to
directions radially outward from the first outer surface portion.
- 15 28. The implantable medical lead of claim 27, wherein the longitudinally-
extending section of the second outer surface portion is substantially devoid of any
electrodes.
29. The implantable medical lead of claim 27, wherein the at least one
20 electrode comprises an exposed subsection that subtends about 30 degrees to about 270
degrees of the outer perimeter of the lead body.
30. The implantable medical lead of claim 27, wherein the at least one
electrode comprises a ring electrode extending around the outer perimeter of the lead
25 body, wherein electrical insulation partially covers a subsection of the ring electrode
residing within the second outer surface portion to block electrical stimulation in
directions radially outward from the second outer surface portion.
31. The implantable medical lead of claim 27, wherein the at least one
30 directional electrode comprises at least one electrode segment extending around less than
one hundred percent of the outer perimeter of the lead body.

32. A method for implanting a medical lead in a patient, the method comprising:

introducing the medical lead into a body of a patient; and

5 advancing the medical lead to a target therapy delivery site within the body of the patient,

wherein the medical lead defines an outer surface comprising a first outer surface portion and a second outer surface portion extending around at least approximately ten percent of an outer perimeter of the medical lead, the medical lead further comprising at least one
10 electrode coupled to the medical lead and a fixation element extending a distance from the first outer surface portion,

wherein the second outer surface portion is substantially devoid of any exposed electrodes, and

wherein a longitudinally-extending section of the second outer surface portion proximate
15 to a distal end of the medical lead is substantially devoid of any fixation elements that extend the distance from the second outer surface portion.

33. The method of claim 32, further comprising orienting the medical lead so that the second outer surface portion faces a superficial direction.

20

34. The method of claim 32, wherein introducing the medical lead into the patient comprises:

introducing an introducer into the body of the patient; and

introducing the medical lead into a lumen of the introducer.

25

35. The method of claim 34, wherein introducing the introducer into the patient comprises introducing the introducer superior to a fascia layer.

36. The method of claim 34, wherein introducing the medical lead into a lumen
30 of the introducer comprises aligning the fixation element with a channel defined by the lumen.

37. The method of claim 32, wherein the at least one electrode comprises a ring electrode extending around the outer perimeter of the lead body and partially covered by electrical insulation.

5 38. The method of claim 32, wherein the at least one electrode comprises at least one electrode segment extending around less than one hundred percent of the outer perimeter of the lead body.

10 39. The method of claim 32, wherein the target therapy delivery site is proximate to at least one of an occipital nerve or a trigeminal nerve.

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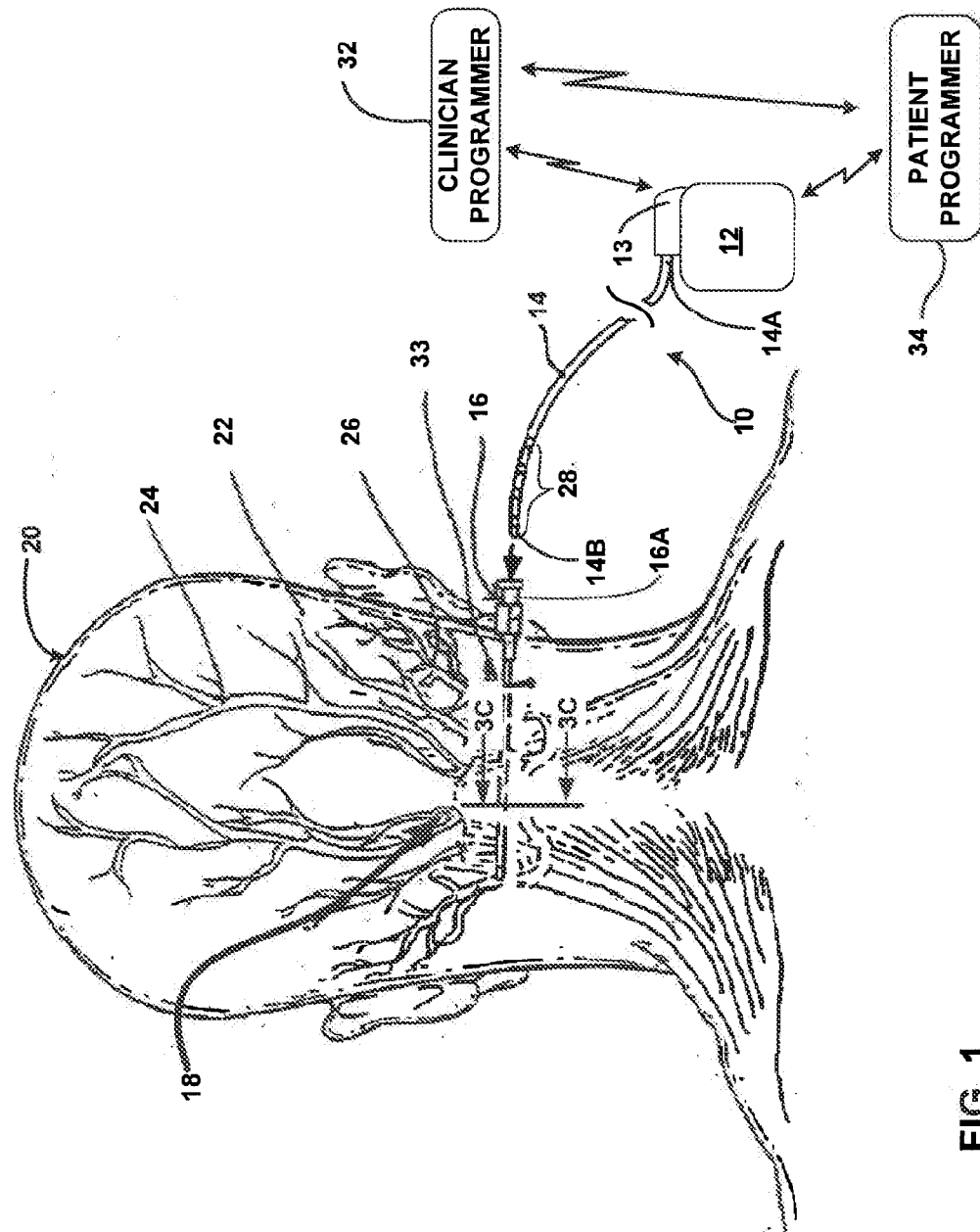


FIG. 1

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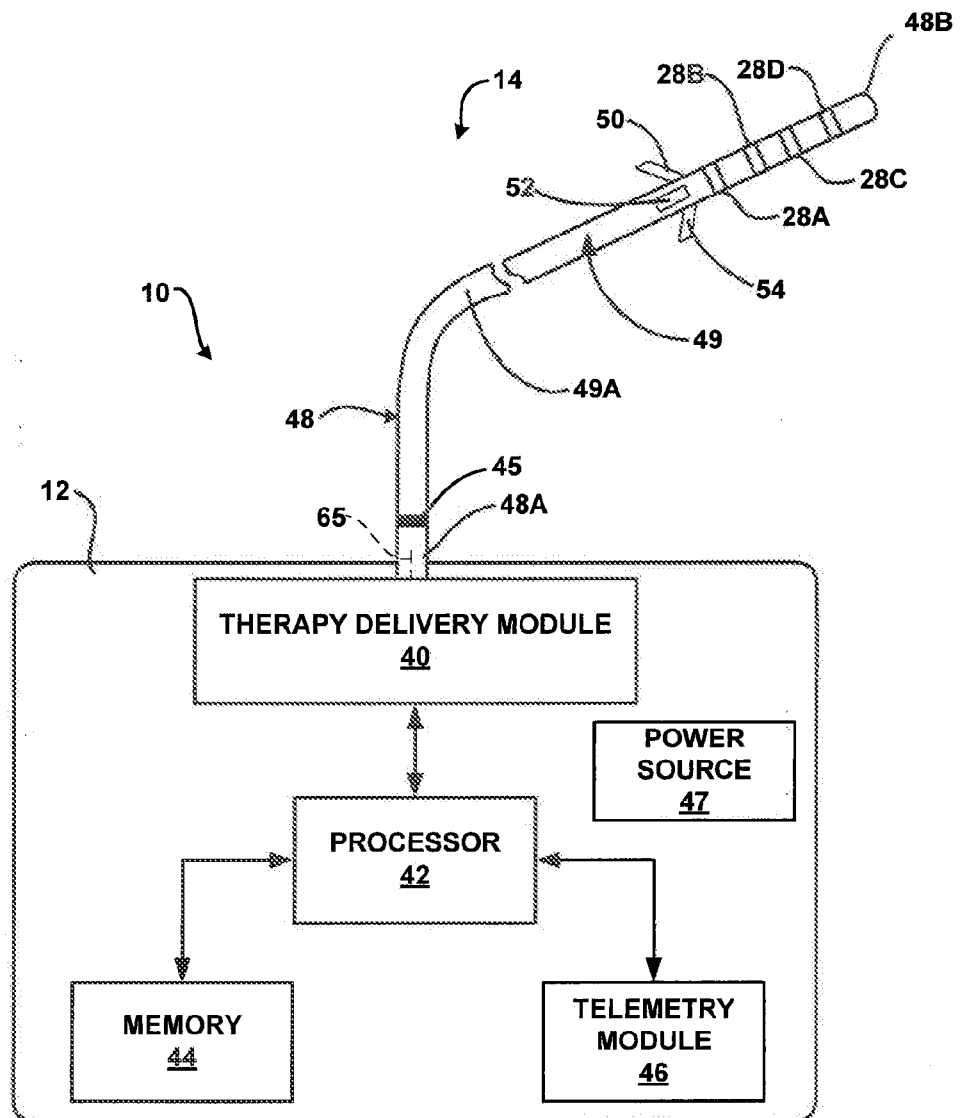


FIG. 2

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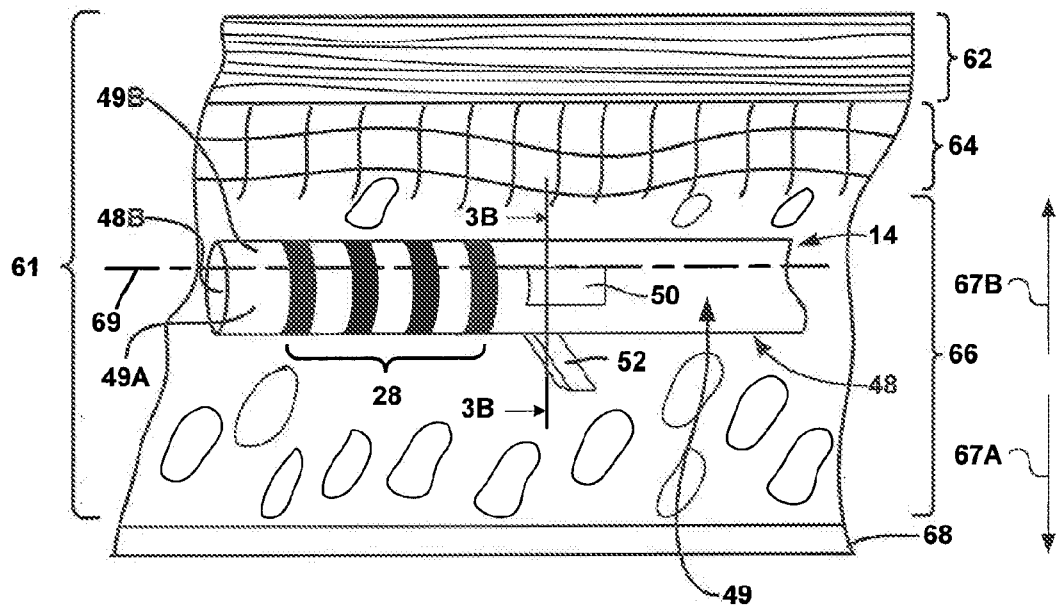


FIG. 3A

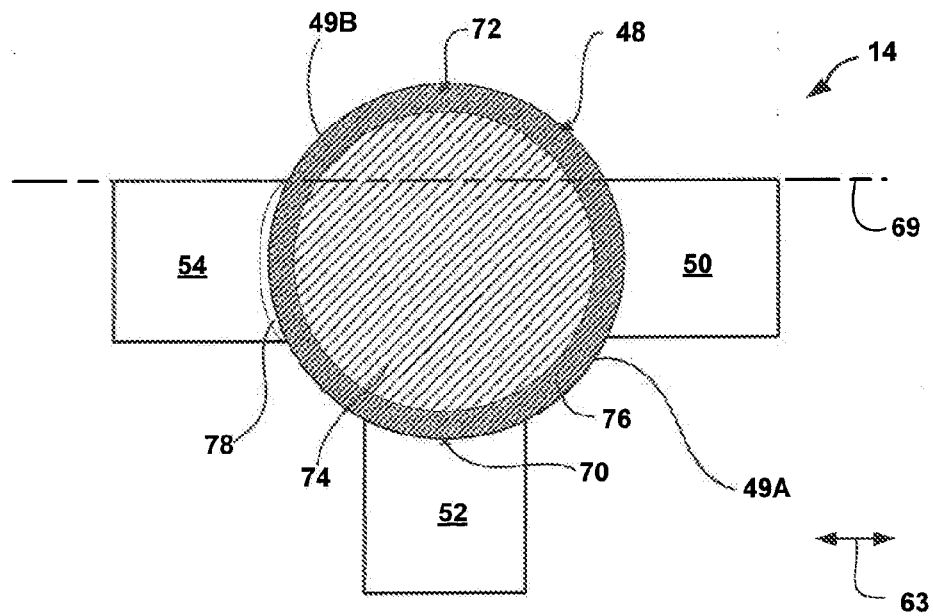


FIG. 3B

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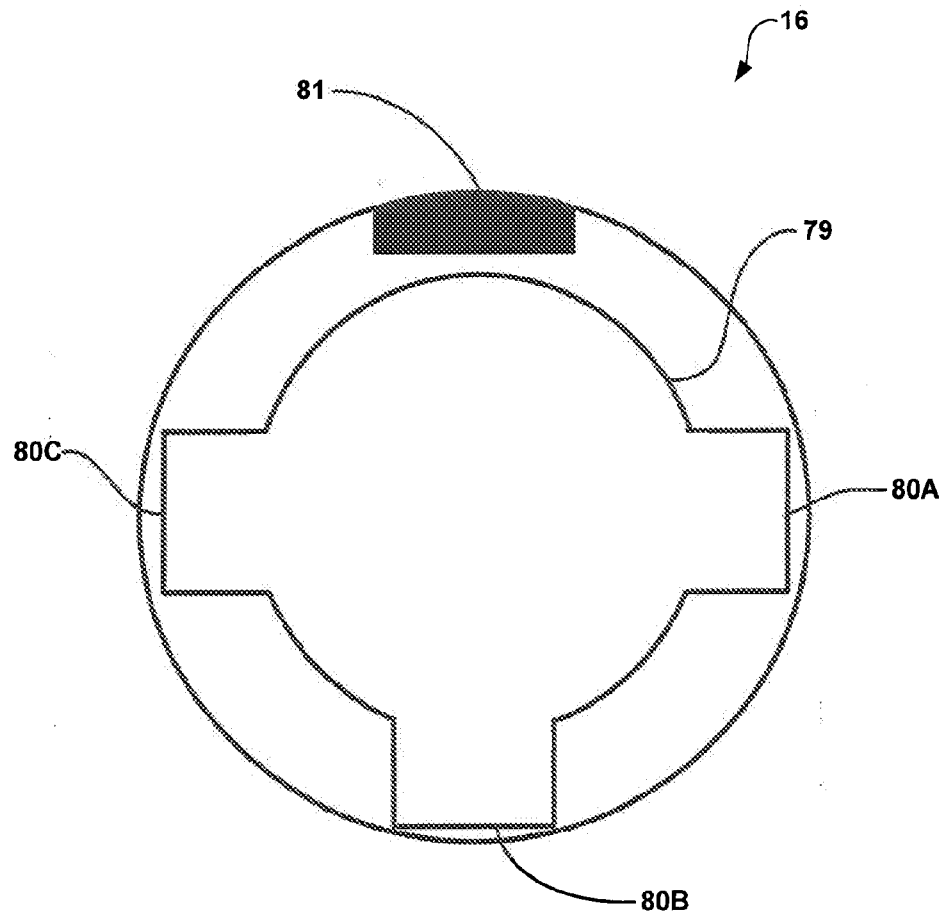


FIG. 3C

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FIG. 4A

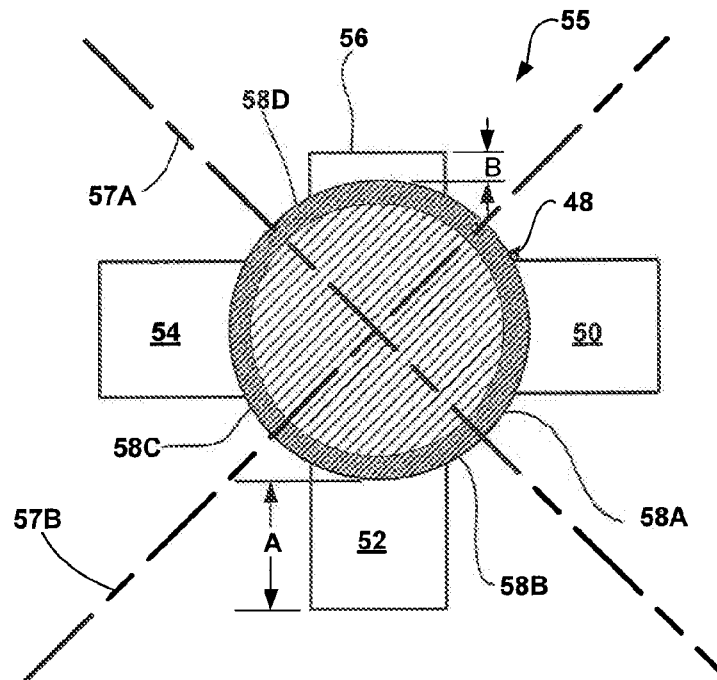
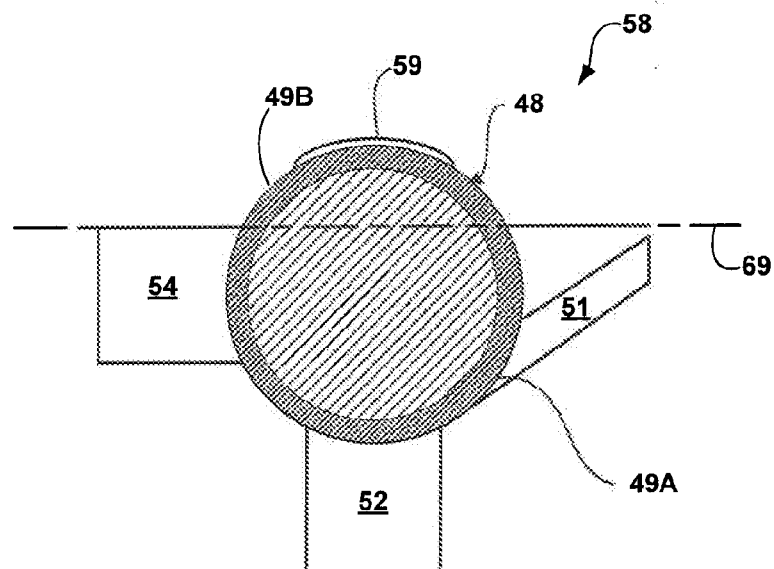


FIG. 4B



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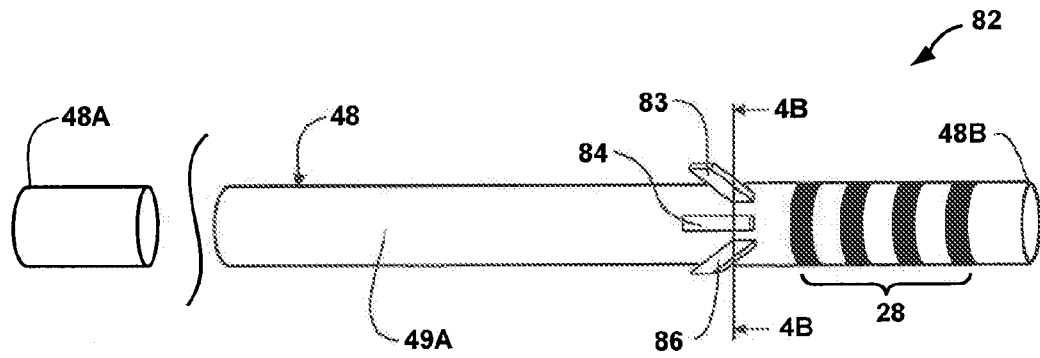


FIG. 5A

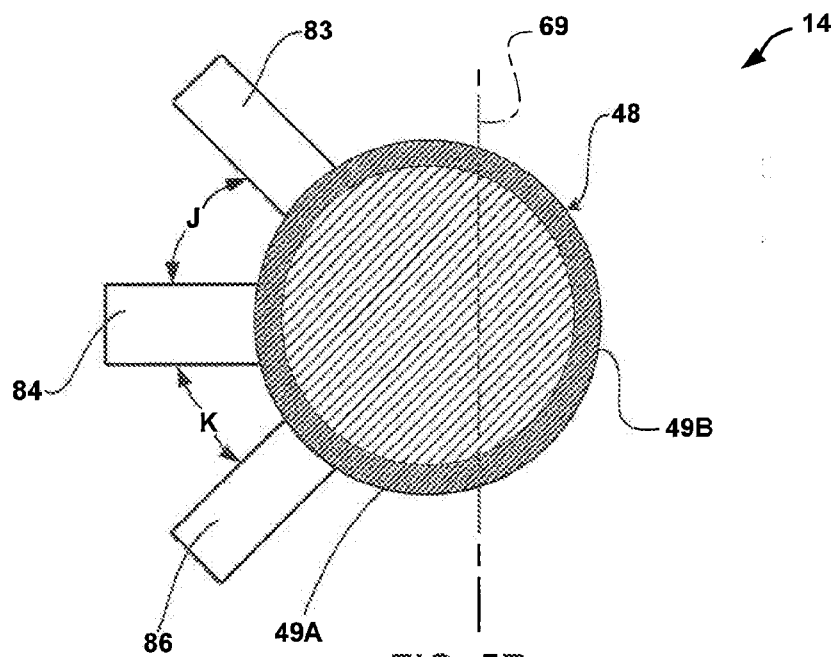


FIG. 5B

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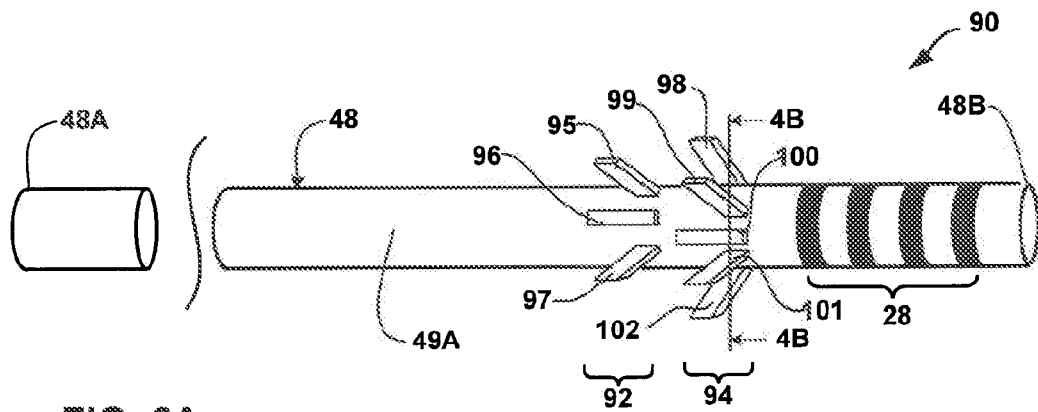


FIG. 6A

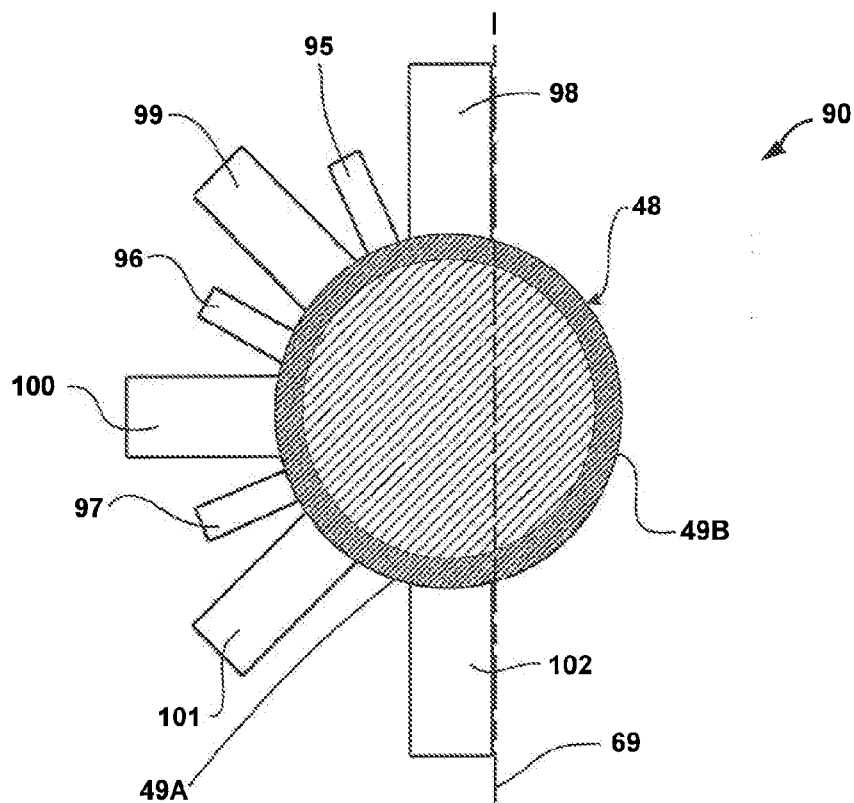


FIG. 6B

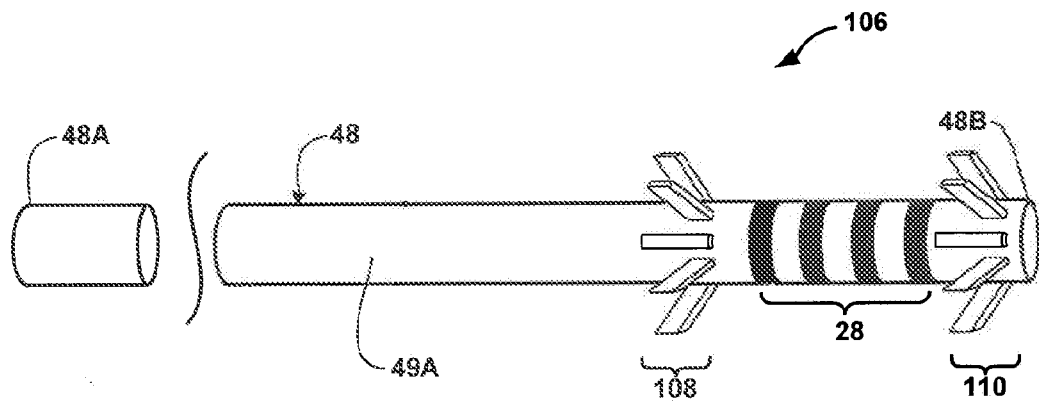


FIG. 7

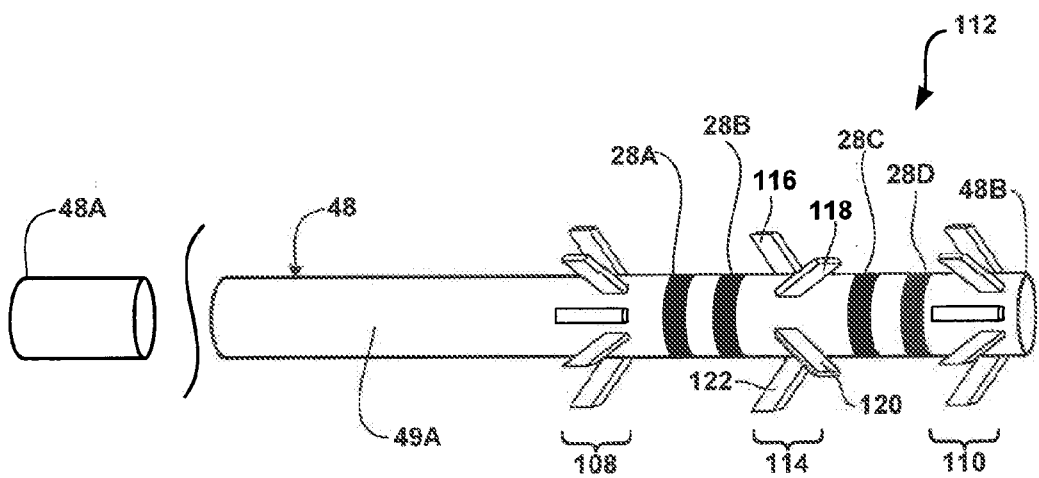
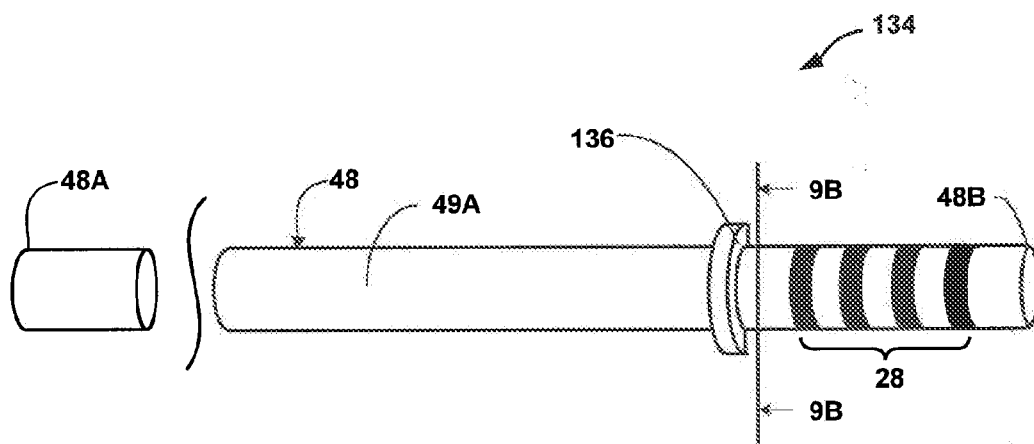
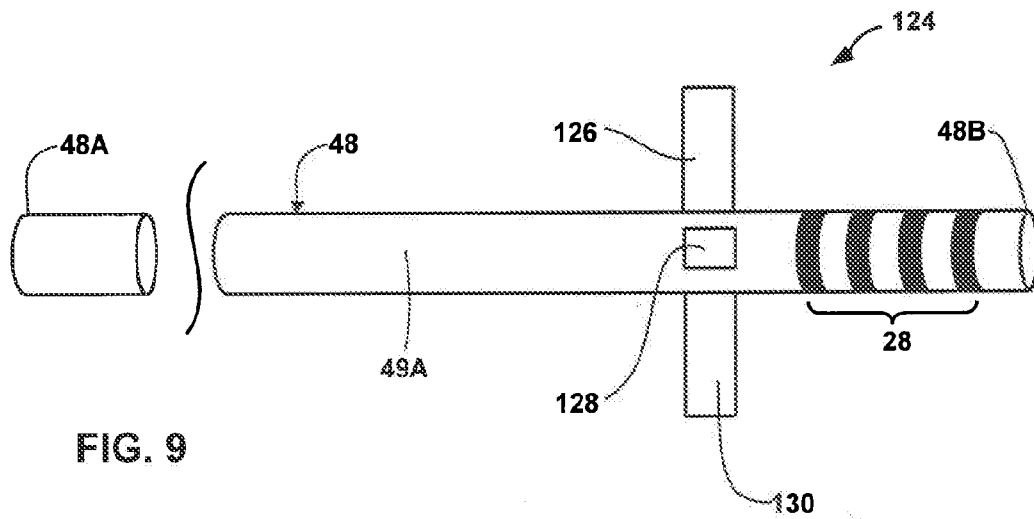


FIG. 8

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FIG. 10B

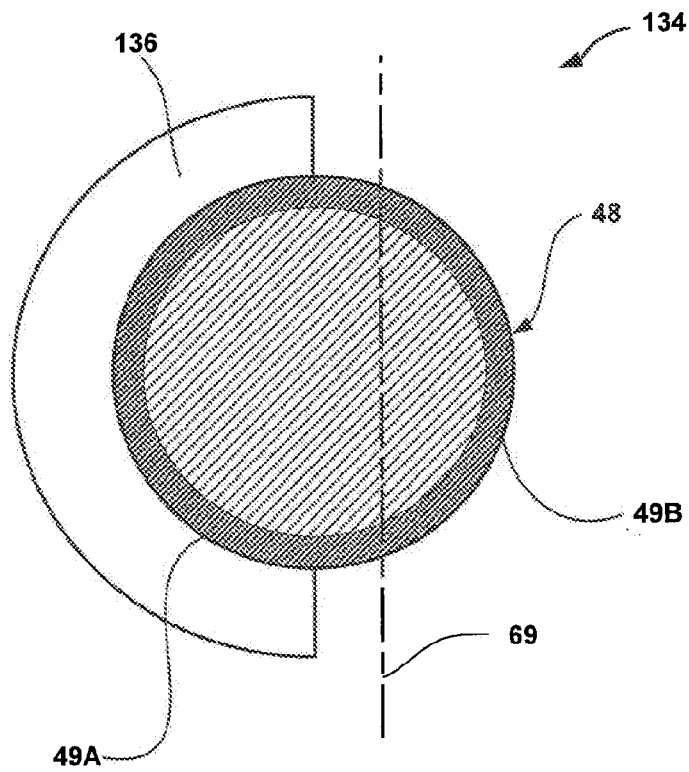
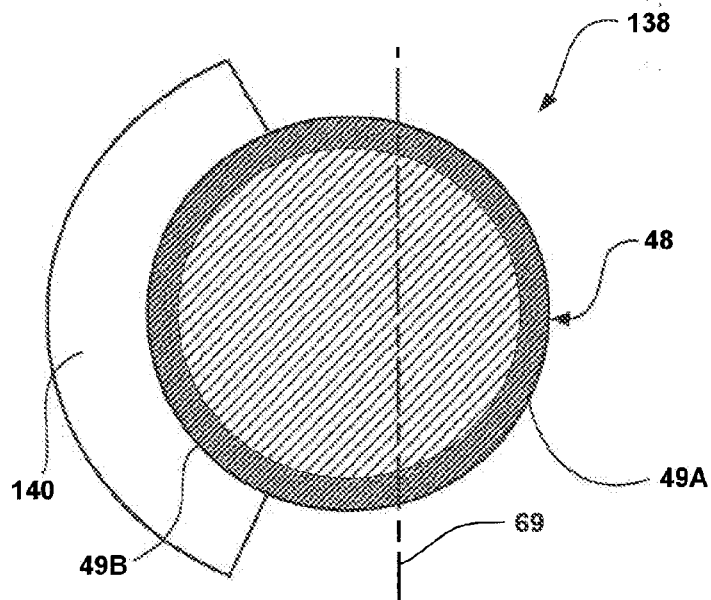


FIG. 11



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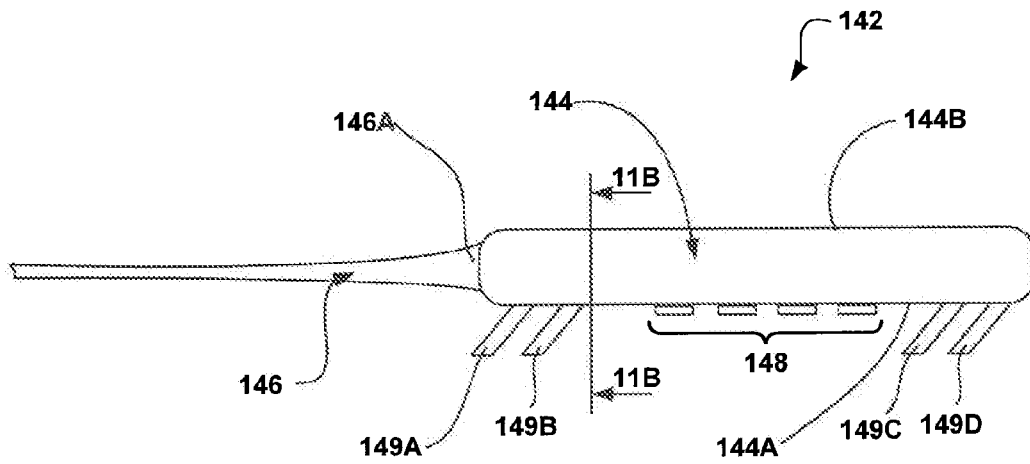


FIG. 12A

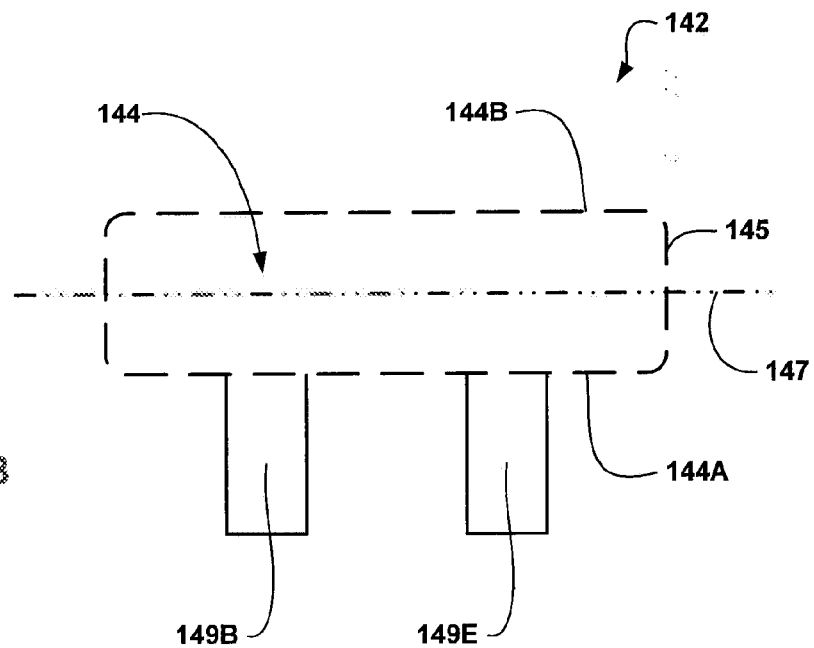


FIG. 12B

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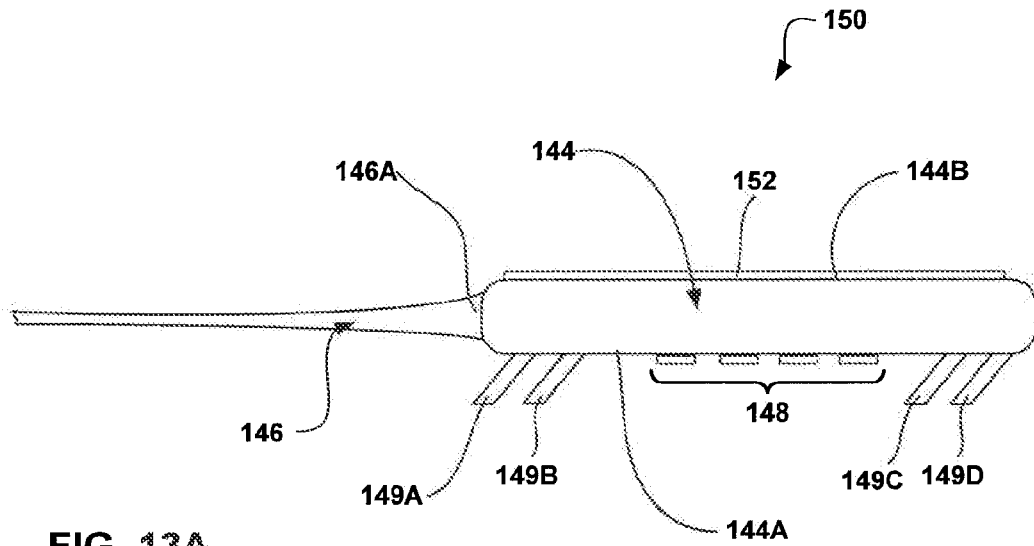


FIG. 13A

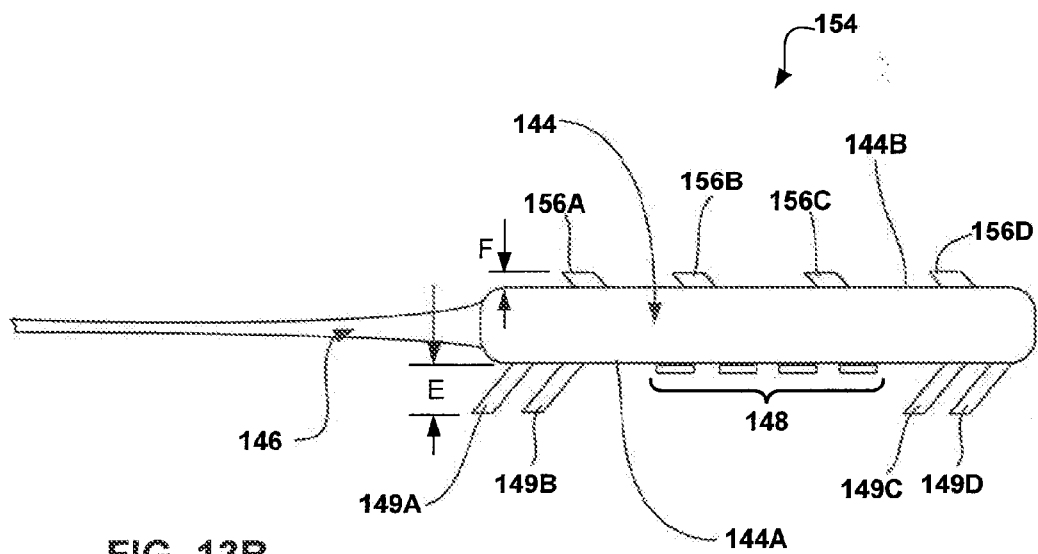


FIG. 13B

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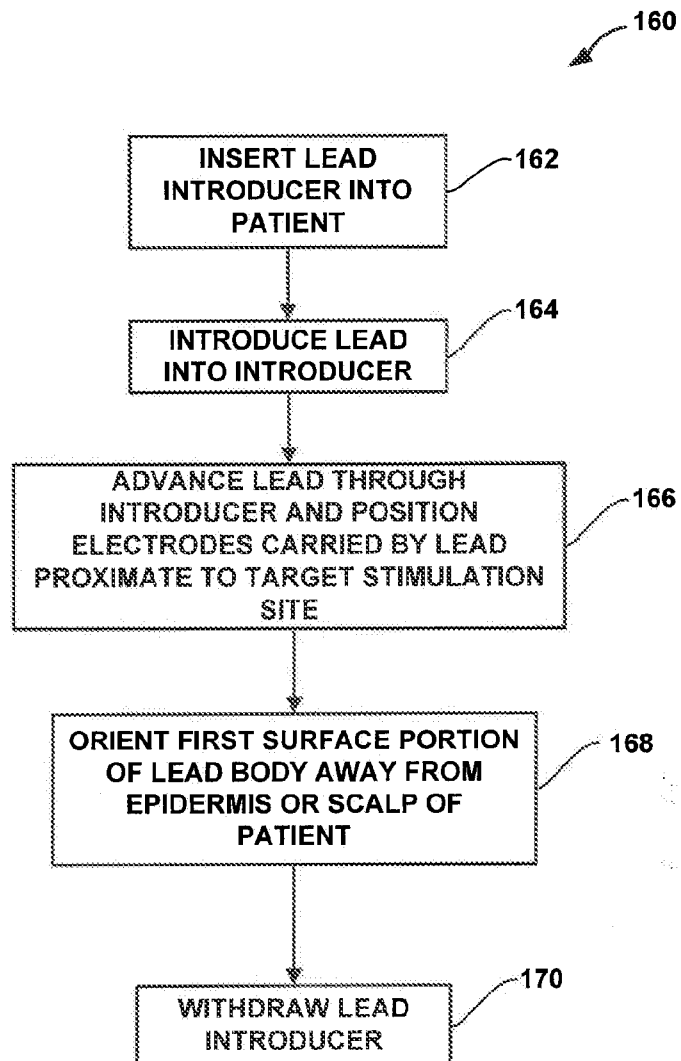
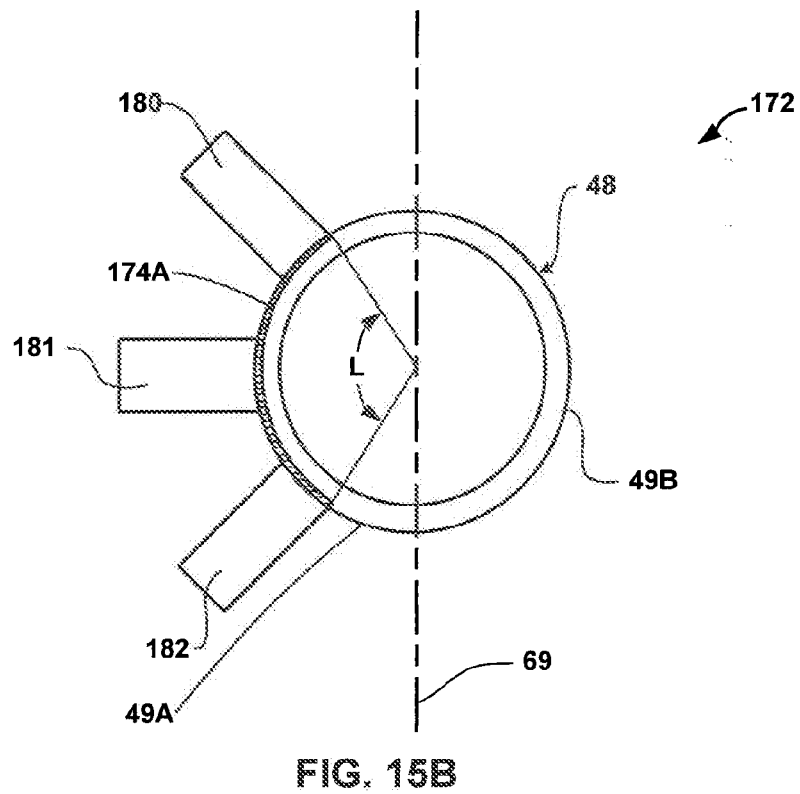
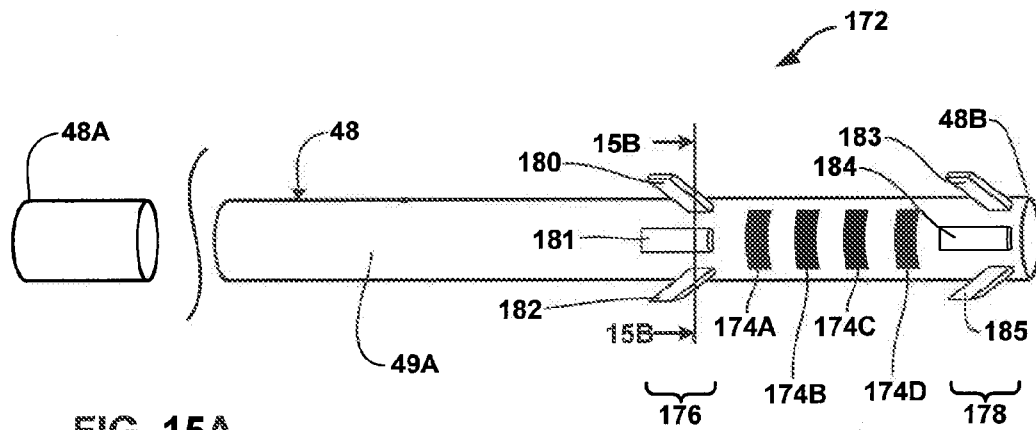


FIG. 14

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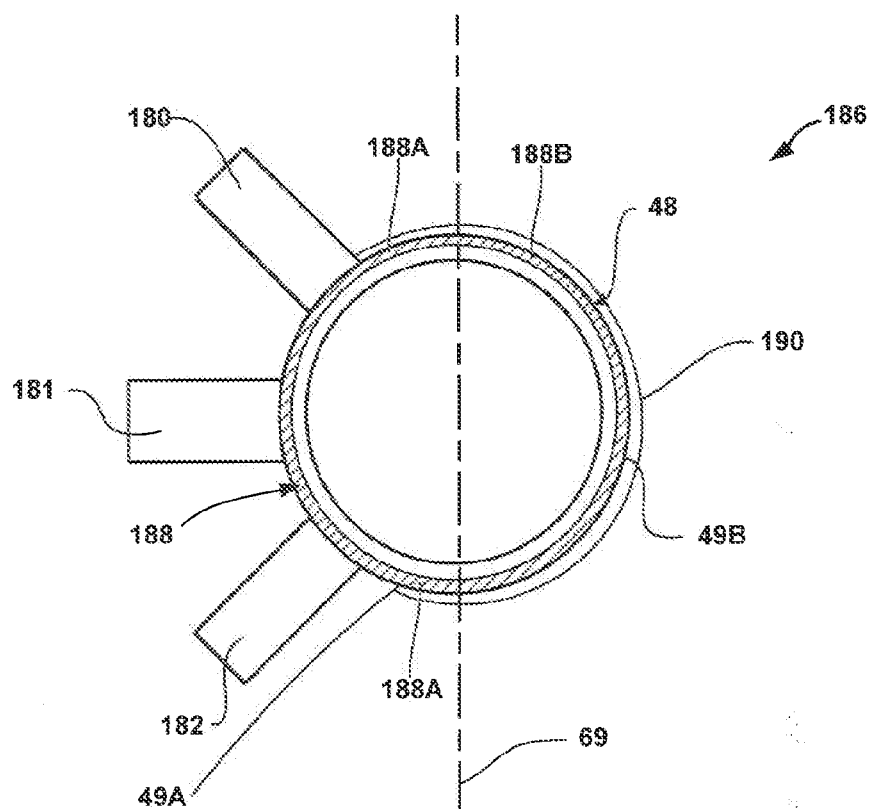


FIG. 15C

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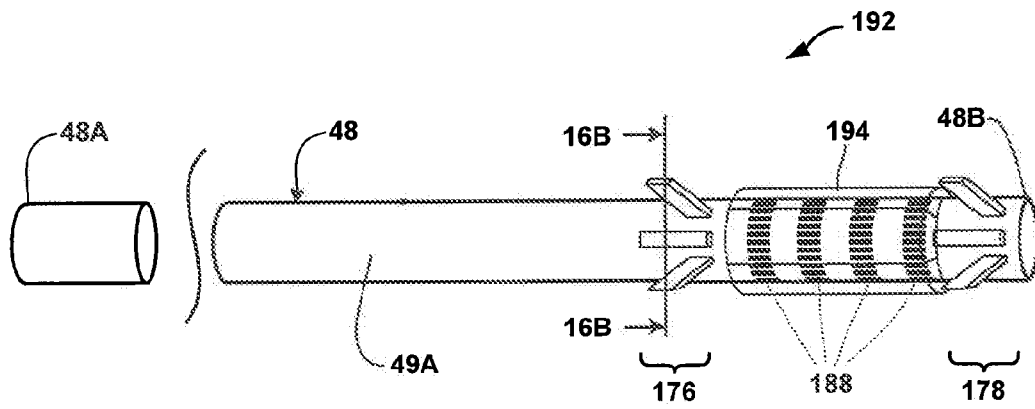


FIG. 16A

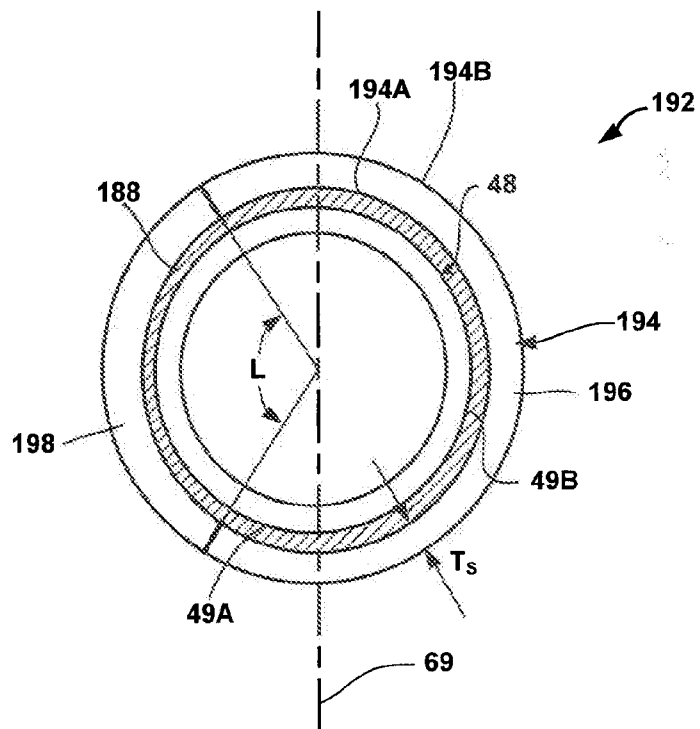


FIG. 16B

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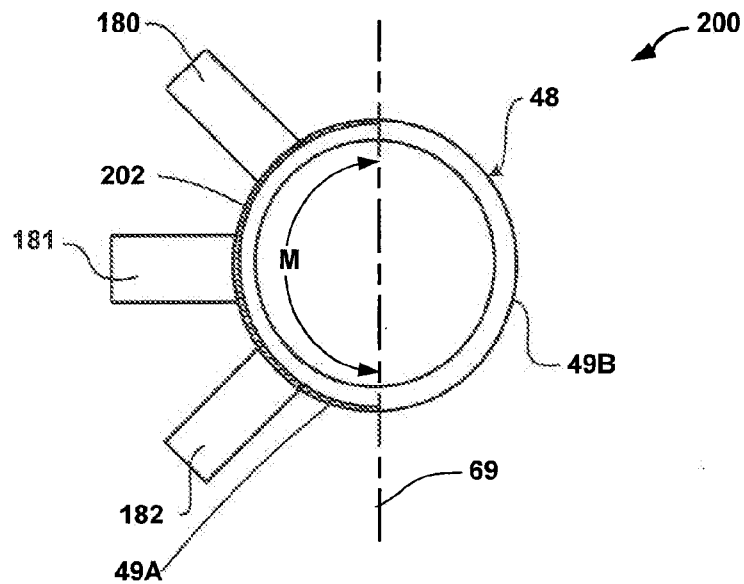


FIG. 17

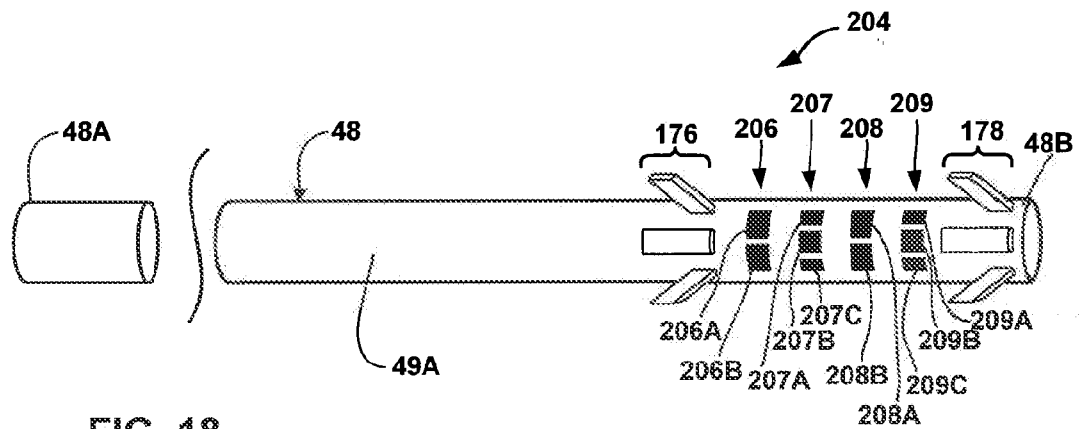


FIG. 18

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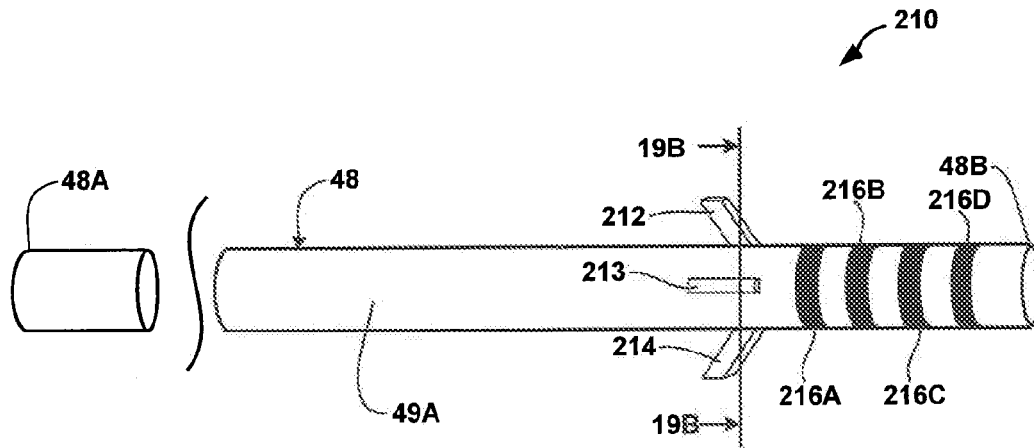


FIG. 19A

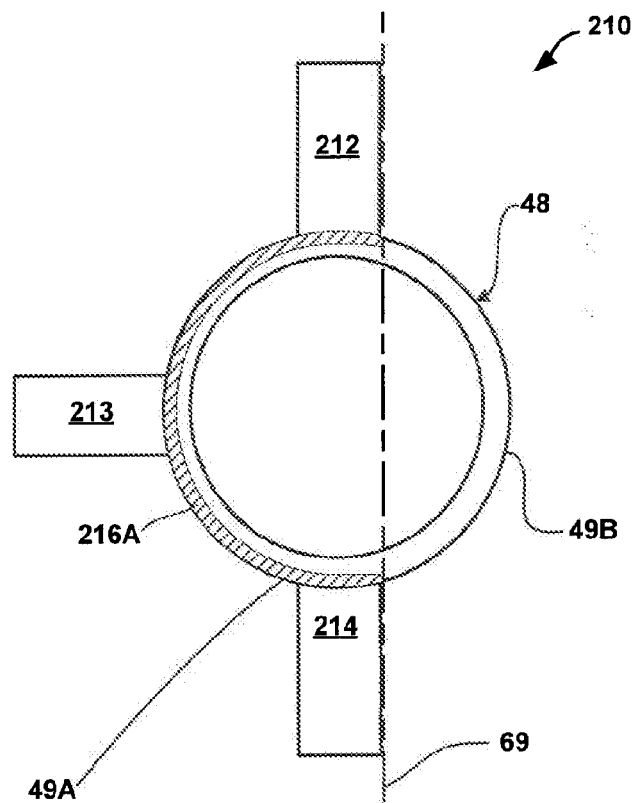


FIG. 19B

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/053543

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 006 139 A (KRUSE IB M [SE] ET AL) 21 December 1999 (1999-12-21)	1-24, 26-29, 31
Y	column 4, line 44 - column 6, line 60; figures 5, 8, 9A-D, 22	25, 30
Y	WO 2006/133445 A (MEDTRONIC INC [US]; ROONEY ETHAN A [US]; WAHLSTRAND CARL D [US]; KING) 14 December 2006 (2006-12-14) paragraphs [0124] - [0128]; figure 5	25
Y	US 2005/171587 A1 (DAGLOW TERRY [US] ET AL) 4 August 2005 (2005-08-04) paragraphs [0049], [0051], [0052]; figure 2A	30
	----- -/--	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

9 July 2008

Date of mailing of the international search report

17/07/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Schoeffmann, Herbert

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/053543

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 991 668 A (LEINDERS ROBERT [NL] ET AL) 23 November 1999 (1999-11-23) column 3, line 51 - column 6, line 57; figure 3	1, 9-11, 14-17, 20-22, 27-31
X	----- US 4 590 949 A (POHNDORF PETER J [US]) 27 May 1986 (1986-05-27) figure 2 -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/053543

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

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

1. ☒ Claims Nos.: 32-39
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/053543

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6006139	A	21-12-1999	AU 693638 B2	02-07-1998
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US 4590949	A	27-05-1986	NONE	