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(54) **PERCUTANEOUS ACCESS FOR SYSTEMS
AND METHODS OF TREATING
SLEEP-RELATED DISORDERED
BREATHING**

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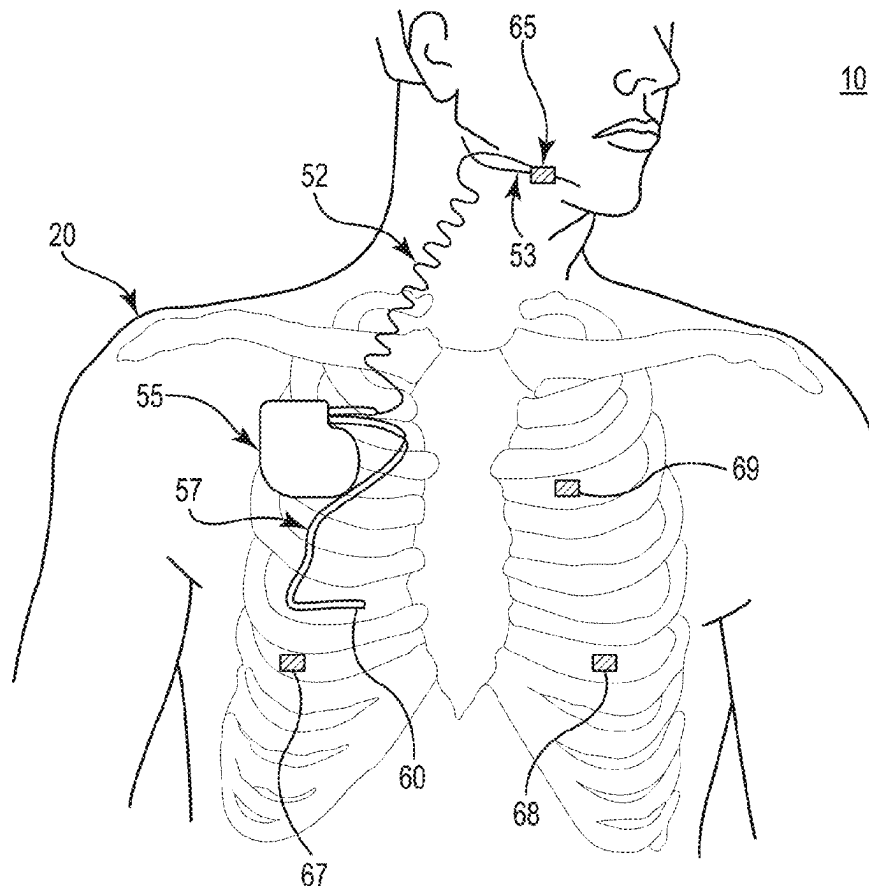
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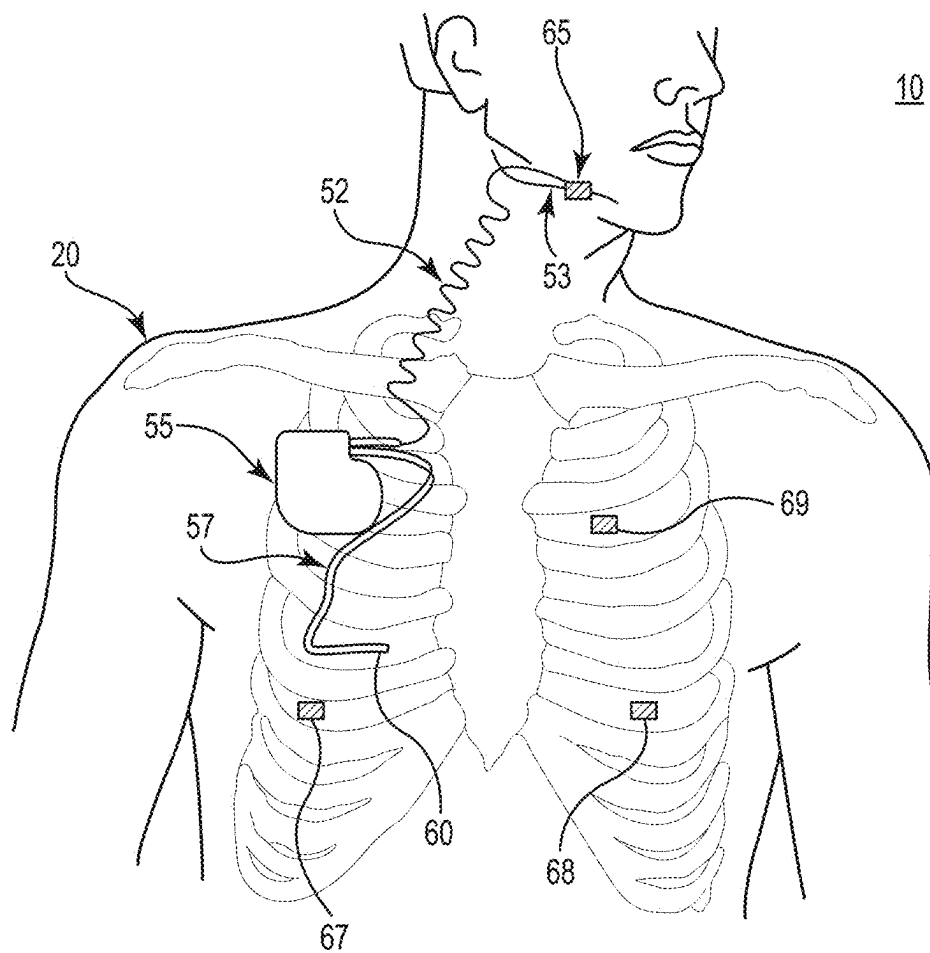
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(57)

ABSTRACT

Systems and methods are described and illustrated for percutaneously implanting a stimulation lead for treating sleep-related disordered breathing.



**Fig. 1**

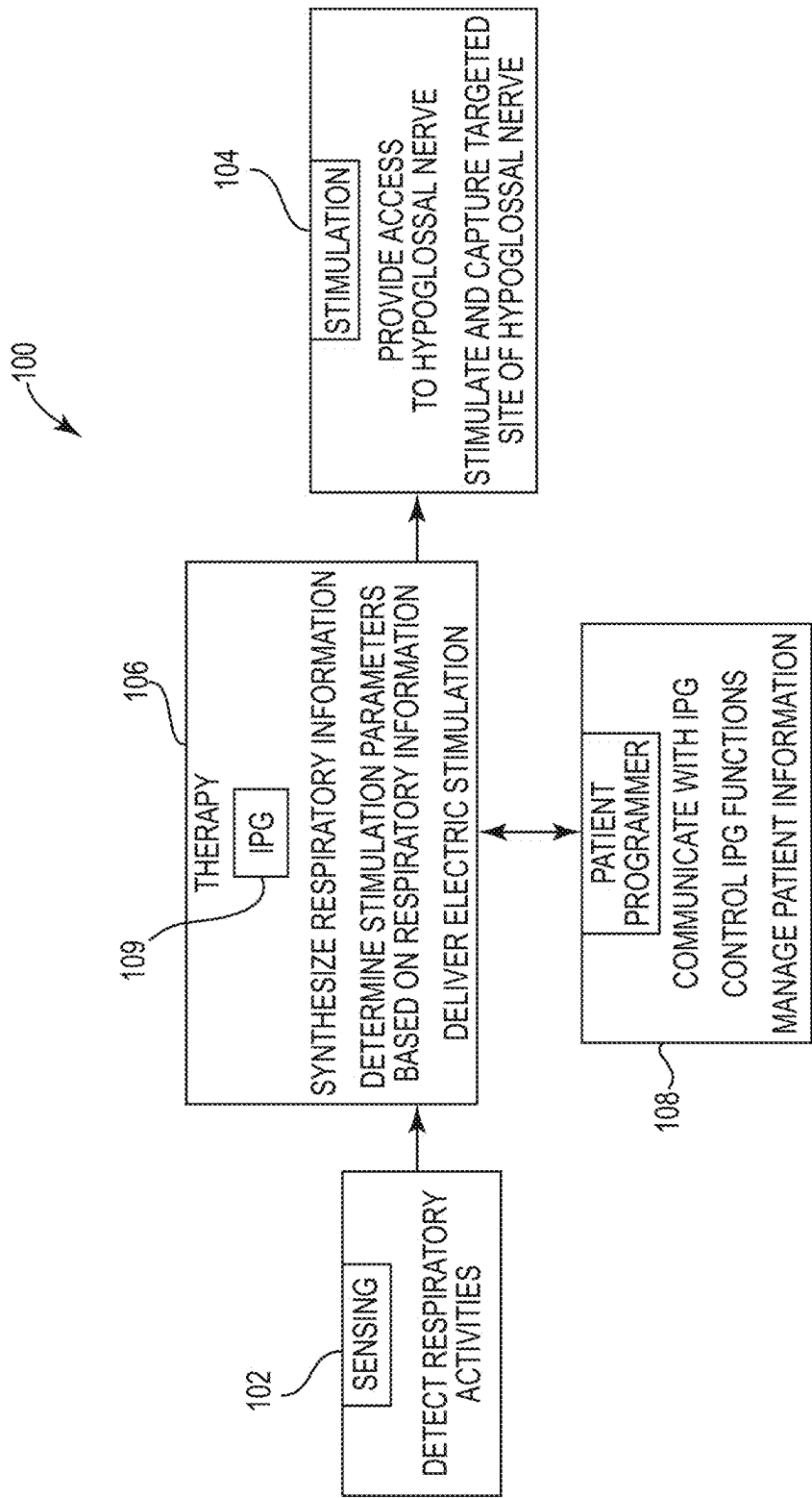


Fig. 2

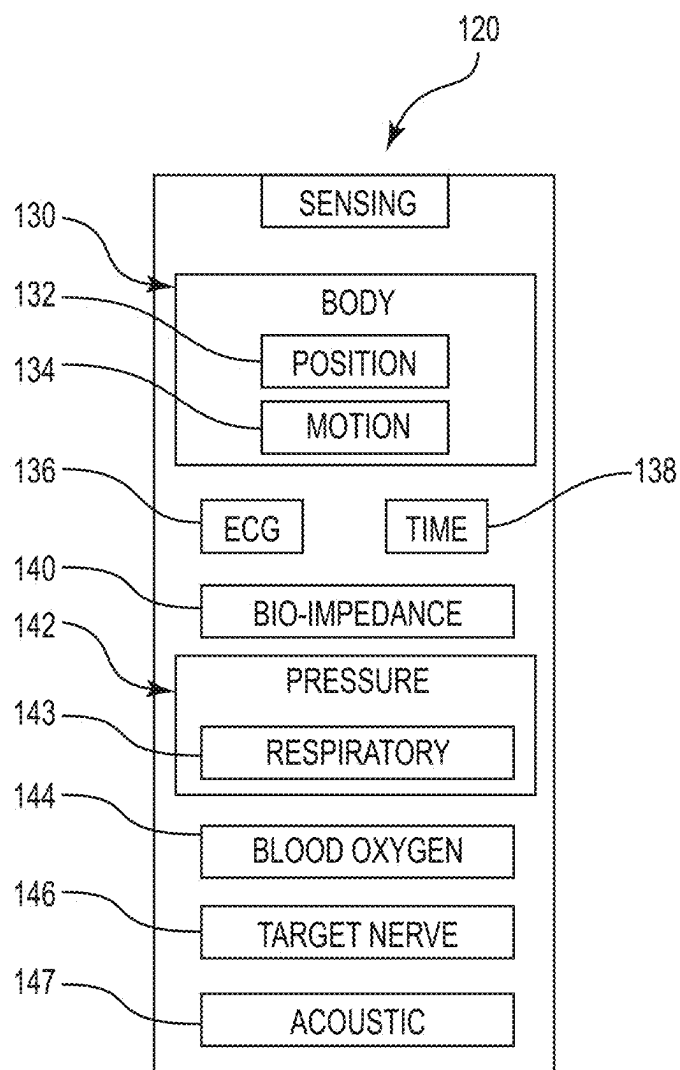


Fig. 3

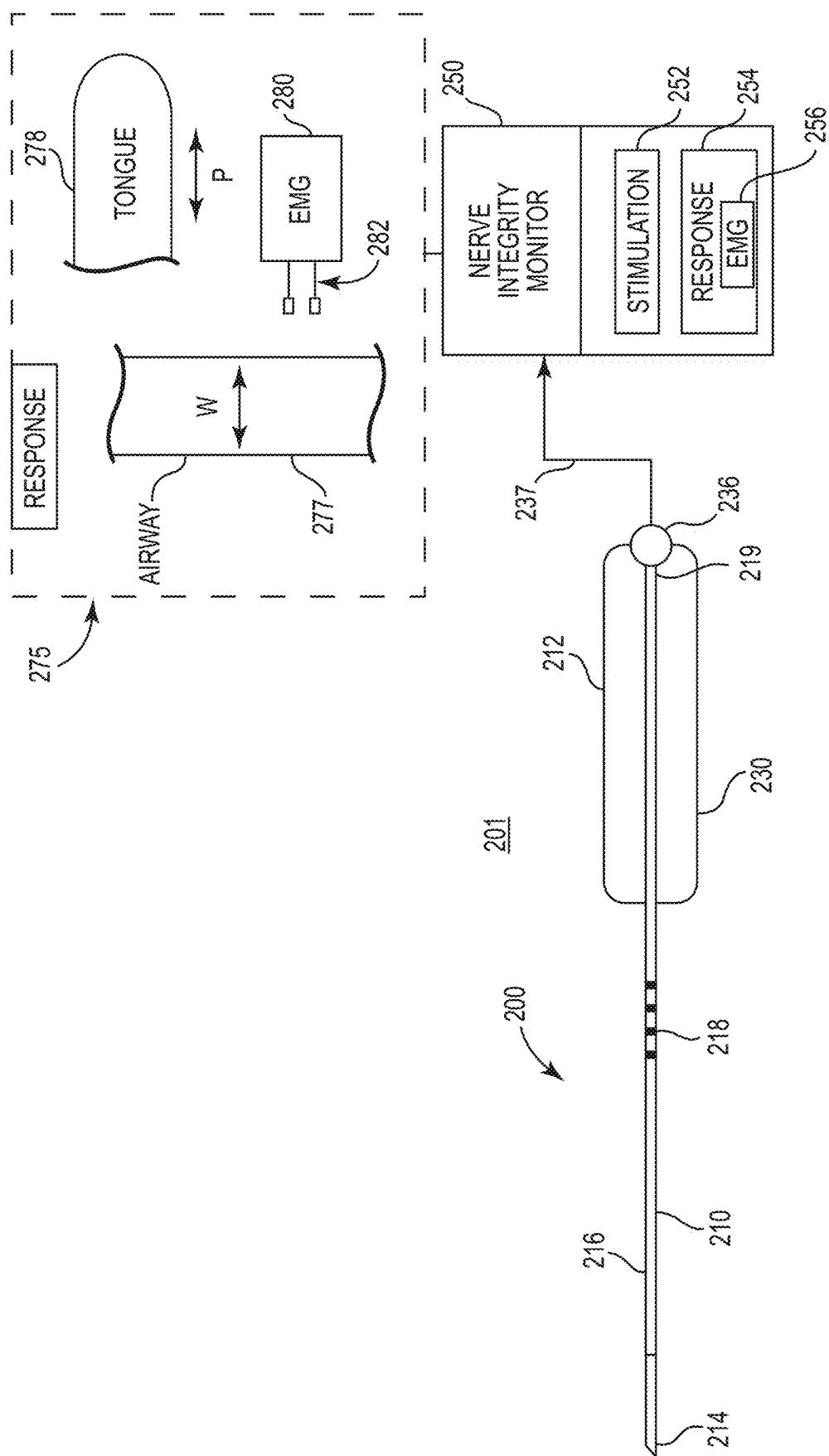
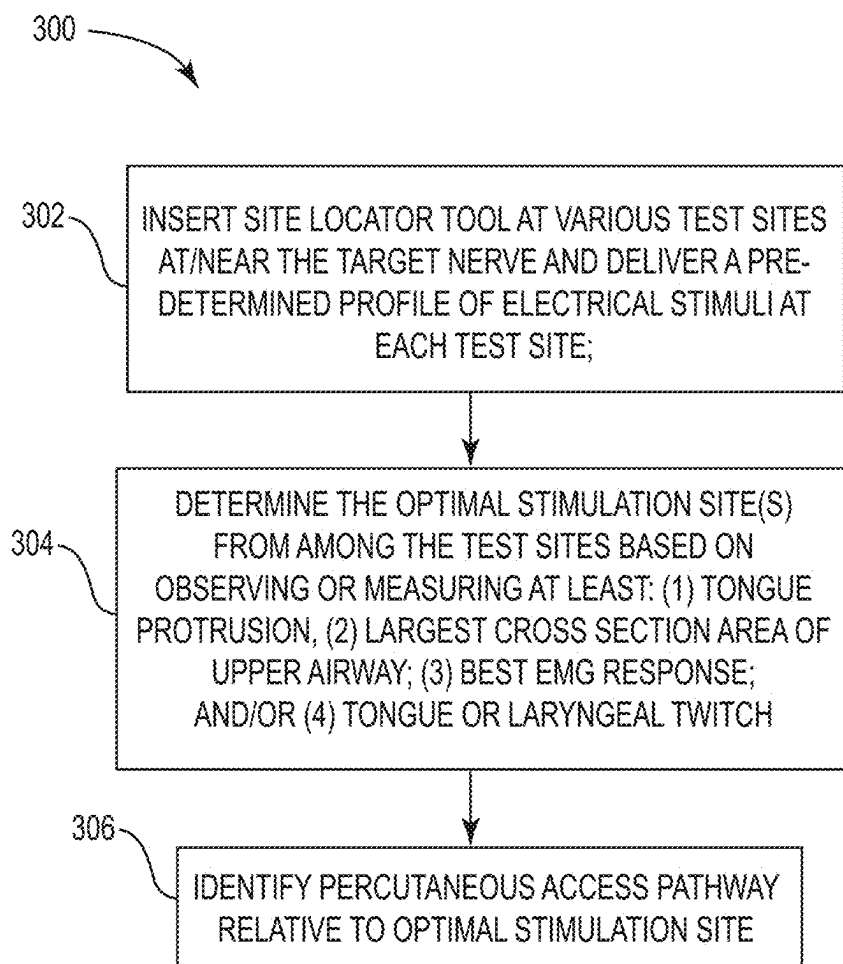
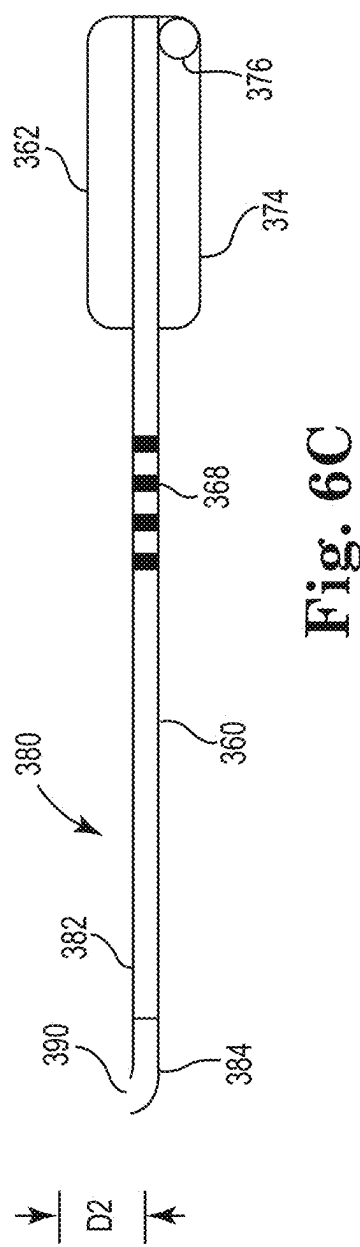
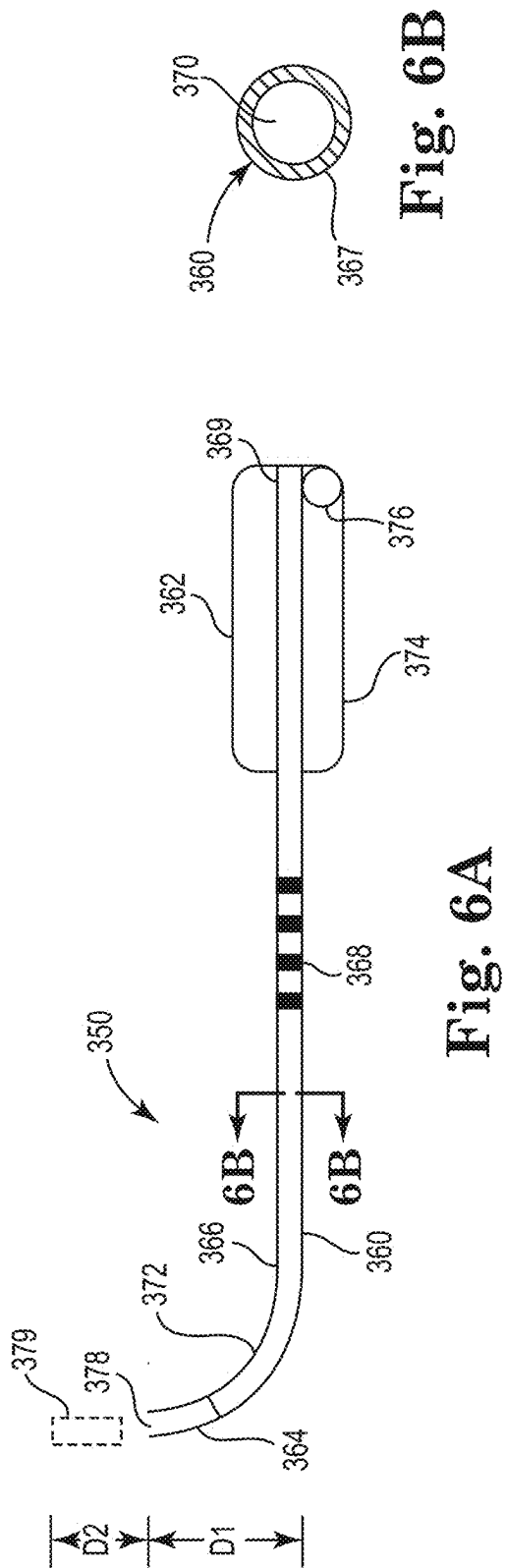


Fig. 4

**Fig. 5**



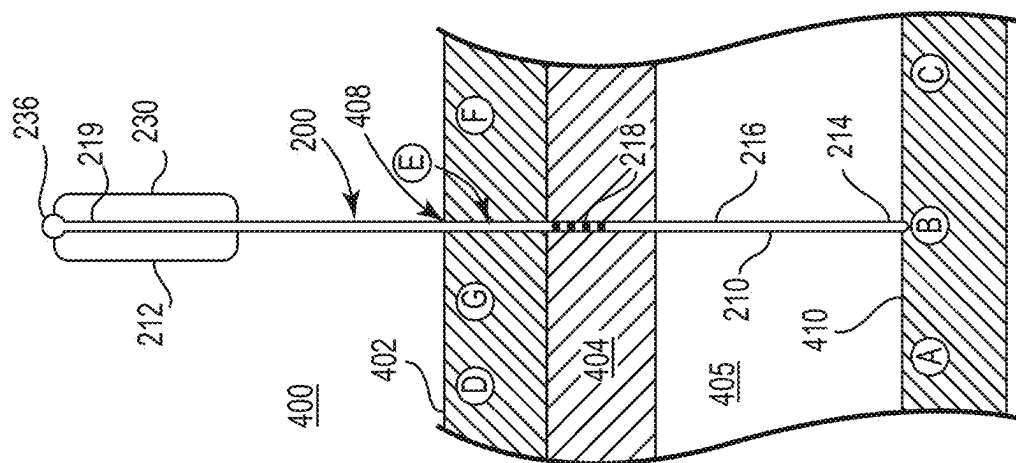


Fig. 7A

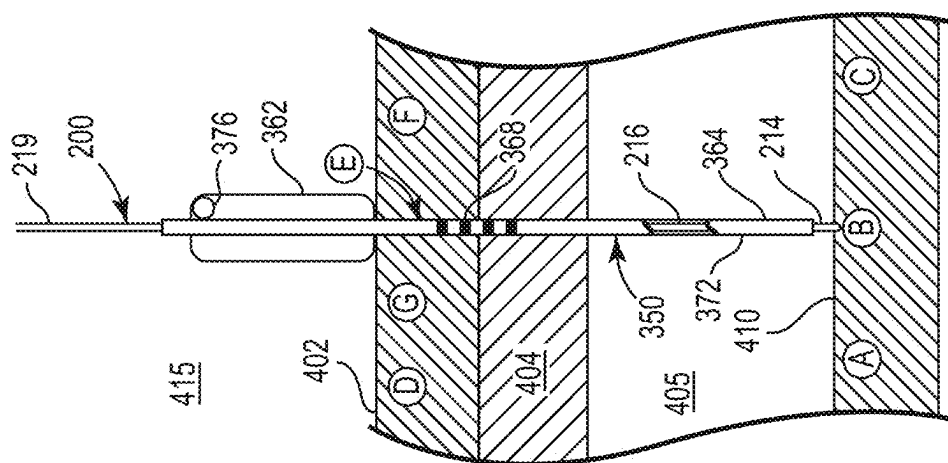


Fig. 7B

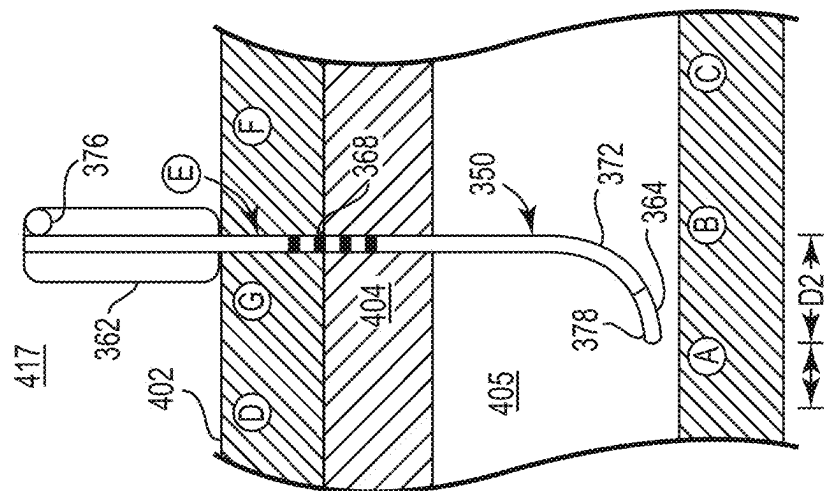


Fig. 70

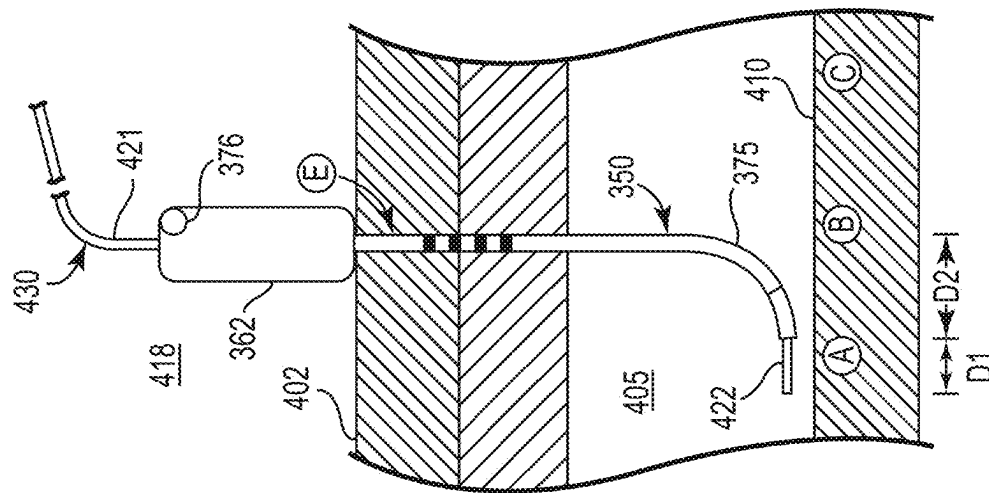


Fig. 7D

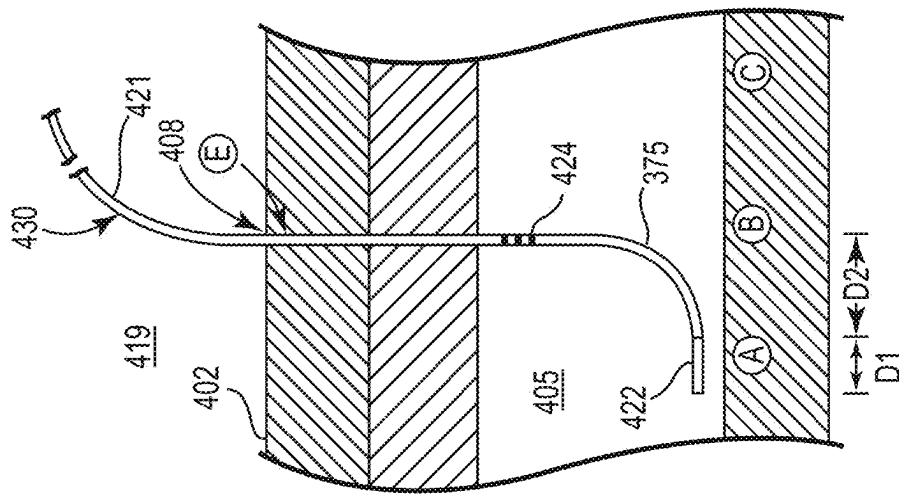


Fig. 7E

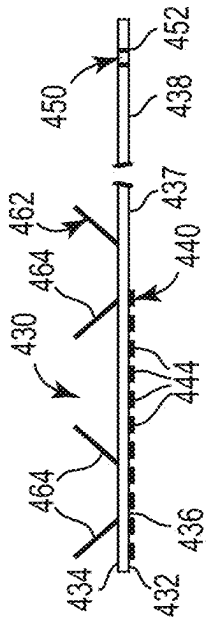
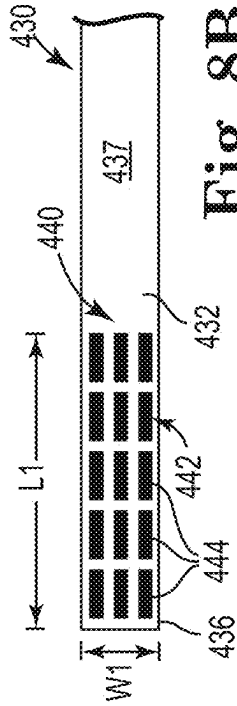


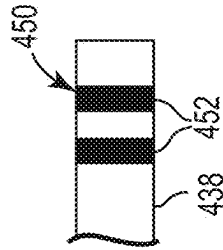
Fig. 8A



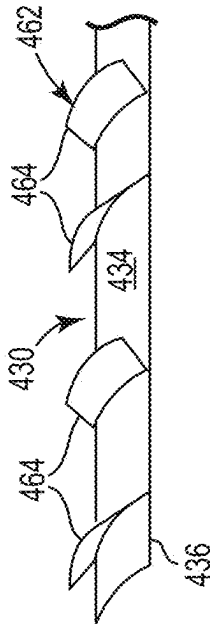
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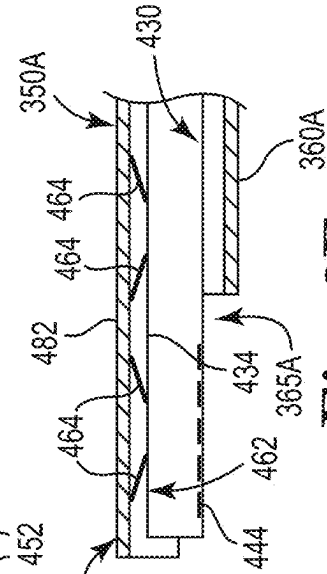
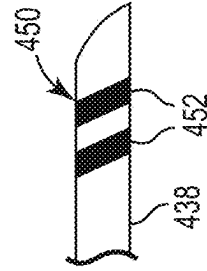
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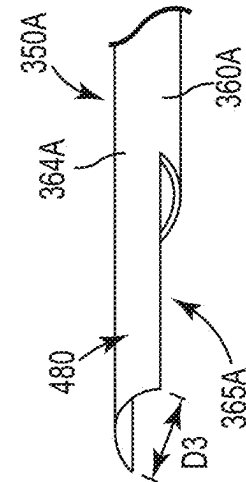
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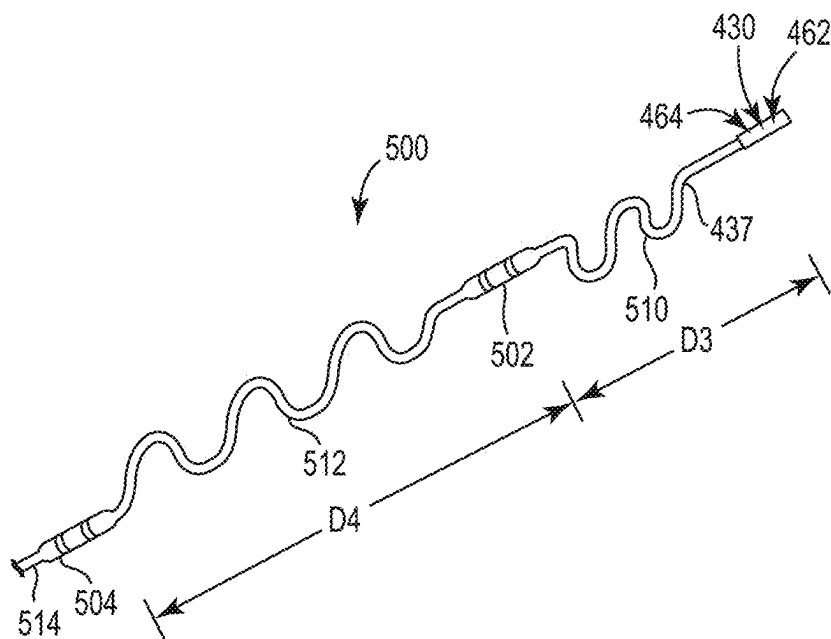


Fig. 9

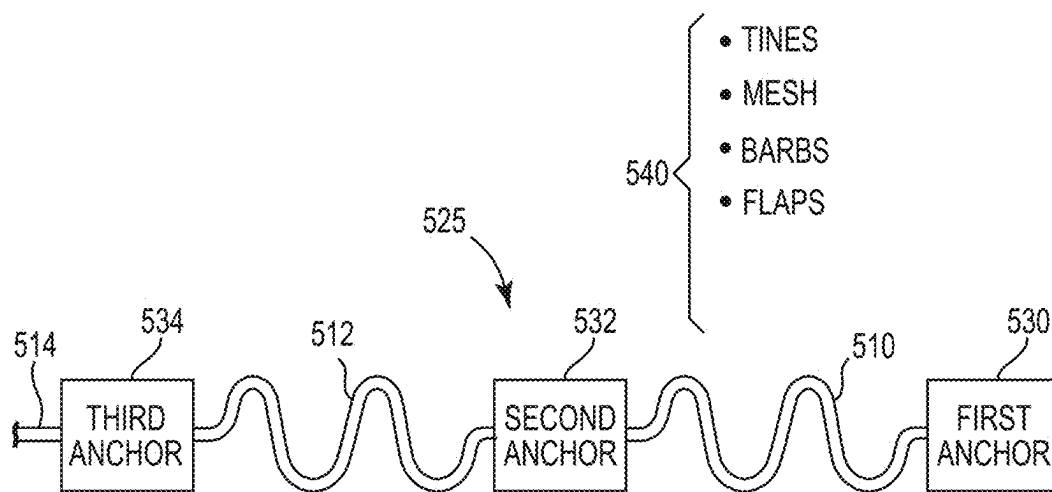
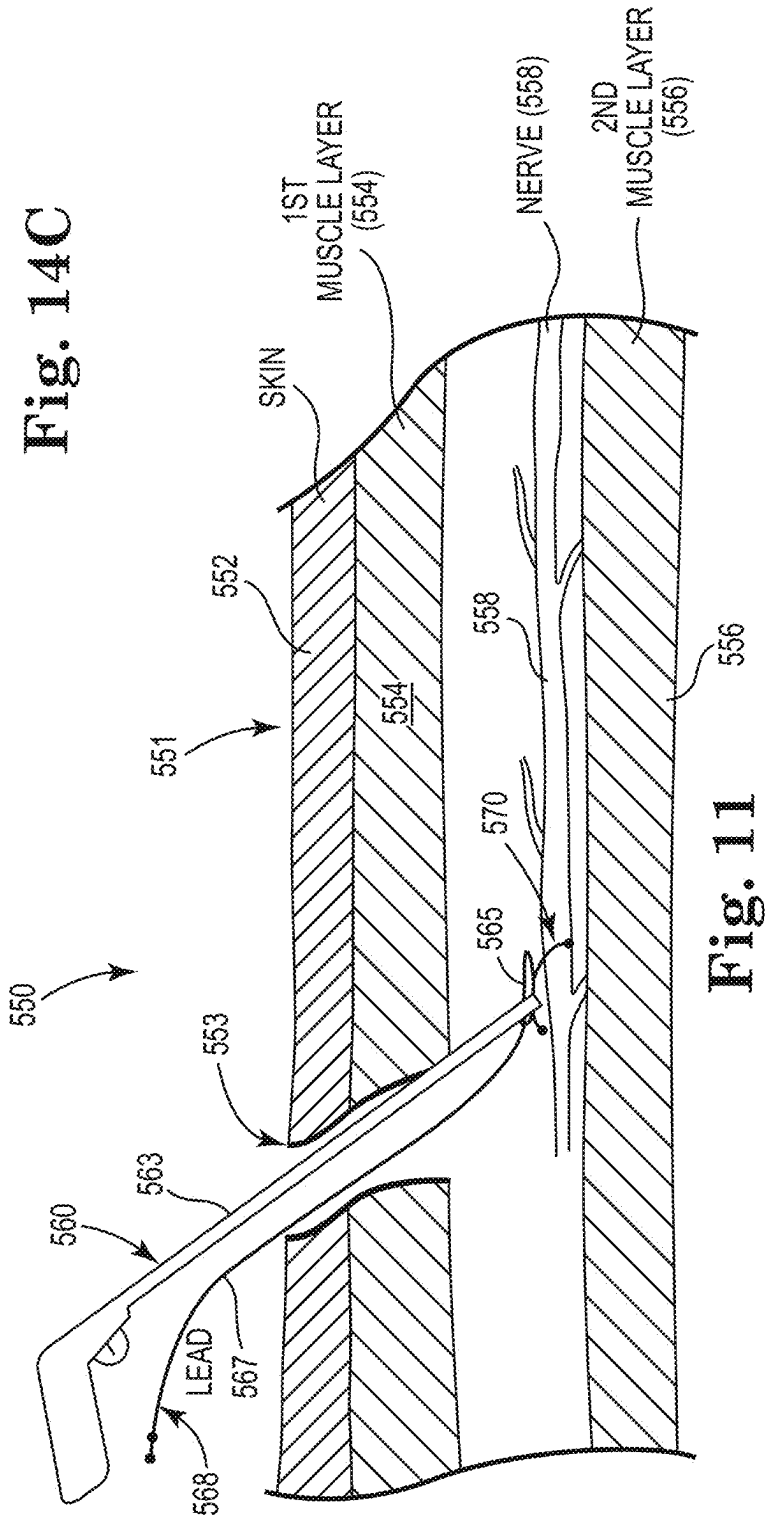
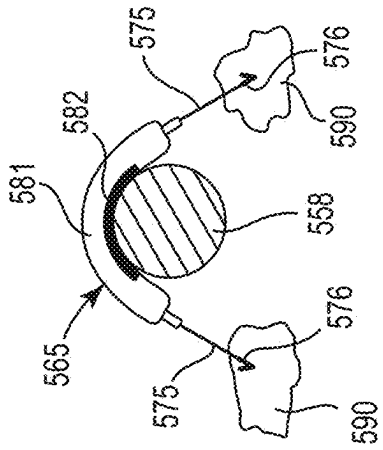
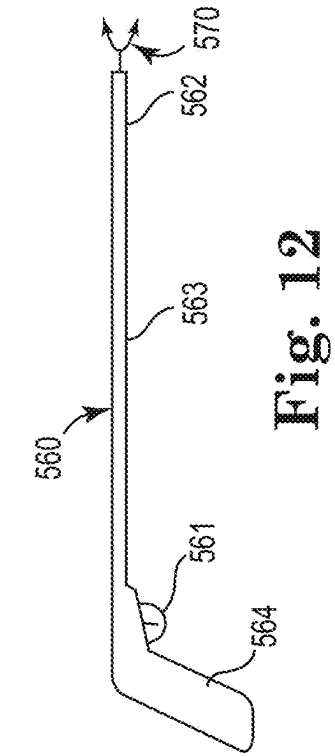


Fig. 10



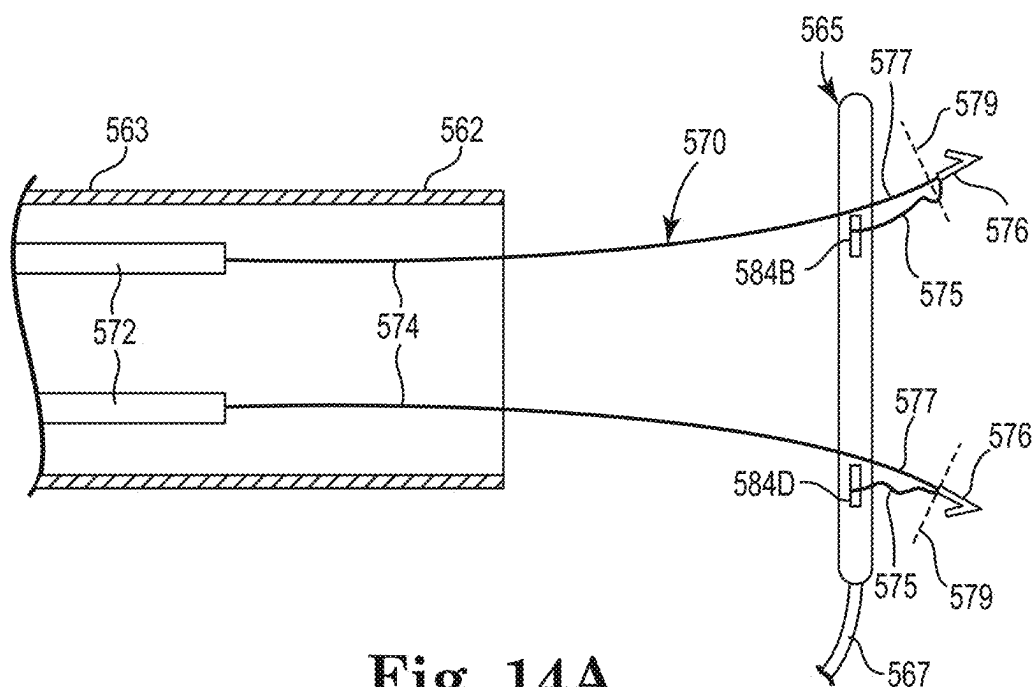


Fig. 14A

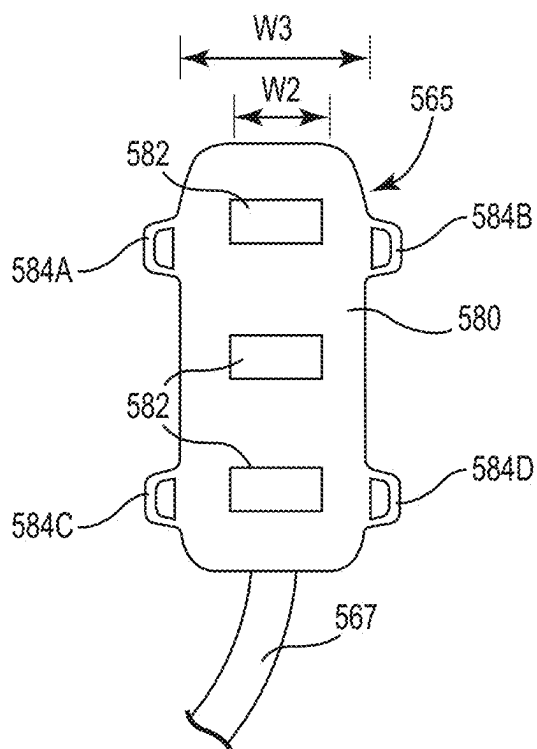


Fig. 13

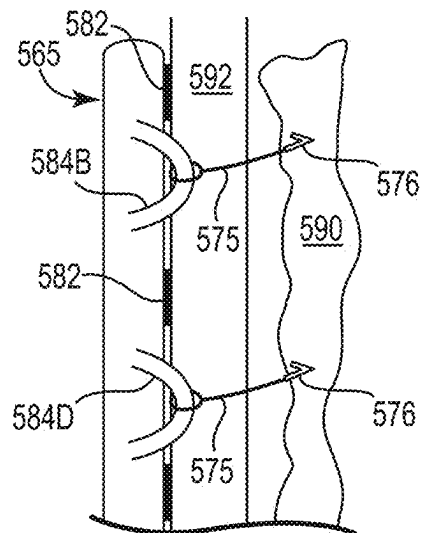


Fig. 14B

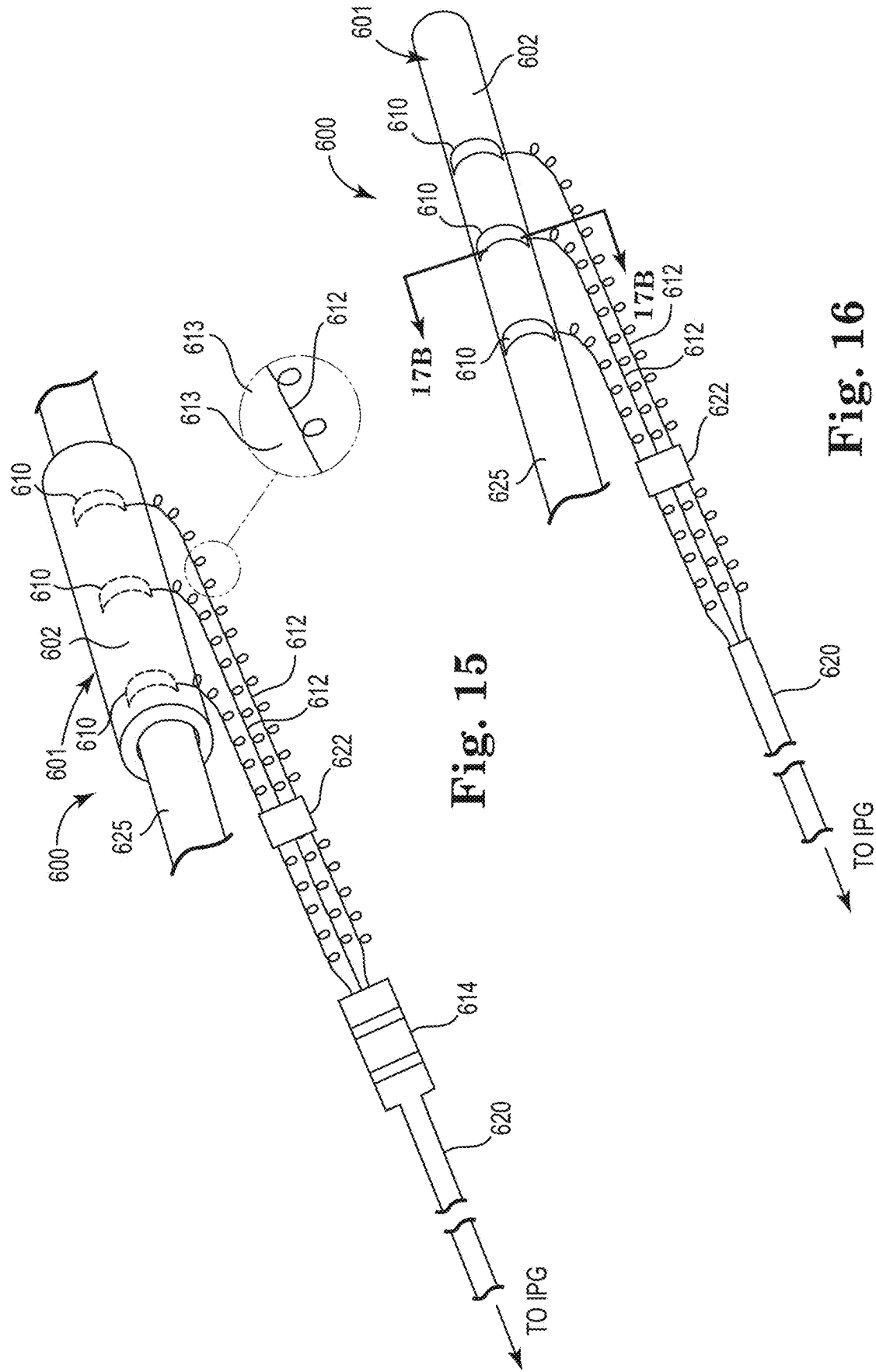


Fig. 15

Fig. 16

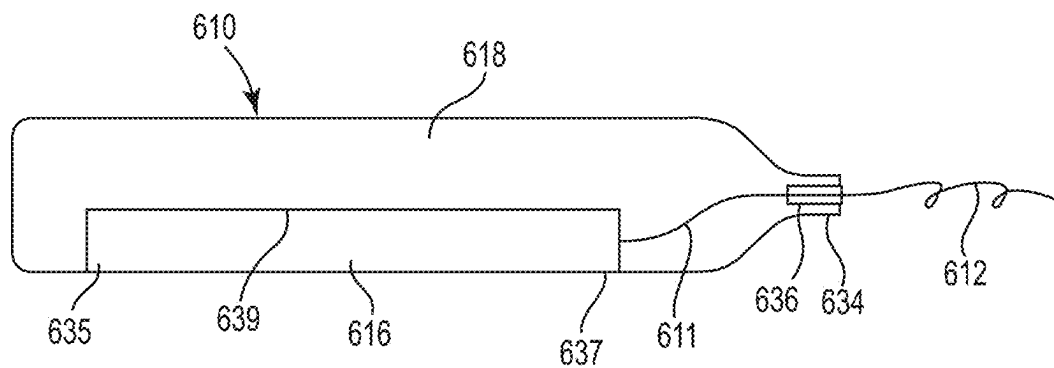


Fig. 17A

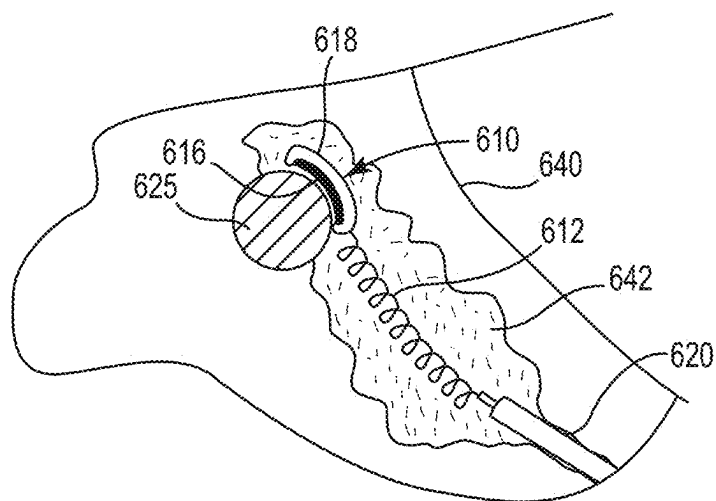


Fig. 17B

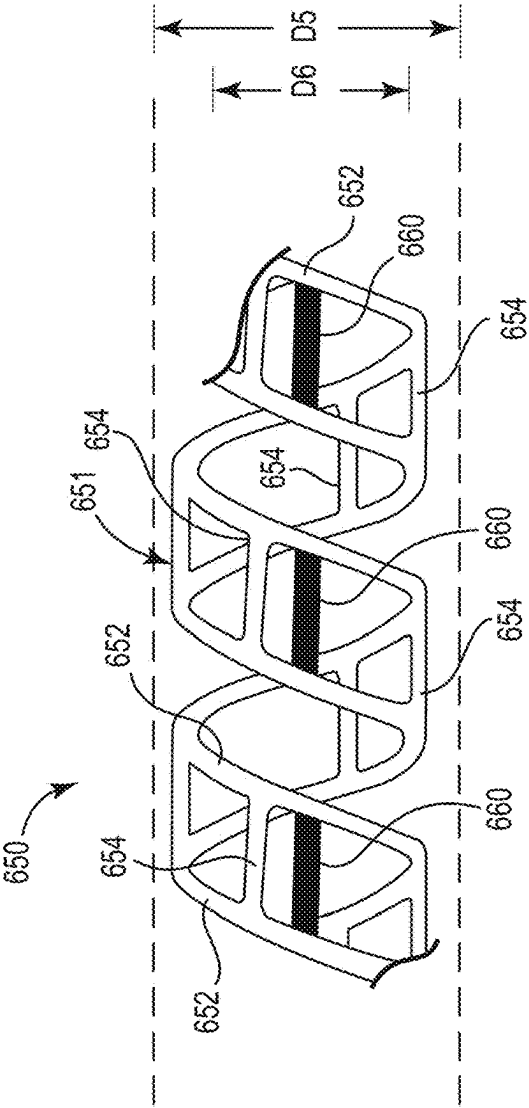


Fig. 18

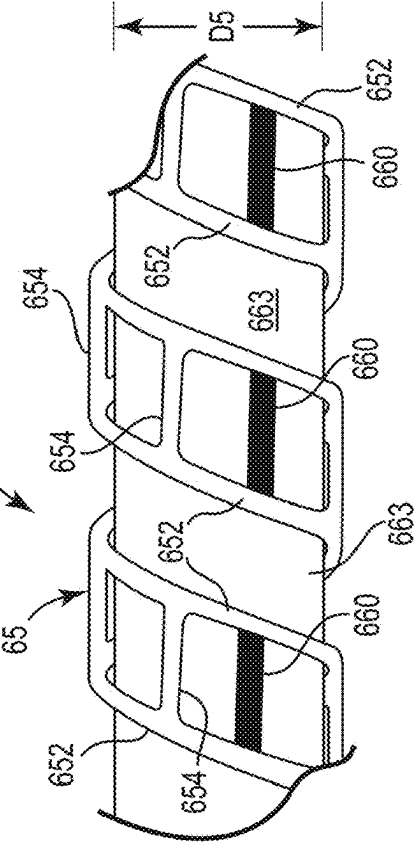


Fig. 19

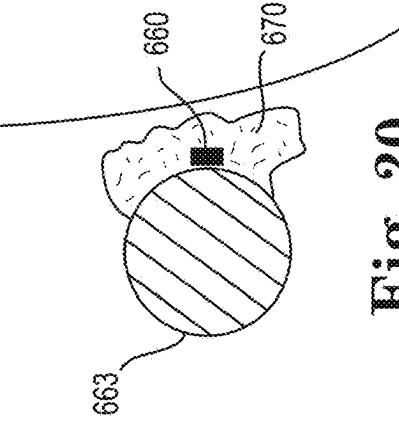


Fig. 20

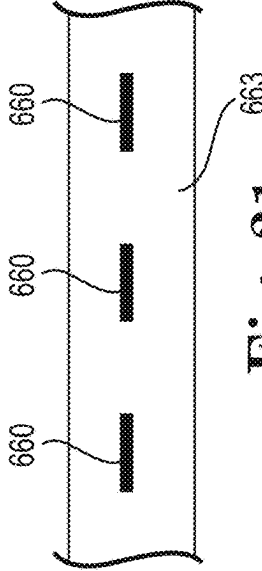


Fig. 21

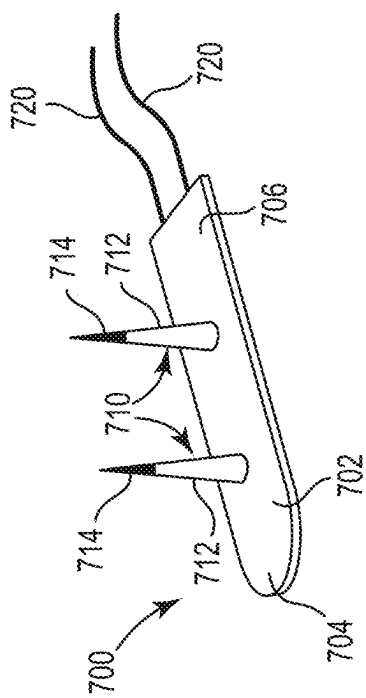


Fig. 22

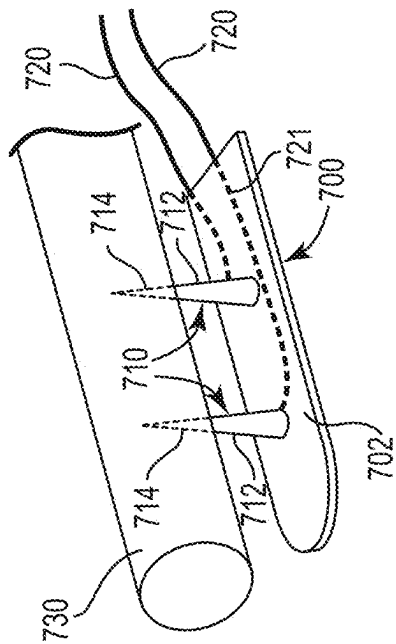


Fig. 23

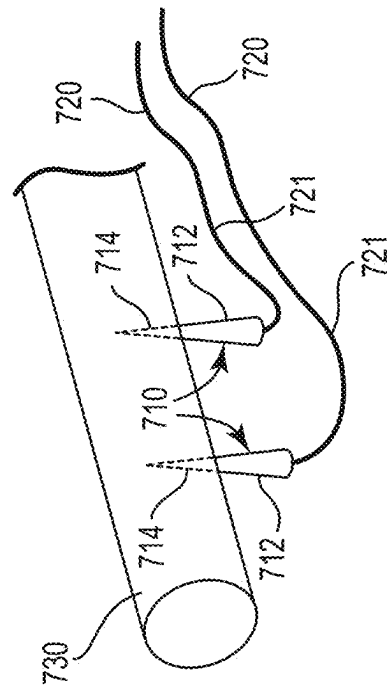
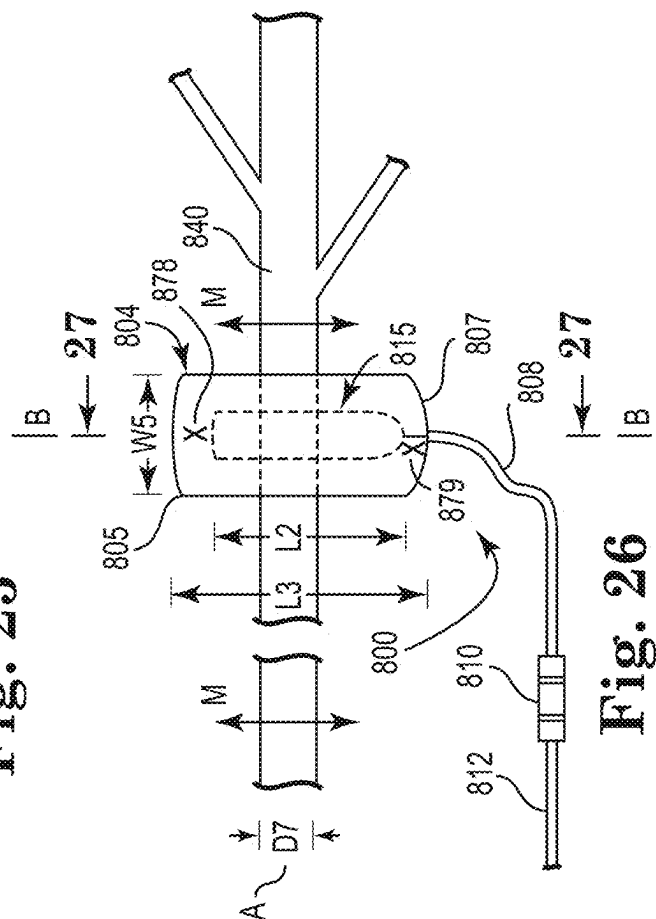
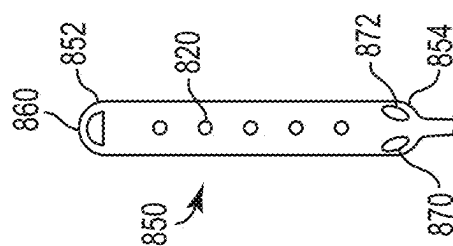
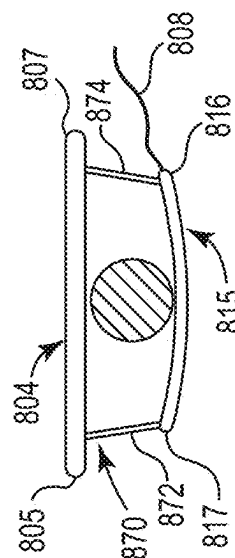
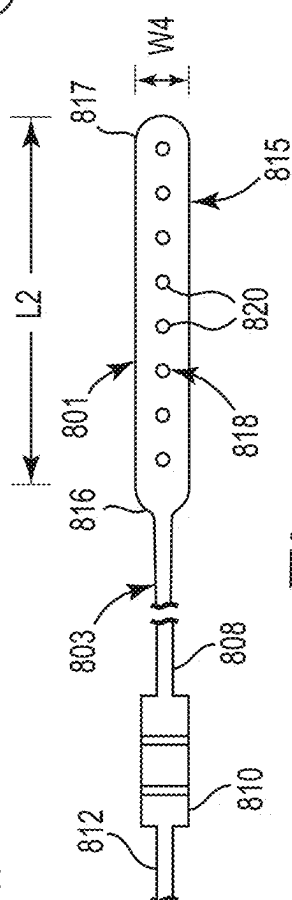
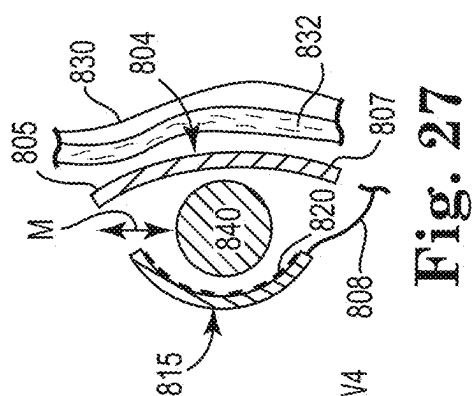


Fig. 24



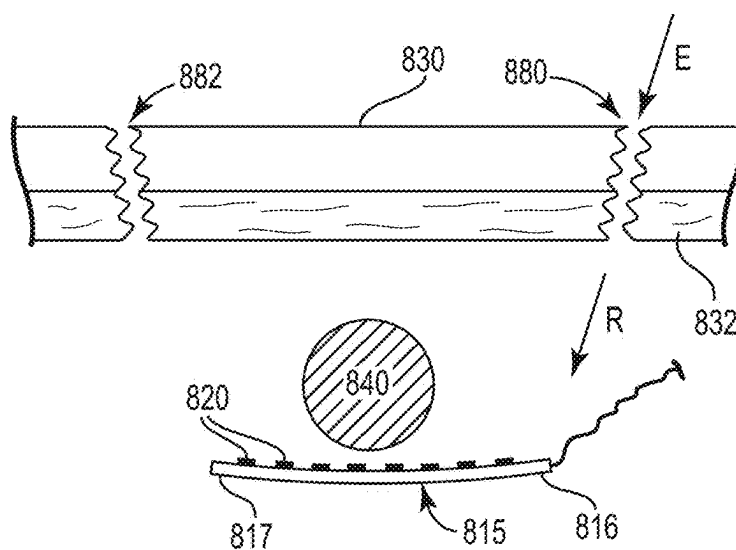


Fig. 30

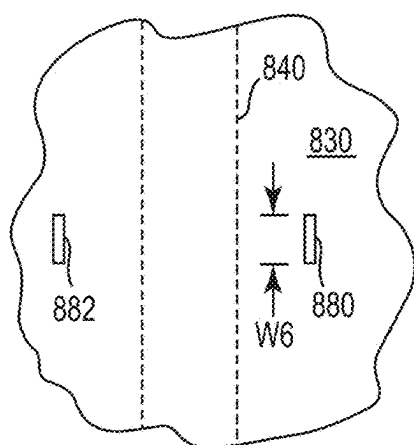


Fig. 31

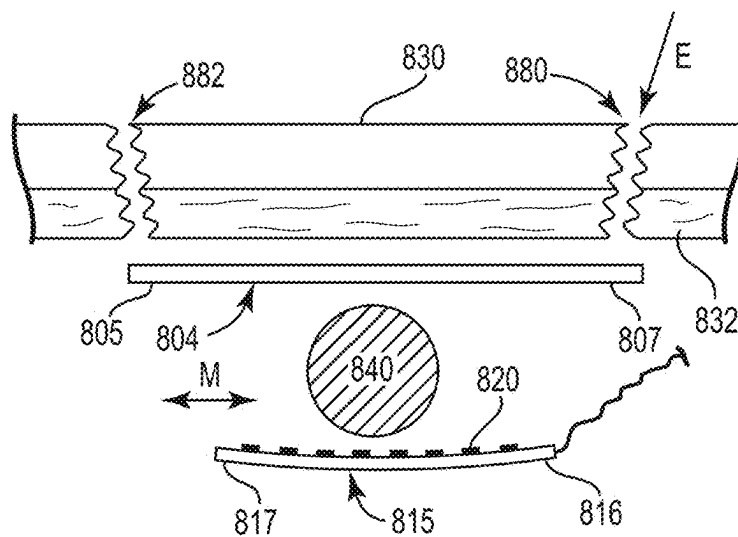


Fig. 32

**PERCUTANEOUS ACCESS FOR SYSTEMS
AND METHODS OF TREATING
SLEEP-RELATED DISORDERED
BREATHING**

**CROSS-REFERENCE TO RELATED
APPLICATIONS**

[0001] This application is a Continuation of U.S. patent application Ser. No. 16/712,501, filed Dec. 12, 2019, which is a Continuation of U.S. patent application Ser. No. 15/345,096, filed Nov. 7, 2016, now U.S. Pat. No. 10,543,366, which is a Continuation of U.S. patent application Ser. No. 13/262,434, filed Dec. 22, 2011, now U.S. Pat. No. 9,486,628, which is a 371 international application of PCT/US10/29253, filed Mar. 30, 2010, which claims the benefit of U.S. Provisional Patent Application Ser. No. 61/165,110, filed Mar. 31, 2009, all of which are incorporated herein by reference.

BACKGROUND

[0002] The present disclosure relates generally to an implantable stimulation system for stimulating and monitoring soft tissue in a patient, and more particularly, the present disclosure relates to systems and methods of using percutaneous delivery of a stimulation lead to treat sleep-related disordered breathing, such as obstructive sleep apnea and other disorders, and relates to various configurations of a stimulation electrode portion of a stimulation lead.

[0003] Sleep apnea generally refers to the cessation of breathing during sleep. One type of sleep apnea, referred to as obstructive sleep apnea (OSA), is characterized by repetitive pauses in breathing during sleep due to the obstruction and/or collapse of the upper airway, and is usually accompanied by a reduction in blood oxygenation saturation.

[0004] One treatment for obstructive sleep apnea has included the delivery of electrical stimulation to the hypoglossal nerve, located in the neck region under the chin. Such stimulation therapy activates the upper airway muscles to maintain upper airway patency. In treatment of sleep apnea, increased respiratory effort resulting from the difficulty in breathing through an obstructed airway is avoided by synchronized stimulation of an upper airway muscle or muscle group that holds the airway open during the inspiratory phase of breathing. For example, the genioglossus muscle is stimulated during treatment of sleep apnea by a cuff electrode placed around the hypoglossal nerve.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Aspects and features of the present disclosure will be appreciated as the same becomes better understood by reference to the following detailed description of the embodiments of the present disclosure when considered in connection with the accompanying drawings, wherein:

[0006] FIG. 1 is a schematic illustration of an implantable stimulation system, according to an embodiment of the present disclosure;

[0007] FIG. 2 is a schematic illustration of a block diagram of an implantable stimulation system, according to an embodiment of the present disclosure;

[0008] FIG. 3 is a schematic illustration of a block diagram of a sensing monitor, according to an embodiment of the present disclosure;

[0009] FIG. 4 is a schematic illustration of a percutaneous access system including a site locator tool, a stimulation monitor, and a response evaluation array, according to an embodiment of the present disclosure;

[0010] FIG. 5 is a schematic illustration of a method of identifying a stimulation site, according to an embodiment of the present disclosure;

[0011] FIG. 6A is a side plan view schematically illustrating a stimulation lead introduction tool, according to an embodiment of the present disclosure;

[0012] FIG. 6B is a sectional view as taken along lines 6B-6B of FIG. 6A, according to an embodiment of the present disclosure;

[0013] FIG. 6C is a side plan view schematically illustrating a stimulation lead introduction tool, according to an embodiment of the present disclosure;

[0014] FIG. 7A is sectional view schematically illustrating insertion of a test locator tool, according to an embodiment of the present disclosure;

[0015] FIG. 7B is sectional view schematically illustrating a configuration upon insertion of an introduction tool, according to an embodiment of the present disclosure;

[0016] FIG. 7C is sectional view schematically illustrating a configuration upon removal of a locator tool, according to an embodiment of the present disclosure;

[0017] FIG. 7D is sectional view schematically illustrating a configuration upon insertion of a stimulation lead via the introduction tool, according to an embodiment of the present disclosure;

[0018] FIG. 7E is sectional view schematically illustrating a configuration of the stimulation lead upon removal of the introduction tool, according to an embodiment of the present disclosure;

[0019] FIG. 8A is a side plan view schematically illustrating a stimulation lead including a distal electrode portion, according to an embodiment of the present disclosure;

[0020] FIG. 8B is a bottom plan view of the stimulation lead of FIG. 8A including a schematic illustration of a stimulation electrode portion, according to an embodiment of the present disclosure;

[0021] FIG. 8C is a perspective view of the stimulation lead of FIGS. 8A-8B including a schematic illustration of an anchoring mechanism, according to an embodiment of the present disclosure;

[0022] FIG. 8D is a perspective view of a distal portion of a stimulation lead introduction tool, according to an embodiment of the present disclosure;

[0023] FIG. 8E is a sectional view of a distal portion of a stimulation lead introduction tool and a stimulation lead extending therethrough, according to an embodiment of the present disclosure;

[0024] FIG. 8F is partial end view of a distal portion of a stimulation lead having convex-shaped electrode portion, according to an embodiment of the present disclosure;

[0025] FIG. 8G is partial end view of a distal electrode portion of a stimulation lead having a concave-shaped electrode portion, according to an embodiment of the present disclosure;

[0026] FIG. 9 is a perspective view of a stimulation lead including an anchoring system, according to an embodiment of the present disclosure;

[0027] FIG. 10 is a perspective view of an alternate anchoring system, according to an embodiment of the present disclosure;

[0028] FIG. 11 is a sectional view schematically illustrating a method of percutaneous delivery of a stimulation lead, according to an embodiment of the present disclosure;

[0029] FIG. 12 is a side plan view of an introduction tool employed in the method associated with FIG. 11, according to an embodiment of the present disclosure;

[0030] FIG. 13 is a bottom plan view of a distal electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

[0031] FIG. 14A is an enlarged sectional view schematically illustrating a selectively deployable anchoring mechanism of the introduction tool of FIGS. 11-12, according to an embodiment of the present disclosure;

[0032] FIG. 14B is an enlarged side view schematically illustrating the anchoring mechanism in a deployed state relative to the surrounding tissue, according to an embodiment of the present disclosure;

[0033] FIG. 14C is a sectional view schematically illustrating a distal electrode portion of a stimulation lead secured relative to a nerve via an anchoring mechanism, according to an embodiment of the present disclosure;

[0034] FIG. 15 is a perspective view schematically illustrating a bio-absorbable stimulation system prior to absorption, according to an embodiment of the present disclosure;

[0035] FIG. 16 is a perspective view schematically illustrating the bio-absorbable stimulation system of FIG. 15 after absorption, according to an embodiment of the present disclosure;

[0036] FIG. 17A is an enlarged side plan view of an electrode portion of the stimulation system of FIGS. 15-16, according to an embodiment of the present disclosure;

[0037] FIG. 17B is a sectional view as taken along lines 17B-17B of FIG. 16, according to an embodiment of the present disclosure;

[0038] FIG. 18 is a side plan view of a bio-absorbable, stent-electrode stimulation lead, according to an embodiment of the present disclosure;

[0039] FIG. 19 is a side plan view schematically illustrating deployment of the stent-electrode stimulation lead of FIG. 18 relative to a nerve, according to an embodiment of the present disclosure;

[0040] FIG. 20 is a sectional view schematically illustrating anchoring of an electrode against a nerve after absorption of the bio-absorbable stent portion of the stimulation lead, according to an embodiment of the present disclosure;

[0041] FIG. 21 is a side plan view schematically illustrating the electrodes of the stimulation lead against the target nerve after absorption of the bio-absorbable stent portion of the stimulation lead, according to an embodiment of the present disclosure;

[0042] FIG. 22 is a perspective view schematically illustrating a bio-absorbable electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

[0043] FIG. 23 is a perspective view schematically illustrating implanted electrodes of the stimulation lead of FIG. 22 prior to absorption, according to an embodiment of the present disclosure;

[0044] FIG. 24 is a perspective view schematically illustrating the implanted electrodes of the stimulation lead of FIG. 22 after absorption, according to an embodiment of the present disclosure;

[0045] FIG. 25 is a top plan view of an electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

[0046] FIG. 26 is a top plan view schematically illustrating a stimulation system as deployed relative to a nerve, including the electrode portion of a stimulation lead and an insulator shield, according to an embodiment of the present disclosure;

[0047] FIG. 27 is a sectional view as taken along lines 27-27 of FIG. 26, according to an embodiment of the present disclosure;

[0048] FIG. 28 is a top plan view of an electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

[0049] FIG. 29 is a side view schematically illustrating an insulator shield releasably connected, via a coupling mechanism, to an electrode portion of a stimulation lead, according to an embodiment of the present disclosure;

[0050] FIG. 30 is a sectional view schematically illustrating one aspect of a method of percutaneous access for a stimulation system, according to an embodiment of the present disclosure;

[0051] FIG. 31 is a top elevational view schematically illustrating one aspect of the method of percutaneous access, according to an embodiment of the present disclosure; and

[0052] FIG. 32 is a sectional view schematically illustrating another aspect of the method of percutaneous access, according to an embodiment of the present disclosure.

DESCRIPTION OF EMBODIMENTS

[0053] The following detailed description is merely exemplary in nature and is not intended to limit the present disclosure or the application and uses of the present disclosure. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, or the following detailed description.

[0054] Embodiments of the present disclosure provide implantable medical devices, systems, and methods for treating sleep-related disordered breathing, such as but not limited to obstructive sleep apnea. In these methods and systems, stimulation is provided to the hypoglossal nerve (or another target nerve) through a lead system that is delivered percutaneously or delivered using other minimally invasive techniques. In addition, embodiments of the present disclosure include various configurations of the stimulation electrode portion of a stimulation lead.

[0055] FIG. 1 is a schematic diagram of an implantable stimulation system that includes a percutaneously placed stimulation electrode, according to an embodiment of the present disclosure. As illustrated in FIG. 1, an example of an implantable stimulation system 10 according to one embodiment of the present disclosure includes an implantable pulse generator (IPG) 55, capable of being surgically positioned within a pectoral region of a patient 20, and a stimulation lead 52 electrically coupled with the IPG 55 via a connector (not shown) positioned within a connection port of the IPG 55. The lead 52 includes a stimulation electrode portion 65 and extends from the IPG 55 so that the stimulation electrode portion 65 is positioned in contact with a desired nerve, such as the hypoglossal nerve 53 of the patient 10, to enable stimulation of the nerve 53, as described below in detail. An exemplary implantable stimulation system in which lead 52 may be utilized, for example, is described in U.S. Pat. No. 6,572,543 to Christopherson et al., and which is incorporated herein by reference in its entirety. In one embodiment, the lead 52 further includes at least one sensor

portion 60 (electrically coupled to the IPG 55 and extending from the IPG 55) positioned in the patient 10 for sensing respiratory effort, such as respiratory pressure.

[0056] In some embodiments, the sensor portion 60 detects respiratory patterns (e.g., inspiration, expiration, respiratory pause, etc.) in order to trigger activation of an electrode portion to stimulate a target nerve. Accordingly, with this arrangement, the IPG 55 (FIG. 1) receives sensor waveforms from the respiratory sensor portion 60, thereby enabling the IPG 55 to deliver electrical stimulation synchronously with inspiration (or another aspect of the respiratory pattern related to inspiration) according to a therapeutic treatment regimen in accordance with embodiments of the present disclosure. It is also understood that the respiratory sensor portion 60 is powered by the IPG 55 and the IPG 55 also contains internal circuitry to accept and process the impedance signal from the stimulation lead 52.

[0057] In some embodiments, the sensor portion 60 is a pressure sensor. In one aspect, the pressure sensor in this embodiment detects pressure in the thorax of the patient. In another aspect, the sensed pressure could be a combination of thoracic pressure and cardiac pressure (e.g., blood flow). With this configuration, the controller is configured to analyze this pressure sensing information to detect the respiratory patterns of the patient.

[0058] In some other embodiments, the respiratory sensor portion 60 comprises a bio-impedance sensor or pair of bio-impedance sensors and can be located in regions other than the pectoral region. In one aspect, such an impedance sensor is configured to sense a bio-impedance signal or pattern whereby the control unit evaluates respiratory patterns within the bio-impedance signal. For bio-impedance sensing, in one embodiment, electric current will be injected through an electrode portion within the body and an electrically conductive portion of a case of the IPG 55 (FIG. 3A) with the voltage being sensed between two spaced apart stimulation electrode portions (or also between one of the stimulation electrode portions and the electrically conductive portion of the case of IPG 55) to compute the impedance.

[0059] In some embodiments, system 10 also comprises additional sensors to further obtain physiologic data associated with respiratory functions. For example, system 10 may include various sensors (e.g., sensors 67, 68, 69 in FIG. 1) distributed about the chest area for measuring a trans-thoracic bio-impedance signal, an electrocardiogram (ECG) signal, or other respiratory-associated signals.

[0060] In some embodiments, the sensing and stimulation system for treating obstructive sleep apnea is a totally implantable system which provides therapeutic solutions for patients diagnosed with obstructive sleep apnea. In other embodiments, one or more components of the system are not implanted in a body of the patient. A few non-limiting examples of such non-implanted components include external sensors (respiration, impedance, etc.), an external processing unit, or an external power source. Of course, it is further understood that the implanted portion(s) of the system provides a communication pathway to enable transmission of data and/or controls signals both to and from the implanted portions of the system relative to the external portions of the system. The communication pathway includes a radiofrequency (RF) telemetry link or other wireless communication protocols.

[0061] Whether partially implantable or totally implantable, the system is designed to stimulate the hypoglossal nerve during inspiration to thereby prevent obstructions or occlusions in the upper airway during sleep. In one embodiment, the implantable system comprises an implantable pulse generator (IPG), a peripheral nerve cuff stimulation lead, and a pressure sensing lead.

[0062] FIG. 2 is a block diagram schematically illustrating an implantable stimulation system 100, according to one embodiment of the present disclosure. In one embodiment, system 100 comprises at least substantially the same features and attributes as system 10 of FIG. 1. As illustrated in FIG. 2, system 100 includes a sensing module 102, a stimulation module 104, a therapy module 106, and a patient management module 108. In one embodiment, the IPG 109 of therapy module 106 comprises at least substantially the same features and attributes as IPG 55 of FIG. 1.

[0063] Via an array of parameters, the sensing module 102 receives and tracks signals from various physiologic sensors (such as a pressure sensor, blood oxygenation sensor, acoustic sensor, electrocardiogram (ECG) sensor, or impedance sensor) in order to determine a respiratory state of a patient, whether or not the patient is asleep or awake, and other respiratory-associated indicators, etc. Such respiratory detection may be received from either a single sensor or any multiple of sensors, or combination of various physiologic sensors which may provide a more reliable and accurate signal.

[0064] For example, in one embodiment, the sensing module 102 comprises a sensing monitor 120, as illustrated in FIG. 3. The sensing monitor 120 includes a body parameter 130, which includes at least one of a position-sensing component 132 or a motion-sensing component 134. In one embodiment, the motion-sensing component 134 tracks sensing of “seismic” activity (via an accelerometer or a piezoelectric transducer) that is indicative of walking, body motion, talking, etc. In another embodiment, the position-sensing component 132 tracks sensing of a body position or posture via an accelerometer or other transducer. In some embodiments, body parameter 130 utilizes signals from both the position-sensing component 132 and the motion-sensing component 134.

[0065] In some embodiments, sensing monitor 120 additionally comprises one or more of the following parameters: an ECG parameter 136; a time parameter 138; a bio-impedance parameter 140; a pressure parameter 142; and a blood oxygen parameter 144. In one aspect, the pressure parameter 142 includes a respiratory pressure component 143. In one aspect, the time parameter 142 tracks time generally (e.g. time intervals, elapsed time, etc.) while in other aspects, the time parameter 142 tracks the time of day in addition to or instead of the general time parameters. In another aspect, the time parameter 142 can be used to activate or deactivate a therapy regimen according to a time of day.

[0066] It is also understood that system 100 (FIG. 2) would include, or be connected to, the analogous physiologic sensor (e.g., LED-type or optical tissue perfusion oxygen saturation) implanted within or attached to the body of the patient to provide data to each one of their respective parameters (e.g., blood oxygenation parameter 144) of the sensing monitor 120. In some embodiments, sensing monitor 120 also includes a target nerve parameter 146 which represents physiologic data regarding the activity of a nerve

to be stimulated, such as the hypoglossal nerve, including specification of the trunk and/or one or more branches of the hypoglossal nerve. In yet other embodiments, sensing monitor **120** also includes an acoustic sensing parameter **147** which represents physiologic data from respiratory airflow or cardiac activity that is sensed acoustically and that is indicative of respiratory effort.

[0067] In further reference to FIG. 2, therapy manager **106** of system **100** is configured to automatically control initiation, termination, and/or adjustment of a sleep apnea therapy, in accordance with the principles of the present disclosure. Therapy manager **106** also tracks and applies various treatment parameters, such as an amplitude, pulse width, electrode polarity, duration, and/or frequency of a neuro-stimulation signal, in accordance with a treatment protocol programmed into the therapy manager **106**.

[0068] In one embodiment, therapy manager **106** comprises one or more processing units and associated memories configured to generate control signals directing the operation of system **100**, including at least sensing module **102**, therapy manager **106**, stimulation module **104**, and patient management module **108**. In particular, in response to or based upon commands received via an input and/or instructions contained in the memory associated with the controller in response to physiologic data gathered via the sensing module **102**, therapy manager **106** generates control signals directing operation of stimulation module **104** to selectively control stimulation of a target nerve, such as the hypoglossal nerve, to restore airway patency and thereby reduce or eliminate apnea events.

[0069] With this in mind, therapy manager **106** acts to synthesize respiratory information, to determine suitable stimulation parameters based on that respiratory information, and to direct electrical stimulation to the target nerve. While any number of physiologic parameters can be used with varying success to detect an apnea, in one embodiment of the present disclosure, the sensing module **102** detects apneas via a thoracic bio-impedance parameter. In particular, a measurement of thoracic impedance is used to track the relative amplitude of the respiratory waveform. Physiologically speaking, the bio-impedance of the lungs varies as the lungs fill and empty with air. Accordingly, thoracic impedance increases during inspiration and decreases during expiration. In another aspect, a varying respiratory drive will also cause the amplitude of the bio-impedance to vary, with a larger respiratory drive increasing the signal amplitude of the bio-impedance.

[0070] Upon obtaining the bio-impedance signal, the bio-impedance signal is further processed to identify an average peak amplitude over time. An apnea is detected by further identifying cyclic amplitude variations that occur for a duration substantially similar to the already known duration of a typical apnea event.

[0071] For purposes of this application, the term “processing unit” shall mean a presently developed or future developed processing unit that executes sequences of instructions contained in a memory. Execution of the sequences of instructions causes the processing unit to perform steps such as generating control signals. The instructions may be loaded in a random access memory (RAM) for execution by the processing unit from a read only memory (ROM), a mass storage device, or some other persistent storage, as represented by a memory associated with the controller. In other embodiments, hard wired circuitry may be used in place of

or in combination with software instructions to implement the functions described. For example, the controller may be embodied as part of one or more application-specific integrated circuits (ASICs). Unless otherwise specifically noted, the controller is not limited to any specific combination of hardware circuitry and software, nor limited to any particular source for the instructions executed by the processing unit.

[0072] In general terms, the stimulation module **104** of system **100** is configured to generate and apply a neuro-stimulation signal via electrode(s) (such as stimulation electrode(s) **65**) according to a treatment regimen programmed by a physician and/or in cooperation with therapy manager **106**.

[0073] In general terms, the patient management module **108** is configured to facilitate communication to and from the IPG **109** in a manner familiar to those skilled in the art. Accordingly, the patient management module **108** is configured to report activities of the IPG **109** (including sensed physiologic data, stimulation history, number of apneas detected, etc.) and is configured to receive initial or further programming of the IPG **109** from an external source, such as a patient programmer, clinician programmer, etc.

[0074] In accordance with at least one embodiment of the present disclosure, a stimulation site locator tool **200** of a percutaneous delivery system **201** is schematically illustrated in the plan view of FIG. 4. In general terms, the site locator tool **200** is configured to facilitate identifying a target or optimal stimulation site and/or a point of penetration to perform a percutaneous delivery of a stimulation lead near the target stimulation site. As shown in FIG. 4, site locator tool **200** includes a needle **210** extending from a handle **212**. The needle **210** includes a distal tip **214**, needle body **216**, and a series of depth markers **218** extending along the needle body **216**. The needle **210** extends proximally from the distal tip **214** and through handle **212**, terminating at proximal end **219**. At proximal end **219**, a connection port **236** provides releasable electrical connection between the needle **210** and a stimulation monitor (as later described in more detail), which provides an electrical stimulation signal at distal tip **214**.

[0075] Referring again to FIG. 4, in one aspect, the needle body **216** includes a dielectric coating on its outer surface while a conductive surface of the distal tip **214** is exposed to allow electrical conductivity between the distal tip **214** and the tissue within the body. The depth markers **218** are visible to the eye and may in some embodiments, be formed of a material that is readily visible through radiographic and/or ultrasound visualization techniques, as later described in more detail.

[0076] Moreover, it is understood that various surgical visualization techniques can be used in association with the embodiments of the present disclosure to assist in determining the location of the site locator tool **200**, the stimulation electrode portion, and other components involved in percutaneous delivery of the stimulation lead.

[0077] By inserting the site locator tool **200** percutaneously at various locations near or adjacent to the hypoglossal nerve (in cooperation with a stimulation monitor) the path of the hypoglossal nerve is identified based on the type and magnitude of neurogenic responses, such as neuromuscular responses, observed upon application of the test stimulation signal at those various test locations. In this way, those test locations that exhibit a neuromuscular response indicative of

a quality nerve capture are used to identify the optimal or target site to place a stimulation electrode portion of a stimulation lead. These observed responses are also used to identify a skin insertion point at which the percutaneous access will be initiated.

[0078] In some embodiments, the neuro-stimulation signal is applied at a single stimulation site along the hypoglossal nerve as illustrated in FIG. 1 (see stimulation electrode portion 65). However, in other embodiments, the neuro-stimulation signal of a sleep apnea therapy is applied from two or more of multiple locations spaced longitudinally along the hypoglossal nerve. In such an arrangement, the separate, spaced apart stimulation electrode portions can be activated simultaneously or activated at different times. With this in mind, it is understood that the percutaneous access method can be applied to locate more than one site along the hypoglossal nerve to identify placement of several different stimulation electrode portions.

[0079] In further reference to FIG. 4, in cooperation with the site locator tool 200 a stimulation monitor, such as a nerve integrity monitor 250 (a stand alone monitor or a monitor integrated into a sleep apnea physician programmer 108, such as programmer 108 in FIG. 2), is connected to the site locator tool 200 via connector 237. The stimulation monitor is used to aide the physician in determining proper electrode placement via stimulation applied via the site locator tool 200. In one embodiment, an IPG 55 (FIG. 1) or IPG 109 (FIG. 2) can be used as the stimulation monitor. In some embodiments, the stand-alone nerve integrity monitor 250 comprises at least substantially the same features and attributes as the nerve integrity monitor described in U.S. Pat. No. 6,334,068, entitled INTRAOPERATIVE NEURO-ELECTROPHYSIOLOGICAL MONITOR, issued on Dec. 25, 2001, and which is hereby incorporated by reference in its entirety. In other embodiments, other nerve integrity monitors or an equivalent array of instruments (e.g., a stimulation probe and electromyography system) are used to apply the stimulation signal and evaluate the response of the muscle innervated by the target nerve.

[0080] As shown in FIG. 4, in some embodiments nerve integrity monitor 250 comprises stimulation module 252 and a response module 254 that includes electromyography monitoring electronics (EMG) 256. In addition, FIG. 4 further illustrates a response evaluation array 275, according to one embodiment of the present disclosure. The response evaluation array 275 provides one or more mechanisms to evaluate the effectiveness of a target site for stimulating a target nerve and to identify an entry point for percutaneous delivery of the stimulation electrode portion. In one embodiment, upon stimulation applied at a potential target site, the response array 275 includes: (1) observing or measuring the extent and location (an extension of the base of the tongue is preferred over extension of the tip) of tongue protrusion 278 (indicated by arrow P); (2) observing or measuring the extent of increased cross-sectional area (indicated by arrow W) of an upper respiratory airway 277, with the observation/measurement being performed via endoscopy, ultrasound, or other visualization techniques; and/or (3) measuring the extent of an EMG response 280 (measured via EMG electronics 256 of monitor 250) of one or more muscles.

[0081] Accordingly, with this in mind, monitor 250 and one or more aspects of the response array 275 are used to evaluate the positioning of site locator tool 200 relative to a potential stimulation site on a target nerve. In one aspect, a

repetitive stimulation pattern is applied from the stimulation module 252 of nerve integrity monitor 250 to the distal tip 214 of site locator tool 200, as the site locator tool 200 is percutaneously inserted into various locations adjacent to the target nerve and into the target nerve. In some embodiments, the applied stimulation pattern is a 1 second burst of stimulation every 3 seconds, a ramping stimulation pattern, and/or a physician controlled burst. In another aspect, electromyography (EMG) monitoring electronics 256 of the nerve integrity monitor 250 enables measuring a muscle response to the nerve stimulation applied during the iterative percutaneous insertion of the site locator tool 200. Accordingly, as further shown in FIG. 4, fine wire electrodes 282 (or similar) are connected in electrical communication with EMG electronics 256 of the nerve integrity monitor 250 and are used to continuously monitor the muscle activity in response to the stimulation patterns applied via site locator tool 200. Using this arrangement, this closed loop feedback will allow the physician to obtain real-time feedback of a position of the site locator tool 200 (relative to the hypoglossal nerve) and feedback regarding the expected ability of a percutaneously implanted electrode lead to capture the target nerve.

[0082] In one embodiment of the present disclosure, as illustrated in FIG. 5, a method 300 of treating apnea includes identifying an optimal site to locate stimulation electrode portion 65 (FIG. 1) along a length of the hypoglossal nerve and treatment of sleep apnea. In particular, as illustrated at 302 in FIG. 5, the site locator tool 200 is inserted percutaneously (through the skin toward the target nerve) into various test stimulation sites at or around the hypoglossal nerve. For example, as further shown in the diagram 400 of FIG. 7A, needle 210 extends through percutaneous access path 408 such that distal tip 214 becomes electrically coupled relative to nerve 410 at one of several potential stimulation sites (e.g., A, B, C) with proximal handle 212 external to skin surface 402. Via surgical navigation techniques, the graduation markers 218 enable measuring a depth of insertion through skin 402 and other subcutaneous tissues 404, 405 surrounding nerve 410. While FIGS. 4 and 7A illustrate just a few such markers 218 for illustrative purposes, it will be understood that markers 218 would extend along a length or substantial length of needle 210 and that the spacing of such markers 218 may vary from that shown in FIGS. 4 and 7A. It will be understood that various components of tool 200 and the surrounding tissues are enlarged and/or minimized for illustrative purposes.

[0083] At each test site, a pre-determined profile of electrical stimuli is applied to identify one or more optimal or preferred target sites on the hypoglossal nerve. As illustrated at 304 in FIG. 5, the optimal or preferred target site are identified from among the test sites based observing or measuring at least: (1) a degree of tongue protrusion; (2) the size of cross-sectional area of the upper airway; (3) a best EMG response indicative of maintaining airway patency; (4) a lack of response from non-target muscles; and/or (5) a twitch from the tongue muscle and/or laryngeal muscle. In one aspect, an optimal or preferred target stimulation site is correlated with the greatest impact on maintaining airway patency during inspiration. After identifying a target site, method 300 includes identifying a percutaneous access pathway to the target site. In one aspect, this identification includes identifying a skin entry site (such as D, E, F, or G),

which may or may not be directly above the target stimulation site on the hypoglossal nerve. Finally, it is understood that these steps 302-306 can be repeated iteratively, as necessary, until all the optimal stimulation locations along the target nerve are identified.

[0084] In one aspect, in evaluating various test stimulation sites, it will be understood that the magnitude of the measured response will be indicative how close the site locator tool 200 is to the hypoglossal nerve and/or which part of the hypoglossal nerve is being stimulated. For example, the distance between the site locator tool 200 and the hypoglossal nerve and the strength of the measured response is expressed in decreasing exponential relationship. In other words, as the distance away from the hypoglossal nerve increases, there is an exponential decrease in the magnitude of the measured response. In one aspect, the distance refers to a distance measured in three dimensions relative to the path of the hypoglossal nerve, as any given test site will involve: a lateral distance extending generally perpendicular relative to a longitudinal axis of the target nerve; (2) a vertical distance relative to the target nerve; and (3) a longitudinal distance extending generally parallel relative to a longitudinal axis of the target nerve. With this in mind, it is understood that as multiple potential sites are tested, a pattern is identified that highlights the best or optimal stimulation site(s) from among the test sites. In addition, other surgical navigation techniques can be used in cooperation with the application of the test stimulus to further pinpoint the optimal/preferred stimulation sites via visualizing the site locator tool 200 within the target anatomical environment at the time that the responses are measured.

[0085] In some embodiments, in evaluating multiple potential stimulation sites along the hypoglossal nerve, at each potential stimulation site the method 300 applies the pre-determined electrical stimuli as a stimulation signal with differing values for each signal parameter (e.g., pulse width, electrode polarity, frequency, duration, and amplitude) to determine which combination of values yields the best impact of the stimulation signal upon the target nerve at a potential site. In this way, each potential site is evaluated under conditions in which the stimulation signal would actually be applied were that potential site chosen as an optimal site for stimulation. In one embodiment, this determination of an optimal stimulation site via evaluating each of the stimulation parameters employs therapy module 106 (including IPG 109) in cooperation with stimulation module 104, a site locator tool 200, and patient programming module 108, as previously described in association with FIGS. 1-4.

[0086] In one aspect, an optimal stimulation site identified via the site locator tool 200 is preserved to allow an accurate delivery of the stimulation electrode portion of the stimulation lead to that site. Accordingly, in some embodiments, while maintaining needle 210 in its inserted position in the optimal site along the hypoglossal nerve, handle 212 is removed from needle body 216 while maintaining the distal tip 214 in a coupled relationship to nerve 410, and then a lead introduction tool is slidably advanced over the proximal portion 219 of needle 210 of site locator tool 200 to produce the configuration shown in FIG. 7B, as will be further described later.

[0087] In general terms, a stimulation lead is inserted percutaneously to result in a distal portion of the stimulation lead being closely adjacent to a target stimulation site of a

nerve. In some embodiments, an introducing mechanism is used to initiate and develop a percutaneous access pathway to the target stimulation site and facilitates introduction of the stimulation lead therethrough. While various different shapes and forms of lead introduction tools can be used, FIG. 6A illustrates one exemplary embodiment of a lead introduction tool 350. As shown in FIG. 6A, lead introduction tool 350 includes a cannula 360 extending through and supported by handle 362. Cannula 360 includes a curved distal portion 375 with a body portion 366 extending proximally from distal portion 375 to a proximal portion 369 within handle 362. In one aspect, cannula 360 includes a series of graduation depth markers 368 to permit measurement of the desired depth of insertion. While FIGS. 6A and 7B illustrate just a few such markers 368 for illustrative purposes, it will be understood that markers 368 would extend along a length or substantial length of cannula 360 and that the spacing of such markers 368 may vary from that shown in FIGS. 6A and 7B. In some embodiments, at least some of the depth markers 368 are also formed of a radiopaque material to enable visualization under fluoroscopy or other visualization techniques to ensure a proper orientation, position, and placement of the cannula 360 relative to a target nerve and/or other tissues, structures, etc. It also will be understood that at least some conductive portions of cannula 360, needle 210 will be visualized under fluoroscopy or other visualization techniques to further aid ensuring proper placement, orientation, and/or position of those respective elements.

[0088] As shown in the sectional view of FIG. 6B, cannula 360 defines a lumen 370 that extends throughout body portion 366. In general terms, cannula 360 is a generally tubular structure with electrically conductive properties. Accordingly, as shown in FIG. 6B, in one aspect, body portion 366 has a dielectric or insulative coating 367 on its outer surface while distal tip 364 of cannula 360 omits a dielectric coating.

[0089] In one embodiment, distal tip 364 includes an end opening 390 sized and shaped to facilitate passage of a stimulation lead therethrough. Moreover, curved distal portion 372 is formed of a generally resilient, flexible material. Accordingly, upon slidably advancing cannula body 366 over a pre-placed site locator tool 200, as illustrated in FIGS. 4 and 7A, curved distal portion 372 assumes a generally straight shape to aid its insertion percutaneously through skin 402 and tissues 404, 405 at an angle generally perpendicular to the hypoglossal nerve, as shown in FIG. 7B. In addition, in this position, the proximal portion and/or handle 362 of tool 350 remains external to skin surface 402. It will be understood that in some embodiments, in the absence of site locator tool 200, a stiffener or stylet, as known to those skilled in the art, can be used to maintain the cannula body 366 in a straight configuration during its insertion percutaneously. One generally example of such stylets is described and illustrated in Buckberg U.S. Pat. No. 5,226,427, which is hereby incorporated by reference in its entirety.

[0090] In its straightened shape, cannula 310 has a shape substantially similar to that shown for tool 380 that is later described in association with FIG. 6C. Referring again to FIG. 6A, once the distal tip 364 is located at a desired depth, the locator tool 200 (or other stiffener) is removed causing the curved distal portion 372 to relax and resume its generally curved shape, as shown in FIG. 7C. This relaxation, in turn, orients distal end opening 378 to be generally

parallel to the hypoglossal nerve **410** as shown in FIG. 7C, thereby assuming a position suitable to direct a stimulation lead to be slidably advanced along the hypoglossal nerve to a desired stimulation site. In some embodiments, upon such relaxation, the distal end opening **378** is oriented at a generally obtuse angle relative to the generally straight proximal portion of the cannula **310**.

[0091] In some embodiments, as will be understood by those skilled in the art, when identifying the optimal stimulation site (A) from among multiple potential sites (e.g. A, B, C, etc.), the site locator tool **200** would also be used to identify a corresponding entry point (e.g., D, E, F, G, etc.) of the lead introduction tool that is distal or proximal to the optimal stimulation site (e.g., A), as illustrated in FIGS. 7A-7E. In one embodiment, the spacing (along an axis generally parallel to the hypoglossal nerve) between the entry point at the skin surface (e.g., E) and the optimal stimulation site (A) on the hypoglossal nerve is substantially equal to the distance (D1) that distal end opening **378** extends from the generally perpendicular (relative to the hypoglossal nerve) orientation of cannula body portion **366** when inserted.

[0092] In another embodiment, the spacing between the skin entry point and the optimal stimulation site is configured to further account for the length (represented by D2 in FIG. 6A) of the stimulation lead (including the electrode portion as represented by dashed lines **395**) that would extend out of end opening **378** to deliver the electrode portion of the stimulation lead at the target stimulation site. This arrangement further insures that the final placement of the electrode portion of the stimulation lead accurately corresponds to the previously identified optimal or target stimulation site (e.g. A in FIGS. 7A-7E). However, it will be further understood that in some embodiments, the distal end of the stimulation lead is positioned to extend beyond the target stimulation site marked at distance D2 to ensure that the target stimulation site remains generally centered along the length of the electrode portion (e.g., electrode array **442** of portion **440** as later described in relation to FIG. 8A-8C) of the stimulation lead. In such embodiments, the distance D2 corresponds to a length no more than a length of the electrode portion and likely less than (e.g. about one-quarter, one-half, or three-quarters) a length of the electrode portion (e.g. electrode array **442** of portion **440** in FIGS. 8A-8C).

[0093] Accordingly, in this embodiment the total spacing (along an axis generally parallel to a longitudinal axis of the hypoglossal nerve in this region) between the skin entry point and the optimal stimulation site would be the combination of the distances D1 and D2. With this in mind, in one embodiment, after the optimal stimulation site (e.g. A from among A, B, C, etc.) is identified via the site locator tool **200**, the site locator tool **200** is used to trace the path of the hypoglossal nerve (or other suitable anatomical landmark) to identify a skin entry point (e.g. E in FIG. 7A-7B) for the lead introduction tool **350** that spaced apart from the optimal stimulation site (e.g. A in FIGS. 7A-7B) by a distance of D1 plus D2.

[0094] In one aspect, tracking these distances D1 and D2 greatly enhances the introduction of the stimulation lead to arrive at the optimal stimulation site because of the relative absence of significant anatomical structures (e.g., bone canals, protuberances, etc.) in the region of the hypoglossal nerve that is to be stimulated.

[0095] In another embodiment, a lead introduction tool **380** (shown in FIG. 6A) includes substantially the same features and attributes as lead introduction tool **350** of FIGS. 6A-6B, except for including a straight distal portion **382** with a side opening **390** instead of the curved distal portion **372** and end opening **378** shown in FIG. 6A. Accordingly, in this embodiment, straight distal portion **382** includes the side opening **390** sized and shaped to facilitate passage of a distal portion of a stimulation lead therethrough. In one aspect, opening **390** is configured as a side-directed, non-coring opening for lumen **370**. With this arrangement, upon insertion percutaneously, the cannula body **360** of tool **380** is oriented generally perpendicular relative to the skin and relative to the hypoglossal nerve, with the distal side opening **390** enabling a stimulation lead to exit cannula body **360** in a path extending at a generally obtuse angle relative to the orientation of body **360** (as it percutaneously extends through a skin surface and tissues) and generally parallel to the hypoglossal nerve to be advanced generally parallel to the hypoglossal nerve.

[0096] When using lead introduction tool **380**, the distance D1 shown in FIG. 6A and FIGS. 7C-7E is generally not tracked because of the straight shape of distal portion **382** (including tip **384**) and because the lead introduction tool **380** is oriented generally perpendicular to the hypoglossal nerve over the optimal stimulation site. However, in one aspect, one can optionally account for the length of the electrode portion of a stimulation lead as it would extend generally outward and away from the distal tip **384** through opening **390** (and generally perpendicular to a longitudinal axis of the cannula body **360**). Accordingly, in the embodiment of lead introduction tool **380**, in addition to identifying the optimal stimulation site (e.g. A in FIGS. 7A-7E) with the site locator tool **200**, the operator would also identify a skin entry point (e.g. G in FIG. 7C) that is spaced by the distance D2 from the optimal stimulation site. The distance D2 generally corresponds to the length of the stimulation lead (including the electrode portion) that would extend out of distal side opening **390** to deliver the electrode portion of the stimulation lead at the target stimulation site. In this way, the operator insures that the electrode portion of the stimulation lead is accurately delivered to the identified target stimulation site (e.g. A). As noted previously, the distance D2 would have a length no more than, and likely less than, a length of the electrode portion (such as electrode array **442** in FIG. 8B) to ensure centering the electrode portion relative to the target stimulation site.

[0097] In some embodiments, the stimulation lead (e.g., stimulation lead **430** as will be described in association with at least FIGS. 8A-8E) is configured to be cooperable with a removably attachable stylet to facilitate advancing the stimulation lead through cannula **380** and through the tissue surrounding the target stimulation site. In particular, as the distal portion of the stimulation lead exits the distal side opening **410**, the distal portion **436** will have to be advanced via tunneling through the surrounding tissue. With this in mind, the stylet will provide rigidity as the stimulation lead is tunneled to the target stimulation site and once the stimulation lead is properly positioned, the stylet is removed from its connection to the stimulation lead. Moreover, in some embodiments, this stylet is also used to selectively deploy an anchoring mechanism associated with the electrode portion of the stimulation lead.

[0098] In some embodiments, the cannula of lead introduction tool 350 or 380 is generally non-conductive and the conductive elements of the site locator tool 200 and/or of the stiffener are used as an electrically conductive pathway to confirm the location of the target stimulation site and/or the location of the skin entry point spaced from the target stimulation site.

[0099] In some embodiments, other types of introducing mechanisms are used to establish a percutaneous access pathway for a stimulation lead. For example, one introducing mechanism includes a guide wire and a needle having a cannula and a stylet. With this arrangement, the needle cannula is percutaneously inserted to establish a percutaneous pathway with aid from the stylet to steer, guide, and/or stiffen the needle cannula. After a path is established by the combination of the cannula and stylet, the stylet is removed. With the cannula still in place, a guide wire is inserted into a proximal portion of the cannula and advanced through the cannula until a distal portion of the guide wire is adjacent the target stimulation site. Next, with the guide wire still in place, the cannula portion of the needle is removed proximally over the guide wire, leaving just the guide wire in place. Using known techniques, a stimulation lead is releasably coupled to the guide wire and advanced, via the guide wire, through the established percutaneous access pathway until an electrode portion of the stimulation lead is adjacent the target stimulation site. With the stimulation lead remaining in place, the guide wire is then removed. Finally, the stimulation lead is anchored to maintain the electrode portion in an electrically coupled relationship with the target stimulation site of the nerve.

[0100] While various different shapes and forms of leads can be used in the methods and systems of the present disclosure, FIGS. 8A-8C illustrate one exemplary embodiment of a stimulation lead 430 is that is configured to be deployed percutaneously. In one embodiment, the stimulation lead 430 is delivered via the tools 200, 350, 380 (as previously described in association with FIGS. 4-7) while in other embodiments, the stimulation lead 430 is delivered via other minimally invasive delivery techniques. Various aspects of the delivery of stimulation lead 430 will be described herein in further detail.

[0101] As shown in FIGS. 8A-8C, stimulation lead 430 includes a front side 432 and a back side 434 with the lead 430 extending between a distal portion 436 and a proximal portion 438.

[0102] At distal portion 436, the front side 432 supports an electrode portion 440 including a first array 442 of electrodes 444. In general terms, substantially the entire length of the electrode portion 440 comprises a generally flat surface and when the back side 434 also forms a generally flat surface, then the entire distal portion 436 defining the electrode portion 440 comprises a generally flat or planar member (with the exception of the to-be-described protrusions 464 on back side 434).

[0103] This generally flat or planar configuration of distal portion 436 (including stimulation electrode portion 440) provides a low profile topography, thereby facilitating its advancement through the tissue surrounding the hypoglossal nerve. In addition, by having at least a generally flat surface of the front side 432 of distal portion 436, a much closer and effective interface between the stimulation electrode portion 440 and the surface of the hypoglossal nerve can be achieved. However, in some other embodiments, the front

side 432 of the distal portion 436 is not generally flat, but has at least some curved portion or undulating portion. In one example, as illustrated in FIG. 8F, the curved portion of the front side 432 of the distal portion 436 forms a generally concave shape configured to accentuate the extent to which the electrode portion 440 reciprocally conforms to the generally arcuate shape of the outer surface of the hypoglossal nerve. In another example, as illustrated in FIG. 8G, the front side 432 of the distal portion 436 forms a generally convex shape. In one aspect, this generally convex shape is configured to accentuate slidable passage of the distal portion through the tissue surrounding the hypoglossal nerve to arrive at the optimal stimulation site.

[0104] Likewise, in some embodiments, the back side 434 of the distal portion 436 is not generally flat, but has at least some curved portion which can be concave or convex. In one aspect, a generally convex shape on the back side 436 is configured to accentuate slidable passage of the distal portion through the tissue surrounding the hypoglossal nerve to arrive at the target stimulation site.

[0105] In another aspect, because the front side 432 carries electrode portion 440, the back side 434 of the distal portion 436 is generally made or coated with an electrically insulative material. With this arrangement, back side 434 effectively acts as a shield to prevent the stimulation signal from affecting the sensory nerves and skin overlying the stimulation site.

[0106] In another aspect, at proximal portion 438 of stimulation lead 430, a second array 450 of electrodes 452 is formed on both the front side 432 and the back side 434 of stimulation lead 430. The first array 442 of electrodes 444 are electrically connected to the second array 450 of electrodes 452 with the second array 450 of electrodes 452 configured to provide electrical connection to the IPG (55 in FIG. 1 or 109 in FIG. 2). Via control from the IPG 55, each electrode 444 of stimulation electrode portion 440 is independently programmable to apply a stimulation signal that has a selectively controllable polarity, amplitude, frequency, pulse width, and/or duration.

[0107] In one embodiment, the first array 442 of electrodes 444 includes a lateral component (i.e., extending along a width W1) or a longitudinal component (i.e., extending along a length L1) of at least three electrodes in a guarded cathode electrode polarity arrangement. This guarded cathode electrode polarity arrangement hyperpolarizes tissues near the hypoglossal nerve while providing for complete depolarization of the volume of the hypoglossal nerve adjacent the electrode portion 440 of the stimulation lead 430. However, as shown in FIG. 8B, in some embodiments, the first array 442 includes a multitude of electrodes 444 (substantially greater than three) extending along the width and along the length of the electrode portion 440. This arrangement permits selection of different combinations of electrodes 444 from among the first array 442, thereby optimizing the stimulation of the hypoglossal nerve via an optimal combination of electrodes 444 within the first array 442. Moreover, in some embodiments, one or more of the electrodes 444 are varied in shape and/or pitch, or varied by staggering of the rows of electrodes 444.

[0108] In some embodiments, with the assumption that a diameter of the target nerve in the region of the target stimulation site is about 3 millimeters, the electrode portion 440 will have a width (W1 in FIG. 8B) of at least about 5 millimeters. Accordingly, in these embodiments, the width

(W1) of the electrode portion 440 is at least substantially equal to or substantially greater than the diameter of the target nerve in the region of the target stimulation site. This relationship insures that the electrical stimulation signal (for treating sleep apnea) will affect the full cross-section of the nerve so that substantially all the axons of the target nerve will potentially be activated (depending upon the parameters of the applied stimulation signal).

[0109] A body portion 437 extends between the electrode portion 440 (at the distal portion 436) and the proximal portion 438. With the exception of electrodes 444, the body portion 437 is a generally insulative member devoid of electrodes on the front side 432 and back side 434. It is understood, of course, that wires extend through an interior of the body portion 437 to connect electrodes 444 to the IPG 55 in FIG. 1 or 109 in FIG. 2). In general terms, the body portion 437 has a length sufficient to extend from the electrode portion 440 to the IPG 55 (FIG. 1).

[0110] In some embodiments, the distal portion 436 of stimulation lead 430 includes an anchoring mechanism 462 located on back side 434, i.e. on an opposite side relative to the stimulation electrode portion 440. In one aspect, the anchoring mechanism 462 provides a cuff-less arrangement to secure the electrode portion 440 in close proximity to the nerve with the anchoring mechanism being disposed on an opposite side of the electrode portion 440 so that the anchoring mechanism 462 faces away from the nerve. This arrangement secures the electrode portion independently of the nerve and in a desired position relative to the nerve without placing any pressure or other mechanical effects on the nerve that might otherwise be used to secure an electrode relative to a nerve.

[0111] In one aspect, the anchoring mechanism 462 includes at least one array of protrusions 464. In one embodiment, the protrusions 464 are flaps formed of a resilient material while in other embodiments, the protrusions 464 are barbs, prongs, or other anchoring components. In some of these embodiments, the protrusions are sized and shaped to induce fibrotic growth at and near the protrusions to cause further anchoring of the distal portion 436 of the stimulation lead 430. In one aspect, within about one month, the protrusions 464 become ingrown with fibrotic tissue. Accordingly, while the protrusions 464 act to provide some long-term stability to the position of stimulation lead 430 within the body, one purpose of the protrusions 464 is to provide such stability for at least about one month, which generally corresponds to the amount of time for fibrotic tissue growth to effect a more permanent, long term stabilization of electrode portion 440 at the target site within the body.

[0112] In one aspect, the protrusions 464 extend generally outward at an angle (e.g., 30, 45, 60 degrees) from a surface of the back side 434 of the distal portion 436 of the stimulation lead 430. As shown in FIGS. 8A and 8B, in some embodiments, at least one pair of the protrusions 464 are provided in a divergent orientation which enhances the stability of the stimulation lead 430 by reducing the likelihood of the stimulation lead 430 from migrating away from its placed location. In particular, once implanted, the divergent orientation of the protrusions 464 enhance maintaining the electrode portion 440 of the stimulation lead 430 in its target location regardless of the direction of applied forces on the stimulation lead. In one aspect, the protrusions 464 have a length and width configured to engage or integrate

with the tissues surrounding the hypoglossal nerve. However, in another aspect, the protrusions 464 form a generally tab-like structure made of a flexible polymer that can collapse upon application of a sufficiently high force, thereby enabling adjustment of the position of the electrode portion 440 of the stimulation lead 430 and/or removal of the stimulation lead 430.

[0113] In some embodiments, the protrusions 464 are sized and shaped to facilitate their disengagement from the surrounding tissues (via the use of a tool) to enable removal of the electrode portion 440 of the stimulation lead 430 from its implanted location adjacent the hypoglossal nerve. Such removal would take place in the event that a trial treatment plan was ineffective or in the event that the stimulation lead 430 was malfunctioning.

[0114] However, in the event that only some of the electrodes 444 were malfunctioning, the stimulation lead 430 need not be removed because the IPG 55 of FIG. 1 (or IPG 109 in FIG. 2) can be used to activate a different set of electrodes 444 within the first array 442 to produce a new combination of electrodes 444 arranged to apply a therapeutic regimen for treating sleep apnea. Moreover, an adjustment of the stimulation parameters (e.g., amplitude, pulse width, frequency, duration, and electrode polarity) via the IPG 55, 109 can compensate for the different position of the electrodes in the new combination of activated electrodes 444 for applying the stimulation signal. In this embodiment, the many varied positions of the electrodes 444 both along the length of the distal portion 436 of the electrode portion 440 of the lead 430 and transversely across the distal portion 436 enables precise activation of selective groups of electrodes 444 (at their various spaced apart locations) to produce an effective stimulation signal. Likewise, in the event that some inadvertent migration of the stimulation lead 430 occurs distally or proximally relative to the optimal stimulation site after the stimulation lead 430 has been considered to be properly placed, then the IPG 55 (or IPG 109 in FIG. 2) is used to activate a different set of electrodes 444 of the first array 442 to achieve a stimulation signal that compensates for the migration to maintain a proper stimulation signal at the target stimulation site.

[0115] The stimulation lead 430 is configured to balance various parameters including optimal electrode orientation, patient comfort, anchor strength, preventing migration of the lead, and providing for removability of the lead, as well as facilitating subcutaneous tunneling of the stimulation lead 430 to the site of the IPG. As such, this stimulation lead 430 provides several advantageous features, including providing for stimulation of the entire cross-sectional volume of the hypoglossal nerve volume in a manner comparable with cuff electrodes. Moreover, by facing the electrodes 444 away from the skin and by backing the electrodes 444 with an insulative layer (body portion 437), the stimulation lead 430 minimizes stimulation of nearby sensory nerves. In addition, by having an array 442 of multiple electrodes 444 that are independently programmable or controllable relative to each other via operation of IPG 55, the therapy can be adjusted in a non-invasive manner in the event that the stimulation lead 430 migrates from its original placement. In other words, the stimulation can be shifted from one combination of electrodes 444 in the array 442 to a different combination of electrodes 444 in the array 442 to account for the shift in the overall position of the electrode portion 440 of the stimulation lead 430 relative to the hypoglossal nerve. Of course,

it will be understood that different combinations of electrodes 444 can be activated simply to achieve a different therapy regimen, even in the absence of migration or malfunction of electrode array 442.

[0116] In use, the stimulation lead 430 is delivered percutaneously via feeding the distal portion 436 into a proximal portion 369 of the cannula 360 of lead introduction tool 350 or 380 and slidably advancing the distal portion 436 therethrough until the distal portion 436 of stimulation lead 430 exits the distal opening (390 or 410, respectively) of the lead introduction tool 350, 380 to be oriented generally parallel and closely adjacent to the hypoglossal nerve at a target stimulation site (e.g. A) with the electrode portion 440 facing toward the nerve and away from the skin (and underlying sensory nerves), as illustrated in FIG. 7D. Next, while maintaining the position of the distal portion 422 (e.g. electrode array 442 in FIG. 8B) stimulation lead 430, the tool 350 is withdrawn proximally from tissues 404, 405 to leave just stimulation lead 430 in place, as illustrated in FIG. 7E. From this configuration, the proximal portion 421 of stimulation lead 430 is tunneled and/or maneuvered subcutaneously to extend from the neck region to a pectoral region, to achieve a general configuration similar to that shown in FIG. 1 for lead 52.

[0117] In some embodiments, as shown in perspective view of FIG. 8D and the sectional view of FIG. 8E, a distal tip 364A of a lead introduction tool 350A includes a shell-like cover 480 protruding distally outward from the cannula body 360A and is configured with a wall 482 to control the deployment of the protrusions 464 of the anchoring mechanism 462 of stimulation lead 430. In particular, the wall 482 of cover 480 acts as a barrier to maintain the protrusions 464 in a collapsed position against or close to the back side 434 of the distal portion 436 of the stimulation lead 430 so that the protrusions 464 do not engage the surrounding tissue prior to proper positioning of the stimulation electrode portion 440 against the hypoglossal nerve. At the same time, the distal portion 364 continues to define an opening 365A generally opposite the cover 480 to enable exposing the electrode array 442 to the target nerve to allow testing or confirming positioning over the target stimulation site prior to deploying the anchor mechanism 462. In some embodiments, the cover 480 defines a half-circular cross-sectional shape having a diameter (D3) generally corresponding to a diameter of cannula 360. Once proper positioning of the stimulation electrode 440 has been achieved and upon proximally withdrawing the tool 350A, the cover 480 is withdrawn from its position over anchoring mechanism 462, thereby releasing protrusions to engage surrounding tissues. Likewise, in the event that the stimulation lead 430 must be removed, the cover 480 of the lead introduction tool 350 will force the collapse of the protrusions 464 (against the body of the distal portion 436 of the stimulation lead 430) as the distal portion 436 of the stimulation lead 430 is withdrawn proximally into the lead introduction tool 350A.

[0118] In another aspect, once implanted, a stimulation system for automatically treating obstructive sleep apnea will preferably remain in a stable position to endure the normal activities of the patient. For example, the neck of a patient moves through a wide range of motion through many different positions. To counteract the potential for a stimulation lead to move back and forth along the hypoglossal nerve (relative to a desired stimulation site), the anchoring mechanism 462 anchors the distal portion 436 of the stimu-

lation lead 430 at the target stimulation site of the nerve. Accordingly, this anchoring mechanism insures that proper placement of the stimulation lead is maintained despite the dynamic motion and varying positions of the neck, which could otherwise cause inadvertent repositioning of the stimulation lead (relative to the target nerve) if the distal anchoring mechanisms were not present.

[0119] In addition, as previously noted, the anchoring mechanism 462 maintains this stable position without encircling the nerve (as a conventional cuff would) via an anchoring mechanism located on a directly opposite side of the distal portion 436 of the stimulation lead 430 with the anchoring mechanism 462 engaging the surrounding tissue instead of engaging the nerve. Nevertheless, to the extent that the electrode portion 440 of the distal portion 436 remains in close proximity or contact with the nerve, this relationship also contributes to the stability of the distal portion 436 because the anchoring mechanism 462 (on the opposite side from the electrode portion 440) is simultaneously securing the distal portion 436 in its desired position.

[0120] Accordingly, in some embodiments, as shown in FIG. 9, a second anchoring mechanism 502 and/or third anchoring mechanism 504 is deployed to further stabilize the position of the stimulation lead 430 in addition to the first anchoring mechanism 462. As shown in FIG. 9, body portion 437 of stimulation lead 430 extends proximally from the electrode portion 440 and from the first anchoring mechanism 462 while the second anchoring mechanism 502 is positioned at a first distance (D3) away from the first anchoring mechanism 462. The third anchoring mechanism 504 is spaced proximally by a second distance (D4) from the second anchoring mechanism 502. As further shown in FIG. 9, a first region 510 (including portion 437) of stimulation lead 430 extends between first anchoring mechanism 462 and second anchoring mechanism 502 while a second region 512 extends between second anchoring mechanism 502 and third anchoring mechanism 504. Finally, a third region 514 of lead 430 extends proximally from third anchoring mechanism 504 for passage toward the IPG (55 in FIG. 1 or 109 in FIG. 2).

[0121] In some embodiments, both the first region 510 and the second region 512 of the lead body 437 are pre-shaped into a serpentine or S-shaped configuration prior to deployment. In this pre-shaped configuration, first region 510 has a first length (D3) while second region 512 has a second length (D4). Once deployed via tunneling subcutaneously in a pathway proximally from the stimulation site, the S-shaped first and second regions 510, 512 provide strain relief mechanisms that act in concert with the first, second, and third anchoring mechanisms 462, 502, 504 to stabilize the position of the stimulation lead 430 while compensating for movements of the body as described above.

[0122] FIG. 10 is a side plan view of a stimulation lead including a dynamic anchoring system 525, according to an embodiment of the present disclosure. As shown in FIG. 10, system 525 includes a first anchor 530, second anchor 532, and a third anchor 534 with portions 510 and 512 of a stimulation lead interposed between the respective anchors. In one embodiment, one, two, or three of the anchors 530, 532, 534 include a biomediating mechanism, that is, a mechanism to induce fibrotic growth in the surrounding tissue at which the respective anchor is located and thereby further anchor the distal portion of a stimulation lead. As shown at 540 in FIG. 10, the anchors 530-534 comprise one

or more of tines, mesh (e.g. Dacron mesh), barbs, flaps, and the like that are configured to mechanically engage the surrounding tissue.

[0123] In addition, in some embodiments, one or more of the anchors **530**, **532**, **534** are configured to provide a surface sized or treated (coated) to induce fibrotic growth to further secure the anchor. The “biomediating” anchors are particularly advantageous in a method of percutaneous delivery because the anchors do not require suturing, and therefore, regions **514**, **512**, and **510** of the stimulation lead can be tunneled toward the IPG **55** in FIG. **1** (or IPG **109** FIG. **2**) without having to apply sutures when the anchors **530**, **532**, **534** arrive at their intended positions. However, it is understood that in some embodiments, minimally invasive suturing techniques can be applied as desired to further secure the respective anchors in place (during the initial period of fibrotic growth) to supplement the securing strength of the mechanical component (e.g., barbs, flaps, etc.) of the respective anchors.

[0124] FIGS. **11-14** schematically illustrate a method **550** of percutaneously delivering an electrode portion of a stimulation lead to a target nerve, according to an embodiment of the present disclosure. In viewing the FIGS. **11-14**, it will be understood that sizes and/or relative spacing of various components of the anatomy (e.g., a size or width of incision, nerves, muscles, skin layer, etc.) and/or components of the tools (e.g., barbs, rods, etc.) have been exaggerated for illustrative clarity to highlight application of the tool. This method achieves placement of the electrode portion without the generally disruptive, and more time consuming, conventional cut-down implantation procedure (which would typically include a full dissection around the target nerve). Moreover, it is understood that prior to deployment of method **550**, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; (2) make an incision to provide a skin entry point generally over the optimal stimulation site; and (3) guide the distal portion of an introduction tool or implantation instrument to that optimal stimulation site.

[0125] As shown in FIG. **11**, method **550** includes making an incision **553** through the skin **552** and through first muscle layer **554** to provide access to the previously identified optimal stimulation site at target nerve **558**, such as the hypoglossal nerve. The incision is relatively small, such as 2 centimeters wide, so that the access to the nerve **558** is considered minimally invasive. Next, via use of an implantation instrument **560**, an electrode portion **565** of a stimulation lead **568** is inserted through the incision **553** and guided to the nerve **558**. As shown in FIG. **12**, the implantation instrument **560** includes a distal tip **562** from which a selectively deployable, engagement mechanism **570** protrudes and a barrel **563** extending proximally between a handle **564** and distal tip **562**. The barrel **563** is configured to support deployment of the engagement mechanism **570**. A trigger **561** mounted at handle **564** is connected to a proximal end of the engagement mechanism **570** and controls selective deployment of the engagement mechanism **570**.

[0126] Moreover, in one embodiment, as shown in FIG. **13**, the electrode portion **565** comprises an insulative carrier **580** supporting an array of spaced apart electrodes **582**

aligned in series. The carrier **580** also includes an array of securing elements **584A**, **584B**, **584C**, **584D** extending outward from the sides and/or ends of the carrier **580** to facilitate securing the carrier **580** relative to the surrounding tissues adjacent the hypoglossal nerve. The securing elements **584A-584D** can be loops or any other structure to which a suture or fastener is securable relative to the surrounding tissue. In this way, the electrodes **582** of the electrode portion **565** become secured relative to nerve **558** with the electrodes **582** facing the nerve **558**. In one embodiment, the electrodes **582** are aligned with a longitudinal axis of the electrode portion **565** and/or of the stimulation lead supporting the electrode portion **565**. As previously noted, the electrode portion **565** is implanted so that the electrodes **582** also face away from the skin **552** (with carrier **580** acting as a shield) to minimize stimulation of sensory nerves at or near the skin **552**.

[0127] In one aspect, as shown in FIG. **13**, the electrodes **582** have a width **W2** (at least 3-5 millimeters) generally equal to or greater than a diameter of the target nerve (e.g., 3 millimeters) while carrier **580** has a width (**W3**) substantially greater than the width **W2** of the electrodes **582** to insure shielding of the skin from the stimulation signal emitted from electrodes **582**.

[0128] Referring again to FIG. **11**, once the electrode portion **565** is properly positioned over the nerve **558**, the implantation instrument **560** secures the electrode portion **565** in position relative to the nerve **558** via engagement mechanism **570**. While the engagement mechanism **570** can take many different forms, in one embodiment shown in FIG. **14**, the anchoring mechanism **570** protrudes from the distal portion **562** of barrel **563** of implantation instrument **560**.

[0129] In particular, the anchoring mechanism **570** includes one or more small diameter rods **572** extending longitudinally within a conduit formed by barrel **563** with each rod **572** supporting a needle **574** configured to selectively extend distally from an end of each respective rod **572**. In one embodiment, barrel **563** includes a generally hollow, elongate tubular member, and the rods **572** extend through a length of the barrel **563** while being longitudinally movable within the barrel **563**.

[0130] Each needle **574** includes a barb **576** removably mounted at a distal end **575** of the needle **574**. In one embodiment, barbs **576** are made from a stainless steel material or a plastic material while having a relatively small length and/or diameter (e.g., 1-3 millimeters) to avoid patient discomfort. In addition, a suture **575** includes a first end connected to the barb **576** and a second end connected to securing elements **584** of electrode portion **565** of the stimulation lead. In a pre-deployment state, the respective sutures **575** are in a relaxed state without tension. In one embodiment, needles **574** are formed of a metal, such as a Nitinol material.

[0131] Accordingly, with the electrode portion **565** positioned over an optimal stimulation site of the nerve **558**, trigger **561** activates anchoring mechanism **570** to automatically cause the rods **572** to force the needles **574** to protrude distally outward and penetrate into surrounding tissues adjacent the nerve **558** and electrode portion **565**, and then the trigger **561** is subsequently relaxed causing retraction of rods **572** and their respective needles **574**. However, the barbs **576** remain fixed in the surrounding tissues because they detach from the needles **574** (at a point of detachment

represented by dashed lines 579) as the needles 574 are retracted. At this point, the implantation instrument 560 is removed from the incision site, leaving the electrode portion 565 in place.

[0132] In one aspect, as the needles 574 are advanced to place the barbs 576 into the tissue the sutures 575 become under tension, and as the needles 574 are retracted into barrel 563 with the barbs 576 remaining in the tissue, the sutures 575 remain under tension which effectively exerts tension on the carrier 580 to urge electrodes 582 into pressing contact against the nerve. For example, as schematically illustrated in the side view of FIG. 14B, with barbs 576 deployed in tissue 590, securing elements 584B, 584D (and their respective sutures 575) are under tension, thereby urging electrode portion 565 (and particularly electrodes 582) against the nerve 592. This arrangement provides longitudinal stability to the secured position of the electrode portion 565 relative to the nerve. While not shown it is understood that the securing elements 584A, 584C on the opposite side of the electrode portion 565 also would be deployed via sutures 575 and barbs 576 so that all four securing elements 584A, 584B, 584C, 584D of electrode portion 565 are deployed. Accordingly, when secured under tension relative to the tissue 592 (via sutures 575 and barbs 576), securing elements 584A and 584C also provide longitudinal stability to the position of the electrode portion 565 relative to the nerve 590.

[0133] Moreover, in such an arrangement, securing element 584A and securing element 584B are positioned on opposite sides of the electrodes 582 to straddle the nerve 592, thereby insuring lateral stability of the electrode portion 565. Likewise, securing element 584C and securing element 584D are positioned on opposite sides of the electrodes 582 to straddle the nerve 592, thereby insuring lateral stability of the electrode portion 565.

[0134] In some embodiments, as shown in FIG. 14B, the securing elements 584 are made of a flexible material to permit their bending toward the tissue to facilitate securing the barbs 576 and sutures 575 under tension. In these embodiments, the carrier 580 supporting the securing elements 584 can be either substantially rigid as shown in FIG. 14B or can be generally flexible as shown in FIG. 14C. In particular, as shown in the schematic sectional view of FIG. 14C, an electrode portion 565 includes a flexible carrier 581 supporting electrodes 582 with the carrier 581 configured to flexibly conform to the arcuate shape of the cross-section of the nerve 558. This arrangement insures close contact of the electrode 582 relative to the nerve 558 and accentuates the application of tension on sutures 575 when barbs 576 are anchored into the surrounding tissue 590. In another aspect, it will be clear from a consideration of both FIGS. 14B and 14C, the securing elements include a first array of barbs for deployment on one side of the electrode portion 565 and a second array of barbs for deployment on an opposite side of electrode portion 565.

[0135] After securing the electrode portion 565, the implantation instrument 560 is removed and the lead body 567 of the stimulation lead 568 is delivered subcutaneously, via a tunneling tool, from the anchored site of the electrode portion 565 to the IPG 55 (FIG. 1).

[0136] Various configurations of stimulation electrode portions of a stimulation lead are described and illustrated in association with the embodiments of FIGS. 15-27. These various stimulation electrode portions can be delivered

percutaneously or via other suitable delivery techniques. In some embodiments, the electrode portions and/or supporting proximal portions of the stimulation lead are configured to have a minimal mechanical impact on the nerve and the surrounding tissues and/or are configured to be implanted via minimally invasive techniques.

[0137] FIGS. 15-17B schematically illustrate stimulation system including a bio-absorbable electrode portion 601 of a stimulation lead 600, according to an embodiment of the present disclosure. It is understood that prior to deployment of electrode portion 600, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool 200 shown in FIG. 3) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site.

[0138] As shown in FIG. 15, stimulation lead 600 comprises an electrode portion 601 including cuff 602 and electrodes 610, as well as wires 612, anchor 614, and non-absorbable portion 620 of stimulation lead 600. In one embodiment, the cuff 602 comprises a generally elongate tubular member that carries electrodes 610 and is configured to wrap around nerve 625 in a releasably secured manner with a generally cylindrical shape, thereby maintaining electrodes 610 in close contact against nerve 625. A wire 612 extends proximally through the cuff 602 from each of the respective electrodes 610 and has a length extending further to anchor 614 and non-absorbable portion 620 so that the wires 612 are in electrical communication with IPG 55 (FIG. 1).

[0139] In some embodiments, as shown in FIG. 17A, each electrode 610 includes a conductive contact portion 616 and an electrically insulative cover 618. The electrically insulative cover 618 extends over the top portion 639 of the contact portion 616, extends beyond all four sides of contact portion 616, including sides 635, 637 viewable in FIG. 17A. At a proximal end 634 of the electrode 610, a strain relief member 636 connects wire 612 to contact portion 616 via wire 611. In one embodiment, electrodes 610 are embedded in the cuff 602 with bottom portion 638 exposed at inner surface of cuff 602. In some embodiments, electrodes 610 are aligned such that a longitudinal axis of each electrode 610 is generally perpendicular to a longitudinal axis of the cuff 602 and the respective electrode 610 are spaced apart from each other along a length of the cuff 610.

[0140] In one aspect, cuff 602 is made of a bio-absorbable material so that over a period of several weeks following the implantation of electrode portion 601, the cuff 602 is absorbed by the body, thereby leaving the electrodes 610 in their desired position relative to nerve 625. At the same time that the cuff 602 is being absorbed, tissue growth occurs at and around the wires 612 and occurs at and around the electrodes 610 as they become exposed from absorption of cuff 602. In some embodiments, wires 612 are arranged with several coiled portions 613 (highlighted in the enlarged caption in FIG. 15) to further induce fibrotic tissue growth at and around the wires 612 such that tissue growth at each coiled portion acts as a separate anchor. After the absorption process for cuff 602 (and any other bio-absorbable components) is complete, the fibrotic tissue growth is sufficient to act as an anchoring mechanism to maintain the position of the electrodes 610 in their generally spaced apart relationship at the intended stimulation site and to secure the wires

612 to further maintain the position of electrodes **610**. The resulting arrangement is illustrated in FIG. 16 and FIG. 17B. In the sectional view of FIG. 17B, fibrotic tissue growth **642** surrounds the electrode **610** and wires **612** to mechanically secure the electrodes **610** in position over nerve **625** beneath skin/muscle portion **640**. As further shown in FIG. 17B, insulative cover **618** protects each electrode **610** from the tissue growth **642**. In one aspect, the insulative cover **618** covers a top portion and sides of each electrode **610** while a bottom portion of each electrode element **610** remains exposed to nerve **625**. In some embodiments, the outer surface of insulative cover **618** includes a coating configured to induce the fibrotic tissue growth.

[0141] In one aspect, by employing a bio-absorbable cuff and inducing tissue growth to secure electrodes **610**, this system provides minimal long-term impact at the implantation site. In particular, the implanted, cuff-less set of electrodes **610** will be comfortable for the patient because of the absence of the relatively bulky size of a conventional cuff. This cuff-less arrangement also will be less likely to induce inadvertent mechanical effects on the target nerve (as compared to a conventional cuff electrode system), which can affect nerve function and comfort.

[0142] In some embodiments, anchor **614** is also made of bio-absorbable material and is absorbed over time within the body. Accordingly, tissue growth also would occur in this region to further secure wires **612** in place.

[0143] However, in some embodiments, as shown in FIGS. 15-16, the stimulation lead **600** includes a non-absorbable fastener **622** configured to maintain the separate wires **612** in a grouped arrangement. In one aspect, fastener **622** insures an orderly transition of the separate wires **622** to the permanent lead portion **620** that extends to the IPG **55** (FIG. 1). In another aspect, fastener **622** also provides strain relief to prevent inadvertent pulling of wires **612** on the target nerve. However, in other embodiments, this fastener **622** is omitted or is made of a bio-absorbable material.

[0144] FIGS. 18-21 schematically illustrate a bio-absorbable electrode portion **650** of a stimulation lead, according to an embodiment of the present disclosure. It is understood that prior to deployment of electrode portion **650**, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site. Finally, it is also understood that the electrodes **660** of electrode portion **650** would be electrically connected via wires and a lead body to an IPG **55** (FIG. 1) and that this general arrangement is omitted in FIGS. 18-21 for illustrative clarity.

[0145] FIGS. 18-19 are plan views of an electrode portion **650** of a stimulation lead in which the electrode portion **650** includes a generally flexible coil member **651** and electrodes **660**. In general terms, the coil member **651** wraps around a nerve **663** and defines a stent-like insulative member that maintains electrodes **660** in close contact against nerve **663**. However, unlike a conventional cardiovascular stent which is deployed within a blood vessel via expanding the stent outward against the wall of the blood vessel, the coil member **651** is configured to wrap around an outer surface

of a nerve **663** in a self-sizing relationship and is not configured to expand radially when deployed in the desired position.

[0146] In some embodiments, the coil member **651** forms a generally helical shape and includes a pair of spaced apart rails **652** with numerous struts **654** extending between and interconnecting the rails **652**. In one embodiment, the rails **652** and struts **654** are made of non-conductive materials. In one aspect, electrodes **660** are sized and shaped to extend between a pair of rails **652**, as shown in FIGS. 18-19, in a manner similar to the struts **654**. In one embodiment, the electrodes **660** are in general alignment with a longitudinal axis of the coil member **651**. However, it will be understood that the coil member **651** is not strictly limited to the arrangement of rails **652** and struts **654** shown in FIGS. 18-19 because numerous variations and arrangements of struts can be used to form the helically shaped coil member.

[0147] As shown in its pre-deployment state in FIG. 18, coil member **651** has an inner diameter (D6) that is substantially less than a diameter (D5) of the target nerve **663** (see also FIG. 19). Accordingly, when coil member **651** is placed about the larger diameter nerve **663**, the coil member **651** wraps about the nerve **663** in a self-sizing manner such that the inner diameter of the coil member **651** substantially matches the diameter of the target nerve **663**, as shown in FIG. 19. To the extent that any spacing is shown between the coil member **651** and nerve **663** in FIG. 19, this spacing is provided for illustrative clarity to clearly define the components of the coil member **651** separately from nerve **663**.

[0148] In some embodiments, the coil member **651** attracts tissue growth at rails **652** and struts **654** with the combination of the tissue growth and the rails **652** and struts **654** acting as an anchoring mechanism to maintain the electrodes **660** in close contact against nerve **663**.

[0149] In some other embodiments, the coil member **651** forms a bio-absorbable material so that after absorption of rails **652** and struts **654** takes place, electrodes **660** remain in close contact to nerve **663** with tissue growth **670** on and around the electrodes **660** holding the electrodes **660** in place relative to the nerve **663**, as shown in FIGS. 20-21. The various components (struts and rails) of the coil member **651** form a latticework or frame configured to induce fibrotic tissue growth in a pattern generally matching the structure of the coil member **651** so that the induced tissue growth forms in a mechanically advantageous framework holding the electrodes **660** in place relative to the nerve **663**. In one aspect, this framework of fibrotic growth forms a bio-cuff in which tissues produced within the body form a cuff to maintain the electrodes **610** in the desired position relative to the nerve.

[0150] It is understood that tissue growth also would occur at and around the wires (not shown) extending proximally from the electrodes **660** toward the IPG **55** (FIG. 1). It is further understood, that similar to previous embodiments, an outer portion of the electrode **660** (the portion that does not contact the nerve **663**) would include an insulative cover to act as a barrier between the contact portion of the electrode **660** and the surrounding tissue.

[0151] Moreover, in one embodiment, each electrode **660** is connected to a respective one of an array of wires with each respective wire connected to, and extending to, a stimulation lead body configured for electrical communication with an IPG **55** (FIG. 1). In one embodiment, the array of wires includes substantially the same features and attri-

butes as the array of wires **612**, as previously described and illustrated in association with FIGS. **15-16**.

[0152] FIGS. **22-24** schematically illustrate an electrode portion **700** of a stimulation lead, according to an embodiment of the present disclosure. It is understood that prior to deployment of electrode portion **700**, one or more potential stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site.

[0153] As shown in FIGS. **22-23**, electrode portion **700** includes a carrier **702** supporting generally spike-shaped electrodes **710** that are spaced apart from each other along a length of the carrier **702**. The carrier **702** includes a distal end **704** and a proximal end **706** while each electrode **710** forms a conductive member including an exposed distal tip **714** and an insulative covered base portion **712**. While just two electrodes **710** are shown, it will be understood that in other embodiments, carrier **702** supports more than two electrodes **710**. In one embodiment, the carrier **702** comprises a generally flat member having a first side and a second side (opposite the first side), with the electrodes **710** extending generally outward from the first side of the generally flat member.

[0154] In another aspect, for each electrode **710**, a separate wire **720** extends through the carrier **704** (shown as dashed lines in FIG. **23**) and is electrically connected to the base portion **712** of each respective electrode **710**. It is further understood that the electrodes **710** are formed of ultra fine wires, as known to those skilled in the art, and that the electrodes **710** are shown in FIGS. **22-24** in an exaggerated, enlarged form strictly for illustrative purposes.

[0155] Once the electrode portion **700** is delivered to the intended stimulation site, pressure is applied to insert the distal tips **714** of the respective electrodes **710** into the nerve **730**. Because of the small dimensions of the ultra fine wire forming each electrode **710**, the electrodes **710** are maintained in this position via the tissue of the nerve effectively capturing the electrodes **710**. With this arrangement, close contact of the electrodes **710** to the nerve **730** is insured, resulting in effective stimulation of the nerve **730**.

[0156] In some embodiments, once the electrode portion **700** is secured in place, the electrode portion **700** attracts tissue growth (not shown) about carrier **702** and base portion **712** of needles **710** with the combination of the tissue growth and the carrier **702** and base portions **712** acting as an anchoring mechanism to maintain the electrode tips **714** in penetrating engagement (i.e. inserted engagement) relative to nerve **730**.

[0157] In some other embodiments, the carrier **702** forms a bio-absorbable material so that carrier **702** is absorbed over time, leaving just electrodes **710** and wire portions **721**, **720** in place at nerve **730**, as shown in FIG. **24**. As the absorption of carrier **702** occurs, electrodes **710** are held in inserted engagement relative to nerve **730** because of tissue growth (not shown) forming on and around the base portion **712** of electrodes **710** (as the carrier is absorbed) to hold the electrodes **710** in penetrating engagement relative to the nerve **730**. It is understood that a similar tissue growth would occur at and around the wire portions **721** and **720** extending proximally from the electrodes **660** toward the IPG **55** (FIG. **1**).

[0158] FIGS. **25-32** schematically illustrate stimulation system **800** and a method of implanting components of system **800**, according to an embodiment of the present disclosure. As shown in FIGS. **25-27**, the stimulation system **800** includes at least an electrode portion **801** of a stimulation lead **802** and a shield **804**. It is understood that prior to deployment of electrode portion **801**, one or more optimal stimulation sites on the hypoglossal nerve have been identified via a site locator tool (e.g. site locator tool **200** shown in FIG. **1**) or via other tools. It is also understood that one or more surgical navigation techniques are used to: (1) employ the site locator tool to identify the optimal stimulation site; and (2) place the electrode portion at that optimal stimulation site.

[0159] As shown in FIG. **25**, stimulation lead **803** includes electrode portion **801** and lead body **808** with the electrode portion **801** including a generally elongate carrier body extending between a distal end **817** and a proximal end **816**, and an electrode strip **815**, which includes an array **818** of electrodes **820** spaced apart along a length of the carrier body. The lead body **808** extends proximally from electrode portion **801** and includes an anchor **810** with a proximal lead portion **812** configured for extension to and electrical connection to an IPG (**55** in FIG. **1** or **109** in FIG. **2**).

[0160] The electrode strip **815** has a length (L2) substantially greater than a diameter of a nerve, and sufficient to extend across a diameter of a nerve **840** and outward from both sides of the nerve **840**, as shown in at least FIGS. **26-27**. In one embodiment, the length (L2) is at least twice the diameter of the nerve. In another embodiment, the length (L2) is at least three times the diameter of the nerve, such that with an expected nerve diameter of about 3 millimeters, the electrode strip **815** has a length (L2) of about 9 millimeters. In this embodiment, about 3 millimeters of the full length of the electrode strip **815** would be in close proximity or contact with the nerve **840** while about 3 millimeters of the length of the electrode strip **815** would extend outward from each side of the nerve **840**, as schematically illustrated in FIGS. **26-27**. In some embodiments, electrode strip **840** has a width (W4) of about 3 millimeter, which facilitates a minimally invasive implantation method in some embodiments (as will be later described in more detail in association with FIGS. **30-32**). In comparison, a conventional cuff electrode might typically have a width of about 9 millimeters.

[0161] In use, the electrode portion **801** is delivered to an intended stimulation site along the hypoglossal nerve **840** and with the electrode strip **815** having a generally perpendicular orientation relative to a longitudinal axis (represented by line A) of the nerve **840** (in the region of the intended stimulation site), as shown in FIG. **26**. In one embodiment, as illustrated in the sectional view of FIG. **27**, the electrode portion **801** is positioned so that the electrodes **820** of electrode strip **815** faces toward nerve **840** to apply the stimulation signal onto the nerve **840**. Moreover, in some embodiments, each electrode **582** is independently programmable or controllable via IPG **55** (FIG. **1**) in a manner substantially similar to previously described embodiments to allow control and adjustment over the stimulation signal without re-positioning the electrode strip **815**. In addition, an insulative shield **804** is interposed between the nerve **840** and skin **830** (and underlying muscle **832**) such that the

shield **804** permits application of the stimulation signal on the nerve **840** while preventing application of the stimulation signal on the skin **830**.

[0162] In this arrangement, nerve **840** is sandwiched between the electrode strip **815** and insulative shield **804** and the electrode portion **801** is deployed so that at least a portion of the electrode strip **806** extends, in close proximity to or in close contact with, about the outer surface of the nerve **840**, as shown in the sectional view of FIG. 27. However, in this sandwiched arrangement, each of the electrode strip **815** and shield **804** are secured independently relative to the surrounding tissue such that neither electrode strip **815** nor shield **804** are secured to the nerve **840**. For example, in one embodiment, electrode strip **815** is secured at each of its ends, via anchors (represented by x **878** and x **879** in FIG. 26), relative to the surrounding tissue and independent of nerve **840**. With the generally perpendicular orientation of both the electrode strip **815** and the shield **804**, this configuration permits movement of the nerve **840** in a lateral direction (represented by arrow M) relative to both the electrode strip **815** and the shield **804**, thereby accommodating shifting of the nerve **840** as the neck of the patient moves through a wide range of motion through many different positions.

[0163] With this in mind, upon lateral movement of nerve (along arrow M), both the electrode strip **815** and shield **804** remain stationary such that the sandwiched arrangement is maintained even when nerve **840** moves. Accordingly, because of the electrode strip **815** has a length (L2) that is substantially longer than the diameter of nerve **840**, in any lateral position of the nerve **840** (within a natural, limited range of motion) the electrode strip **815** remains in a position to apply an efficacious stimulation signal to nerve **840**. Similarly, because the shield **804** has length (L3) substantially longer than the diameter of nerve **840** and substantially longer than the length (L2) of the electrode strip **815**, the shield is always positioned to block application of the stimulation signal to the skin **830** (and underlying sensory nerves). In one embodiment, shield **804** defines an area substantially greater than an area of an electrical field produced by electrodes **820** toward a skin surface.

[0164] While the electrode portion **801** extends generally perpendicular to the longitudinal axis of the nerve **840** (at the stimulation site), in some embodiments the lead body **808** extends generally parallel to the longitudinal axis of the nerve **840** to follow a path toward the IPG **55** (FIG. 1). As previously noted, the lead body **808** includes an anchor **810** to permit securely anchoring the lead body **808** (and therefore the electrode portion **801** as well) relative to the anatomical structures and tissues nearby to the nerve **840**. From the anchor **810**, a proximal portion **812** of the lead body **808** extends further toward the IPG **55** (FIG. 1) via a subcutaneous tunnel.

[0165] In some embodiments, the application of a perpendicular orientation of an electrode strip (e.g. electrode strip **815**) relative to nerve **840** is used with other cuff-less electrode configurations. For example, embodiments associated with FIGS. 11-14C can be deployed to orient the electrode portion **565** to be generally perpendicular to the nerve such that the series of electrodes **582** are aligned transverse to a longitudinal axis of the target nerve without a cuff encircling the circumference of the nerve **840**. It will be understood that the number of electrode contacts will be

adjusted, as appropriate, in the electrode portion **565** to insure capture of the nerve throughout a full cross-section (or diameter) of the nerve.

[0166] In further reference to FIGS. 25-29, in some embodiments, electrode portion **801** includes one or more anchoring mechanisms. Accordingly, FIG. 28 is a top plan view of an electrode portion **850** including a series of electrode contacts **820**, a distal end **852**, and a proximal end **854**. At distal end **852**, one or more loops (or other securing elements) **860** are provided to enable suturing or otherwise fastening the distal end **852** relative to surrounding tissue adjacent the nerve **840**. Similarly, at proximal end **854**, one or more loops (or other securing elements) **870**, **872** are provided to enable suturing or otherwise fastening the proximal end **854** relative to surrounding tissue adjacent the nerve **840**. In this way, the electrode strip **850** is securable in a stable position close to nerve **840** (but independently of the nerve) without being secured to the nerve **840** itself and/or without encircling the nerve **840**.

[0167] In some other embodiments, as schematically illustrated in the sectional view of FIG. 29, electrode strip **815** and shield **804** are secured together. In these embodiments, the sandwiched configuration of electrode strip **815** and shield **804** is maintained relative to nerve **840** to thereby permit lateral movement (directional arrow M) of nerve **840** while still providing electrical stimulation of nerve **840** via electrode strip **815** and while still protecting skin **830** via shield **804**. In particular, fastening mechanism **870** includes a first component **872** and a second component **874**, with each respective component **872**, **874** sized to extend between the electrode strip **815** and the shield **804**. In one non-limiting aspect, by providing first component **872** on one lateral side of nerve **840** (connected to the first ends of the respective strip and shield) and by providing second component **874** on an opposite lateral side of nerve **840** (connected to the second ends of the respective strip and shield), the fastening mechanism **870** provides a lateral boundary or barrier to insure that nerve **840** will remain between electrode strip **815** and shield **804** while permitting lateral movement of nerve **840**. In other embodiments, only one end of the respective electrode strip **815** and the shield **804** are secured together, leaving the other end open.

[0168] In one embodiment, the first component **872** of securing mechanism **870** comprises a buckle-belt mechanism that is connectable to the distal end **817** of electrode strip **815** and connectable to the distal end **805** of the shield **804**. Likewise, the second component **874** comprises a buckle-belt mechanism that is connectable to the proximal end **816** of electrode strip **815** and connectable to the proximal end **807** of the shield **804**.

[0169] In some embodiments, the combination of the shield **804** and the electrode strip **815** are delivered percutaneously in a minimally invasive implantation method, as schematically illustrated in FIGS. 30-32. In particular, because the electrode strip **815** is quite narrow (e.g., 3 millimeters wide as shown in FIGS. 25-27), the procedure begins via making two small incisions **880**, **882** in the skin **830** (and underlying tissues/muscles **832**) on opposite lateral sides of the underlying nerve **840**, as shown in FIG. 31. At least one of the incisions **880**, **882** will have a width (W6) generally corresponding to the width (W4 in FIG. 25) of the electrode strip **815**. Using a forceps (not shown), the electrode strip **815** is maneuvered through incision **880** and via incision **882** (as represented via arrows E and R) until the

electrode strip **815** is in position underneath nerve **840** with electrode contacts **820** in close contact with the nerve **840** and facing skin **830**, as shown in FIG. **30**. Next, using a similar technique involving incisions **880** and/or **882**, the shield **804** is introduced into a position interposed between nerve **840** and skin **830**. If necessary, either incision **880**, **882** can be widened slightly to accommodate introduction of the larger width (W5) of shield **804** through the respective incision. With this minimally invasive method of implantation, the sandwiched configuration of the electrode strip **815** and the shield **804** relative to the nerve **840** is achieved with minimal disruption to the skin and tissues above and near the nerve **840**. Accordingly, the combination of the electrode strip **815** and the shield **804** enable a minimally invasive method of implanting those elements while also providing a stimulation system that minimally impacts the natural state of the nerve by acting as a cuff-less electrode.

[0170] Several different embodiments have been described in association with FIGS. **1-14**, in which an IPG **55** is implanted in a pectoral region and in which a sensor electrode(s) and a stimulation electrode(s) (extending from the IPG **55**) are delivered percutaneously to sense respiratory patterns and to apply a stimulation signal, respectively. In addition, several embodiments of stimulation electrode arrays (and associated anchor mechanisms) have been described in association with FIGS. **15-32**. Moreover, it is understood that in some of these embodiments, a lead is percutaneously placed in each side of the body (left and right) such that bilateral (simultaneous or alternating) stimulation takes place on the left and/or right hypoglossal nerve (or other target nerve). With these various embodiments in mind, it is further understood that among those embodiments, several configurations are provided in which at least two electrodes are spaced apart in the body in the vicinity of the upper airway such that an impedance is measurable between the two spaced apart electrodes to provide an indication of airway patency (e.g., opening and/or closing of the upper airway). In some configurations, the spaced electrodes are both stimulation electrodes, while in other configurations, the spaced apart electrodes comprise one stimulation electrode and one respiratory sensor electrode. In yet other configurations, the two spaced apart electrodes (used for measuring an impedance indicative of airway patency) include one of the electrodes comprising at least one of a stimulation electrode and a respiratory sensor electrode and the other one of the electrodes comprising an electrode formed by an electrically conductive portion of a case or housing of the IPG **55**.

[0171] Moreover, in some embodiments, the respective electrode portions provide a dual function in that each electrode provides a respiratory sensing function or a stimulation function as well as acting as a part of a pair of impedance sensing electrodes. On the other hand, in other embodiments, at least one electrode of the pair of impedance sensing electrodes does not also act to sense respiration (e.g. inspiration) or to stimulate but rather is dedicated for use in sensing impedance to detect or indicate a degree of airway patency.

[0172] At least some embodiments of the percutaneously-delivered electrode portions (described herein) enable precise location of an electrode portion adjacent to an optimal neurostimulation site because the percutaneous approach enables the surgeon to vary the position of an electrode portion of a stimulation lead along the length of the hypo-

glossal nerve. In addition, this precise placement is performed in a minimally invasive manner unlike the anatomically disruptive conventional cut-down procedure for placing stimulation leads. The methods and systems of the present disclosure allows the surgeon to identify a precise optimal stimulation site that causes contraction of one or more specific muscles (suited to restore airway patency) prior to fixing the location of the electrode portion relative to the target nerve.

[0173] Embodiments of the present disclosure provide an implantable system to provide therapeutic solutions for patients diagnosed with obstructive sleep apnea. The system is designed to stimulate the hypoglossal nerve during inspiration thereby preventing occlusions in the upper airway during sleep.

[0174] While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that variations exist. It should also be appreciated that the exemplary embodiment or exemplary embodiments are only examples, and are not intended to limit the scope, applicability, or configuration of the present disclosure in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the exemplary embodiment or exemplary embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope of the present disclosure as set forth in the appended claims and the legal equivalents thereof.

1. (canceled)
2. A lead for an implantable medical device, the lead comprising:
 - a body portion extending between a distal portion and a proximal portion; and
 - an electrode portion at the distal portion of the body portion,
 wherein the electrode portion comprises an anchoring mechanism configured to be in a collapsed state with the electrode portion within a lead introduction tool and in a deployed state with the electrode portion withdrawn from the lead introduction tool.
3. The lead of claim 2, wherein the anchoring mechanism comprises a resilient material.
4. The lead of claim 2, wherein the anchoring mechanism comprises a flexible polymer.
5. The lead of claim 2, wherein the anchoring mechanism comprises a plurality of flaps.
6. The lead of claim 2, wherein the anchoring mechanism comprises a plurality of anchoring components.
7. The lead of claim 6, wherein the anchoring components comprise barbs, prongs, or tines.
8. The lead of claim 2, wherein the electrode portion comprises an electrode array.
9. The lead of claim 2, wherein the lead introduction tool comprises a cannula body.
10. A lead for an implantable medical device, the lead comprising:
 - a body portion extending between a distal portion and a proximal portion; and
 - an electrode portion at the distal portion of the body portion,
 wherein the electrode portion comprises an anchoring mechanism comprising a plurality of protrusions configured to be in a collapsed state with the electrode

portion within a lead introduction tool and in a deployed state with the electrode portion withdrawn from the lead introduction tool.

11. The lead of claim **10**, wherein at least one pair of the plurality of protrusions comprise a divergent orientation.

12. The lead of claim **10**, wherein the plurality of protrusions comprise a flexible polymer.

13. The lead of claim **10**, wherein the plurality of protrusions each have a length and a width configured to engage or integrate with tissue in a patient.

14. The lead of claim **10**, wherein the plurality of protrusions comprise a plurality of flaps.

15. A lead for an implantable medical device, the lead comprising:

a body portion extending between a distal portion and a proximal portion,

wherein the distal portion comprises:

a front side supporting an electrode portion; and

a back side comprising an anchoring mechanism configured to be in a collapsed state with the distal portion within a lead introduction tool and in a deployed state with the distal portion withdrawn from the lead introduction tool.

16. The lead of claim **15**, wherein the electrode portion comprises an electrode array.

17. The lead of claim **15**, wherein the front side comprises a generally flat surface and the back side comprises a generally flat surface.

18. The lead of claim **15**, wherein the front side comprises a curved portion or an undulating portion.

19. The lead of claim **18**, wherein the curved portion comprises a concave shape.

20. The lead of claim **18**, wherein the curved portion comprises a convex shape.

21. The lead of claim **15**, wherein the back side comprises an electrically insulative material.

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