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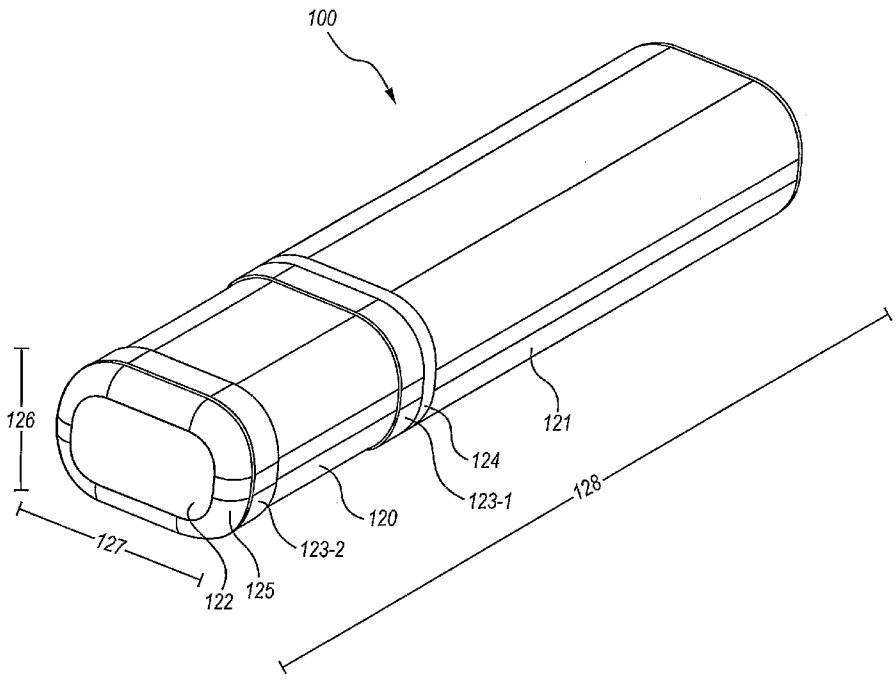
(54) Title: IMPLANTABLE STIMULATOR CONFIGURED TO BE IMPLANTED WITHIN A PATIENT IN A PRE-DETERMINED ORIENTATION



(57) Abstract: Implantable stimulators include a main assembly (120) configured to house one or more components configured to generate and apply at least one stimulus to at least one stimulation site within a patient. The main assembly (120) has a shape allowing said stimulator to be implanted within said patient in a pre-determined orientation.

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Implantable Stimulator Configured to be Implanted Within a Patient in a Pre-determined Orientation

RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Patent Application Serial Number 11/280,620, filed November 16, 2005, U.S. Patent Application Serial Number 11/280,582, filed November 16, 2005, and U.S. Patent Application Serial Number 11/322,788, filed December 30, 2005. U.S. Patent Application Serial Number 11/322,788 claims the priority under 35 U.S.C. § 119 (e) of U.S. Provisional Patent Application No. 60/661,700, filed March 14, 2005.

BACKGROUND

[0002] A wide variety of medical conditions and disorders have been successfully treated using an implantable stimulator. Implantable stimulators typically stimulate internal tissue, such as a nerve, by emitting an electrical stimulation current according to programmed stimulation parameters.

[0003] One type of implantable stimulator is known as a microstimulator. Microstimulators are typically formed with a small, cylindrical housing containing electronic circuitry that produces the desired electric stimulation current between spaced electrodes. These stimulators are implanted proximate to the target tissue so that the stimulation current produced by the electrodes stimulates the target tissue to reduce symptoms or otherwise provide therapy for a wide variety of conditions and disorders.

[0004] Another type of implantable stimulator is known as an implantable pulse generator (IPG). A typical IPG includes a multi-channel pulse generator housed in a rounded titanium case. The IPG is generally coupled to a lead with a number of electrodes disposed thereon. Stimulation current is generated by the IPG and delivered to target tissue via the electrodes on the lead.

[0005] As will be readily appreciated, a key part of patient treatment using an implanted stimulator is the proper placement of the stimulator such that the stimulation electrodes are proximate to the stimulation site to be stimulated. If the stimulation electrodes are optimally placed near the stimulation site, stimulation can be affected over a wide range of

parameters and power consumption can be minimized. However, optimal placement of a stimulator within a patient is often difficult to accomplish.

SUMMARY

[0006] Exemplary implantable stimulators include a main assembly configured to house one or more components configured to generate and apply at least one stimulus to at least one stimulation site within a patient. The main assembly has a shape allowing said stimulator to be implanted within said patient in a pre-determined orientation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The accompanying drawings illustrate various embodiments of the principles described herein and are a part of the specification. The illustrated embodiments are merely examples and do not limit the scope of the disclosure.

[0008] FIG. 1 is a block diagram illustrating a number of components of an exemplary implantable stimulator according to principles described herein.

[0009] FIG. 2 illustrates an exemplary structure of the implantable stimulator according to principles described herein.

[0010] FIG. 3 is a perspective view of an exemplary first assembly according to principles described herein.

[0011] FIG. 4 is a perspective view of an exemplary second assembly according to principles described herein.

[0012] FIG. 5 illustrates an exemplary electrode assembly coupled to the stimulator according to principles described herein.

[0013] FIG. 6 is a perspective view of an exemplary feed through assembly according to principles described herein.

[0014] FIG. 7 illustrates an exemplary electrode assembly with a number of electrodes disposed thereon according to principles described herein.

[0015] FIG. 8 is a graph illustrating the relative current threshold values of monopolar, bipolar, and tripolar electrode configurations as a function of distance from a stimulation site according to principles described herein.

[0016] FIG. 9A is an assembled perspective view of the stimulator with an exemplary electrode contact arrangement that may be used to provide monopolar and/or multipolar stimulation to a stimulation site according to principles described herein.

[0017] FIG. 9B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 9A according to principles described herein.

[0018] FIG. 10A is an assembled perspective view of the stimulator that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site in accordance with principles described herein.

[0019] FIG. 10B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 10A according to principles described herein.

[0020] FIG. 10C is an assembled perspective view of the stimulator that illustrates that the anode may alternatively include an array of individual electrode contacts according to principles described herein.

[0021] FIG. 11 is an assembled perspective view of the stimulator that illustrates a cathode array and anode extending along a portion of the first assembly according to principles described herein.

[0022] FIG. 12A is an assembled perspective view of the stimulator that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site according to principles described herein.

[0023] FIG. 12B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 12A according to principles described herein.

[0024] FIG. 13A is an assembled perspective view of the stimulator that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site according to principles described herein.

[0025] FIG. 13B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 13A according to principles described herein.

[0026] FIG. 14A is an assembled perspective view of the stimulator that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site according to principles described herein.

[0027] FIG. 14B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 14A according to principles described herein.

[0028] FIG. 15A is an assembled perspective view of the stimulator that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site according to principles described herein.

[0029] FIG. 15B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 15A according to principles described herein.

[0030] FIG. 16A is an assembled perspective view of the stimulator that illustrates another exemplary electrode contact arrangement that may be used to provide monopolar and/or multipolar stimulation to a stimulation site according to principles described herein.

[0031] FIG. 16B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 16A according to principles described herein.

[0032] FIG. 17A is an assembled perspective view of the stimulator that illustrates another exemplary electrode contact arrangement that may be used to provide monopolar and/or multipolar stimulation to a stimulation site according to principles described herein.

[0033] FIG. 17B is a cross-sectional view of the stimulator taken along the perspective line indicated in FIG. 17A according to principles described herein.

[0034] FIG. 18 illustrates an exemplary stimulator coupled to a lead having a number of electrode contacts disposed thereon.

[0035] FIG. 19 illustrates various systems and external devices that may be used to support the implanted stimulator according to principles described herein.

[0036] FIG. 20 depicts a number of stimulators configured to communicate with each other and/or with one or more external devices according to principles described herein.

[0037] Throughout the drawings, identical reference numbers designate similar, but not necessarily identical, elements.

DETAILED DESCRIPTION

[0038] An implantable stimulator having a shape that allows the stimulator to be implanted within a patient in a pre-determined orientation and methods of using such a stimulator are described herein. The stimulator includes at least a main assembly and one or more electrodes (also referred to herein as "electrode contacts") disposed on an external surface thereof. The main assembly is configured to house one or more components that generate at least one stimulus that is applied to at least one stimulation site within a patient.

[0039] In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present systems and methods. It will be apparent, however, to one skilled in the art that the present systems and methods may be practiced without these specific details. Reference in the specification to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. The

appearance of the phrase "in one embodiment" in various places in the specification are not necessarily all referring to the same embodiment.

[0040] As used herein and in the appended claims, the term "stimulator" will be used broadly to refer to any type of device that is implanted to deliver a stimulus to a stimulation site within a patient. As used herein and in the appended claims, unless otherwise specifically denoted, the term "stimulation site" will be used to refer to any nerve, muscle, organ, or other tissue within a patient that is stimulated by an implantable stimulator.

[0041] The stimulus applied to the stimulation site may include electrical stimulation, also known as neuromodulation. Electrical stimulation will be described in more detail below. The stimulator may additionally or alternatively be configured to infuse therapeutic dosages of one or more drugs into the stimulation site or function in a coordinated manner with a drug delivery system configured to infuse the therapeutic dosages of one or more drugs into the stimulation site. Consequently, as used herein and in the appended claims, the term "stimulus" or "stimulation," unless otherwise indicated, will broadly refer to an electrical stimulation, drug stimulation, or both.

[0042] FIG. 1 is a block diagram illustrating a number of components of an exemplary implantable stimulator or system control unit (SCU) (100). The components of the stimulator (100) of FIG. 1 may be similar to the components included within a BION® microstimulator (Advanced Bionics® Corporation, Valencia, CA), for example. However, it will be recognized that the stimulator (100) may include any additional or alternative components as best serves a particular application.

[0043] As shown in FIG. 1, the stimulator (100) may include electrical circuitry (101), a power source (102), a programmable memory unit (103), a coil (104), and/or a pump (105) and infusion outlets (106). The power source (102) is configured to output a voltage used to supply the various components within the stimulator (100) with power. The power source (102) also provides power for any stimulation current applied by the stimulator (100) to the stimulation site. The power source (102) may include a primary battery, a rechargeable battery, super capacitor, a nuclear battery, a mechanical resonator, an infrared collector (receiving, e.g., infrared energy through the skin), a thermally-powered energy source (where, e.g., memory-shaped alloys exposed to a minimal temperature difference generate power), a flexural powered energy source (where a flexible section subject to flexural forces is part of the stimulator), a bioenergy power source (where a chemical reaction provides an energy source), a fuel cell, a bioelectrical cell (where two or more electrodes use tissue-generated potentials and currents to

capture energy and convert it to useable power), an osmotic pressure pump (where mechanical energy is generated due to fluid ingress), or the like. Alternatively, the stimulator (100) may include one or more components configured to receive power from another device that is implanted within the patient.

[0044] The amount of power or energy that the power source (102) may provide to the various components of the stimulator (100) is substantially proportional to the physical size of the power source (102). Hence, the larger the power source (102), the more power the power source (102) can provide to the components of the stimulator (100). Some conventional microstimulators have relatively small batteries and therefore have to be recharged multiple times every day. In some embodiments, the power source (102) of the stimulator (100) described herein is relatively larger than power sources found in conventional microstimulators. Therefore, the life of the power source (102) may be up to fifteen times greater or more than the battery life of conventional stimulator power sources.

[0045] The stimulator (100) may also include a coil (104) configured to receive and/or emit a magnetic field (also referred to as a radio frequency (RF) field) that is used to communicate with or receive power from one or more external devices that support the implanted stimulator (100), examples of which will be described below. Such communication and/or power transfer may include, but is not limited to, transcutaneously receiving data from the external device, transmitting data to the external device, and/or receiving power used to recharge the power source (102).

[0046] The stimulator (100) may also include electrical circuitry (101) configured to produce electrical stimulation pulses that are delivered to the stimulation site via a number of electrodes (110). In some embodiments, as will be described in more detail below, the stimulator (100) may be configured to produce monopolar stimulation. The stimulator (100) may alternatively or additionally be configured to produce multipolar stimulation including, but not limited to, bipolar or tripolar stimulation.

[0047] The electrical circuitry (101) may include one or more processors configured to decode stimulation parameters and generate the corresponding stimulation pulses. In some embodiments, the stimulator (100) has at least four channels and drives up to sixteen electrodes or more. The electrical circuitry (101) may include additional circuitry such as capacitors, integrated circuits, resistors, coils, and the like configured to perform a variety of functions as best serves a particular application.

[0048] The programmable memory unit (103) is used for storing one or more sets of data, for example, stimulation parameters. The stimulation parameters may include, but are not limited to, electrical stimulation parameters and drug stimulation parameters. The programmable memory unit (103) allows a patient, clinician, or other user of the stimulator (100) to adjust the stimulation parameters such that the electrical stimulation and/or drug stimulation are at levels that are safe and efficacious for a particular medical condition and/or for a particular patient. Electrical stimulation and drug stimulation parameters may be controlled independently. However, in some instances, the electrical stimulation and drug stimulation parameters are coupled, e.g., electrical stimulation may be programmed to occur only during drug stimulation. The programmable memory unit (103) may include any type of memory unit such as, but not limited to, random access memory (RAM), static RAM (SRAM), a hard drive, or the like.

[0049] The electrical stimulation parameters may control various parameters of the stimulation current applied to the stimulation site including, but not limited to, the frequency, pulse width, amplitude, burst pattern (e.g., burst on time and burst off time), duty cycle or burst repeat interval, ramp on time and ramp off time of the stimulation current that is applied to the stimulation site. The drug stimulation parameters may control various parameters including, but not limited to, the amount of drugs infused into the stimulation site, the rate of drug infusion, and the frequency of drug infusion.

[0050] Specific electrical stimulation and drug stimulation parameters may have different effects on different types of medical conditions. Thus, in some embodiments, the electrical stimulation and/or drug stimulation parameters may be adjusted by the patient, a clinician, or other user of the stimulator (100) as best serves a particular medical condition. The electrical stimulation and/or drug stimulation parameters may also be automatically adjusted by the stimulator (100), as will be described below. For example, the amplitude of the stimulation current applied to a target nerve may be adjusted to have a relatively low value so as to target relatively large diameter fibers of the target nerve. The stimulator (100) may also increase excitement of a target nerve by applying a stimulation current having a relatively low frequency to the target nerve (e.g., less than 100 Hz). The stimulator (100) may also decrease excitement of a target nerve by applying a relatively high frequency to the target nerve (e.g., greater than 100 Hz). The stimulator (100) may also be programmed to apply the stimulation current to a target nerve intermittently or continuously.

[0051] As shown in FIG. 1, the stimulator (100) is coupled to a number of electrodes E_1-E_n (110) configured to apply the electrical stimulation to the stimulation site. As shown in FIG. 1, there may be any number of electrodes (110) as best serves a particular application. In some examples, one or more of the electrodes (110) may be designated as stimulating electrodes and one of the electrodes (110) may be designated as an indifferent electrode used to complete one or more stimulation circuits. One or more portions of the outer surface of the stimulator (100) may additionally or alternatively be used as an indifferent electrode.

[0052] In some embodiments, as will be described in more detail below, the electrodes (110) are leadless and are disposed on or coupled to the body of the stimulator (100). The electrodes (110) may alternatively be a part of a lead that is coupled to the body of the stimulator (100). The electrodes (110) will be described in more detail below.

[0053] The pump (105), also referred to herein as a controlled drug release device, may include any of a variety of different drug delivery systems. Controlled drug release devices based upon a mechanical or electromechanical infusion pump may be used. In other examples, the pump (105) may include a diffusion-based delivery system, e.g., erosion-based delivery systems (e.g., polymer-impregnated with drug placed within a drug-impermeable reservoir in communication with the drug delivery conduit of a catheter), electrodiffusion systems, and the like. The pump (105) may additionally or alternatively include a convective drug delivery system (e.g., a system based upon electroosmosis), a vapor pressure pump, an electrolytic pump, an effervescent pump, a piezoelectric pump, an osmotic pump, and/or a micro-drug pump.

[0054] FIG. 2 illustrates an exemplary structure of the implantable stimulator (100). In some embodiments, as shown in FIG. 2, the stimulator (100) has a rectangular cross-section with corner rounding. The rectangular cross-sectional shape allows the stimulator (100) to be implanted within a patient in a pre-determined orientation. In addition, the slightly significant aspect ratio (cross-section) of the stimulator (100) minimizes the profile, or height (126), of the stimulator (100), which reduces implantation discomfort in many patients. The minimized height (126) also improves the aesthetic appeal of the stimulator (100) when implanted.

[0055] As mentioned, the rectangular with corner rounding shape of the stimulator (100) is advantageous in some applications because it allows the stimulator (100) to be implanted within a patient in a pre-determined orientation. In comparison, a cylindrically shaped stimulator can easily rotate during and after implantation, and therefore cannot be implanted with a pre-determined orientation about its central axis. Hence, a single stimulation electrode is often arranged in a ring-like formation about a cylindrical stimulator so that the stimulator can be

implanted in any arbitrary orientation. This ring-like arrangement of the electrode causes the electrical field emitted by the stimulator to spread in all 360 degrees of space. In cases where the target stimulation site is only located on one side of the stimulator, a 360 degree spread of energy is inefficient, reduces the battery life of the stimulator, and/or increases the battery recharging frequency of the stimulator. Furthermore, the stimulation current may become uncomfortable to the patient if it is increased to compensate for the inefficient energy spread.

[0056] It will be recognized, however, that the rectangular shape of the stimulator (100) shown in FIG. 2 is merely exemplary of the many different dimensional configurations of the stimulator (100). For example, the stimulator (100) may have a long oval shape or any other shape that allows the stimulator (100) to be implanted within the patient in a pre-determined orientation. In general, the stimulator (100) may have any non-cylindrical shape such that the stimulator (100) may be implanted within the patient in a pre-determined orientation.

[0057] As shown in FIG. 2, the stimulator (100) has a height (126), width (127), and length (128). An exemplary height (126) is substantially equal to 4.25 millimeters (mm), an exemplary width (127) is substantially equal to 7.25 mm, and an exemplary length (128) is substantially equal to 28 mm. It will be recognized that these dimensions are merely illustrative and that the dimensions of the stimulator (100) may be greater or less than the given exemplary dimensions as best serves a particular application.

[0058] As shown in FIG. 2, the stimulator (100) may include multiple assemblies. For example, the stimulator (100) may include a first or main assembly (120) coupled to a second assembly (121). Each assembly may be configured to house different components of the stimulator (100), as will be described in more detail below. FIG. 2 also shows a cap assembly (122) and a number of connecting rings (123-125) that, as will be described in more detail below, are configured to form a hermetic enclosure for the components housed within the first and second assemblies (120, 121).

[0059] In some examples, the first assembly (120) houses the electrical circuitry (101), the programmable memory unit (103), the pump (105), the coil (104), and/or any other components of the stimulator (100) as best serves a particular application. The first assembly (120) may be made out of any suitable material that allows the coil (104) to emit and receive a magnetic field used to communicate with an external device or with another implanted device. For example, the first assembly (120) may be made out of a ceramic material, glass, plastic, a polymer, a metal (e.g., Titanium) configured to allow the passage of a magnetic field, or any other suitable material. Because the first assembly (120) is sometimes made out of a ceramic

material, it is sometimes referred to as a ceramic tube assembly. The first assembly (120) will be described in more detail below.

[0060] The second assembly (121) shown in FIG. 2 may be configured to house the power source (102). However, in some alternative examples, the second assembly (121) may house any additional or alternative components of the stimulator (100) as best serves a particular application. The second assembly (121) has a cross section substantially equal to the cross section of the first assembly (120) and may be made out of any insulative material such as ceramic or glass. Additionally or alternatively, the outer surface of the second assembly (121) may be coated with a non-conductive coating, such as, but not limited to, Parylene™ or Teflon™. In some alternative embodiments, the second assembly (121) is made out of a conductive material (e.g., Titanium).

[0061] In some examples, the stimulator (100) may also include a cap assembly (122) coupled to either end of the stimulator body. The cap assembly (122) may be made out of any suitable material such as, but not limited to, a ceramic material, glass, plastic, a polymer, or a metal (e.g., Titanium). As shown in FIG. 2, a connecting ring (125) may be hermetically brazed or otherwise attached to the cap assembly (122). The connecting ring (125) may be made out of titanium or any other suitable material for hermetically coupling the cap assembly (122) to the first assembly (120). In some alternative examples, the stimulator (100) does not include the cap assembly (122).

[0062] For illustrative purposes only, it will be assumed in the examples given herein that the stimulator (100) includes at least the first assembly (120) and the second assembly (121). However, it will be recognized that the stimulator (100) may include any number of assemblies made out of any combination of materials. For example, the stimulator (100) may only include a single assembly that houses all the components of the stimulator (100). In general, the external surface of the stimulator (100) may be made out of glass, ceramic, plastic, polymers, metal, metal-alloys, or any other suitable material.

[0063] FIG. 3 is a perspective view of an exemplary first assembly (120). As shown in FIG. 3, the first assembly (120) includes a main hollow body (130) with connecting rings (123) connected thereto at either end. The main body (130) houses the electrical circuitry (101), programmable memory unit (103), pump (105), coil (104), and/or any other components of the stimulator (100) as best serves a particular application.

[0064] In some examples, a connecting ring (123) is hermetically coupled to both ends of the main body (130). The connecting rings (123) are used to hermetically seal or couple

the first assembly (120) to the second assembly (121) and/or to the cap assembly (122). The connecting rings (123) may be made out of titanium or any other suitable material (e.g., platinum, iridium, tantalum, titanium nitride, niobium, alloys of any of these, a titanium alloy, etc.). Additionally or alternatively, the connecting rings (123) may be made out of glass, ceramic materials, or other biocompatible materials. Moreover, the connecting rings (123) may be hermetically coupled to the main body (130) using any suitable process (e.g., brazing, welding, molding, and/or bonding with adhesive).

[0065] FIG. 4 is a perspective view of an exemplary second assembly (121). As shown in FIG. 4, the second assembly (121) may include one or more terminals (140) configured to electrically couple a power source (102) that is housed within the second assembly (121) to one or more components within the first assembly (120). In some examples, a connecting ring (124) may be hermetically brazed or otherwise coupled to a proximal end of the second assembly (121). The connecting ring (124) is configured to hermetically seal the second assembly (121) to the first assembly (120) and may be made out of titanium or any other material suitable for hermetically coupling the second assembly (121) to the first assembly (120).

[0066] Hence, returning to FIG. 2, the cap assembly (122), first assembly (120), and second assembly (121) are hermetically coupled to form a hermetic enclosure for the internal components of the stimulator (100). As shown in FIG. 2, the connecting ring (124) of the second assembly (121) is hermetically coupled to the connecting ring (123-1) of the first assembly (120) and the connecting ring (125) of the cap assembly (122) is hermetically coupled to the connecting ring (123-2) of the first assembly (120). It will be recognized that the assemblies shown in FIG. 2 may be hermetically coupled using any suitable coupling procedure such as, but not limited to, laser welding, brazing, co-firing, molding, and/or bonding with conductive epoxy.

[0067] In some examples, as shown in FIG. 5, an electrode assembly (150) with a number of electrodes (110) disposed thereon may be coupled to the stimulator (100). The electrode assembly (150) will be described in more detail below. To facilitate the use of the electrode assembly (150), a feed through assembly (152) may be coupled to one of the ends of the stimulator (100). As will be described in more detail below, the feed through assembly (152) includes a number of electric feed throughs (151) configured to facilitate electrical connection between the electrodes (110) disposed on the electrode assembly (150) and the electrical circuitry (101) located within the stimulator (100).

[0068] FIG. 6 is a perspective view of an exemplary feed through assembly (152). The feed through assembly (152) has a cross section substantially equal to the cross section of the first assembly (120). The feed through assembly (152) includes an outer surface or wall (160) made of an insulative material such as ceramic or glass. A connecting ring (125) may be hermetically brazed or otherwise attached to the feed through assembly (152). The connecting ring (125) may be made out of titanium or any other suitable material for hermetically coupling the feed through assembly (152) to the first assembly (120).

[0069] A number of feed throughs (151), each corresponding to one of the electrodes (110), are electrically coupled to the electrical circuitry (101) housed within the first assembly (120). In some embodiments, the feed throughs (151) include metal contact pads located on the outer wall (160) that are coupled to metal vias extending through the feed through assembly (152) to an inside wall (not shown) of the feed through assembly (152). These metal vias may be hermetically buried or brazed inside the feed through assembly (152) and electrically coupled to the outputs of the electrical circuitry (101) housed within the first assembly (120). In this manner, the feed throughs (151) facilitate electrical connection between the electrical circuitry (101) and the electrodes (110) disposed on the electrode assembly (150).

[0070] FIG. 7 illustrates an exemplary electrode assembly (150) with a number of electrodes (110) disposed thereon. The electrode assembly (150) may be made out of a polymer film or any other suitable material. The polymer film may have any thickness as best serves a particular application. Eight electrodes (110) are shown in FIG. 7 for illustrative purposes only. However, it will be recognized that any number of electrodes (110) may be disposed on the electrode assembly (150) as best serves a particular application.

[0071] As shown in FIG. 7, the electrode assembly (150) may include a number of metal traces (170) to facilitate electrical connection between the electrodes (110) and the feed throughs (151) of the feed through assembly (120). The metal traces (170) may be deposited on the electrode assembly (150) using any suitable technique (e.g., sputtering or etching). The metal traces (170) may be covered or insulated by a thin film of polymer.

[0072] The electrode assembly (150) may also include a number of metal contacts (171) that are positioned to make electrical contact with the feed throughs (151) that are a part of the feed through assembly (152). In this manner, a conductive path may be formed between the feed throughs (151) and the electrodes (110). It will be recognized that the metal contacts (171) may be made using any suitable method or technique.

[0073] As shown in FIG. 7 and in FIG. 5, the electrode assembly (150) is configured to wrap around one or more sides of the body of the stimulator (100) such that the electrodes (110) are aligned along one or more sides of the body of the stimulator (100). The electrode assembly (150) may be coupled to the body of the stimulator (100) using a medical adhesive or any other suitable attachment material or device.

[0074] In some embodiments, the electrode assembly (150) includes a first extending member (172) and a second extending member (173) each including a number of electrodes (110). However, the electrode assembly (150) may alternatively only include one extending member (e.g., the top extending member (172)).

[0075] In yet another alternative embodiment, the electrode assembly (150) includes more than two extending members. These multiple extending members may be aligned along any side of the body of the stimulator (100). For example, the electrode assembly (150) may include four extending members that extend along all four sides of the stimulator (100). Each of the four extending members may include one or more electrodes (110).

[0076] The electrode assembly (150) is merely exemplary of the many possible electrode configurations that may be used with the exemplary stimulator (100) described herein. Additionally or alternatively, as will be described in more detail below, the electrodes (110) may be disposed directly on the surface of the stimulator (100) and/or on a lead coupled to the stimulator (100).

[0077] As mentioned, the stimulator (100) may be configured to provide monopolar and/or multipolar electrical stimulation to a stimulation site via a number of electrodes (110) disposed on an electrode assembly (150), the stimulator (100) itself, and/or on a lead. In some examples, each electrode (110) may be selectively configured to act as an anode or as a cathode. Monopolar stimulation is achieved by configuring an electrode that is adjacent to or near a stimulation site as a cathode (or anode), and configuring an electrode that is relatively "far away" from the stimulation site with an opposite polarity. Multipolar stimulation is achieved by placing a number of anodes and cathodes adjacent to or near a stimulation site. For example, bipolar stimulation is achieved by placing an anode-cathode pair adjacent to or near a stimulation site. Tripolar stimulation is achieved by placing a cathode surrounded by two anodes or an anode surrounded by two cathodes adjacent to or near a stimulation site.

[0078] Monopolar and multipolar electrode configurations have different stimulation properties. For example, as illustrated in FIG. 8, relative current threshold values vary as a function of distance from the stimulation site for each of these electrode configurations. As used

herein and in the appended claims, the term "current threshold value" will be used to refer to the minimum amount of current required to stimulate a stimulation site. FIG. 8 is a graph illustrating the relative current threshold values of monopolar, bipolar, and tripolar electrode configurations as a function of distance from the stimulation site. The graph is based on a theoretical mathematical model of neural stimulation. The current threshold values are normalized by the current threshold of the monopolar configuration.

[0079] As shown in FIG. 8, when the stimulation site is relatively near the electrode configuration, lower stimulation thresholds may be achieved with a properly spaced bipole or tripole electrode configuration than with a monopole electrode configuration. However, as the distance between the stimulation site and the electrode configuration increases, the thresholds for the bipolar and tripolar electrode configurations begin to exceed that of the monopolar electrode configuration. Thus, monopolar stimulation is often used when the stimulation site is relatively "far" from the electrode configuration and multipolar stimulation is often used when the stimulation site is relatively "close" to the electrode configuration.

[0080] Additionally, monopolar and multipolar electrode configurations often have different stimulation localization properties. For example, a monopolar electrode configuration emits a multidirectional electrical field that may be used to stimulate a relatively general stimulation site. A multipolar electrode configuration, on the other hand, emits a more localized electrical field that is often used to stimulate a relatively specific stimulation site, and may be used to stimulate stimulation sites that have a particular orientation.

[0081] A number of electrode arrangements that may be used to apply monopolar and/or multipolar stimulation to one or more stimulation sites will now be described in connection with FIGS. 9A-17B. Each of the electrodes described in connection with these figures is disposed on the external surface of the stimulator (100) for illustrative purposes only. It will be recognized that the electrodes may be additionally or alternatively be disposed on the electrode assembly (150) and/or a lead as best serves a particular application. Moreover, it will be recognized that the electrodes may be disposed on external surface of the stimulator (100) in any arrangement. The electrodes will also be referred to herein and in the appended claims, unless otherwise specifically denoted, as "electrode contacts" or simply "contacts."

[0082] The electrode contacts described in the following examples and in the appended claims may be made of a conducting ceramic, conducting polymer, copper, and/or a noble or refractory metal, such as gold, silver, platinum, iridium, tantalum, titanium, titanium nitride, niobium, and/or an alloy thereof. The use of one or more of these materials in

constructing the electrode contacts may serve to minimize corrosion, electrolysis, and/or damage to surrounding tissues. The surfaces of the electrode contacts may have any of a number of properties. For example, the surfaces may be smooth or rough. A rough surface increases the actual surface area of an electrode contact and may, with some materials (e.g., platinum or iridium), increase the pseudo-capacitance of the electrode contact. An increased pseudo-capacitance may serve to minimize the risk of adverse electrical affects to a patient being treated.

[0083] Moreover, the electrode contacts may have any suitable size or shape. Differently shaped electrode contacts provide different current densities. For example, an oval electrode contact may provide a more uniform current density than an electrode contact that is rectangular. Hence, the shape of the electrode contacts may vary as best serves a particular application.

[0084] It will also be recognized that each of the electrode contacts described in the following examples may be individually configured to act as stimulating electrodes through which stimulation current is applied to one or more stimulation sites. Likewise, each of the electrode contacts described in the following examples may be configured to individually act as an anode in some instances and as a cathode in other instances. Hence, although reference will be made to certain electrode contacts acting as cathodes and certain electrodes acting as anodes, it will be recognized that each of the electrodes may additionally or alternatively be configured with the opposite polarity.

[0085] FIG. 9A is an assembled perspective view of the stimulator (100) with an exemplary electrode contact arrangement that may be used to provide monopolar and/or multipolar stimulation to a stimulation site. As shown in FIG. 9A, one or more arrays of cathodic electrode contacts (190) (also referred to herein and in the appended claims, unless otherwise specifically denoted, as "cathodes") are included on the external surface of the stimulator (100). For example, an array of cathodes (190) may be located along a substantially flat top surface (195) of the stimulator (100). However, as will be shown in FIG. 9B, the array of cathodes (190) may additionally or alternatively be located along a substantially flat bottom surface (196; FIG. 9B) of the stimulator (100).

[0086] The cathode array (190) of FIG. 9A includes eight electrode contacts aligned in a single row for illustrated purposes only. It will be recognized that each array of cathodes (190) may include any number of individual electrode contacts of any suitable size as best serves a particular application. Moreover, it will be recognized that the spacing in between each electrode contact within the array (190) may vary as best serves a particular application.

[0087] As shown in FIG. 9A, the array of cathodes (190) is arranged such that the row of electrode contacts within the array (190) is in parallel with the length of the stimulator (100). The cathode array (190) may extend along any portion of the stimulator (100). For example, the array of cathodes (190) in FIG. 9A extends along the length of the second assembly (121). However, it will be recognized that the array may additionally or alternatively extend along a portion of the first assembly (120) as best serves a particular application.

[0088] In addition to the array of cathodes (190), an anodic electrode contact (191) (also referred to herein and in the appended claims, unless otherwise specifically denoted, as an "anode") is included on the external surface of the stimulator (100). In some examples, as shown in FIG. 9A, the anode (191) surrounds a portion, or all, of the perimeter of the stimulator (100). An electrode contact that surrounds a portion, or all, of the perimeter of the stimulator (100), such as the anode (191) shown in FIG. 9A, will be referred to herein and in the appended claims, unless otherwise denoted, as a "ring electrode contact." The anode (191) may additionally or alternatively include a portion of the cap assembly (122).

[0089] As shown in FIG. 9A, the ring anode (191) may be separated by a distance (199) from the array of cathodes (190) to achieve monopolar stimulation. The distance (199) may be adjusted as best serves a particular application to achieve monopolar stimulation.

[0090] FIG. 9B is a cross-sectional view of the stimulator (100) taken along the perspective line indicated in FIG. 9A that illustrates an exemplary location of the array of cathodes (190) and the ring anode (191). As shown in FIG. 9B, the stimulator (100) includes a substantially flat top surface (195), a substantially flat bottom surface (196), a first substantially rounded side surface (197), and a second substantially rounded side surface (198). FIG. 9B shows two arrays of cathodes (190) and one ring anode (191) for illustrative purposes. It will be recognized that there may be any number of suitable arrays of cathodes (190) and any number of ring anodes (191) as best serves a particular application.

[0091] As shown in FIG. 9B, an array of cathodes (190) may be located along the top flat surface (195) and/or along the bottom flat surface (196) of the stimulator (100). Additionally or alternatively, an array of cathodes (190) may be located along the first and/or second rounded side surfaces (197, 198). FIG. 9B also shows that the ring anode (191) surrounds at least a portion of the perimeter of the stimulator (100).

[0092] The arrays of cathodes (190) are shown to be centered along the width of the stimulator (100) for illustrative purposes only. However, it will be recognized that one or more

of the arrays of cathodes (190) may be offset by any suitable distance from the center of the width of the stimulator (100) as best serves a particular application.

[0093] FIG. 10A is an assembled perspective view of the stimulator (100) that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site. As shown in FIG. 10A, an array of cathodes (210), similar to the array of cathodes (190) described in connection with FIG. 9A, and an anodic electrode contact (anode) (211) are located along the top flat surface (195) of the stimulator (100). As will be shown in FIG. 10B, the cathode array (210) and anode (211) may additionally or alternatively be located along the bottom flat surface (196) of the stimulator (100).

[0094] FIG. 10B is a cross-sectional view of the stimulator (100) of FIG. 10A taken along the perspective line indicated in FIG. 10A that illustrates an exemplary location of the array of cathodes (210) and the anode (211). As shown in FIG. 10B, the cathode array (210) and the anode (211) may be located along the top flat surface (195) and/or along the bottom flat surface (196) of the stimulator. Additionally or alternatively, an array of cathodes (210) and/or an anode (211) may be located along the first and/or second rounded side surfaces (197, 198).

[0095] As shown in FIG. 10B, each cathode array (210) is separated by a distance (212) from its nearest anode (211). The distance (212) between each cathode array (210) and its nearest anode (211) may be adjusted to minimize a threshold current value and/or achieve different bipolar stimulation characteristics. For example, in some applications, a minimum threshold current corresponding to a stimulation site 5 millimeters (mm) away from the stimulator (100) may be achieved when the distance (212) between each cathode array (210) and its nearest anode (211) is substantially equal to 6 mm.

[0096] Each anode (211) in FIG. 10B may be selectively switched on or off so that bipolar stimulation may be delivered to a stimulation site located near either the top or bottom surfaces (195, 196) of the stimulator (100). For example, the anode (211) located along the bottom surface (196) of the stimulator (100) may be switched off when it is desired to deliver bipolar stimulation only to a stimulation site near the top surface (195) of the stimulator (100). Likewise, the anode (211) located along the top surface (195) may be switched off when it is desired to deliver bipolar stimulation only to a stimulation site near the bottom surface (196) of the stimulator (100).

[0097] Each array of cathodes (210) in FIG. 10B may also be selectively switched on or off so that monopolar and/or bipolar stimulation may be delivered to a stimulation site located near either the top or bottom surfaces (195, 196) of the stimulator (100). For example, the

cathode array (210) located along the top surface (195) of the stimulator (100) may be active and the cathode array (210) located along the bottom surface (196) of the stimulator (100) may be turned off. In this case, bipolar stimulation may be achieved by activating the anode (211) located along the top surface (195) of the stimulator (100) and monopolar stimulation may be achieved by activating the anode (211) located along the bottom surface (196) of the stimulator (100).

[0098] The anode (211) shown in FIGS. 10A and 10B may include a single, long, narrow electrode contact referred to herein and in the appended claims, unless otherwise specifically denoted, as a stripe electrode contact or a stripe anode. The anode (211) may alternatively include an array of individual electrode contacts, as illustrated in FIG. 10C. In some examples, the individual electrode contacts in the anode array (211) are electrically coupled with wires or other conductive mediums. Electrically coupled electrode contacts will be referred to herein and in the appended claims as "ganged." The individual electrode contacts may alternatively be individually controlled. Hence, although the following examples will be illustrated with stripe anodes, it will be recognized that the anodes may alternatively or additionally include individually controllable and/or ganged electrode contacts.

[0099] The array of cathodes (210) and/or the anode (211) shown in FIGS. 10A and 10B may extend along any portion of the stimulator (100). For example, the array of cathodes (210) and/or the anode (211) may extend along the length of the second assembly (121), as shown in FIG. 10A. However, as illustrated in the assembled perspective view of the stimulator (100) shown in FIG. 11, the cathode array (210) and/or the anode (211) may also extend along a portion of the first assembly (120). Hence, it will be recognized that the cathodes and/or anodes described in the examples given herein may extend along any portion of the stimulator (100).

[0100] FIG. 12A is an assembled perspective view of the stimulator (100) that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site. As shown in FIG. 12A, an array of cathodes (220) similar to the array of cathodes (190) described in connection with FIG. 9A is located along the top surface (195) of the stimulator (100). Additionally or alternatively, as will be shown in FIG. 12B, the cathode array (220) may also be located along the bottom flat surface (196) of the stimulator (100). The stimulator (100) also includes an anodic electrode contact (anode) (221) located along the first rounded side surface (197). The anode (221) is similar to the anode (211) described in connection with FIG. 10A. A second anode (221) may additionally or alternatively

be located along the second rounded side surface (198) of the stimulator (100), as will be described in more detail in connection with FIGS. 13A and 13B.

[0101] The array of cathodes (220) and/or the anode (221) illustrated in FIG. 12A may extend along any portion of the stimulator (100). For example, the array of cathodes (220) and/or the anode (221) may extend along the length of the second assembly (121), as shown in FIG. 12A. The cathode array (220) and/or the anode (221) may also extend along a portion of the first assembly (120).

[0102] FIG. 12B is a cross-sectional view of the stimulator (100) of FIG. 12A taken along the perspective line indicated in FIG. 12A that illustrates an exemplary location of the array of cathodes (220) and the anode (221). As shown in FIG. 12B, the cathode array (220) may be located along the top flat surface (195) and/or along the bottom flat surface (196) of the stimulator (100). The cathode arrays (220) are offset towards the second rounded side surface (198). However, it will be recognized that the cathode arrays (220) may be located along any portion of the top and bottom surfaces (195, 196).

[0103] The anode (221) is located along the first rounded side surface (197) and may be used with either of the cathode arrays (220). Hence, bipolar stimulation may be applied to a stimulation site on either the top or bottom surfaces (195, 196) of the stimulator (100).

[0104] FIG. 13A is an assembled perspective view of the stimulator (100) that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site. As shown in FIG. 13A, an array of cathodes (230) similar to the array of cathodes (190) described in connection with FIG. 9A is located along the top surface (195) of the stimulator (100). Additionally or alternatively, as will be shown in FIG. 13B, the cathode array (230) may also be located along the bottom flat surface (196) of the stimulator (100). The stimulator (100) also includes an anodic electrode contact (anode) (231) located along the first rounded side surface (197). The anode (231) is similar to the anode (211) described in connection with FIG. 10A. A second anode (231), as will be shown in FIG. 13B, is also located along the second rounded side surface (198) of the stimulator (100).

[0105] The array of cathodes (230) and/or the anodes (231) may extend along any portion of the stimulator (100). For example, the array of cathodes (230) and/or the anodes (231) may extend along the length of the second assembly (121), as shown in FIG. 13A. The cathode array (230) and/or the anodes (231) may also extend along a portion of the first assembly (120).

[0106] FIG. 13B is a cross-sectional view of the stimulator (100) of FIG. 13A taken along the perspective line indicated in FIG. 13A that illustrates an exemplary location of the arrays of cathodes (230) and the anodes (231). As shown in FIG. 13B, the cathode arrays (230) may be located along the top flat surface (195) and/or along the bottom flat surface (196) of the stimulator (100). The cathode arrays (230) are centered along the width of the stimulator (100) for illustrative purposes only. However, it will be recognized that one or more of the arrays of cathodes (230) may be offset by any suitable distance from the center of the width of the stimulator (100) as best serves a particular application.

[0107] The anodes (231) are located along the first and second rounded side surfaces (197, 198) and may be used with either of the cathode arrays (230). Hence, in some examples, tripolar stimulation may be applied to a stimulation site with one of the cathode arrays (230) and both of the anodes (231). Tripolar stimulation may alternatively be applied to a stimulation site with one of the anodes (231) and both of the cathode arrays (230). Bipolar stimulation may alternatively be applied to a stimulation site with one of the anodes (231) and one of the arrays of cathodes (230).

[0108] FIG. 14A is an assembled perspective view of the stimulator (100) that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site. As shown in FIG. 14A, an array of cathodes (240) similar to the array of cathodes (190) described in connection with FIG. 9A is located along the top surface (195) of the stimulator (100). The stimulator (100) also includes, as will be shown in FIG. 14B, two anodic electrode contacts (anodes) (241) along its bottom surface (196). The anodes (241) are similar to the anode (211) described in connection with FIG. 10A. It will be recognized that the cathode array (240) may alternatively be located along the bottom surface (196) and that the anodes (241) may alternatively be located long the top surface (195) of the stimulator (100).

[0109] The array of cathodes (240) and/or the anodes (241) may extend along any portion of the stimulator (100). For example, the array of cathodes (240) may extend along the length of the second assembly (121), as shown in FIG. 14A. The cathode array (240) and/or the anodes (241) may also extend along a portion of the first assembly (120).

[0110] FIG. 14B is a cross-sectional view of the stimulator (100) of FIG. 14A taken along the perspective line indicated in FIG. 14A that illustrates an exemplary location of the array of cathodes (240) and the anodes (241). As shown in FIG. 14B, the cathode array (240) is located along the top flat surface (195) of the stimulator (100) and the anodes (241) are located

along the bottom flat surface (196) of the stimulator (100). The anodes (241) may additionally or alternatively be located along the first and/or second rounded side surfaces (197, 198). The cathode array (240) is centered along the width of the stimulator (100) for illustrative purposes only. However, it will be recognized that the cathode array (240) may be offset by any suitable distance in either direction from the center of the width of the stimulator (100) as best serves a particular application. Likewise, the anodes (241) illustrated in FIG. 14B may be separated by any suitable distance along the width of the bottom surface (196) of the stimulator (100).

[0111] In some examples, the array of cathodes (240) and the anodes (241) are symmetrically arranged. In other words, the array of cathodes (240) is laterally centered in between the anodes (241), as shown in FIG. 14B. Such a symmetric arrangement may be advantageous in some tripolar stimulation configurations. However, in some alternative examples, the array of cathodes (240) and the anodes (241) are asymmetrically arranged.

[0112] The anode (241) and cathode (240) configuration of FIG. 14B may be used to apply tripolar stimulation to a stimulation site and allows the stimulation current to remain predominately on the side of the stimulator (100) that includes the array of cathodes (240). In some examples, the configuration of FIG. 14B may excite a larger area than the configuration of FIG. 13B because of the distance of separation between the anodes (241) and the array of cathodes (241) in FIG. 14B. Bipolar stimulation may alternatively be applied to a stimulation site by switching off one of the anodes (241). The asymmetrical arrangement of the electrode arrays of FIG. 14B is particularly suitable for enabling multiple possible separation distances between the anodes (241) and array of cathodes (240).

[0113] FIG. 15A is an assembled perspective view of the stimulator (100) that illustrates another exemplary electrode contact arrangement that may be used to provide multipolar stimulation to a stimulation site. As shown in FIG. 15A, an array of cathodes (250) similar to the array of cathodes (190) described in connection with FIG. 9A is located along the top surface (195) of the stimulator (100). Additionally or alternatively, as will be shown in FIG. 15B, the cathode array (250) may also be located along the bottom flat surface (196) of the stimulator (100). The stimulator (100) also includes an anodic electrode contact (anode) (251) located along the first rounded side surface (197). The anode (251) is similar to the anode (211) described in connection with FIG. 10A. A second anode (251), as will be shown in FIG. 15B, may also be located along the second rounded side surface (198) of the stimulator (100).

[0114] The array of cathodes (250) and/or the anodes (251) may extend along any portion of the stimulator (100). For example, the array of cathodes (250) and/or the anodes

(251) may extend along the length of the second assembly (121), as shown in FIG. 15A. The cathode array (250) and/or the anodes (251) may also extend along a portion of the first assembly (120).

[0115] FIG. 15B is a cross-sectional view of the stimulator (100) of FIG. 15A taken along the perspective line indicated in FIG. 15A that illustrates an exemplary location of the arrays of cathodes (250) and the anodes (251). As shown in FIG. 15B, the cathode arrays (250) may be located along the top flat surface (195) and along the bottom flat surface (196) of the stimulator (100). One of the cathode arrays (250) is offset towards the first rounded side surface (197) and one of the cathode arrays (250) is offset towards the second rounded side surface (198). However, it will be recognized that the cathode arrays (250) may be located along any portion of the top and bottom surfaces (195, 196) as best serves a particular application.

[0116] The anodes (251) are located along the first and second rounded side surfaces (197, 198) and may be used with either of the cathode arrays (250). Hence, in some examples, tripolar stimulation may be applied to a stimulation site with one of the cathode arrays (250) and both of the anodes (251). Tripolar stimulation may alternatively be applied to a stimulation site with one of the anodes (251) and both of the cathode arrays (250). Bipolar stimulation may alternatively be applied to a stimulation site with one of the anodes (251) and one of the arrays of cathodes (250). Moreover, in this exemplary arrangement, multiple distances between the anodes (251) and arrays of cathodes (250) are achievable.

[0117] FIG. 16A is an assembled perspective view of the stimulator (100) that illustrates another exemplary electrode contact arrangement that may be used to provide monopolar and/or multipolar stimulation to a stimulation site. FIG. 16B is a cross-sectional view of the stimulator (100) taken along the perspective line indicated in FIG. 16A. As illustrated in FIGS. 16A and 16B, the electrode contact arrangement is similar to that described in connection with FIGS. 12A and 12B with the addition of an anode (261-1) that surrounds a portion, or all, of the perimeter of the stimulator (100). Hence, as shown in FIG. 16B, a cathode array (260) is located along the top flat surface (195) and/or along the bottom flat surface (196) of the stimulator (100). The cathode arrays (260) are offset towards the second rounded side surface (198). However, it will be recognized that the cathode arrays (260) may be located along any portion of the top and bottom surfaces (195, 196).

[0118] An anode (261-2), which may be a stripe electrode contact or a ganged electrode contact, is located along the first rounded side surface (197) and may be used with either of the cathode arrays (260). Hence, bipolar stimulation may be applied to a stimulation

site on either the top or bottom surfaces (195, 196) of the stimulator (100). In addition, the anode (261-1) surrounds a portion, or all, of the perimeter of the stimulator (100).

[0119] Each anode (261-1, 261-2) may be selectively switched on or off so that the stimulator (100) may deliver monopolar or bipolar stimulation to a stimulation site. For example, the anode (261-1) may be switched off when it is desired to deliver bipolar stimulation to a stimulation site. Likewise, the anode (261-2) may be switched off when it is desired to deliver monopolar stimulation to a stimulation site.

[0120] FIG. 17A is an assembled perspective view of the stimulator (100) that illustrates another exemplary electrode contact arrangement that may be used to provide monopolar and/or multipolar stimulation to a stimulation site. FIG. 17B is a cross-sectional view of the stimulator (100) taken along the perspective line indicated in FIG. 17A. As illustrated in FIGS. 17A and 17B, the electrode contact arrangement is similar to that described in connection with FIGS. 15A and 15B with the addition of an anode (271-1) that surrounds a portion, or all, of the perimeter of the stimulator (100). Hence, as shown in FIG. 17B, a cathode array (270) is located along the top flat surface (195) and along the bottom flat surface (196) of the stimulator (100). One of the cathode arrays (270) is offset towards the first rounded side surface (197) and one of the cathode arrays (270) is offset towards the second rounded side surface (198). However, it will be recognized that the cathode arrays (270) may be located along any portion of the top and bottom surfaces (195, 196) as best serves a particular application.

[0121] An anode (271-2), which may be a stripe electrode contact or a ganged electrode contact, is located along the first and second rounded side surfaces (197, 198) and may be used with either of the cathode arrays (270). In addition, as shown in FIG. 17B, the anode (271-1) surrounds a portion, or all, of the perimeter of the stimulator (100).

[0122] Each anode (271-1, 271-2) may be selectively switched on or off so that the stimulator (100) may deliver monopolar, bipolar, or tripolar stimulation to a stimulation site. For example, the anode (271-1) may be switched off when it is desired to deliver tripolar stimulation to a stimulation site. Likewise, the anode (271-1) and one of the anodes (271-2) may be switched off when it is desired to deliver bipolar stimulation to a stimulation site. Finally, both of the anodes (271-2) may be switched off when it is desired to deliver monopolar stimulation to a stimulation site.

[0123] As mentioned previously and as illustrated in FIG. 18, the stimulator (100) may be coupled to a lead (280) having a number of electrode contacts (110) disposed thereon. In some examples, as shown in FIG. 18, a distal end of the lead (280) may be formed as a flat

surface (281), referred to herein as a paddle. As shown in FIG. 18, one or more of the electrodes (110) may be disposed on the surface of the paddle (281). The lead (280) is implanted such that one or more of the electrodes (110) are in communication with a stimulation site. As used herein and in the appended claims, the term "in communication with" refers to one of the electrodes (110) or other devices being adjacent, in the general vicinity, in close proximity, directly next to, or directly on the stimulation site such that a desired stimulation can be effectively delivered. It will be recognized that the lead (280) may alternatively be cylindrical in shape.

[0124] One of the difficulties that arises in using a lead (280) with an implantable stimulator (100) within a patient is determining the optimal stimulation parameters for that patient, both initially and over time. In particular, it is difficult to account for lead migration. Implanted stimulators are implanted, generally, on a long-term or permanent basis. However, with time and the natural movement of the patient, a lead from an implanted stimulator tends to move away from the location where it was first implanted. For example, a simple nod of the head may cause the position of a lead that is implanted in the neck to shift positions. This tendency is known as lead migration, or simply, migration.

[0125] As the lead moves or migrates, the stimulator may continue to operate under the same stimulation parameters and output the same stimulus. However, because the position of the stimulator and/or its lead(s) has changed due to migration, the resulting stimulation experienced by the patient may be different. This may result due to a change in tissue impedance or distance or orientation of the electrodes caused by migration relative to the stimulation site. Consequently, lead migration may render the lead unable to provide the optimal treatment with minimal power consumption that was realized when the lead was more properly positioned.

[0126] In some examples, adjustment in the stimulation parameters as migration occurs may compensate for the change in position and allow the stimulator to continue to provide effective treatment. In some examples, as will be described in more detail below, a technique known as "current steering" may be used to determine the optimal stimulation parameters and/or compensate for lead migration. Current steering is also know as neuronavigation or e-trolling. As used herein and in the appended claims, the term "current steering" will be used to describe a process used to determine the optimal stimulation parameters for a particular patient.

[0127] In some examples, current steering may be performed by testing a number of combinations of anodes and cathodes until the optimal cathode-anode configuration is found. It will be recognized that the current may be steered in any path as best serves a particular application and that other stimulation parameters (e.g., frequency, pulse width, amplitude, burst pattern (e.g., burst on time and burst off time), duty cycle or burst repeat interval, ramp on time, and/or ramp off time) may additionally or alternatively be adjusted to determine the optimal stimulation parameters for a particular application. Moreover, it will be recognized that the current steering methods described herein may be used with any of the electrode configurations described herein.

[0128] In some examples, current steering may be used when the electrodes (110) and stimulator (100) are initially implanted within the patient to determine the initial stimulation parameters that are best suited for the particular patient. Additionally or alternatively, the current steering methods and systems described herein may be used subsequently to account for lead migration and other changes within the patient that may occur after implantation.

[0129] In some examples, current steering may be performed automatically with a computerized programming station or another suitable programming device. The programming device may include a self-contained hardware/software system, or it may include software running on a standard personal computer (PC). In some examples, the programming device is included within the stimulator (100).

[0130] In some alternative examples, current steering may be performed manually. For example, a physician or patient may manually steer the current with the aid of a computer, hand-held programmer, joystick, or other device.

[0131] FIG. 19 illustrates an exemplary implanted stimulator (100) and examples of the various systems and external devices that may be used communicate with and/or transfer power to the stimulator (100). For example, an external battery charging system (EBCS) (291) may provide power used to recharge the power source (102) via an RF link (292). External devices including, but not limited to, a hand held programmer (HHP) (295), clinician programming system (CPS) (297), and/or a manufacturing and diagnostic system (MDS) (293) may be configured to activate, deactivate, program, and test the stimulator (100) via one or more RF links (294, 296). It will be recognized that the RF links (292, 294, 296) may be any type of link such as an optical link, a thermal link, or any other energy-coupling link.

[0132] Additionally, if multiple external devices are used in the treatment of a patient, there may be some communication among those external devices, as well as with the

implanted stimulator (100). For example, the CPS (297) may communicate with the HHP (295) via an infrared (IR) link (298), with the MDS (293) via an IR link (300), and/or directly with the stimulator (100) via an RF link (290). These communication links (290, 298, 300) are not limited to IR and RF links and may include any other type of communication link. Likewise, the MDS (293) may communicate with the HHP (295) via an IR link (299) or via any other suitable communication link.

[0133] The HHP (295), MDS (293), CPS (297), and EBCS (291) are merely illustrative of the many different external devices that may be used in connection with the stimulator (100). Furthermore, it will be recognized that the functions performed by any two or more of the HHP (295), MDS (293), CPS (297), and EBCS (291) may be performed by a single external device. One or more of the external devices (293, 295, 297) may be embedded in a seat cushion, mattress cover, pillow, garment, belt, strap, pouch, or the like so as to be positioned near the implanted stimulator (100) when in use.

[0134] The stimulator (100) of FIG. 19 may be configured to operate independently. Alternatively, as will be described in more detail below, the stimulator (100) may be configured to operate in a coordinated manner with one or more additional stimulators, other implanted devices, or other devices external to the patient's body.

[0135] To determine the strength and/or duration of electrical stimulation required to most effectively treat a particular medical condition, various indicators of the medical condition and/or a patient's response to treatment may be sensed or measured. These indicators include, but are not limited to, muscle or limb activity (e.g., electromyography (EMG)), electrical activity of the brain (e.g., EEG), neurotransmitter levels, hormone levels, and/or medication levels. In some embodiments, the stimulator (100) may be configured to change the stimulation parameters in a closed loop manner in response to these measurements. The stimulator (100) may be configured to perform the measurements. Alternatively, other sensor devices may be configured to perform the measurements and transmit the measured values to the stimulator (100).

[0136] Thus, it is seen that one or more external appliances may be provided to interact with the stimulator (100), and may be used to accomplish at least one or more of the following functions:

[0137] Function 1: If necessary, transmit electrical power to the stimulator (100) in order to power the stimulator (100) and/or recharge the power source (102).

[0138] Function 2: Transmit data to the stimulator (100) in order to change the stimulation parameters used by the stimulator (100).

[0139] Function 3: Receive data indicating the state of the stimulator (100) (e.g., battery level, stimulation parameters, etc.).

[0140] Additional functions may include adjusting the stimulation parameters based on information sensed by the stimulator (100) or by other sensing devices.

[0141] By way of example, an exemplary method of treating a particular medical condition within a patient may be carried out according to the following sequence of procedures. The steps listed below may be modified, reordered, and/or added to as best serves a particular application.

[0142] 1. A stimulator (100) is implanted so that one or more of its electrode contacts are in communication with a stimulation site.

[0143] 2. The stimulator (100) is programmed to apply electrical stimulation to the stimulation site.

[0144] 3. When the patient desires to invoke stimulation, the patient sends a command to the stimulator (100) (e.g., via a remote control) such that the stimulator (100) delivers the prescribed stimulation. The stimulator (100) may be alternatively or additionally configured to automatically apply the stimulation in response to sensed indicators of a particular medical condition.

[0145] 4. To cease stimulation, the patient may turn off the stimulator (100) (e.g., via a remote control).

[0146] 5. Periodically, the power source (102) of the stimulator (100) is recharged, if necessary, in accordance with Function 1 described above.

[0147] For the treatment of any of the various types of medical conditions, it may be desirable to modify or adjust the algorithmic functions performed by the implanted and/or external components, as well as the surgical approaches. For example, in some situations, it may be desirable to employ more than one stimulator (100), each of which could be separately controlled by means of a digital address. Multiple channels and/or multiple patterns of electrical may thereby be used to treat multiple medical conditions.

[0148] For instance, as shown in the example of FIG. 20, a first stimulator (100) implanted beneath the skin (301) of the patient provides a stimulus to a first location; a second stimulator (100') provides a stimulus to a second location; and a third stimulator (100") provides a stimulus to a third location. As previously mentioned, the implanted devices may operate independently or may operate in a coordinated manner with other implanted devices or other devices external to the patient's body. That is, an external controller (308) may be configured to

control the operation of each of the implanted devices (100, 100', and 100"). In some embodiments, an implanted device, e.g. stimulator (100), may control or operate under the control of another implanted device(s), e.g. stimulator (100') and/or stimulator (100"). Control lines (302-307) have been drawn in FIG. 20 to illustrate that the external controller (308) may communicate or provide power to any of the implanted devices (100, 100', and 100") and that each of the various implanted devices (100, 100', and 100") may communicate with and, in some instances, control any of the other implanted devices.

[0149] As a further example of multiple stimulators (100) operating in a coordinated manner, first and second stimulators (100, 100') of FIG. 20 may be configured to sense various indicators of a particular medical condition and transmit the measured information to the third stimulator (100"). The third stimulator (100") may then use the measured information to adjust its stimulation parameters and apply electrical stimulation to a stimulation site accordingly.

[0150] Alternatively, the external controller (308) or other external devices communicating with the external device may be configured to sense various indicators of a patient's condition. The sensed indicators can then be transmitted to the external device (250) or to one or more implanted stimulators which may adjust stimulation parameters accordingly. In other examples, the external controller (308) may determine whether any change to stimulation parameters is needed based on the sensed indicators. The external device (250) may then signal a command to one or more of the stimulators to adjust stimulation parameters accordingly.

[0151] The stimulator (100) described herein may be implanted within a patient using any suitable surgical procedure such as, but not limited to, injection, small incision, open placement, laparoscopy, or endoscopy. In some examples, the stimulator (100) may be implanted within a patient with a surgical tool such as a hypodermic needle, bore needle, or any other tool specially designed for the purpose.

[0152] The stimulator (100) described herein may be used in the treatment of a wide variety of different medical, psychiatric, and neurological conditions and/or disorders. Moreover, it will be recognized that stimulation may be applied with the stimulator (100) to any nerve, tissue, organ, or other site within the patient to treat any medical condition or disorder.

[0153] The preceding description has been presented only to illustrate and describe embodiments of the invention. It is not intended to be exhaustive or to limit the invention to any precise form disclosed. Many modifications and variations are possible in light of the above teaching.

WHAT IS CLAIMED IS:

1. An implantable stimulator, said stimulator comprising:

a main assembly (120) configured to house one or more components configured to generate and apply at least one stimulus to at least one stimulation site within a patient;

wherein said main assembly (120) has a shape allowing said stimulator to be implanted within said patient in a pre-determined orientation.

2. The stimulator of claim 1, further comprising:

a electrode assembly (150) having one or more electrodes (110) disposed thereon;

wherein said electrode assembly (150) is coupled to said main assembly (120) such that said electrodes (110) extend along one or more sides of said main assembly (120); and

wherein said stimulus comprises a stimulation current delivered via one or more of said electrodes (110).

3. The stimulator of claim 2, wherein said electrode assembly (150) is made out of a polymer film.

4. The stimulator of claim 2, further comprising a feed through assembly (150) coupled to said main assembly (120) and to said electrode assembly (150), said feed through assembly (150) comprising one or more conductive feed throughs (151) configured to electrically couple one or more of said components housed within said main assembly (120) to said electrodes (110) disposed on said electrode assembly (150).

5. The stimulator of claim 4, wherein said main assembly (120) comprises a first connecting ring (123) hermetically coupled to a proximal end thereof and wherein said feed through assembly (150) comprises a second connecting ring (125) coupled to a distal end thereof, wherein said first connecting ring (123) of said main assembly (120) is hermetically coupled to said second connecting ring (125) of said feed through assembly (150).

6. The stimulator of claim 2, wherein said electrode assembly (150) comprises a first member (172) with at least one of said electrodes (110) disposed thereon and a second member (173) with at least one of said electrodes (110) disposed thereon, said first member

(172) coupled to and extending along a first side of said main assembly (120) and said second member (173) coupled to and extending along a second side of said main assembly (120).

7. The stimulator of claim 2, wherein one or more of said electrodes (110) is programmable to have either a first polarity or a second polarity.

8. The stimulator of claim 7, wherein said stimulator further comprises a programming device configured to test different electrode polarity configurations in which a programmed polarity of one or more of said electrodes (110) is varied.

9. The stimulator of claim 1, further comprising a second assembly (121) coupled to said main assembly (120), wherein said second assembly (121) is configured to house a power source (102) configured to provide power for said components housed within said main assembly (120).

10. The stimulator of claim 1, further comprising an indifferent electrode disposed on an external surface of said main assembly (120).

11. The stimulator of claim 1, wherein said main assembly (120) is configured to allow passage therethrough of a magnetic field.

12. The stimulator of claim 1, wherein said components housed within said main assembly (120) comprise:

a programmable memory unit (103) for storing one or more stimulation parameters; and

electrical circuitry (101) configured to generate said stimulus, said stimulus comprising a stimulation current delivered to said stimulation site in accordance with said stimulation parameters.

13. The stimulator of claim 1, further comprising:

a sensor device for sensing at least one indicator related to a medical condition of said patient;

wherein said stimulator uses said at least one sensed indicator to adjust said stimulus applied to said at least one stimulation site.

14. The stimulator of claim 1, wherein said main assembly (120) comprises:

a substantially flat top surface (195);

a substantially flat bottom surface (196) disposed opposite said top surface (195);

a first substantially rounded side surface (197) configured to physically couple said top and bottom surfaces (195, 196); and

a second substantially rounded side surface (198) disposed opposite said first side surface (197) and configured to physically couple said top and bottom surfaces (195, 196).

15. The stimulator of claim 1, further comprising:

a lead (280) coupled to said main assembly (120), said lead (280) having one or more electrodes (110) disposed thereon;

wherein said electrodes (110) are individually configurable to have said first polarity or said second polarity.

16. An implantable stimulator, said stimulator comprising:

a main assembly (120) having an external surface configured to house one or more components configured to generate and apply at least one stimulus to at least one stimulation site within a patient;

wherein said external surface of said main assembly (120) comprises:

a substantially flat top surface (195);

a substantially flat bottom surface (196) disposed opposite said top surface (195);

a first substantially rounded side surface (197) configured to physically couple said top and bottom surfaces (195, 196); and

a second substantially rounded side surface (198) disposed opposite said first side surface (197) and configured to physically couple said top and bottom surfaces (195, 196).

17. The stimulator of claim 16, further comprising:

at least one electrode contact array (190, 210, 220, 230, 240, 250, 260, 270) having multiple electrode contacts disposed on said external surface, wherein said electrode contacts are configured to have a first polarity; and

at least one additional electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) disposed on said external surface, wherein said at least one additional electrode

contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) is configured to have a second polarity;

wherein one or more of said electrode contacts disposed on said external surface are configured to deliver at least one or more of a monopolar stimulation and a multipolar stimulation.

18. The stimulator of claim 17, wherein said at least one electrode contact array comprises:

a first electrode contact array (190, 210, 220, 230, 240, 250, 260, 270) disposed on said substantially flat top surface (195); and

a second electrode contact array (190, 210, 220, 230, 240, 250, 260, 270) disposed on said substantially flat bottom surface (196).

19. The stimulator of claim 18, wherein said first and second electrode contact arrays (190, 210, 220, 230, 240, 250, 260, 270) are centered with reference to a width of said stimulator.

20. The stimulator of claim 18, wherein said first and second electrode contact arrays (190, 210, 220, 230, 240, 250, 260, 270) are offset from a center of a width of said stimulator.

21. The stimulator of claim 17, wherein said at least one additional electrode contact comprises:

a first electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) disposed on said substantially flat top surface (195); and

a second electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) disposed on said substantially flat bottom surface (196).

22. The stimulator of claim 17, wherein said at least one additional electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) is disposed on said first substantially rounded side surface (197).

23. The stimulator of claim 17, wherein said at least one additional electrode contact comprises:

a first electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) disposed on said first substantially rounded side surface (197); and

a second electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) disposed on said second substantially rounded side surface (198).

24. The stimulator of claim 17, wherein:

said at least one electrode contact array (190, 210, 220, 230, 240, 250, 260, 270) is disposed on said substantially flat top surface (195); and

said at least one additional electrode contact comprises a first electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) disposed on said substantially flat bottom surface (196) and a second electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) disposed on said substantially flat bottom surface (196).

25. The stimulator of claim 17, further comprising a cap assembly (122) coupled to a distal end of said main assembly (120), wherein said at least one additional electrode contact (191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) is disposed on said cap assembly (122).

26. The stimulator of claim 17, wherein said electrode contacts (190, 210, 220, 230, 240, 250, 260, 270, 191, 211, 221, 231, 241, 251, 261-1, 261-2, 271-1, 271-2) having said first polarity and said second polarity are configured to deliver at least one or more of a bipolar stimulation and a tripolar stimulation.

27. The stimulator of claim 17, wherein one or more of said multiple electrode contacts within said at least one electrode contact array (190, 210, 220, 230, 240, 250, 260, 270) are configured to have said second polarity.

28. The stimulator of claim 17, further comprising:

a lead (280) coupled to said main assembly (120), said lead (280) having one or more electrode contacts (110) disposed thereon;

wherein said electrode contacts (110) are individually configurable to have said first polarity or said second polarity.

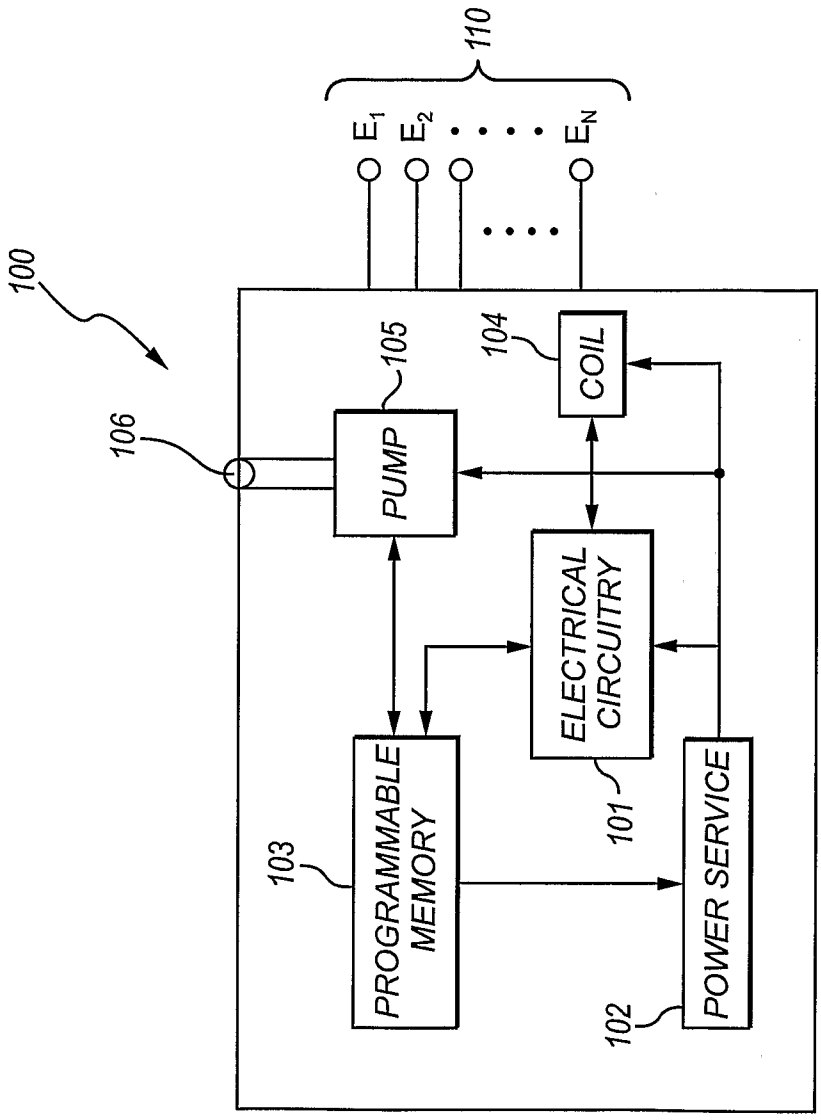
110
E1
E2
EN
100
105
104
COIL
106
PUMP
ELECTRICAL CIRCUITRY
PROGRAMMABLE MEMORY
103
101
POWER SERVICE
102

FIG. 1

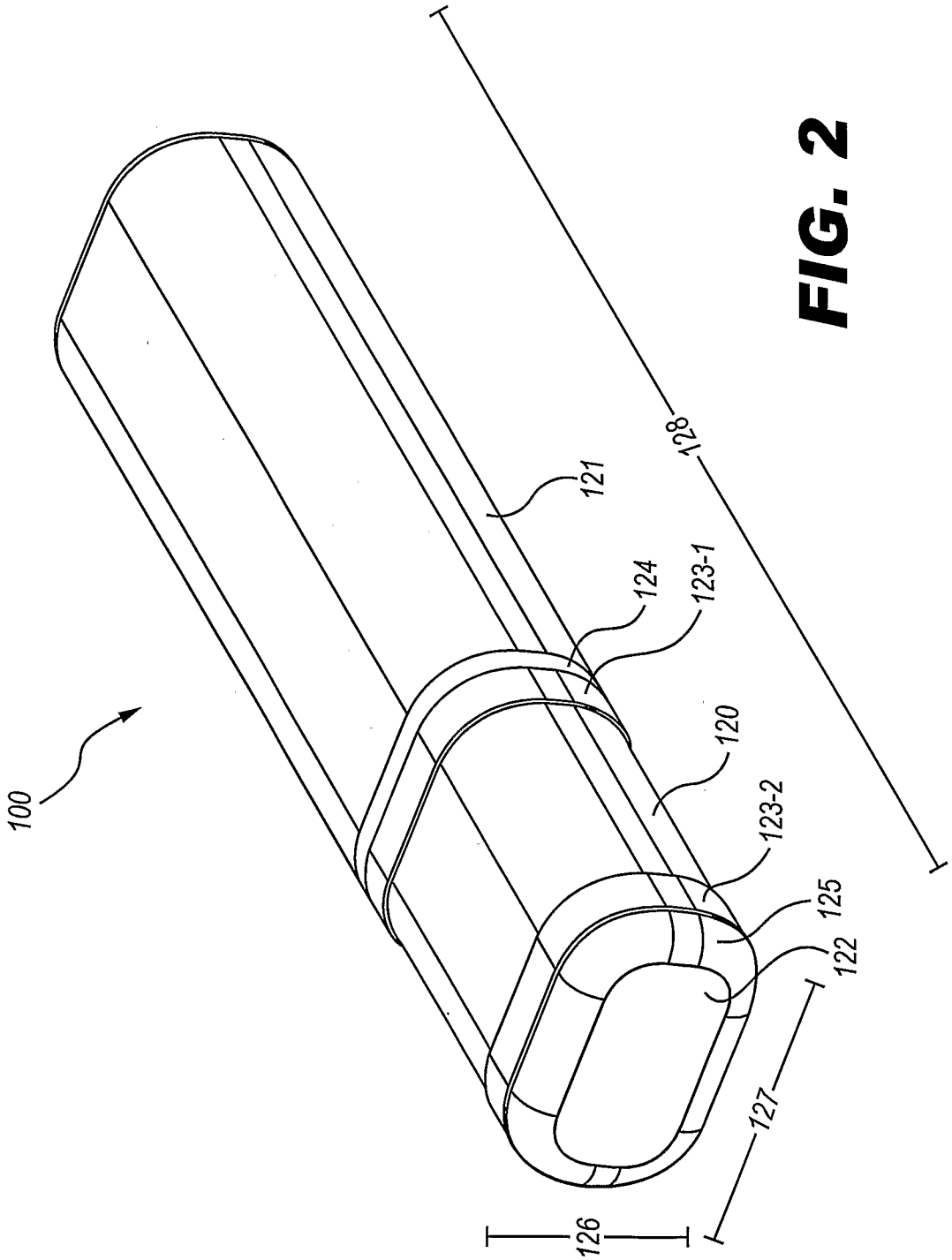

FIG. 2

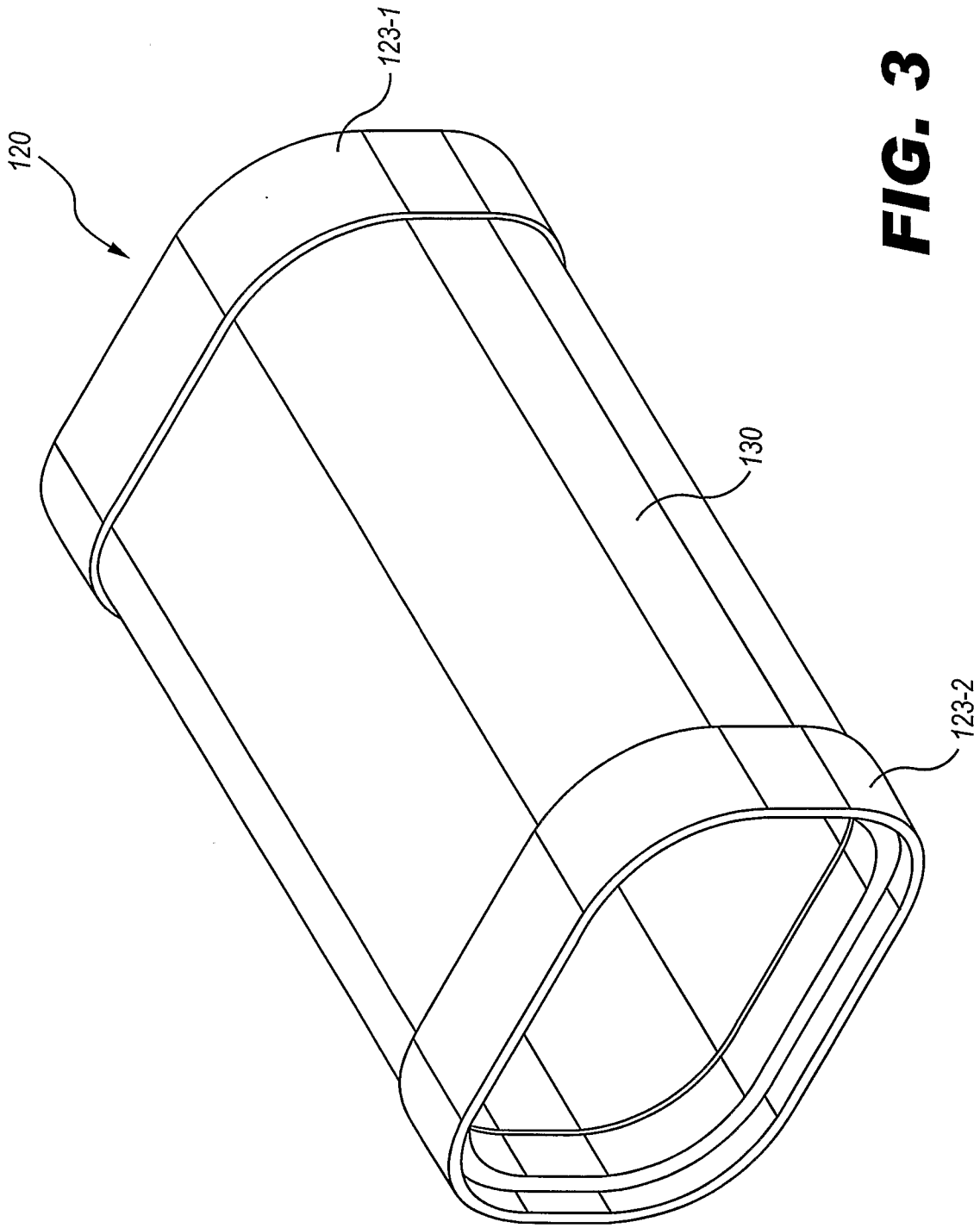

FIG. 3

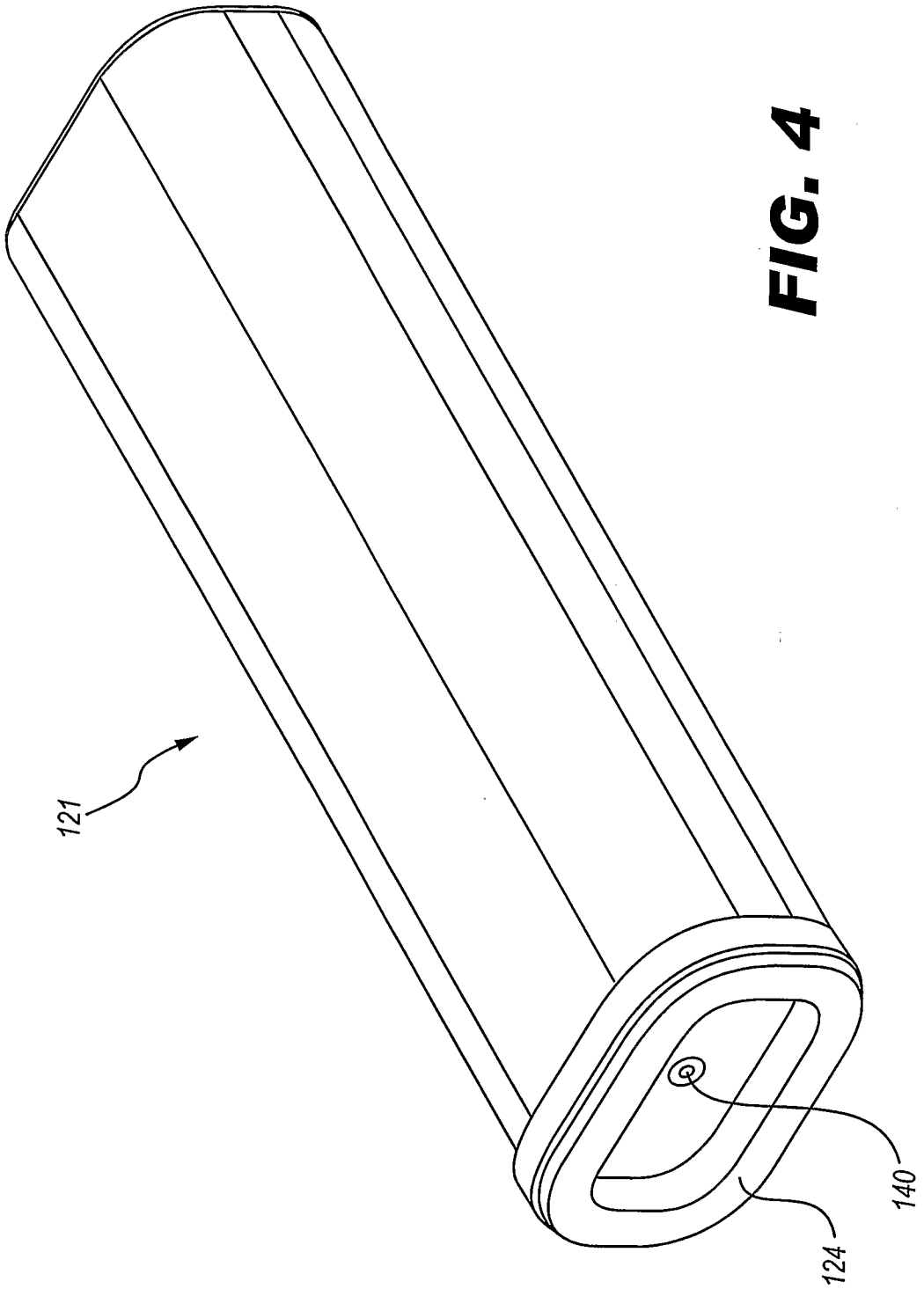

FIG. 4

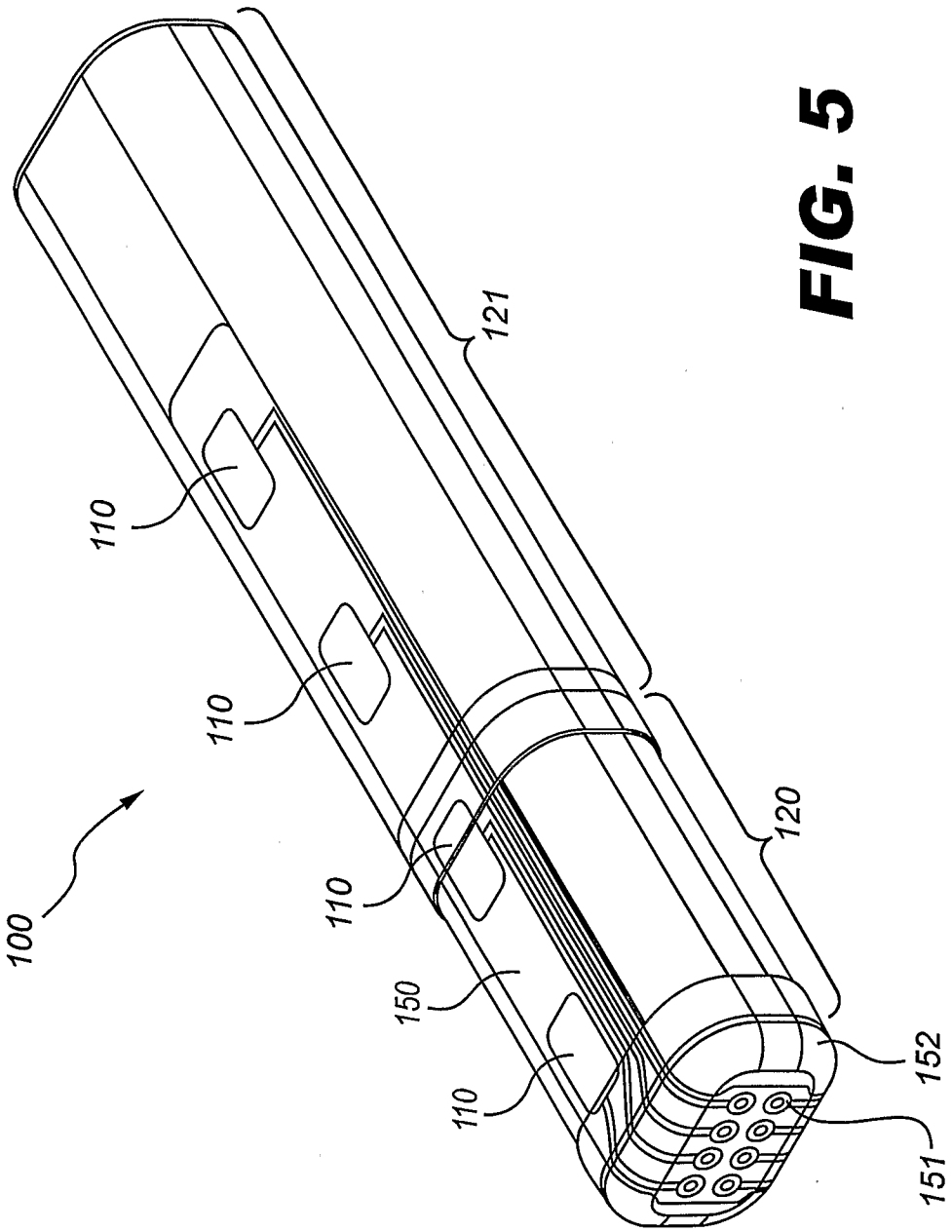

FIG. 5

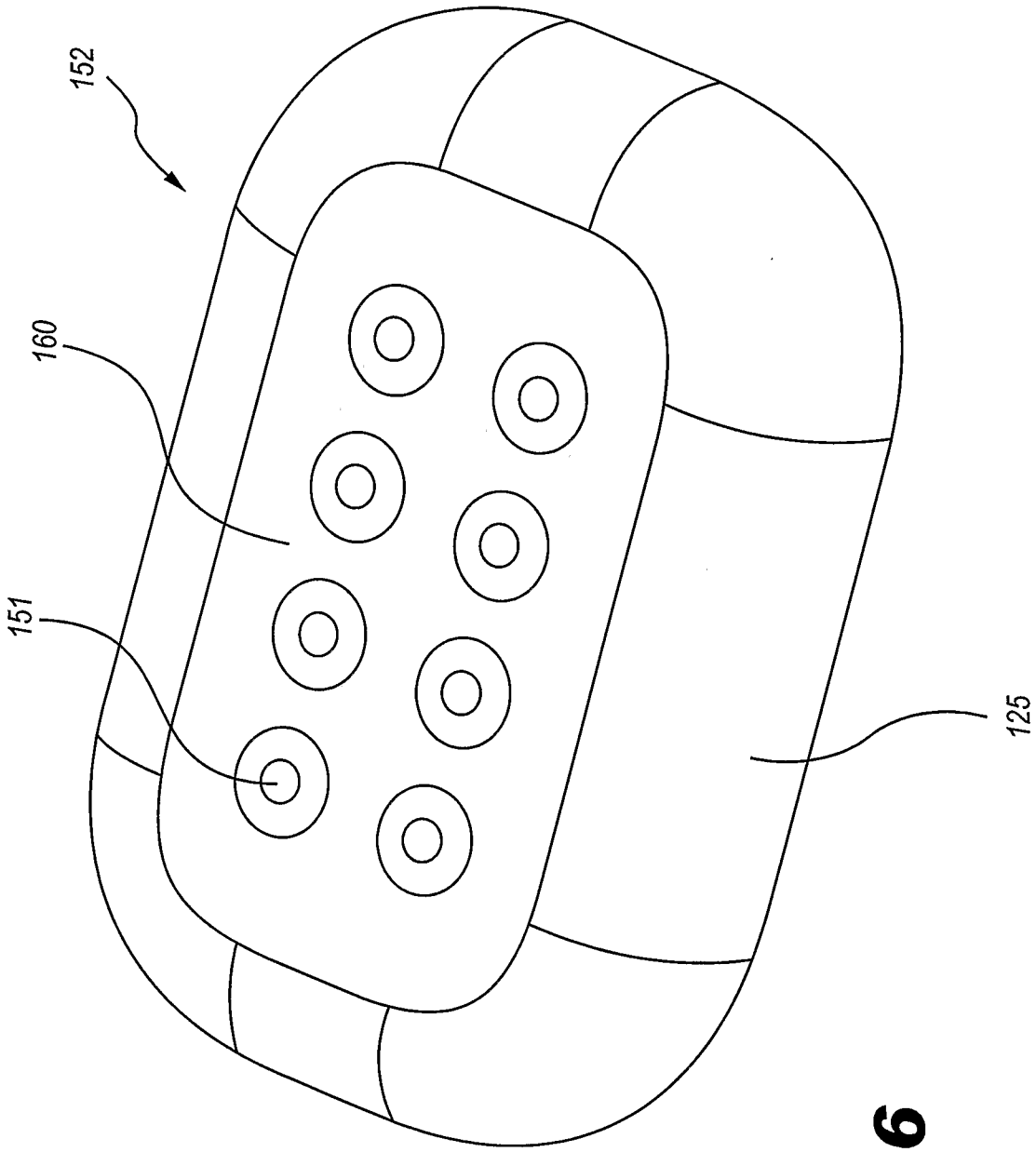

FIG. 6

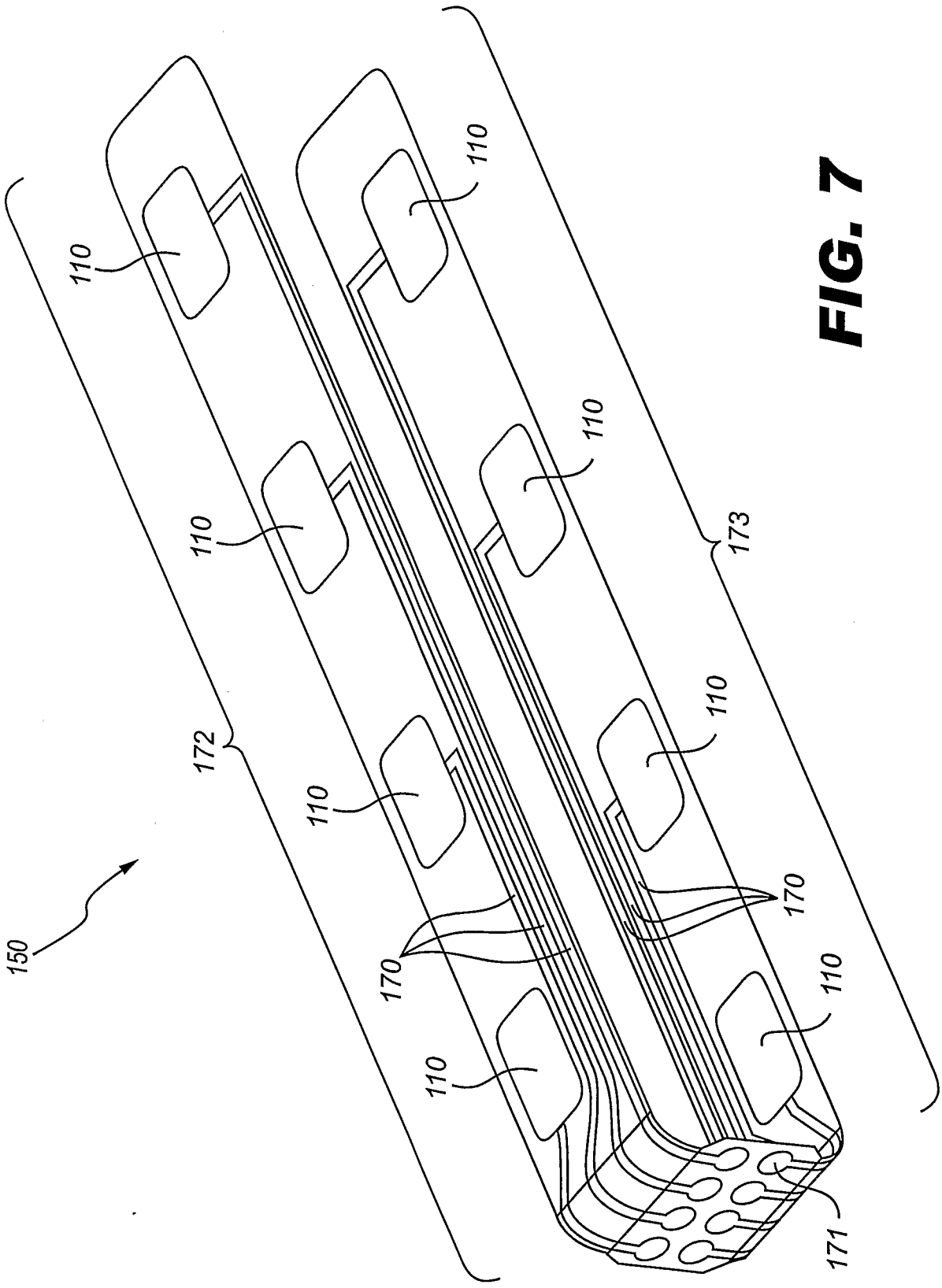

FIG. 7

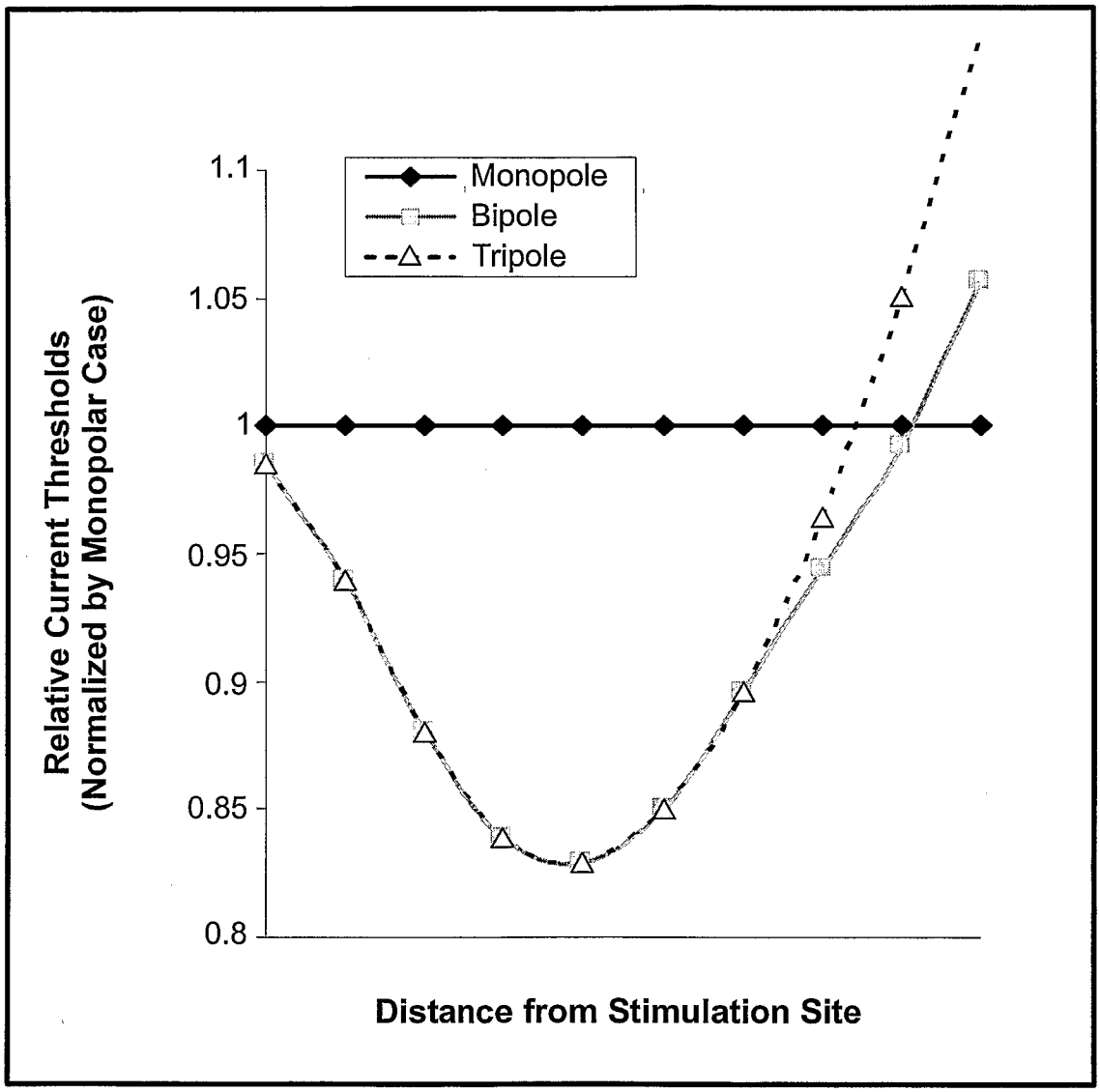
Monopole
Bipole
Tripole
1.1
1.05
1
0.95
0.9
0.85
0.8
Relative Current Thresholds
(Normalized by Monopolar Case)
Distance from Stimulation Site

FIG. 8

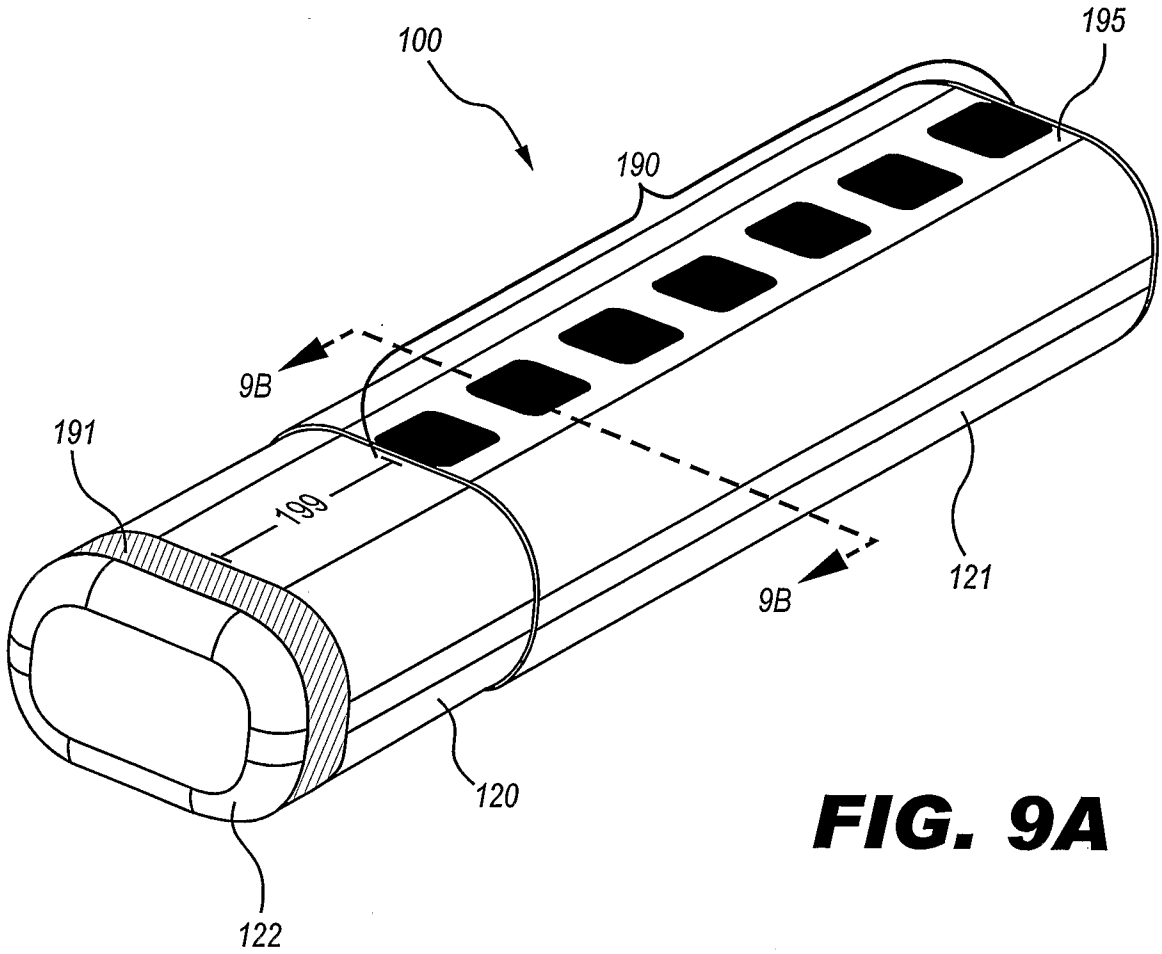
100
195
190
9B
191
199
9B
121
120
122

FIG. 9A

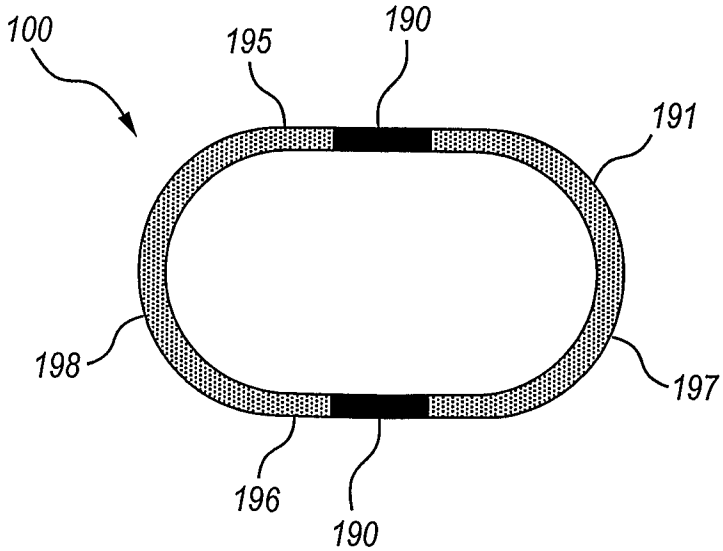
100
195
190
191
198
197
196
190

FIG. 9B

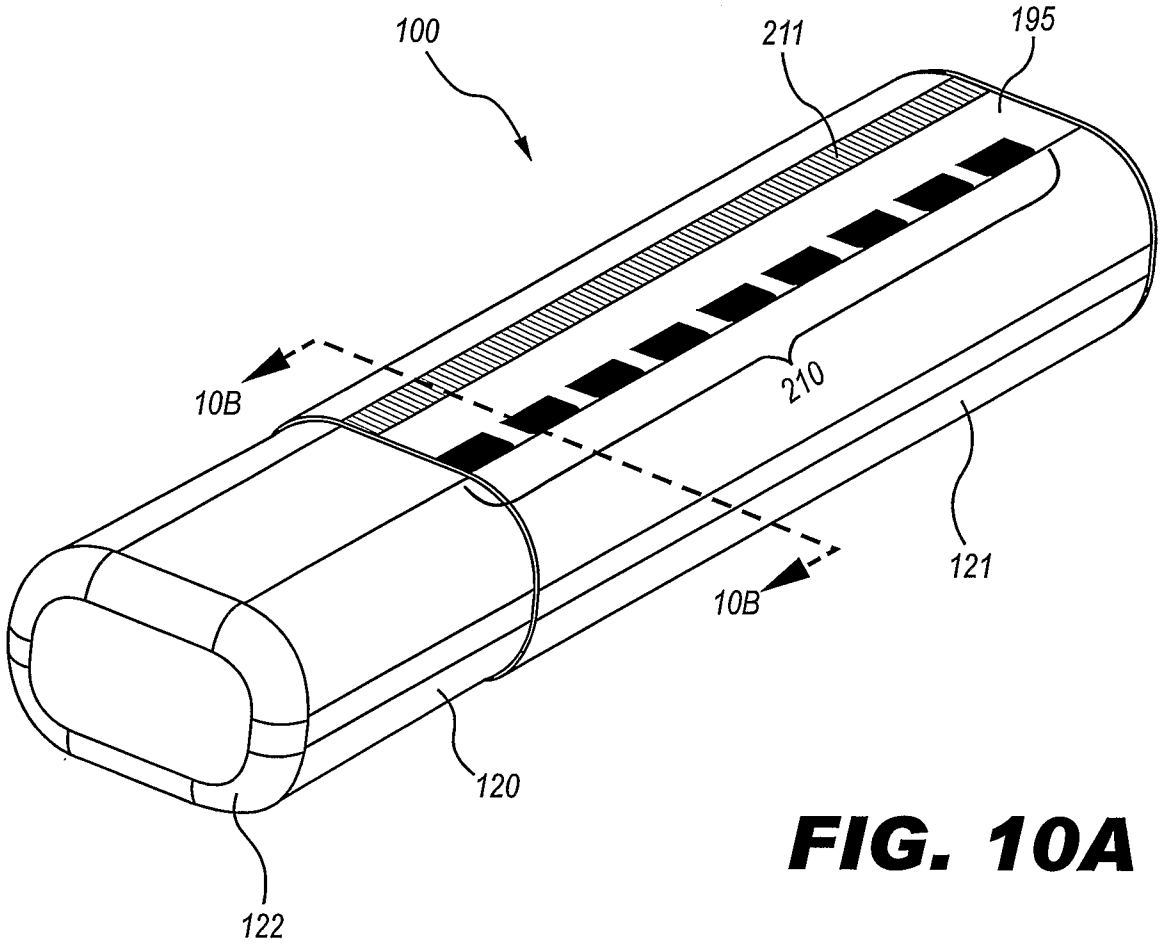

FIG. 10A

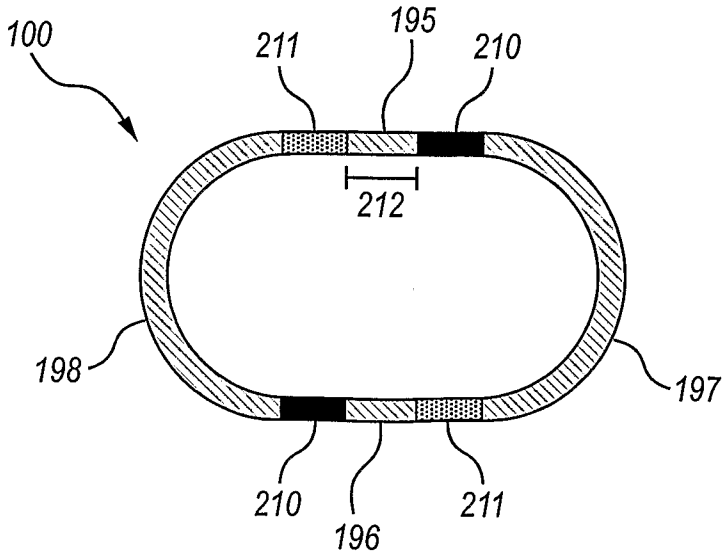

FIG. 10B

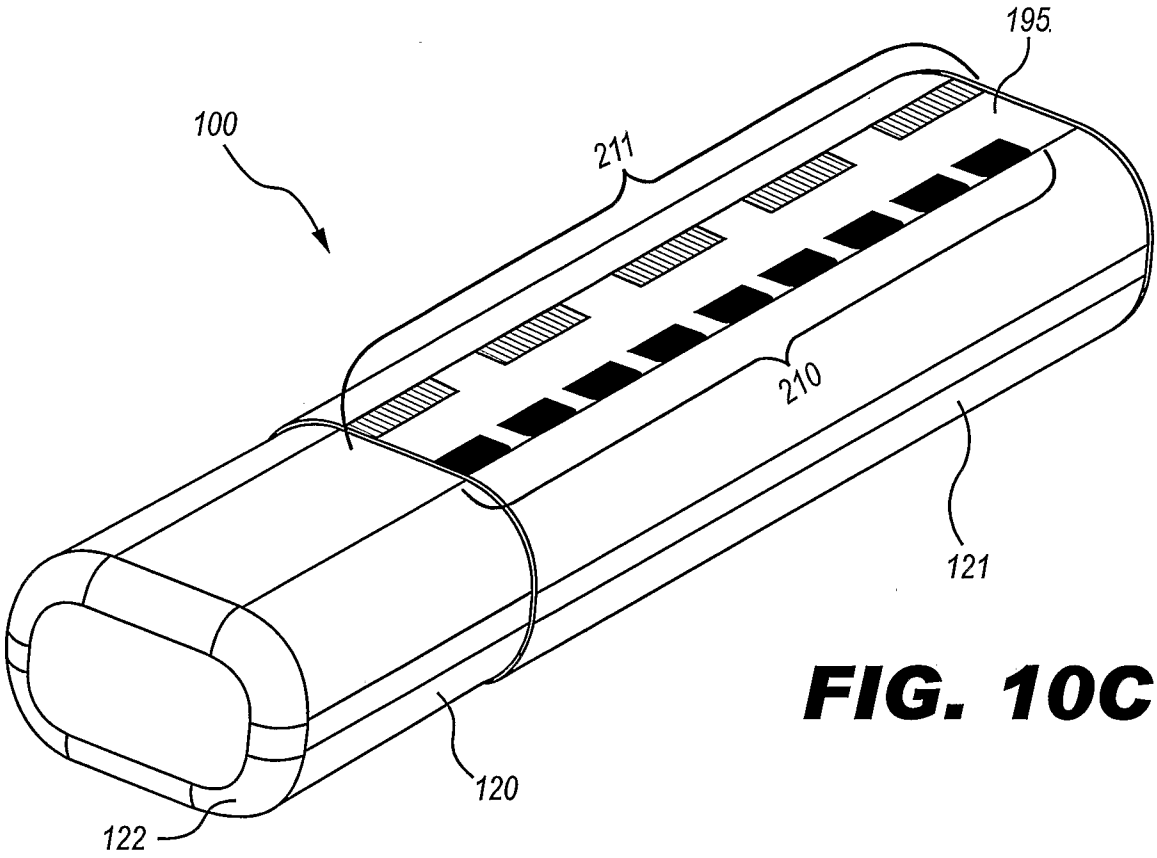

FIG. 10C

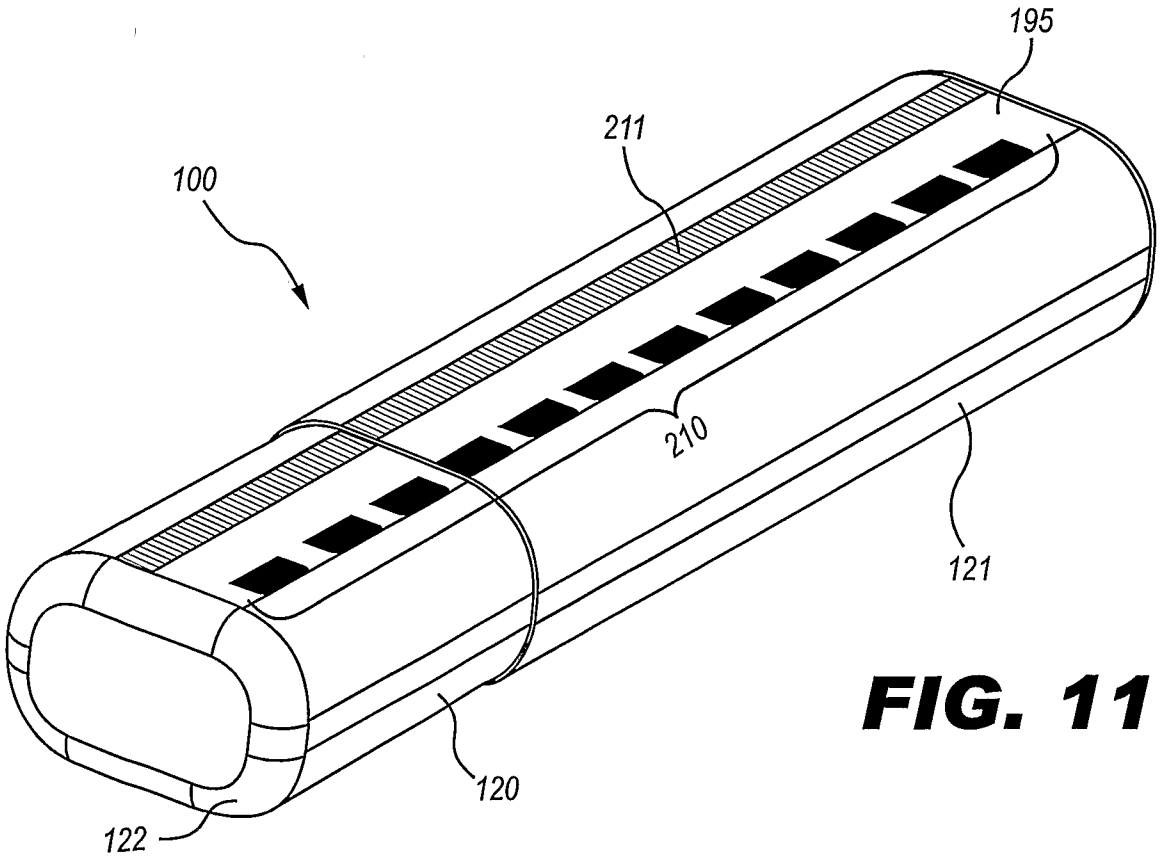

FIG. 11

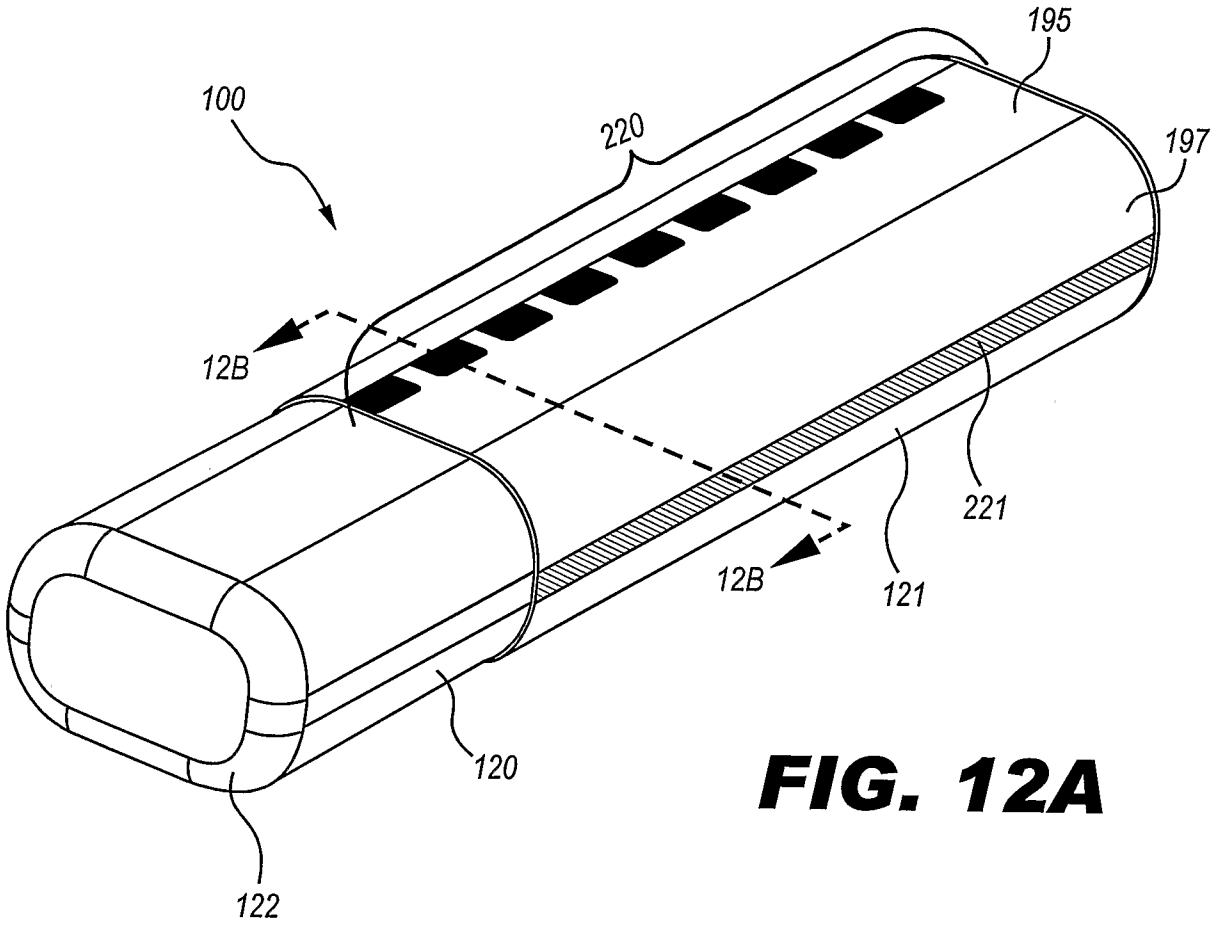

FIG. 12A

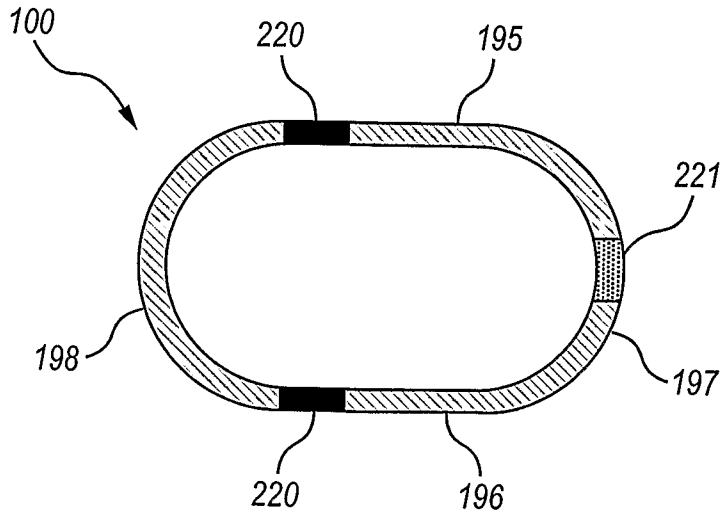

FIG. 12B

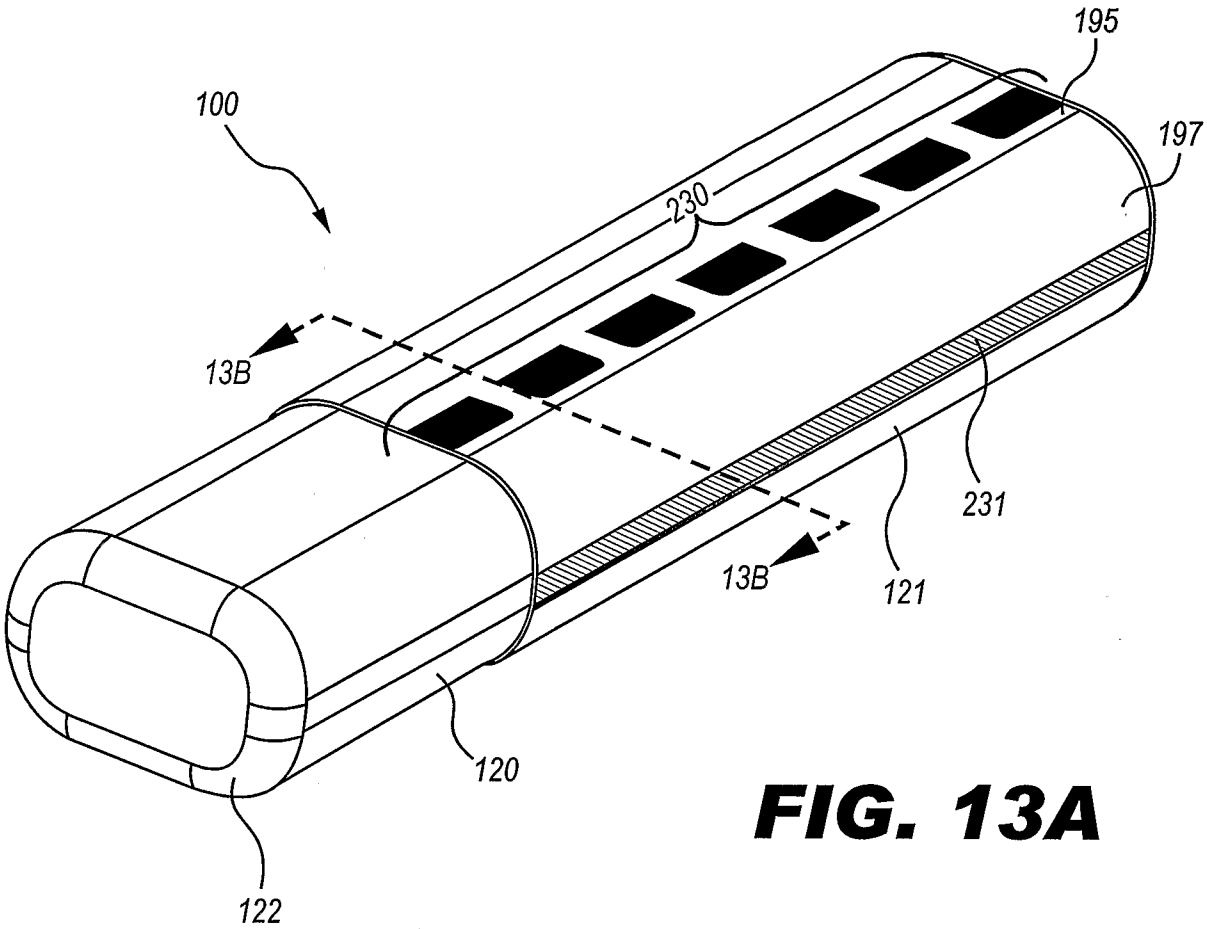

FIG. 13A

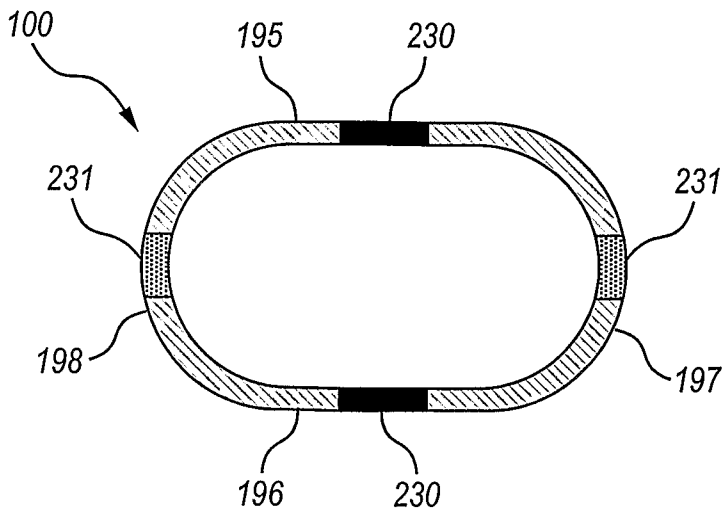

FIG. 13B

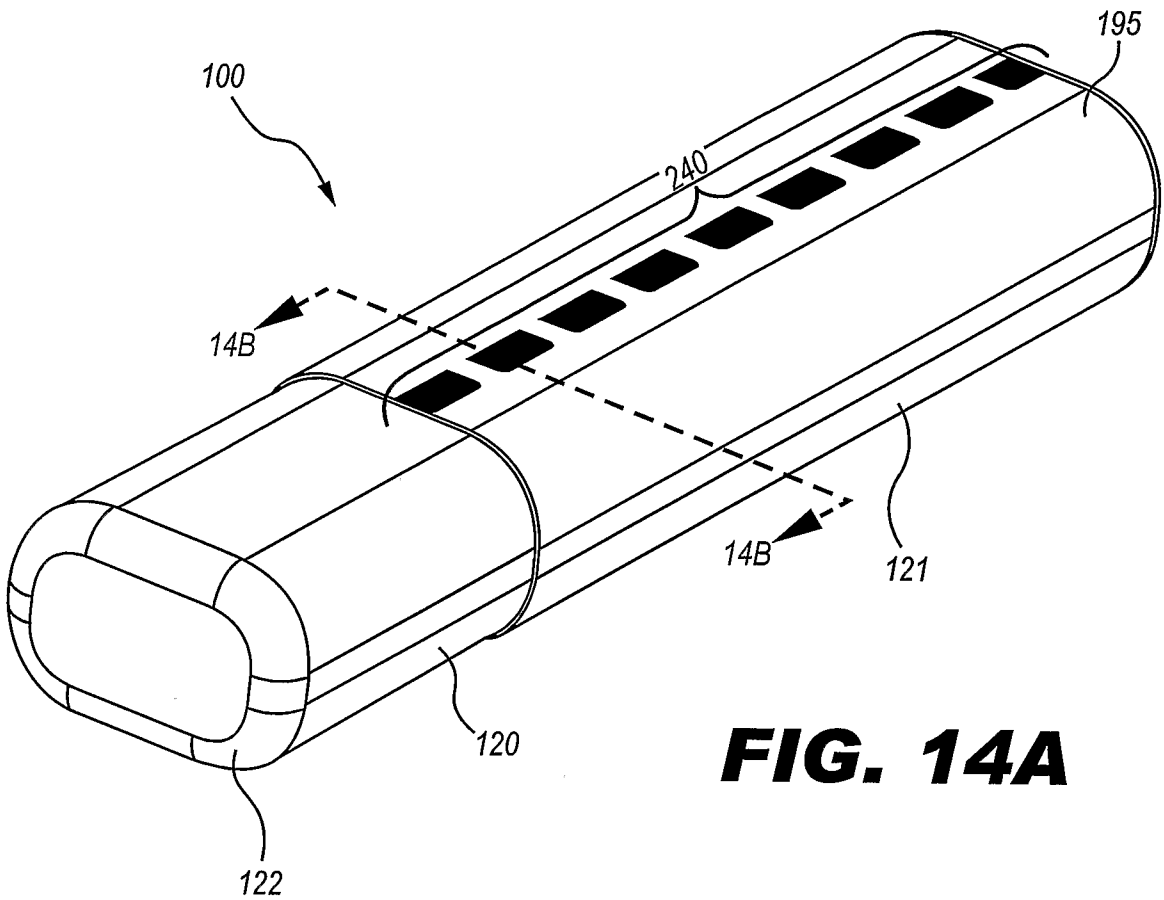

FIG. 14A

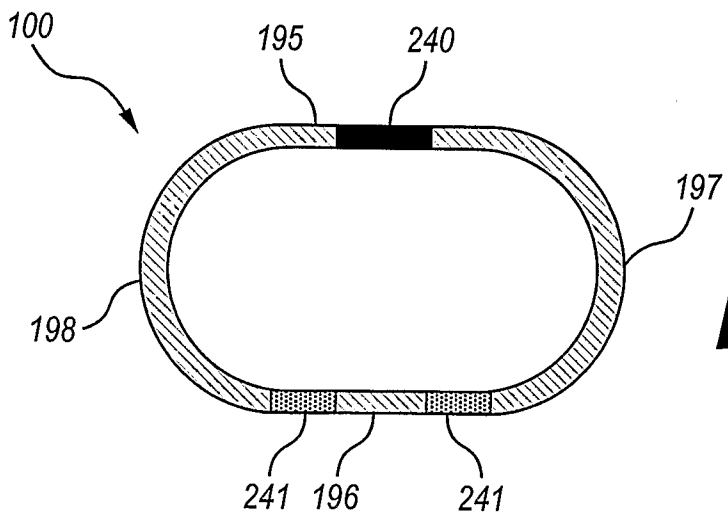

FIG. 14B

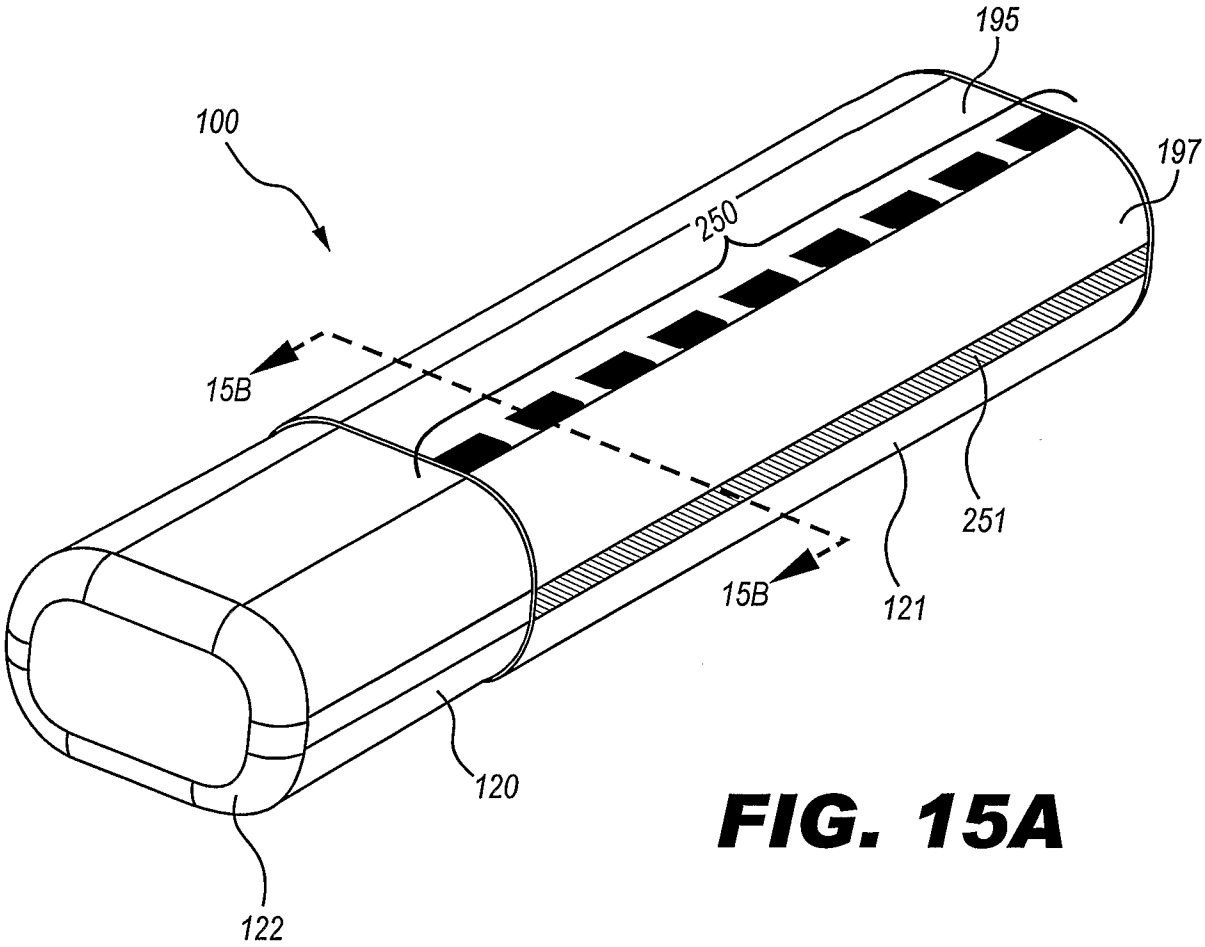

FIG. 15A

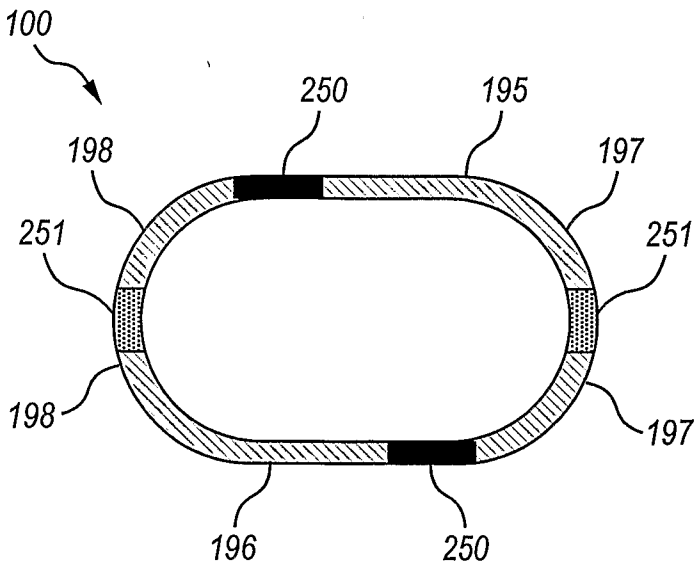

FIG. 15B

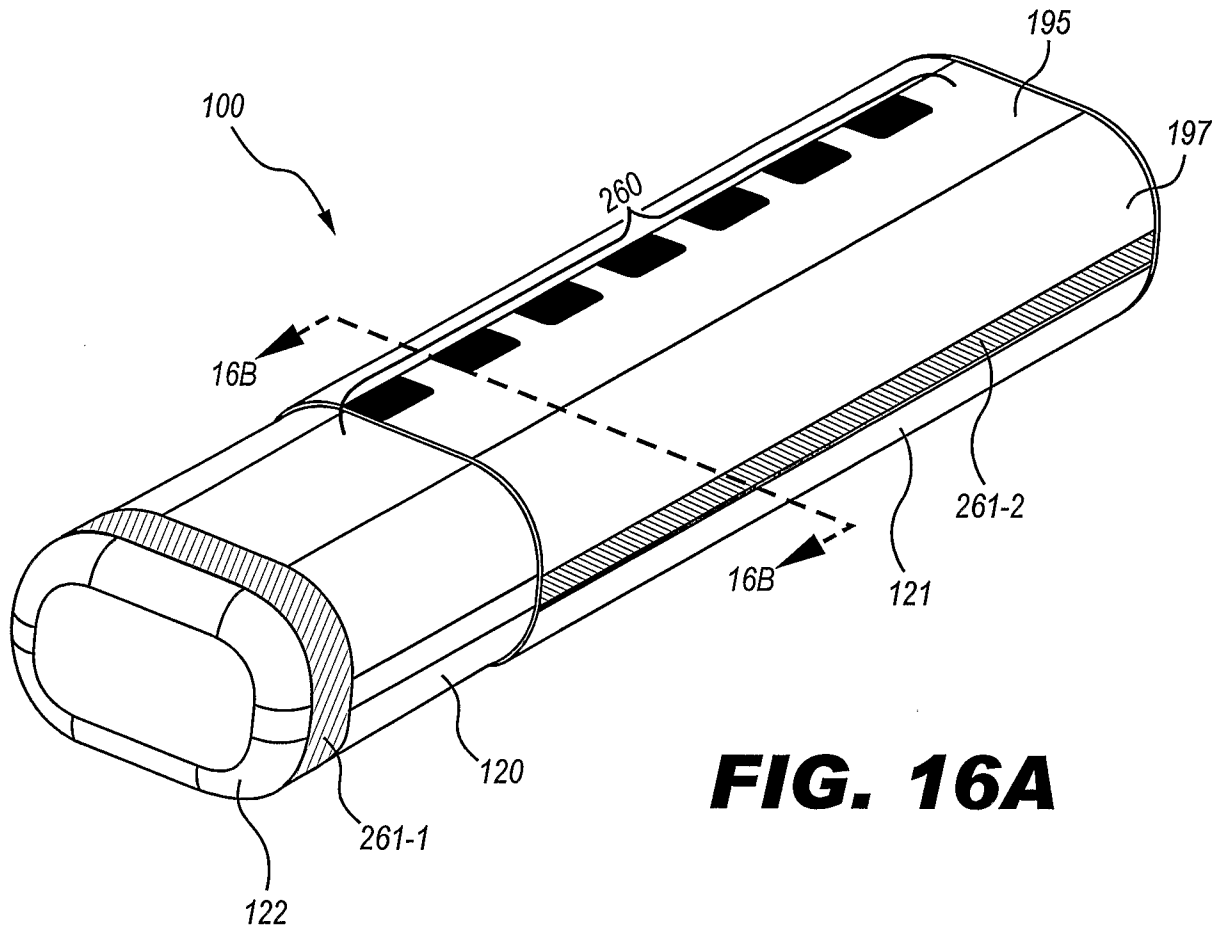

FIG. 16A

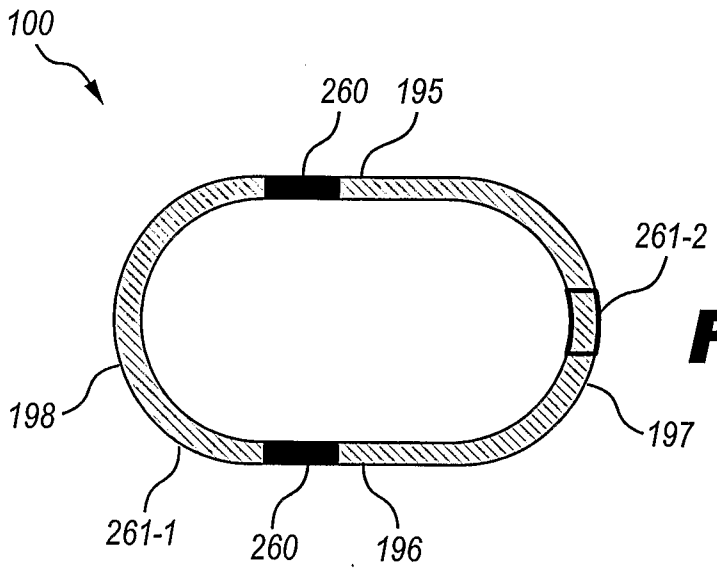

FIG. 16B

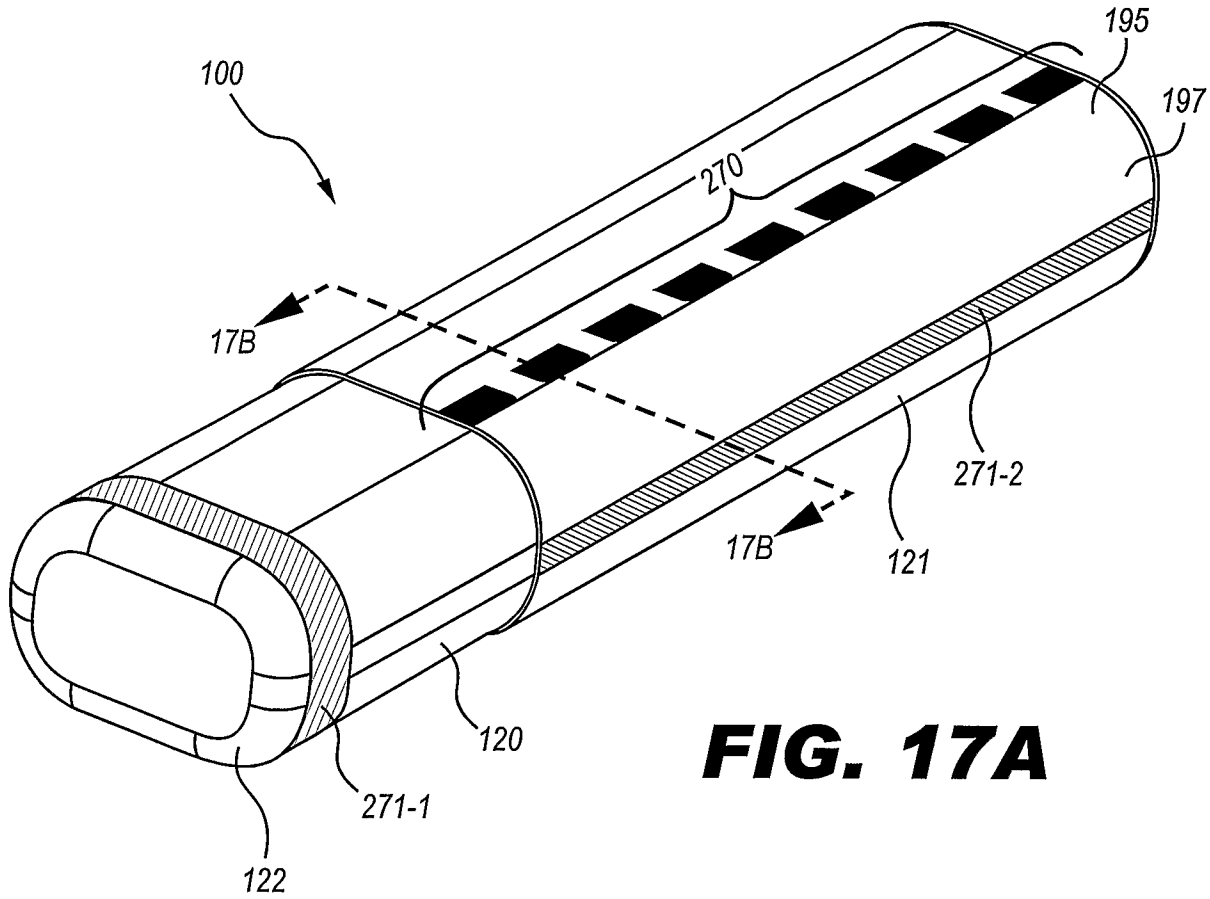

FIG. 17A

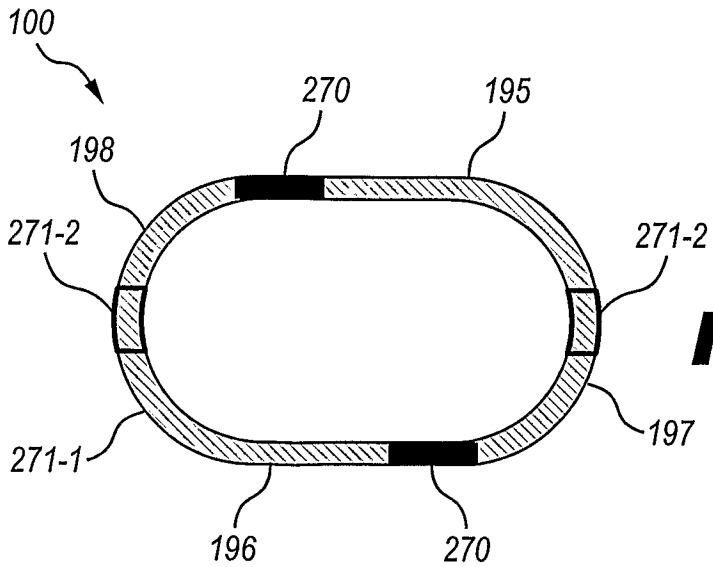

FIG. 17B

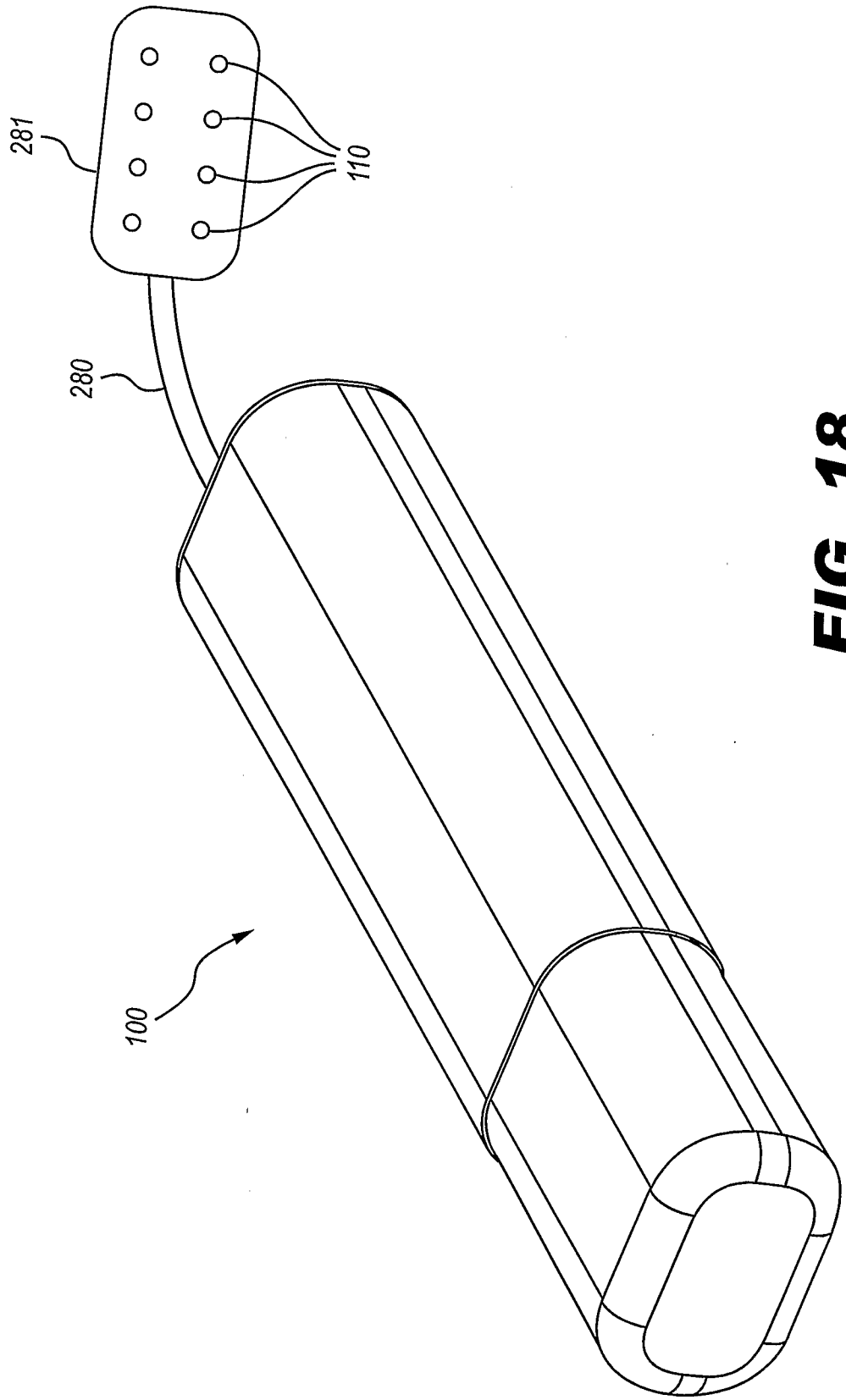

FIG. 18

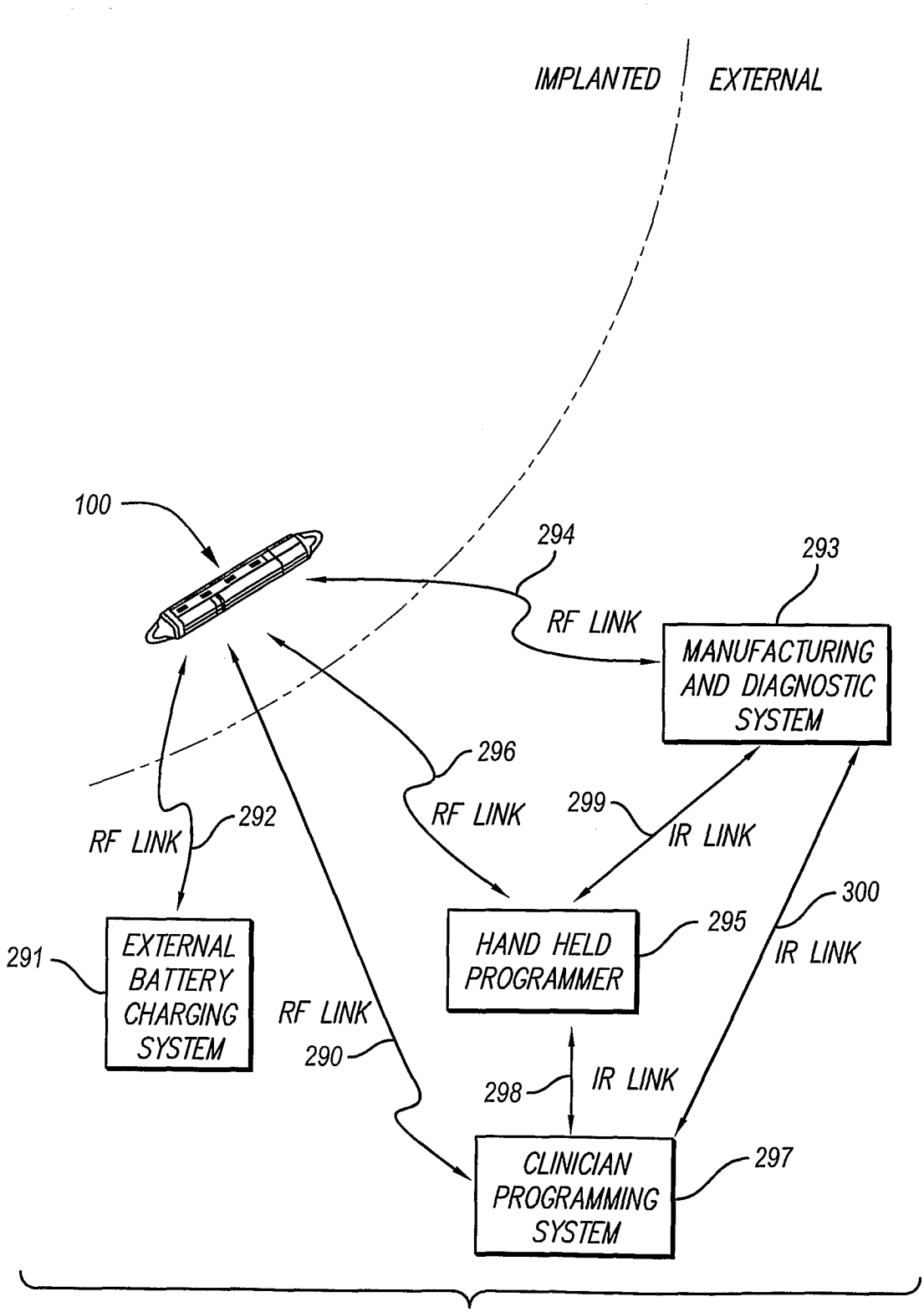
IMPLANTED
EXTERNAL
100
294
RF LINK
293
MANUFACTURING AND DIAGNOSTIC SYSTEM
296
RF LINK
299
IR LINK
RF LINK
292
300
IR LINK
291
EXTERNAL BATTERY CHARGING SYSTEM
HAND HELD PROGRAMMER
295
RF LINK
290
298
IR LINK
CLINICIAN PROGRAMMING SYSTEM
297

FIG. 19

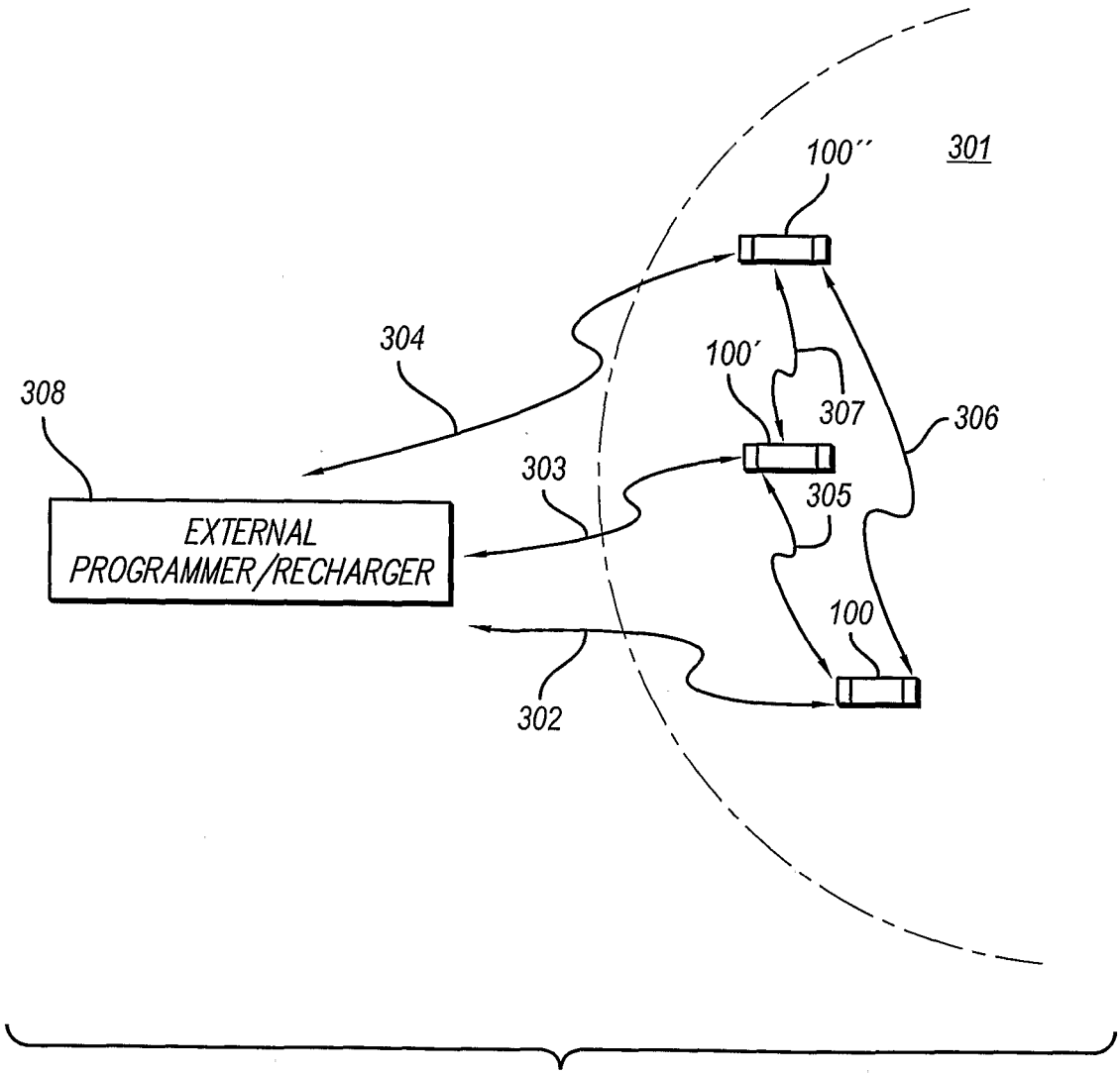
100''
301
304
100'
308
307
306
303
305
EXTERNAL
PROGRAMMER/RECHARGER
100
302

FIG. 20