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(54) **Title**: MAGNETIC RESONANCE IMAGING SHUNT ELECTRODES WITH SELF-HEALING COATINGS

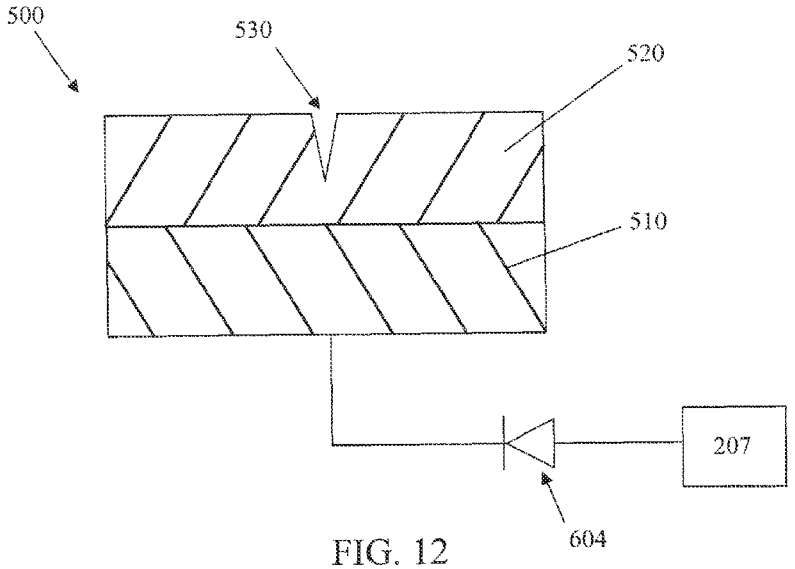


FIG. 12

(57) **Abstract**: Implantable medical device leads and electrode assemblies for use with implantable medical devices (IMDs) and medical device systems including such leads and electrode assemblies. An electrode assembly includes a shunted lead circuit configured to shunt currents induced by relatively high frequency radiation, such as MRI radiation. The shunted lead circuit includes a self-healing material that includes a conductive layer and a dielectric layer. Medical device systems that include an electrode assembly can be configured to control the regeneration rate of the self-healing material.

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MAGNETIC RESONANCE IMAGING SHUNT ELECTRODES WITH SELF-HEALING COATINGS

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/049,335, filed April 30, 2008, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The invention relates to medical devices and, more particularly, to implantable medical device leads and electrodes for use with implantable medical devices (IMDs).

BACKGROUND

[0003] In the medical field, implantable leads are used with a wide variety of medical devices. For example, implantable leads are commonly used to form part of implantable cardiac pacemakers that provide therapeutic stimulation to the heart by delivering pacing, cardioversion or defibrillation pulses. The pulses can be delivered to the heart via electrodes disposed on the leads, e.g., typically near distal ends of the leads. In that case, the leads may be used to position the electrodes with respect to various cardiac locations so that the pacemaker can deliver pulses to the appropriate locations. Leads are also used for sensing purposes, or for both sensing and stimulation purposes. Implantable leads are also used in neurological devices, muscular stimulation therapy, and devices that sense chemical conditions in a patient's blood or gastric system stimulators.

[0004] Another type of IMD is an implantable neurological stimulation device (sometimes referred to as an implantable neurostimulator or INS). INS devices can generate electrical stimulation signals that are used to influence the human nervous system or organs. Conventionally, the INS devices have been surgically implanted into a patient in a subcutaneous pocket in the abdomen, pectoral region, or upper buttocks area. Electrical contacts carried on the distal end of a lead are placed at the desired stimulation site (e.g., at a location in the spine or directly in the brain) and the proximal end of the lead is connected to the INS. The lead typically has one or more insulated electrical conductors (filers) that connect the electrical contacts, or electrodes, to the INS. For neurostimulation of the spine or brain, the leads may typically have 4 or 8 sets of conductors and electrodes.

[0005] It may be desirable to implant the INS at a location in the patient's head in cases where the distal end of the lead is provided at a site directly in the brain. For example, it may be desirable to implant the INS under the scalp on top of the patient's head (either on top of the surface of the skull or in a pocket formed in the skull).

[0006] Deep brain stimulation implants may be used for the treatment of a variety of diseases including epilepsy and Parkinson's Disease. In these devices, the electrodes are implanted in the brain of the patient to provide electric stimulation to affected regions of the brain.

[0007] Alternatively, the leads may be placed in the epidural region of the spine to stimulate the dorsal horn of the spinal cord for the treatment of pain, or other diseases such as angina.

[0008] Occasionally, patients that have implantable leads may benefit from a magnet resonance image (MRI) being taken of a particular area of his or her body, such as to monitor a disease or to diagnose an unrelated injury or disorder. MRI systems use radio frequency radiation in the presence of a strong magnetic field to produce diagnostic images of the patient. MRI techniques can achieve an effective image of the soft tissues of the heart and vascular system. MRI procedures can also image these features without delivering a high dosage of radiation to the body of the patient, and as a result, MRI procedures may be repeated reliably and safely. However, MRI devices may operate at frequencies of 10 megahertz or higher, which may cause energy to be transferred to the lead and can produce a voltage that can interact with surrounding tissue.

BRIEF DESCRIPTION OF DRAWINGS

[0009] Aspects and features of the present invention will be appreciated as the same becomes better understood by reference to the following detailed description of the embodiments of the invention when considered in connection with the accompanying drawings, wherein:

[0010] FIGURE 1 is a schematic view of an implantable medical device placed in a human body.

[0011] FIGURE 2 is a schematic view of another implantable medical device placed in a human body.

[0012] FIGURE 3 is a conceptual perspective view of a medical device system including a medical device coupled to a lead according to an embodiment of the present invention.

[0013] FIGURE 4 is a cross-sectional view of one embodiment of an electrode assembly located at a distal end of a medical lead.

[0014] FIGURE 5 depicts multiple layers of insulating material over a conductive element of the electrode assembly depicted in FIGURE 4.

[0015] FIGURE 6A depicts a cross-sectional view of a conductive ring coupled to a conductive sealer for the electrode assembly depicted in FIGURE 4.

[0016] FIGURE 6B depicts a top view of a conductive ring coupled to a conductive sealer for the electrode assembly depicted in FIGURE 4.

[0017] FIGURE 6C depicts an exploded view of conductive members, specifically conductive rings and a conductive sealer coupled to a shaft.

[0018] FIGURE 6D depicts an angled view of a conductive sealer.

[0019] FIGURE 7A depicts a cross-sectional view of an electrode assembly with a magnetostrictive element integrated into the electrical circuit for the electrode.

[0020] FIGURE 7B depicts a cross-sectional view of an electrode assembly with a magnetostrictive element integrated into the electrical circuit for the electrode wherein an open circuit condition exists.

[0021] FIGURE 8A is a schematic diagram of a simplified bipolar circuit for a medical device system under pacing and sensing conditions.

[0022] FIGURE 8B is a schematic unipolar circuit for a medical device system.

[0023] FIGURE 9A is a schematic bipolar circuit for a simplified medical device system.

[0024] FIGURE 9B is a schematic unipolar circuit for a simplified medical device system.

[0025] FIGURE 10 is a flow diagram that depicts the method of producing an electrode assembly.

[0026] FIGURE 11A is a cross-sectional view of materials that form a capacitor.

[0027] FIGURE 11B is a cross-sectional view of materials that form a capacitor, whereby one of the materials is damaged.

[0028] FIGURE 11C is a cross-sectional view of materials that form a capacitor, whereby the damage to one of the materials has been repaired or healed.

[0029] FIGURE 12 is a schematic of a capacitor and diode arrangement.

[0030] FIGURE 13A is a schematic bipolar circuit for a simplified medical device system containing a capacitor and diode arrangement.

[0031] FIGURE 13B is a schematic unipolar circuit for a simplified medical device system containing a capacitor and diode arrangement.

DETAILED DESCRIPTION

[0032] The present invention is directed to a medical lead, techniques for manufacturing such a lead, and systems that include a medical device coupled to a medical lead according to the present invention.

[0033] FIG. 1 illustrates a schematic view of a medical device system 100 (e.g., an implantable medical device or IMD) implanted within a body or torso 132 of a patient 130. The medical device system 100 may include electrodes having thermally and/or magnetorestrictive sensitive switches. The medical device system 100 includes a device 110 in the form of an implantable medical device that for purposes of illustration is shown as a defibrillator configured to provide a therapeutic high voltage (e.g., 700 volt) treatment for the patient 130.

[0034] The device 110 includes a container or housing 102 that is hermetically sealed and biologically inert according to an exemplary embodiment. The container may be made of a conductive material. One or more leads 106 electrically connect the device 110 to an organ or tissue such as the patient's heart 120 via a vein 122. Electrodes are provided to sense cardiac activity of the organ or tissue and/or provide an electrical potential to the organ or

tissue such as the heart 120. At least a portion of the leads 106 (e.g., an end portion of the leads shown as exposed electrodes 111 attached to heart tissue 112) may be provided adjacent or in contact with one or more of a ventricle and an atrium of the heart 120.

[0035] The device 110 includes a battery 140 provided therein to provide power for the device 110. The size and capacity of the battery 140 may be chosen based on a number of factors, including the amount of charge required for a given patient's physical or medical characteristics, the size or configuration of the device, and any of a variety of other factors. According to an exemplary embodiment, the battery is a 5 mAh battery. According to another exemplary embodiment, the battery is a 300 mAh battery. According to various other exemplary embodiments, the battery may have a capacity of between approximately 10 and 1000 mAh.

[0036] According to another exemplary embodiment shown in FIG. 2, an implantable neurological stimulation device 150 (an implantable neurostimulator or INS) may include a battery 162 such as those described above with respect to the various exemplary embodiments. Examples of some neurostimulation products and related components are shown and described in a brochure titled "Implantable Neurostimulation Systems" available from Medtronic, Inc.

[0037] An INS generates one or more electrical stimulation signals that are used to influence the human nervous system or organs. Electrical contacts carried on the distal end of a lead are placed at the desired stimulation site such as the spine or brain and the proximal end of the lead is connected to the INS. The INS is then surgically implanted into an individual such as into a subcutaneous pocket in the abdomen, pectoral region, or upper buttocks area. A clinician programs the INS with a therapy using a programmer. The therapy configures parameters of the stimulation signal for the specific patient's therapy. An INS can be used to treat conditions such as pain, incontinence, movement disorders such as epilepsy and Parkinson's disease, and sleep apnea. Additional therapies appear promising to treat a variety of physiological, psychological, and emotional conditions.

[0038] The INS 150 typically includes a lead extension 152 and a stimulation lead 154. The stimulation lead 154 is one or more insulated electrical conductors with a connector 156 on the proximal end and electrical contacts (not shown) on the distal end. Some stimulation leads are designed to be inserted into a patient percutaneously, such as the

Model 3487A Pisces-Quad® lead available from Medtronic, Inc. of Minneapolis Minn., and some stimulation leads are designed to be surgically implanted, such as the Model 3998 Specify® lead also available from Medtronic. Although the lead connector 156 can be connected directly to the INS 150 (e.g., at a point 158), typically the lead connector 156 is connected to a lead extension 152. The lead extension 152, such as a Model 7495 available from Medtronic, is then connected to the INS 150. Implantation of an INS 150 typically begins with implantation of at least one stimulation lead 154, usually while the patient is under a local anesthetic. The stimulation lead 154 can either be percutaneously or surgically implanted. Once the stimulation lead 154 has been implanted and positioned, the stimulation lead's 154 distal end is typically anchored into position to minimize movement of the stimulation lead 154 after implantation. The stimulation lead's 154 proximal end can be configured to connect to a lead extension 152. The INS 150 is programmed with a therapy and the therapy is often modified to optimize the therapy for the patient (i.e., the INS may be programmed with a plurality of programs or therapies such that an appropriate therapy may be administered in a given situation).

[0039] According to an embodiment, a medical device lead includes a lead body, and electrode shaft and a tip electrode. A magnetostrictive element, coupled to an electrode shaft, serves as an "on/off" switch to manage high frequency RF signals (e.g. 21megaHertz (Mhz) to 128MHz) generated from a magnetic resonance imaging (MRI) machine away from the tip electrode. The switch is comprised of a magnetostrictive element made of any suitable material with sufficient magnetostrictive properties. Exemplary magnetostrictive materials include terfenol-D or galfenol. Magnetostriction is a property that causes certain ferromagnetic materials to change shape in response to a magnetic field. In particular, the magnetostrictive element expands or contracts. When the lead is not exposed to magnetic resonance imaging (MRI), the magnetostrictive material is contracted. In contrast, when the lead is exposed to MRI, the magnetostrictive material expands. In one embodiment, expansion of the magnetostrictive material causes a first segment to move away from a second segment of the electrode shaft. A gap is created between the first and second segments of the electrode shaft. Therefore, current, induced in the lead due to exposure to the MRI, no longer has a direct electrical path to the tip electrode. Instead, the electrical current induced by high frequency passes through a high impedance component such as a radiofrequency (RF) trap, whereas the low frequency current for sensing and/or pacing is able to pass to and/or from the electrode tip. Consequently, a patient with a medical lead

may undergo an MRI procedure without significantly affecting the operation of the medical lead.

[0040] In another embodiment, magnetostrictive material is disposed in or near conductive members that are coupled to the electrode shaft. When the lead is exposed to MRI, the magnetostrictive material expands to create a contact to an additional electrode surface, which allows the induced current to dissipate over a larger surface area. In one embodiment, a tenfold (i.e. 10X) larger surface area ratio results in about tenfold lower temperatures at the tip electrode, assuming a ring electrode has low impedance at high frequencies. The principles described herein are applicable to all types of medical electrical leads. For example, the disclosure applies to cardiovascular leads (e.g. high voltage leads, low voltage leads etc.), neurological leads, or other suitable applications. Any size of lead can be used such as a size 13 French lead or less.

[0041] FIG. 3 depicts a medical device system 100. According to an embodiment, a medical device system 100 includes a medical device housing 102 having a connector module 104 that electrically couples various internal electrical components of medical device housing 102 to a proximal end 105 of a medical lead 106. A medical device system 100 may comprise any of a wide variety of medical devices that include one or more medical lead(s) 106 and circuitry coupled to the medical lead(s) 106. An exemplary medical device system 100 may take the form of an implantable cardiac pacemaker, an implantable cardioverter, an implantable defibrillator, an implantable cardiac pacemaker-cardioverter-defibrillator (PCD), a neurostimulator, or a muscle stimulator. IMDs are implanted in a patient in an appropriate location. Exemplary IMDs are commercially available as including one generally known to those skilled in the art, such as the Medtronic CONCERTO®, SENSIA®, VIRTUOSO®, RESTORE®, RESTORE ULTRA®, sold by Medtronic, Inc. of Minnesota. Non-implantable medical devices or other types of devices may also utilize batteries such as external drug pumps, hearing aids and patient monitoring devices or other suitable devices. Medical device system 100 may deliver, for example, pacing, cardioversion or defibrillation pulses to a patient via electrodes disposed on distal ends 107 of one or more lead(s) 106. In other words, lead 106 may position one or more electrodes with respect to various cardiac locations so that medical device system 100 can deliver pulses to the appropriate locations.

[0042] FIG. 4 depicts an electrode assembly 200 of a medical lead 106. Electrode assembly 200 senses physiologic data from a patient and/or delivers electrical stimuli to tissue of a patient. Electrode assembly 200 optionally includes a sleeve head 201 coupled to an electrode 207 (also referred to as a tip electrode), a monolithic controlled-release device (MCRD) 213, a conductive electrode shaft 203, a conductive sealer 212, conductive members 224, a ring electrode 216, and a non-conductive spacer 217. At a distal end 244 of electrode assembly 200, a sharpened distal tip (not shown) facilitates fixation of the distal end of helically shaped electrode 207 into tissue of a patient. The proximal end of electrode 207 is securely seated between MCRD 213, electrode shaft 203, and a securing member 219 that protrudes from an inner diameter of sleeve head 201. MCRD 213 provides chronic steroid elution to maintain a low pacing threshold for a medical device system 100.

[0043] Sleeve head 201 (optionally, a RF-shunted sleeve head) is electrically connected to a conductive electrode shaft 203 (e.g. platinum etc.) via two parallel conductive members 224 (e.g. C-rings etc.) a conductive sealer 212 (also referred to as a sealing washer), and a magnetostrictive element 215 insulated with insulative layer 260 (see, for example, FIG. 7A and 7B). Insulative layer 260 is comprised of, for example, hydrolytically stable polyimide [commonly referred to as Langley Research Center SI ("LaRC SI") commercially available from Imitec located in Schenectady, NY.] Other insulative materials can also be used such as fluoropolymers [polytetrafluroethylene (PTFE), tetrafluroethylene (ETFE), etc.), thermoplastics [polyether ether ketone (PEEK), polyethersulfone (PES), etc.] and ceramic oxides (alumina, tantalum oxide, etc.). At a proximal end 206 of electrode assembly 200, coil 230 is electrically coupled to conductive electrode shaft 203. In another embodiment, electrode shaft 203 is made of nonconductive polymeric material.

[0044] Sleeve head 201 comprises a conductive element 202 surrounded or at least partially covered by an insulating material 204 (also referred to as a dielectric material). In one embodiment, conductive element 202 is cylindrically shaped (e.g. ring, etc.) or may possess other suitable shapes. Exemplary dimensions for conductive element 202 include a diameter of about 6.5 French (Fr.) by about 9 millimeters (mm) in length, an outer diameter of about 82 mils and an inner diameter of about 62 mils. Conductive element 202, in one embodiment, includes an increased diameter at the distal end and a reduced diameter at the proximal end of the conductive element 202. The surface area of conductive element 202 is about 60 mm^2 which is much larger than the 5.5 mm^2 surface area of electrode 207.

Conductive element 202 comprises materials that are chemically stable, biocompatible, and x-ray transparent. Exemplary material used to form conductive element 202 includes tantalum, tantalum alloys, titanium, titanium alloy, conductive polymers, and/or other suitable materials.

[0045] Referring to FIG. 5, insulative material 204 may be formed from a single layer or multiple layers such as first layer 220, second layer 222, and N layer 223, where N is a whole number that is less than 100, and is typically less than about 30 layers. Each layer may comprise different insulating materials, two or more different insulating materials, or the same insulating materials. Insulative material 204 includes a thickness from about 1 nanometer (nm) to about 1 millimeter (mm) and extends from about 1 mm to about 20 mm along the length of conductive element 202. Insulative material 204 may be formed from any of a wide variety of insulating materials. Exemplary insulating materials comprise at least one or more of parylene, polyamide, polyetheretherketone (PEEK), ceramics, ceramic composites, polymer composites, metal oxides, polyimide, urethane, silicone, tetrafluroethylene (ETFE), polytetrafluroethylene (PTFE), or the like. Parylene is a preferred insulating material 204. The preferred parylene is parylene C. Parylene C is formed through a dimer vacuum deposition process. The dimer is commercially available from Specialty Coating Systems located in Clear Lake, Wisconsin. Numerous techniques may be employed to introduce insulating material 204 over the outside of sleeve head 201 and/or partially inside sleeve head 201. Exemplary techniques include physical vapor deposition, chemical vapor deposition, dip coating, spraying, electrophoretic deposition or thermal extrusion.

[0046] Conductive sealer 212 conducts current and also prevents fluid from passing through lumen 246. Referring to FIGs. 6A-6D, conductive sealer 212 is substantially ring (i.e. o-ring) or disk shaped but other suitable shapes may also be employed. In one embodiment, conductive sealer 212 is defined by X1, X2 and radius (r1). X1 can range from about 0.1 mm to about 0.50 mm, X2 can range from about 0.1 mm to about 1.0 mm, and r1 can range from about 0.5 mm to about 1.0 mm. Curved end 252 extends to about 1.25 mm from the center of shaft 203 and includes a curve defined by a radius of about 0.5 mm.

[0047] Conductive sealer 212 comprises a polymer and a conductive polymer such as a conductive powder (e.g. carbon, carbon nanotube, silver, platinum etc.). The conductive

polymer can range from about 1% to about 25% of conductive sealer 212. The polymer (e.g. silicone etc.) is commercially available from Nusil Technology LLC, located in Carpinteria, California. Polyurethane is commercially available from The Polymer Technology Group Inc. located in Berkeley, California.

[0048] Conductive members 224 are shaped, in one embodiment, as a ring (e.g. C-ring, etc.) to receive conductive sealer 212. Conductive members 224 can have an outer diameter of about 1.5 mm, an inner diameter of about 0.7 mm, and a thickness that ranges from about 0.25 mm (T1) to about 0.5 mm (T2). Conductive members 224 can be comprised of platinum or other suitable materials.

[0049] In one embodiment, magnetostrictive element 215 is coupled to at least one conductive member 224, specifically a conductive ring. When lead 106 is exposed to MRI, magnetostrictive element 215 expands, which creates a larger surface area in which to dissipate the current induced in lead 106.

[0050] In another embodiment, as depicted in FIGs. 7A-7B, magnetostrictive element 215, is disposed between first and second segments 240a, 240b of electrode shaft 203. The magnetostrictive element 215 may be coated with an insulative material layer (such as polyimide) in a cylindrical shape of approximately 0.5mm – 2.0 mm in diameter by 1.0mm – 4.0 mm long and bonded at the ends of segment 240a, 240b. The outer surface of members 240a, 240b may also maintain contact through an elastic member assembled on the outside diameter. No gap exists between first and second segments 240a, 240b when MRI is not applied to lead 106, as shown in FIG. 7A. When lead 106 is exposed to MRI, magnetostrictive element 215 expands, causing first segment 240a to move away from second segment 240b, thereby creating a gap 242, as shown in FIG. 7B. Gap 242 breaks the direct electrical connection between first and second segments 240a, 240b and the tip electrode 207. Instead, the current induced by MRI is shunted to a RF trap. In particular, high impedance inductor (L) 262 connected to the electrode shaft 203, blocks the high frequency RF signals. L passes the low frequency pacing signals from one end 280a to another end 280b of the electrode shaft 203. Therefore, the high frequency RF signals experienced during MRI are shunted by the magnetostrictive element 215 as shown in FIG. 7B.

[0051] FIG. 8A depicts a simplified bipolar circuit 300 for a medical device system 100 during normal pacing conditions and when exposed to MRI. Pacing conditions typically involve low frequency signals (e.g. 1000Hz). Circuit 300 includes an implantable medical device (IMD) circuit 302 (e.g. a pacemaker circuit, neurostimilator circuit etc.) connected to a bipolar shunted lead circuit 304a. IMD circuit 302 comprises two filter capacitors C1 and C2 connected to housing 102. C1 and C2 filter high frequency electromagnetic interference (EMI) so that high frequency signals from a MRI machine do not affect the sensing operation of medical lead 106. Exemplary values for C1 is about 1 to 10 nanoFarad (nF) and C2 is 1-10nF.

[0052] Bipolar shunted lead circuit 304a includes ring electrode 216, magnetostrictive element 215, and tip electrode 207. Capacitors C3 and C5 correspond to ring electrode 216, and tip electrode 207, respectively and inductor L is associated with magnetostrictive element 215. Resistor R1 represents the impedance created by tissue and/or blood of the patient. R6 represents impedance or resistance associated with coil 230. R3 and R5, along with capacitors C3 and C5, represent the electrode to tissue interface impedances. V_{REF} represents the device ground to the body whereas $V_{_Pace}$ represents the voltage of the pacing current. Generally, larger area electrodes result in larger values of capacitance and smaller values of resistance. Exemplary values for bipolar shunted lead circuit 304a include L C3 at 10 microF (uF), L is 4 uHenry, R3 is 100 Ohm (Ω), C5 is 1 uF, and R1 is 500 Ω, and R5 is Ω.

[0053] Bipolar shunted lead circuit 304a operates when the patient is not exposed to a MRI procedure or during a MRI procedure. When MRI conditions are not present and pacing pulses are required by a patient, pacing current is generated from C1 or C2 and passes through first and second segments 240a, 240b, as shown in greater detail in FIG 7A. Thereafter, the pacing current passes through tip electrode 207, ring electrode 216 and back to medical device housing 102.

[0054] When a patient is exposed to a MRI procedure, a MRI current (I_{MRI}) is transferred from tip electrode 207 through ring electrode 216 back to medical device housing 102, which avoids or substantially prevents the MRI from affecting the operation of lead 106 from delivering electrical stimuli (i.e. pacing pulses) to the patient. If the patient requires pacing during the MRI, the pacing current, typically generated from C1, passes through an

inductor (L), depicted in Fig. 7B, and thereafter passes through tip electrode 207, ring electrode 216 and then back to medical device housing 102.

[0055] FIG. 8B depicts a simplified unipolar circuit 300 for a medical device system 100 during normal pacing conditions and when exposed to MRI. Circuit 300 includes an IMD circuit 302 (e.g. a pacemaker circuit, neurostimilator circuit etc.) connected to a unipolar shunted lead circuit 304b. IMD circuit 302 comprises two filter capacitors C1 and C2 connected to housing 102. C1 and C2 filter high frequency EMI so that high frequency signals from a MRI machine do not affect the sensing operation of medical lead 106.

[0056] Unipolar shunted lead circuit 304b includes magnetostrictive element 215, and tip electrode 207. Capacitor C5 corresponds to tip electrode 207 and inductor L is associated with magnetostrictive element 215. Resistor R1 represents the impedance created by tissue and/or blood of the patient. R6 represents impedance or resistance associated with coil 230. R5 along with capacitor C5, represent the electrode to tissue interface impedance.

[0057] Generally, under typical pacing conditions, pacing current flows from C1 or C2 through tip electrode 207 and then returns to IMD circuit 302. Under a low frequency or DC application, inductor L acts like a short circuit to a constant voltage across its terminals. A portion of the pacing current passes to the patient's tissue (e.g. heart tissue), represented as resistor R1, due to the large capacitance of C5 associated with tip electrode 207. When lead 106 is exposed to MRI, I_{MRI} is induced, as depicted by the ghost lines. As shown, the I_{MRI} is transferred from tip electrode 207 back to medical device housing 102. If the patient requires pacing during an MRI procedure, a pacing current is generated from C1 or C2 and passes through inductor L, (shown in FIG. 8B), tip electrode 207 back to medical device housing 102.

[0058] FIGs. 9A-9B depict another simplified circuit 400 for a medical device system 100 during pacing and MRI conditions, respectively. Referring to FIG. 9A, circuit 400 includes an IMD circuit 402 (e.g. a pacemaker circuit, neurostimulator circuit etc.) and a bipolar shunted lead 304b. Circuit 400 includes the same elements as circuit 300 depicted in FIG. 8A, except magnetostrictive element 215 is coupled to a capacitor (C4) instead of inductor L. Specifically, C4 serves to bypass first and second elements 240a, 240b when a patient undergoes a MRI procedure. Magnetostrictive material 215 only acts as a switch to turn on and off capacitor C4 in circuit 400. In this embodiment, high frequency signals (i.e. from

the MRI) pass to C4, whereas low frequency signals pass to and from tip electrode 207. C4 is shorted when exposed to high frequency signals. C4 acts as an "open circuit" when exposed to low frequency signals, which causes the pacing pulses to pass directly to tip electrode 207. An exemplary value for C4 is about 1-10 uF. For the bipolar shunted lead circuit 404a depicted in Fig. 9A, i_{MRI} is transferred from tip electrode 207 through ring electrode 216 back to medical device housing 102, which avoids or substantially prevents the MRI from affecting the operation of lead 106 from delivering electrical stimuli (i.e. pacing pulses) to the patient.

[0059] FIG. 10 is a flow diagram that depicts a method of producing a medical lead. At block 300, a lead body is provided. At block 310, a magnetostrictive element is inserted or placed between a lead body and an electrode shaft. The magnetostrictive element is comprised of a ferromagnetic material (e.g. terfenol-D, galfenol etc.), commercially available from Extrema Products Inc. located in Ames, Iowa. Terfenol-D, an alloy of terbium, dysprosium, and iron metals with the formula of terbium (Tb)(0.3) dysprosium (Dy)(0.7) iron (Fe)(1.9), was developed at the Naval Ordnance Laboratory in America. Generally, terfenol has the largest room temperature magnetostriction of any material. In mechanical terms, a 2.5 inch diameter rod of terfenol-D is capable of generating over 50,000 pounds of dynamic force. In one embodiment, the magnetostrictive element can comprise one or more terfenol-D or galfenol. In another embodiment, the magnetostrictive element can comprise terfenol-D and/or galfenol in combination with other suitable materials.

[0060] At block 320, the RF is prevented from affecting the sensing operation of the medical lead. In one embodiment, the magnetostrictive element reduces by at least 80 percent the current, induced in the lead by the MRI. In another embodiment, the magnetostrictive element reduces by at least 50 percent the current induced by the MRI.

[0061] A possible issue with the use of materials that function as a capacitor to shunt energy induced in an electrode assembly, such as in the embodiments described above in regard to FIGs. 9A and 9B, is the performance of these materials after they have been implanted or during their use with a patient. For example, the materials forming a capacitor could become damaged. Such damage could diminish performance of the capacitor. For instance, such damage could cause an unintended interaction of an induced voltage with surrounding materials during a pacing operation of an associated electrode assembly.

[0062] According to some embodiments, damage caused to capacitor materials is repaired or "healed" when "self-healing" materials are used as capacitor materials. Some self-healing materials can compensate for damage to the capacitor materials because the self-healing materials can re-grow or regenerate upon a damaged area, thus fixing the damage caused to the capacitor materials (e.g., oxidize). Other self-healing materials can migrate or chemically diffuse to a damaged area and subsequently harden, thus fixing the damage caused to the capacitor.

[0063] FIG. 11A shows an embodiment of a shunt capacitor 500 that includes a conducting layer 510 and a dielectric layer 520. The capacitor 500 can be connected to another conductor to provide an additional conductor on the opposite side of the dielectric material 520 to conductor 510. For example, a conductive component of an electrode assembly 200, such as a ring electrode 216, can be connected to the capacitor 500 to provide an additional conductor. According to a further embodiment, the dielectric layer 520 is an exterior layer of an electrode assembly 200 and is formed of a material that is biocompatible, whereby an additional conductor is connected to the dielectric layer 520. According to a further embodiment, the conducting layer 510 and the dielectric layer 520 can be applied as coating layers to an electrode assembly of a medical device system.

[0064] FIG. 11B shows the capacitor 500 in a state in which the dielectric layer 520 has sustained damage 530. Damage 530 could have been sustained for any of a variety of reasons for example, during implantation or use of the electrode for which the capacitor 500 is associated. Damage 530 could occur in one or more of many forms including scratches, gouges, dents, cracks or other forms of damage that can occur to capacitor materials and coatings for such materials. Such damage 530 can be problematic to the performance of the capacitor 500. For example, damage could result in stray voltages during a pacing operation of an electrode assembly to which the damaged capacitor is connected.

[0065] FIG. 11C shows a capacitor 500 that has regenerated or re-grown material 532 to heal the damage caused to the dielectric layer 520 of the capacitor 500. Regenerated or re-grown material 532 can be created through the use of self-healing capacitor materials for the conductor 510 and/or the dielectric 520. This re-growth or "healing" operation will reduce damage to the dielectric layer and thereby reduce the potential problem of stray voltage discussed above.

[0066] According to an embodiment, the capacitor 500 includes a dielectric material 520 that can be regenerated or re-grown via anodization, passivation, or oxidation. For example, the dielectric material 520 can be regenerated or re-grown via anodization, passivation, or oxidation of the conductor 510. In some embodiments, a pulsed voltage filtered through a diode (positive or negative) facilitates the anodization, passivation, or oxidation processes in a material having an oxidized outer surface with an interior volume of a different phase or chemical composition, as will be further explained.

[0067] According to a further embodiment, the conductor 510 can be made of an inorganic material. For example, the conductor 510 can be made of a metal and in particular, the conductor 510 can be made of a metal, such as, for example, tantalum, titanium, hafnium, yttrium, niobium, zinc, beryllium, aluminum, zirconium, tungsten, rhenium, and their alloys. According to one embodiment, the dielectric material 520 is made of an oxide corresponding to the material of the conductor 510. The dielectric material 520 can be made of oxides, such as, for example, tantalum oxide, titanium oxide, hafnium oxide, yttrium oxide, zinc oxide, beryllium oxide, niobium oxide, aluminum oxide, zirconium oxide, tungsten oxide, rhenium oxide, and oxides of an alloy used for the conductor 510.

[0068] According to another embodiment, the dielectric material 520 can be a composite or an organic coating that is applied over a conductor 510 made of a metal. For example, the dielectric material 520 can be made of a nanocomposite of nanoparticles, polymer-particle or -nanoparticle composites, or other materials in which an insulating entity or particle network can migrate or diffuse to the damaged area to regenerate or re-grow dielectric material in the damaged area. Nanoparticles or particles can be made of, for example, tantalum oxide, titanium oxide, niobium oxide, aluminum oxide, zirconium oxide, tungsten oxide, rhenium oxide, and oxides of an alloy used for the conductor 510, as discussed above. In another example, the dielectric material can be made of an active composite-layered system in which layers of a passive coating matrix are alternated with layers that include an active coating component that promotes self-healing of the composite system. In another example, a composite layer can include a matrix embedded with nanocontainers that contain active coating components for promoting self-healing of the composite layer. According to this example, the nanocontainers can rupture upon the application of a stimulus, thus releasing the active coating components contained by the

nanocontainers, the nanocontainers can be designed to be at least semi-permeable to the active coating components, or the nanocontainers can be configured to release the active coating components through another method known in the art, such as those as described in "Layer-by-Layer Assembled Nanocontainers for Self-Healing Corrosion Protection," by D. Shchukin et al. published in Advanced Materials, volume 18, pages 1672-78 on June 27, 2006, which is incorporated herein by reference in its entirety; Self-healing Polymeric Materials: A Review of Recent Developments," by D. Wu et al. published in Progress in Polymer Science, volume 33 pages 479-522, which is incorporated herein by reference in its entirety; and "Self-Healing Materials with Microvascular Networks," by K. Toohey et al. published in Nature Materials, volume 6, pages 581-585 in August of 2007, which is incorporated herein by reference in its entirety. Some embodiments employing microvascular networks, as described in the latter article by Toohey et al., allow for continuous delivery of the self-healing materials (e.g., epoxy or resin matrix), providing the ability to regrow or regenerate dielectric materials in areas of the capacitor 500 that are repeatedly damaged.

[0069] In still yet another embodiment, the dielectric material 520 can be made of any biocompatible material, including biocompatible oxides, having prescribed qualities. Specifically, dielectric materials that are both biocompatible and have a dielectric constant in the range of 1 to 100 are suitable for use according to the invention. However particular dielectric layer thicknesses and surface areas of some embodiments vary as a function of selected materials. For example, a particular surface area and a particular layer thickness may be arranged such that their ratio is linearly proportional to a desired capacitance for the capacitor 500, where the constant of proportionality of the linear relationship just described is directly related to the dielectric constant of the selected material.

[0070] Regeneration or re-growth of capacitor material, such as dielectric material 520, can occur during use of a medical device system. For example, voltage pulses produced when an electrode assembly is used for pacing can affect the materials of the conductor 510 and the dielectric 520, causing these materials to migrate or diffuse. According to this example, pacing voltages can cause capacitor materials to migrate or diffuse to a damaged area, such as a damaged area 530 in a dielectric layer 520. Migrating or diffusing materials can anodize, passivate, or oxidize at the damaged area 530, causing the capacitor material to regenerate or re-grow. For example, a damaged area 530, such as a scratch, can create an

area of increased current density, which in turn increases the regeneration or regrowth rate of capacitor material due to anodization, passivation, or oxidation. The rate of self-healing depends upon voltage magnitude and polarity, material selection and arrangement, and a particular type and degree of damage. In some embodiments an increased voltage pulse magnitude increases the rate of self-healing.

[0071] According to a further embodiment, a medical device system can be configured so that the regeneration or re-growth rate of a self-healing capacitor material, such as a dielectric material, is controlled. For example, a pacing mode of a medical device system typically produces voltage pulses of alternating negative and positive polarity. When such pacing voltage pulses are used to migrate or diffuse capacitor materials to a damaged area, one polarity of the voltage pulses may be more useful than others due to the characteristic ionic charge of the capacitor materials. For example, a positive voltage can be used to cause capacitor materials to migrate or diffuse to a damaged area and be further anodized, passivated, or oxidized, thus regenerating or re-growing the capacitor materials. Conversely, negatively charged voltage pulses may cause little growth, no growth, or even inhibit further growth or regeneration. Therefore, a medical device system can be configured to control, for example, voltages applied to a self-healing capacitor material in order to control the regeneration or re-growth rate of the self-healing material.

[0072] According to a further embodiment, the voltage applied to the materials of a capacitor 500 is controlled in order to control the regeneration or re-growth rate of the capacitor materials. For example, a device that controls direction of current flow, such as a diode, can be used to control the voltage that is applied to the materials of a capacitor 500. In a further example, a diode can have the attributes described in "Schottky Barrier Diodes for General Purpose Applications," a technical data publication by Agilent Technologies, which is hereby incorporated by reference in its entirety.

[0073] FIG. 12 shows an embodiment of a configuration used for controlling the regeneration or re-growth rate of a damaged area 530 of a capacitor 500. A device 604 to control the direction of current flow can be used and arranged so that positive voltage pulses can be applied to the capacitor 500 during pacing, thus fostering regeneration and re-growth of capacitor material. The current flow control device 604 can be a diode, such as in the example of FIG. 12, or another device configured to control the flow of current. The device 604 is further configured to control the direction of current flow so that negative voltage

pulses are blocked and not applied to the capacitor materials. By blocking negative voltage pulses, the current control device 604 can be configured to promote the regeneration or re-growth of self-healing capacitor materials that heal when positive voltage pulses are applied so that negative voltage pulses that could inhibit regeneration or re-growth are not applied to the self-healing capacitor material. As shown in the example of FIG. 12, the current flow control device 604 can be connected between the capacitor 500 and the tip electrode 207. Furthermore, the device 604 can be configured so that the device 604 has a low impedance to RF currents induced during MRI but a high impedance to a selected voltage pulse polarity during a pacing operation of a medical device system.

[0074] According to another embodiment, the current flow control device 604 is configured to permit application of negative voltage pulses to capacitor materials and to block positive voltage pulses.

[0075] The current flow control device 604 is configured to have a sufficient reverse bias voltage rating to withstand a potential of a voltage pulse that the device 604 is configured to block, according to a further embodiment. For example, the current flow control device 604 should have a reverse bias voltage rating of at least approximately 10V if the potential of a blocked pulse is 10V. In another example, the current flow control device 604 should have a reverse bias voltage rating of at least approximately 20V. The current flow control device 604 can also be configured so that the forward bias voltage rating is at a minimum in order to permit maximum transfer of current when the voltage pulse that the device 604 is configured to pass is applied. For example, the forward voltage rating of the device can be approximately 0.41V. In another example, the forward voltage rating of the device can be approximately 150 mV. The wattage rating of the device 604 should be sufficient to withstand the current conducted by the device 604. For example, the device 604 can have a wattage rating of approximately 100 mW. In another example, the device 604 can have a wattage rating of approximately 250 mW. Furthermore, a device 604 can have combinations of these rating values.

[0076] FIGs. 13A and 13B depict another embodiment that includes a simplified circuit 600 for a medical device system during pacing and MRI conditions, respectively. Circuit 600 includes an IMD circuit 602 (e.g. a pacemaker circuit, neurostimulator circuit etc.) and a bipolar shunted lead 304c. Circuit 600 includes the same elements as circuit 300 depicted in FIGs. 9A-9B, except that the magnetostrictive element 215 and the capacitor (C4) are

further coupled to a current flow control device 604. As in the examples of FIGs. 9A and 9B, high frequency signals (i.e. from the MRI) pass to C4, causing currents produced by the high frequency signals to short C4 and bypass the tip electrode 207. Conversely, low frequency signals pass to and from tip electrode 207. C4 is shorted when exposed to high frequency signals, as shown by current I in FIG. 9B (see also FIG. 13B). C4 acts as an "open circuit" when exposed to low frequency signals, which causes the current I_2 of pacing pulses to pass directly to tip electrode 207, as shown FIG. 9A (see also FIG. 13A). Furthermore, current flow control device 604 controls the polarity of voltage that is applied to capacitor C4, thus controlling the rate of regeneration or re-growth of capacitor material, as described in any of the embodiments above.

[0077] It is understood that the present invention is not limited for use in pacemakers, cardioverters of defibrillators. Other uses of the innovations described herein may include uses in patient monitoring devices, or devices that integrate monitoring and stimulation features, such as INS devices. In those cases, the leads may include sensors disposed on distal ends of the respective lead for sensing patient conditions.

[0078] The leads described herein may be used with a neurological device such as a deep-brain stimulation device or a spinal cord stimulation device. In those cases, the leads may be stereotactically probed into the brain to position electrodes for deep-brain stimulation, or into the spine for spinal stimulation. In other applications, the leads described herein may provide muscular stimulation therapy, gastric system stimulation, nerve stimulation, lower colon stimulation, drug or beneficial agent dispensing, recording or monitoring, gene therapy, or the like. In short, the leads described herein may find useful applications in a wide variety medical devices that implement leads and circuitry coupled to the leads.

[0079] Various embodiments of the invention have been described. These and other embodiments are within the scope of the following claims. For example, electrode 207 may include variously shaped electrodes such as ring shaped or other suitable shapes. Additionally, skilled artisans appreciate that other dimensions may be used for the mechanical and electrical elements described herein.

What is claimed is:

1. An electrode assembly for a medical device system, comprising:

an electrode, and

a shunted lead circuit; and

a self-healing material integrated into the shunted lead circuit, the self-healing material comprising a dielectric layer including at least one of an oxide, an organic coating, and a composite.

2. The electrode assembly of claim 1 wherein the dielectric layer includes an oxide comprising at least one of tantalum oxide, titanium oxide, hafnium oxide, yttrium oxide, zinc oxide, beryllium oxide, niobium oxide, aluminum oxide, zirconium oxide, tungsten oxide, rhenium oxide, and oxides including any combination of these oxides.

3. The electrode assembly of claim 1, wherein the dielectric layer includes a composite comprising at least one of organic nanoparticles, inorganic nanoparticles, polymer-particles, nanoparticle composites, and any combination of these compounds.

4. The electrode assembly of claim 3, wherein the composite includes a nanocomposite with particles comprising at least one of tantalum oxide, titanium oxide, hafnium oxide, yttrium oxide, zinc oxide, beryllium oxide, niobium oxide, aluminum oxide, zirconium oxide, tungsten oxide, rhenium oxide, and oxides including any combination of these oxides.

5. The electrode assembly of claim 3, wherein the composite includes an active composite-layered system in which layers of a passive coating matrix are alternated with layers that include an active coating component that promotes self-healing of the composite.

6. The electrode assembly of claim 3, wherein the composite includes a matrix embedded with nanocontainers that contain active coating components for promoting self-healing of the composite.

7. The electrode assembly of claim 1, wherein the dielectric layer is formed from a material having a dielectric constant in the range of 1 to 100.

8. A medical device system, comprising:

a medical device adapted to provide a therapeutic electrical stimulation to a person;

a lead electrically connected to the medical device, the lead comprising at least one electrode assembly comprising

an electrode, and

a shunted lead circuit with a self-healing material integrated onto a surface of at least a portion of the lead, the medical device system being configured to control the regeneration rate of the self-healing material.

9. The medical device system of claim 8, further comprising a current control device adapted to control the regeneration rate of the self-healing material.

10. The medical device system of claim 9, wherein the current control device comprises a diode.

11. The medical device system of claim 10, wherein the diode is adapted to block voltages of negative polarity.

12. The medical device system of claim 10, wherein the diode is adapted to block voltages of positive polarity.

13. The medical device system of claim 10, wherein the diode has a reverse bias voltage rating of at least approximately 10V.

14. The medical device system of claim 13, wherein the diode has a forward bias voltage rating of approximately 0.41V, and a wattage rating of approximately 100 mW.

15. The medical device system of claim 10, wherein the diode has a reverse bias voltage of at least approximately 20V, a forward bias voltage rating of approximately 150 mV, and a wattage rating of approximately 250 mW.

16. A medical device system comprising:

an implantable medical device adapted to be implanted within a body of a patient;

an electrical lead connected to the implantable medical device, the electrical lead adapted to perform at least one of

sensing electrical activity of an organ of the patient, and

delivering an electrical stimulation to the organ of the patient;

an electrical circuit to electrically connect the implantable medical device and the electrical lead, the electrical circuit comprising a capacitor having a dielectric material that can be regenerated while implanted within the body of the patient.

17. A medical device system according to claim 16, wherein the dielectric material is configured to be regenerated through at least one of anodization, passivation, and oxidation.

18. A medical device system according to claim 17, wherein the dielectric layer includes an oxide comprising at least one of tantalum oxide, titanium oxide, hafnium oxide, yttrium oxide, zinc oxide, beryllium oxide, niobium oxide, aluminum oxide, zirconium oxide, tungsten oxide, rhenium oxide, and oxides including any combination of these oxides.

19. A medical device system according to claim 16, wherein the dielectric material includes a composite comprising at least one of organic nanoparticles, inorganic nanoparticles, polymer-particles, nanoparticle composites, and any combination of these compounds.

20. A medical device system according to claim 19, wherein the composite includes a nanocomposite with particles comprising at least one of tantalum oxide, titanium oxide, hafnium oxide, yttrium oxide, zinc oxide, beryllium oxide, niobium oxide, aluminum oxide, zirconium oxide, tungsten oxide, rhenium oxide, and oxides including any combination of these oxides.

21. A medical device system according to claim 19, wherein the composite includes an active composite-layered system in which layers of a passive coating matrix are alternated with layers that include an active coating component that promotes self-healing of the dielectric material.

22. A medical device system according to claim 19, wherein the composite includes a matrix embedded with nanocontainers that contain active coating components for promoting self-healing of the dielectric material.

23. A medical device system according to claim 16, wherein the electrical circuit further comprises a current control device adapted to control the regeneration rate of the dielectric material.

24. A medical device system according to claim 23, wherein the current control device comprises a diode.

25. A medical device system according to claim 24, wherein the diode is adapted to block voltages of negative polarity.

26. A medical device system according to claim 24, wherein the diode is adapted to block voltages of positive polarity.

27. A medical device system according to claim 24, wherein the diode has a reverse bias voltage rating of at least approximately 10V.

28. A medical device system according to claim 27, wherein the diode has a forward bias voltage rating of approximately 0.41V, and a wattage rating of approximately 100 mW.

29. A medical device system according to claim 24, wherein the diode has a reverse bias voltage of at least approximately 20V, a forward bias voltage rating of approximately 150 mV, and a wattage rating of approximately 250 mW.

30. A medical device system according to claim 16, wherein the dielectric material is formed from a material having a dielectric constant in the range of 1 to 100.

31. A method for making a medical device system having regenerative capabilities comprising the steps of:

providing an implantable medical device adapted to be implanted within a body of a patient;

providing an electrical lead connected to the implantable medical device, the electrical lead adapted to perform at least one of

sensing electrical activity of an organ of the patient, and

delivering an electrical stimulation to the organ of the patient;

providing an electrical circuit to electrically connect the implantable medical device and the electrical lead; and

providing in the electrical circuit a dielectric material that can be regenerated while implanted within the body of the patient.

32. A method for making a medical device system according to claim 31, wherein the dielectric material is configured to be regenerated through at least one of anodization, passivation, and oxidation.

33. A method for making a medical device system according to claim 31, wherein the dielectric material is configured to be regenerated through diffusion of a matrix material to a damaged area where the matrix material solidifies to regenerate the dielectric material.

34. A method for making a medical device system according to claim 33, wherein the matrix material is configured to diffuse to the damaged area through a microvascular network, and the dielectric material is configured to be repeatedly regenerated.

35. A method for using a medical device system having regenerative capabilities comprising the steps of:

providing a medical device having an electrical circuit to electrically connect the medical device and an electrical lead, the electrical lead adapted to perform at least one of

sensing electrical activity of an organ of a patient, and

delivering an electrical stimulation to the organ of the patient,

the electrical circuit including a dielectric material that can be regenerated while implanted within a body of the patient;

implanting the medical device into the body of the patient; and

coupling the electrical lead to the organ of the patient.

36. A method for using a medical device system according to claim 35, wherein the dielectric material is configured to be regenerated through at least one of anodization, passivation, and oxidation.

37. A method for using a medical device system according to claim 35, wherein the dielectric material is configured to be regenerated through diffusion of a matrix material to a damaged area where the matrix material solidifies to regenerate the dielectric material.

38. A method for using a medical device system according to claim 37, wherein the matrix material is configured to diffuse to the damaged area through a microvascular network, and the dielectric material is configured to be repeatedly regenerated.

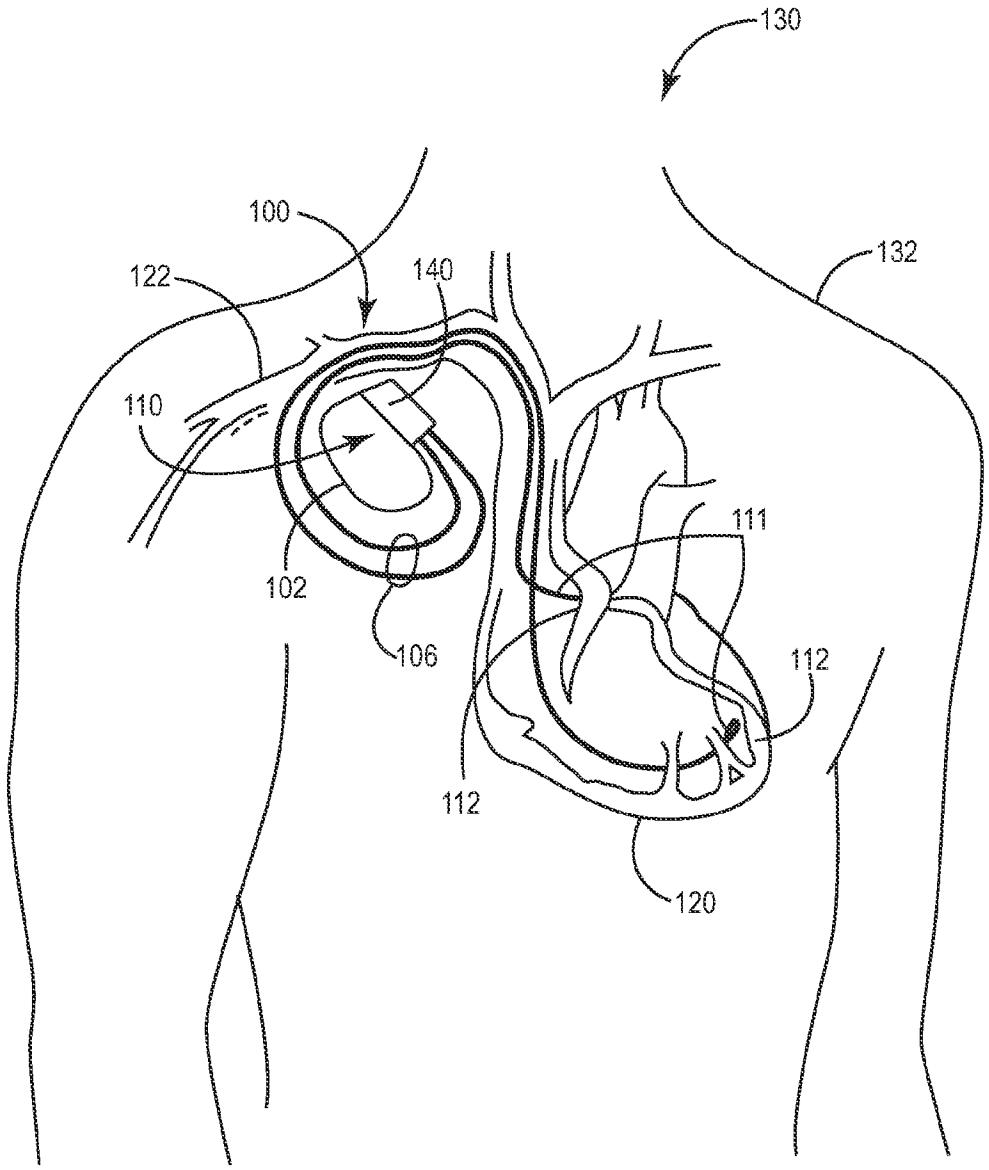


Fig. 1

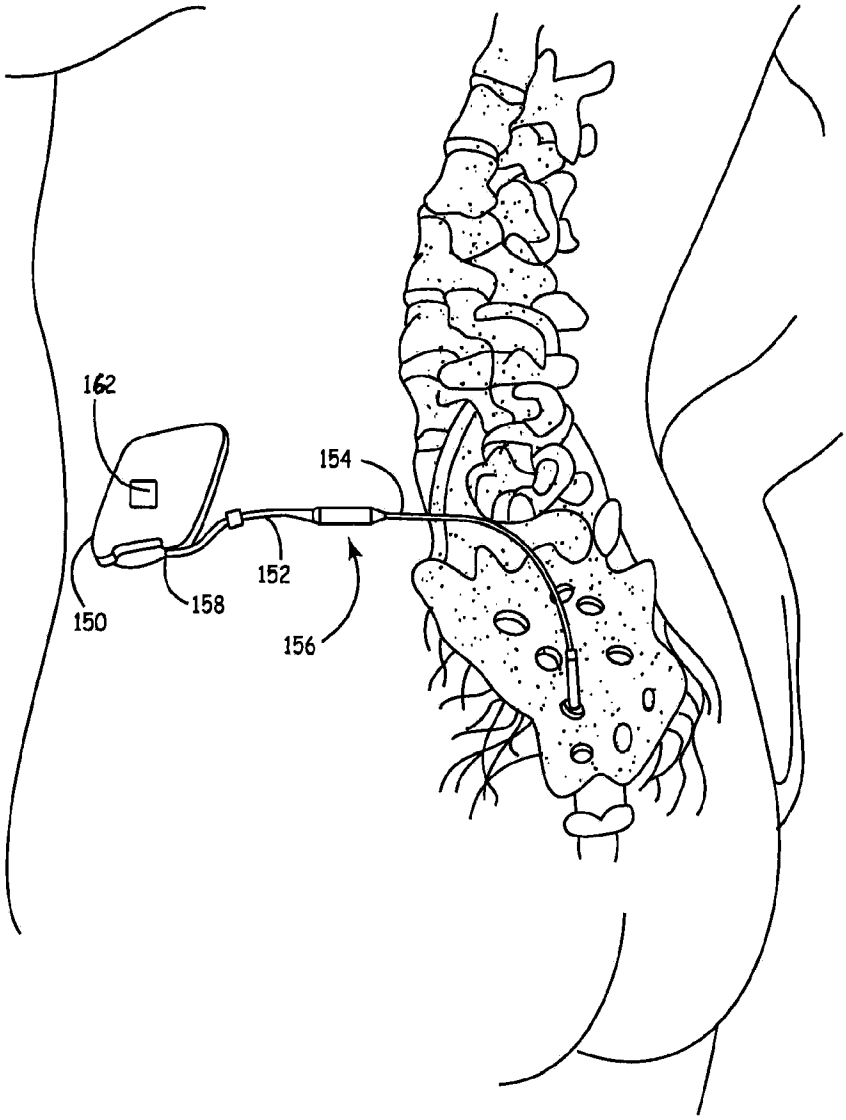


Fig. 2

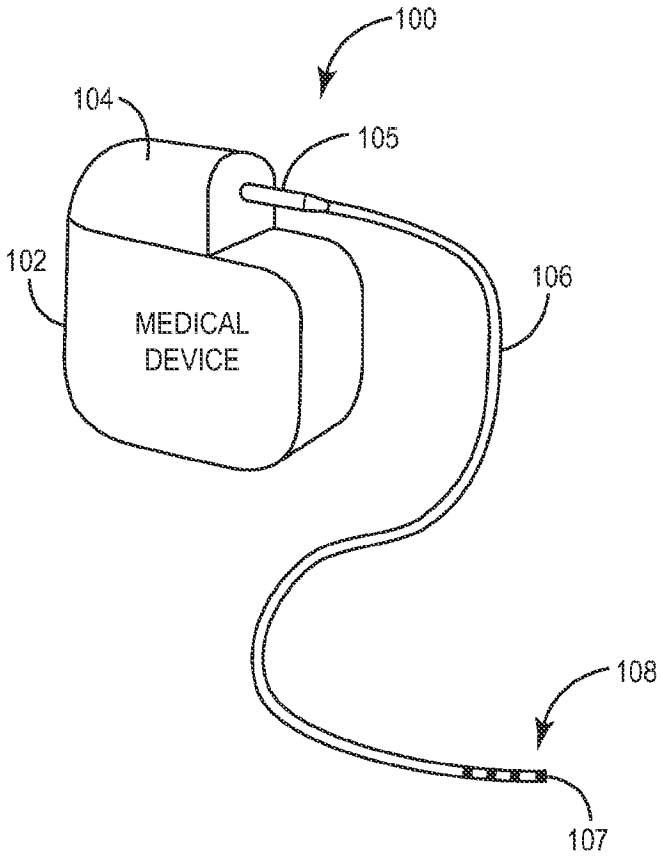


Fig. 3

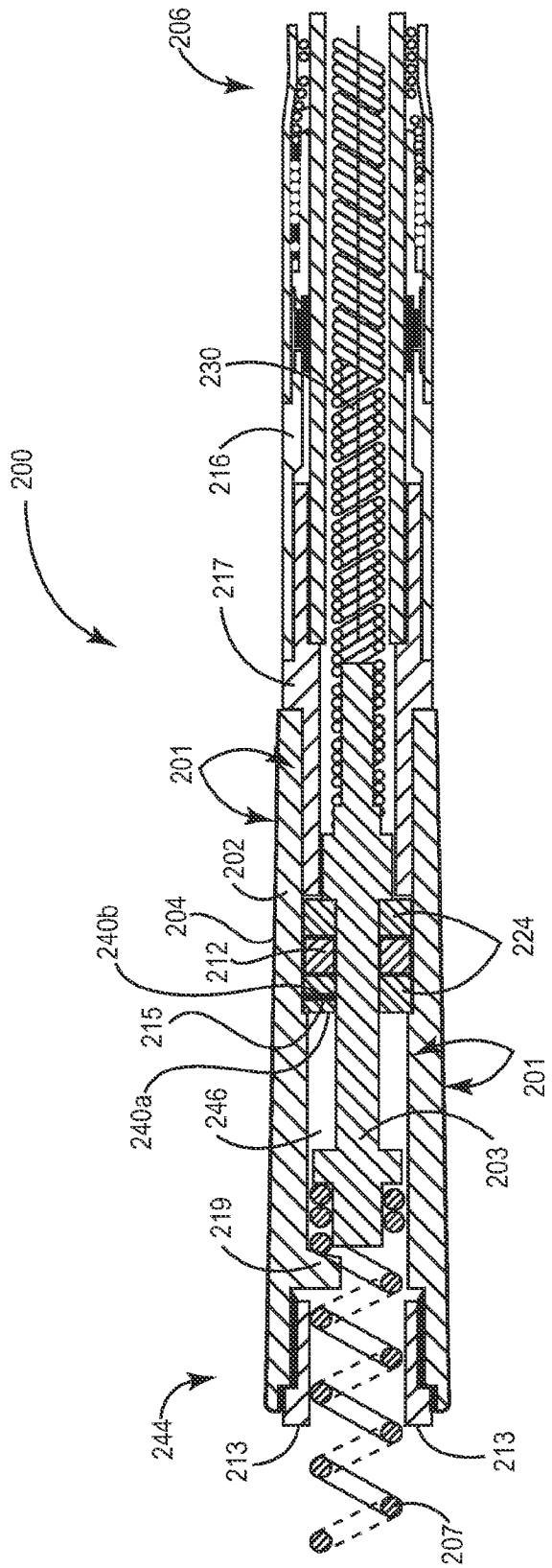

206
230
216
200
217
201
202
204
240b
212
224
215
201
240a
246
203
219
244
213
213
207

Fig. 4

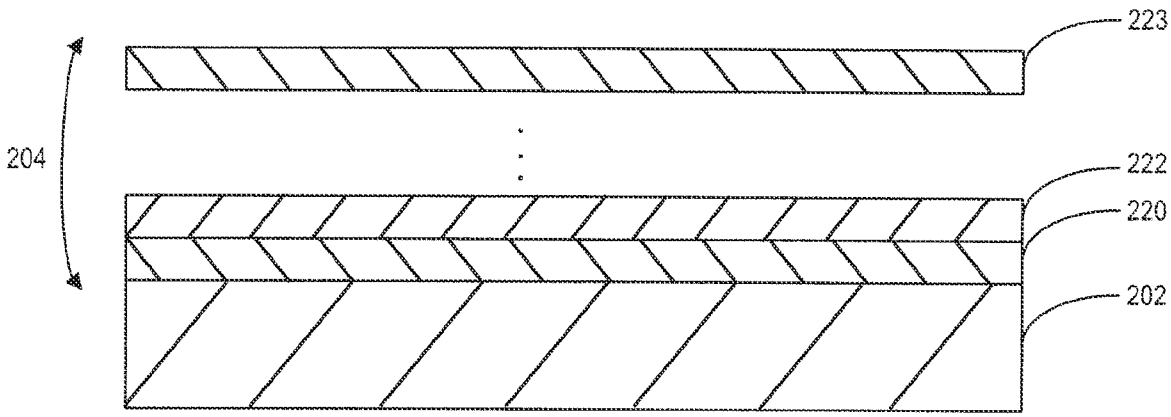


FIG. 5

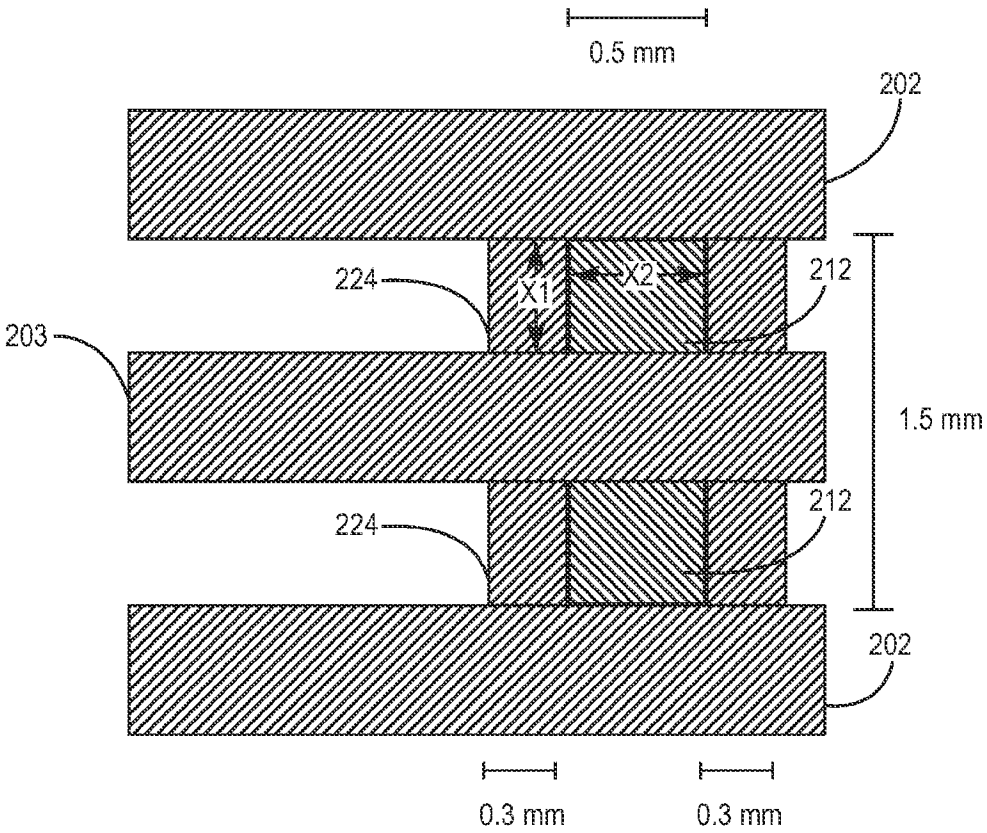


Fig. 6A

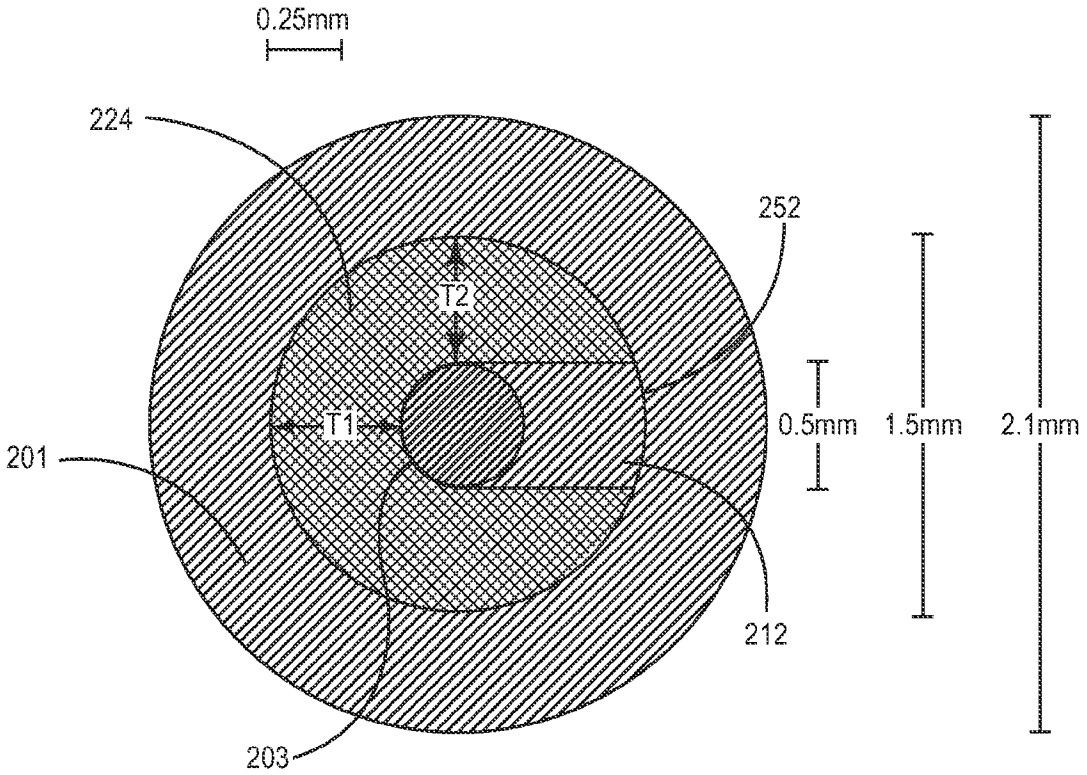


Fig. 6B

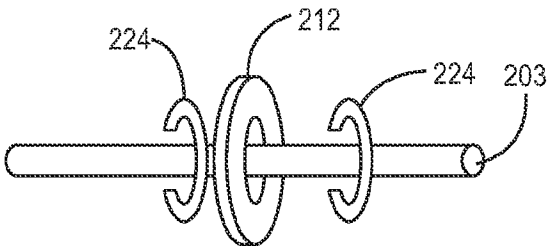


Fig. 6C

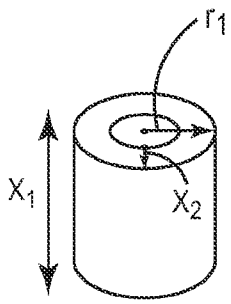


Fig. 6D

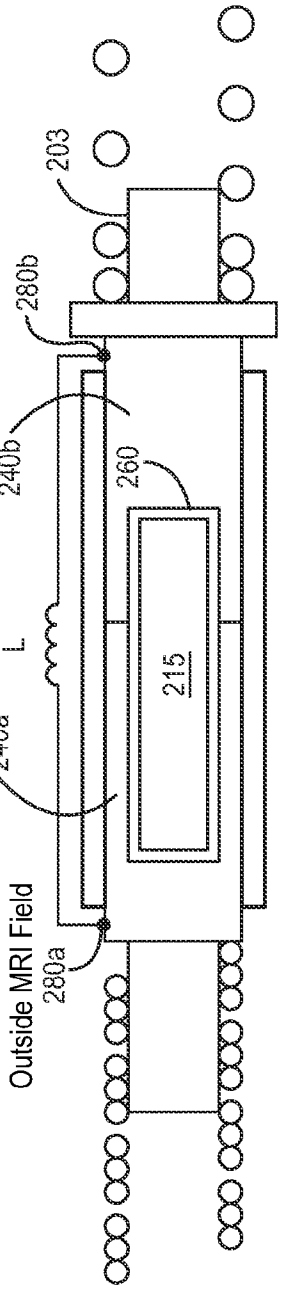

203
280b
240b
260
L
215
240a
Outside MRI Field
280a

Fig. 7A

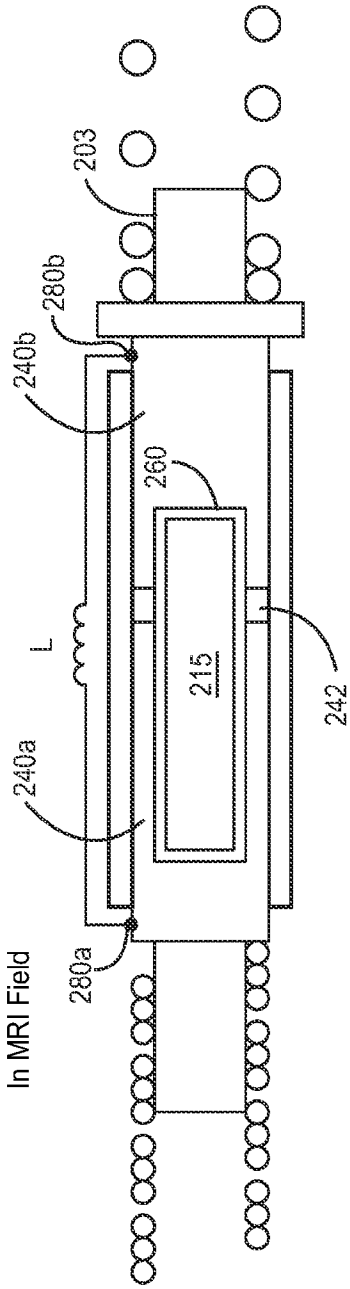

203
280b
240b
260
L
215
242
240a
In MRI Field
280a

Fig. 7B

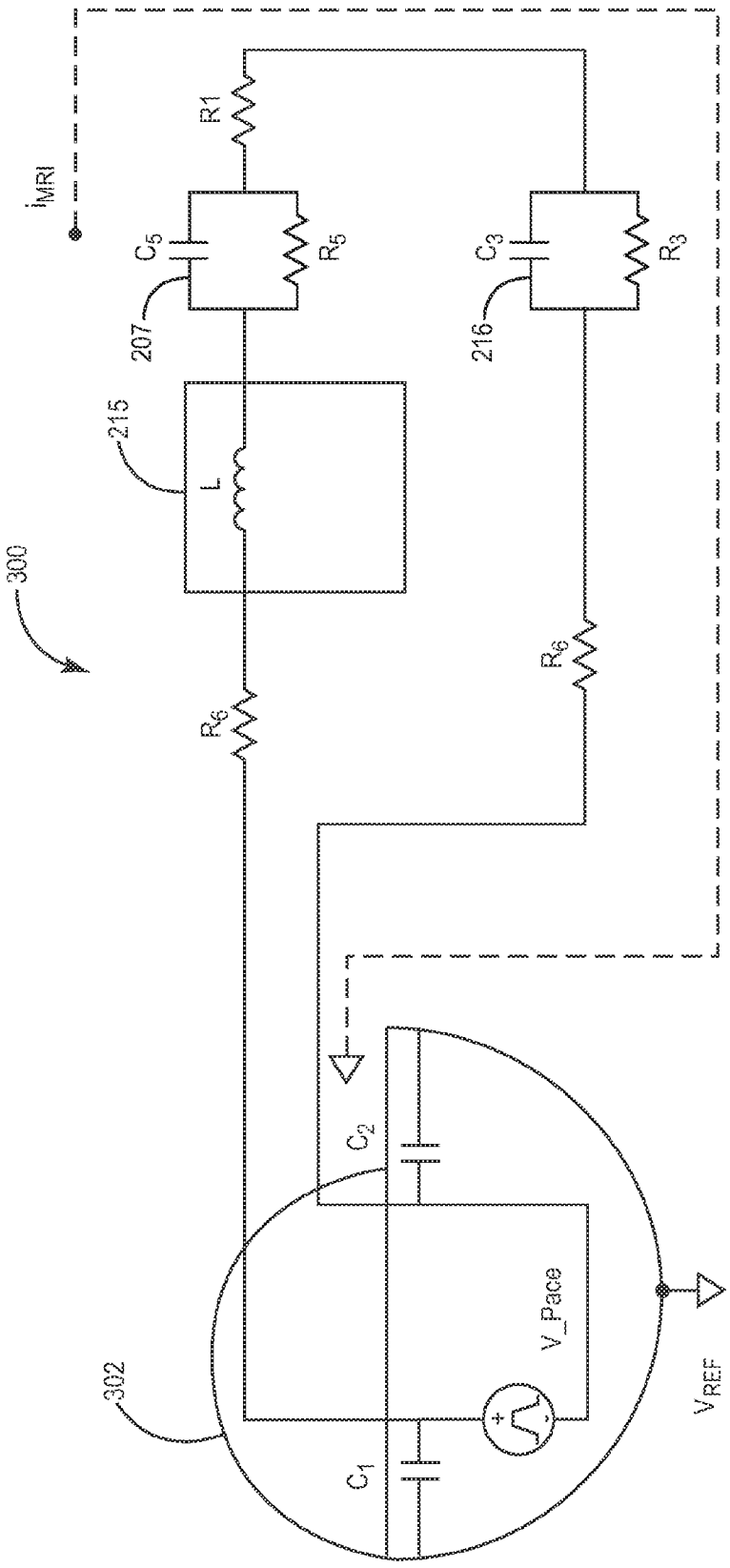

300
302
304a
215
207
216
i_{MRI}
R1
C_5
R_5
C_3
R_3
L
R_6
R_6
C_2
C_1
V_Pace
V_{REF}

Fig. 8A

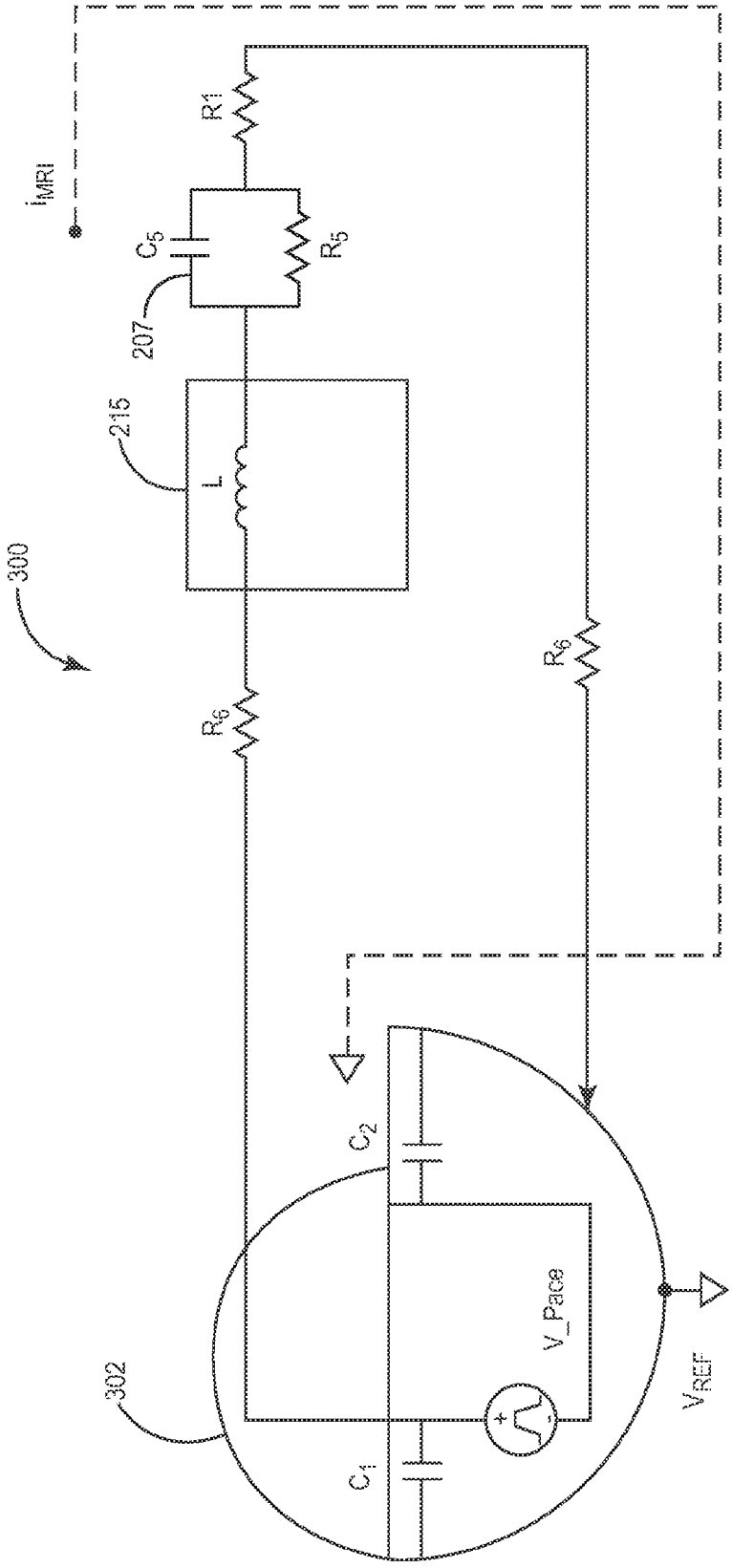


Fig. 8B

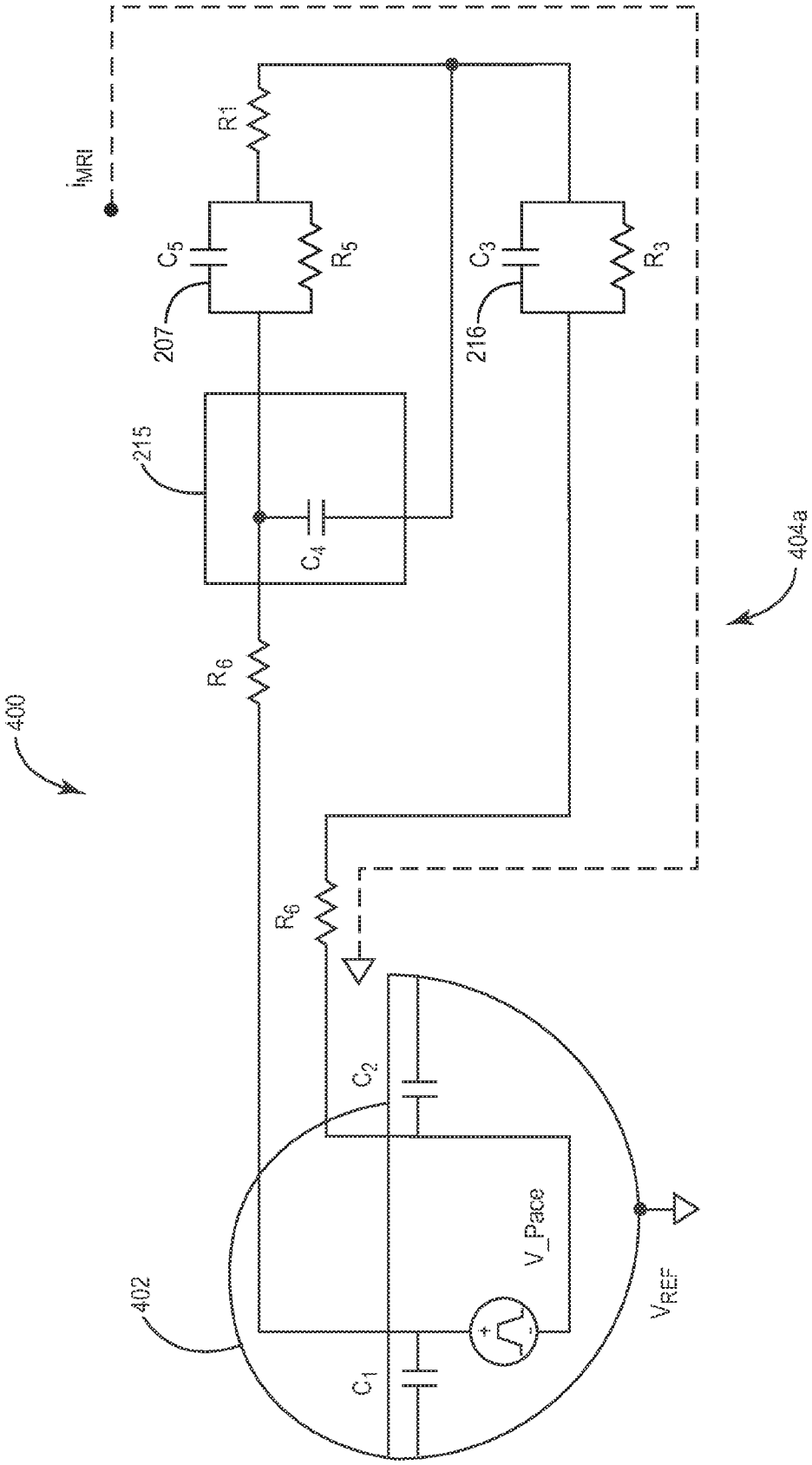

400
402
404a
i_{MRI}
R_1
C_5
R_5
207
C_3
R_3
216
215
C_4
R_6
R_6
C_2
V_Pace
V_{REF}
C_1

Fig. 9A

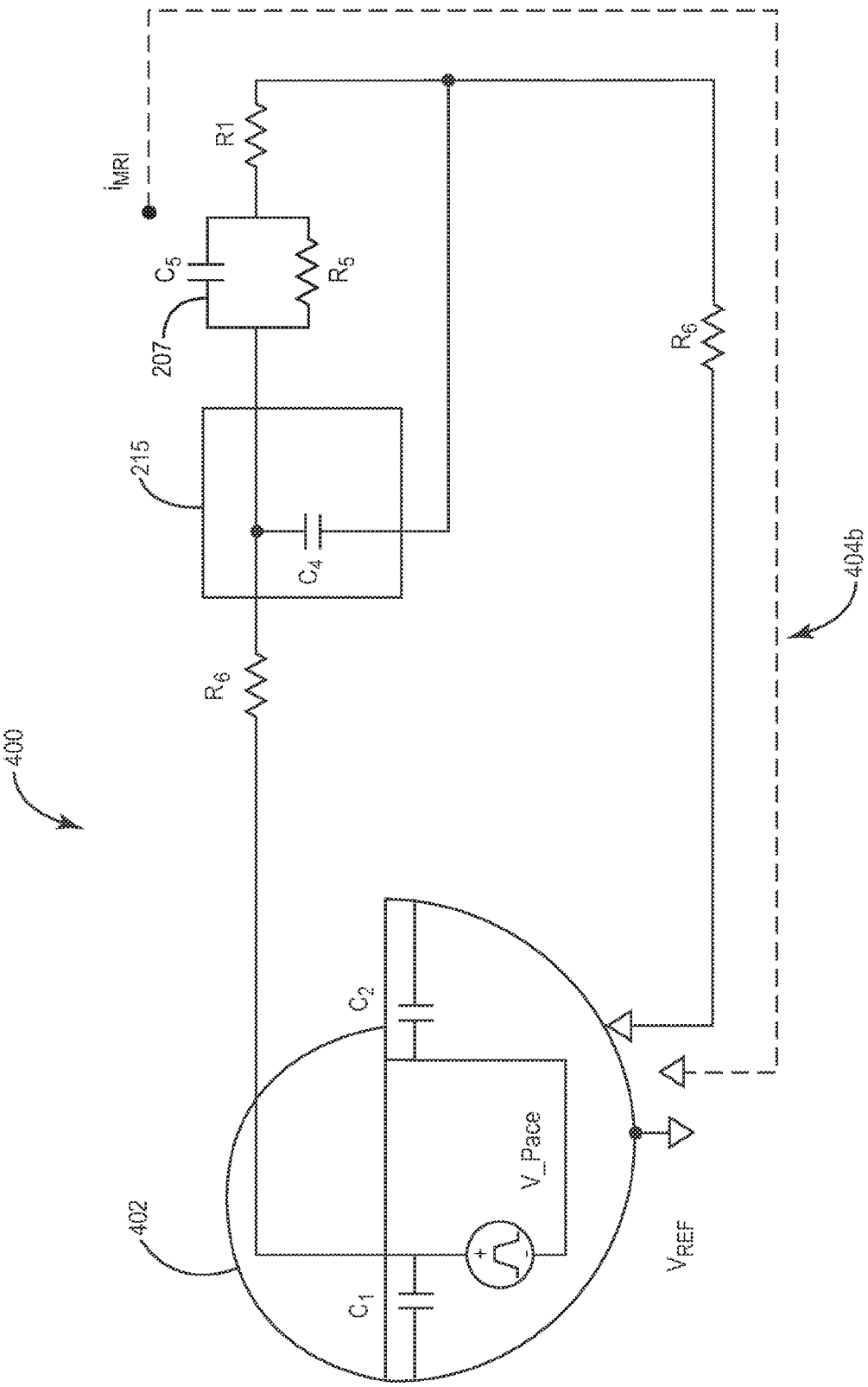


Fig. 9B

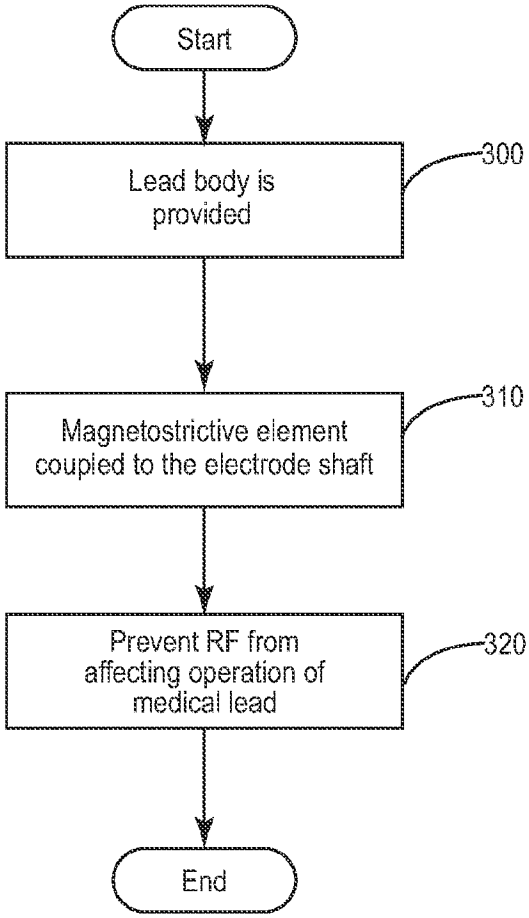

Start
Lead body is provided
300
Magnetostrictive element coupled to the electrode shaft
310
Prevent RF from affecting operation of medical lead
320
End

Fig. 10

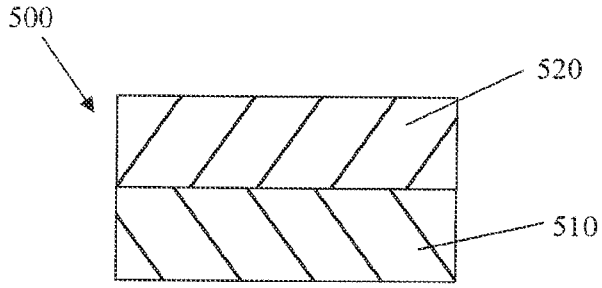


FIG. 11A

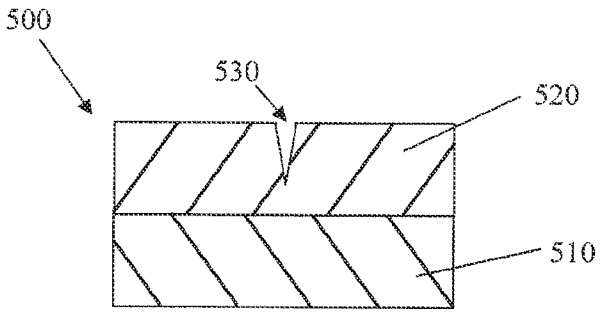


FIG. 11B

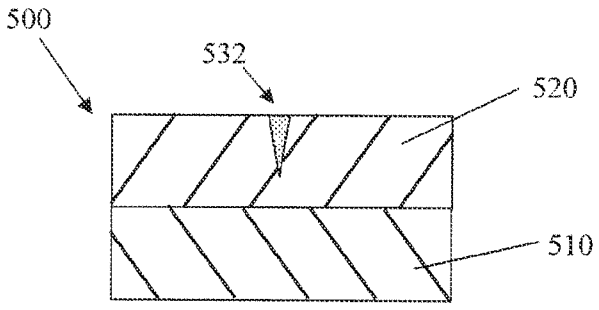


FIG. 11C

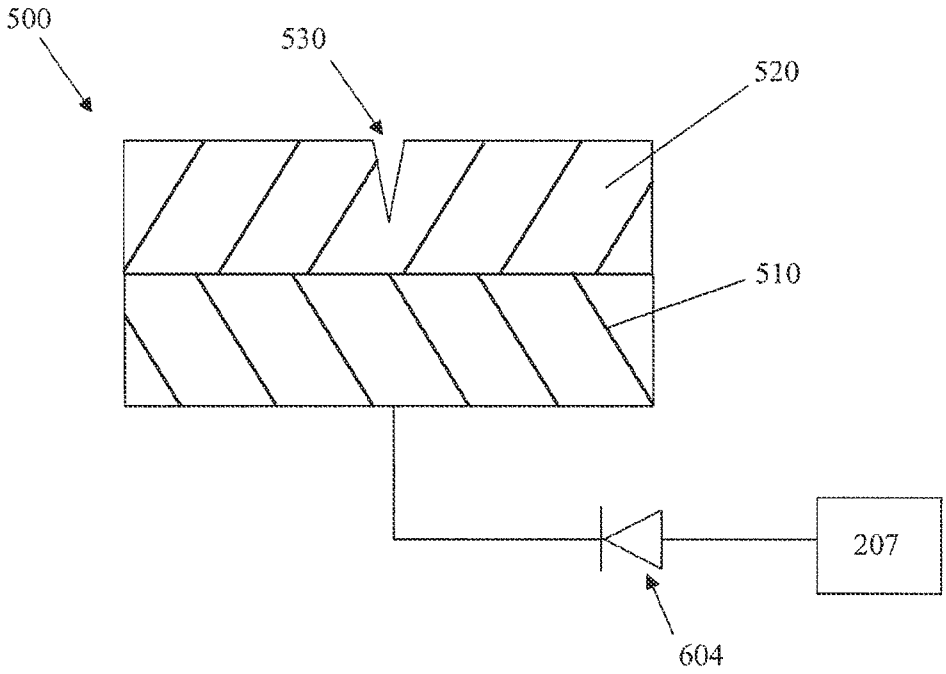


FIG. 12

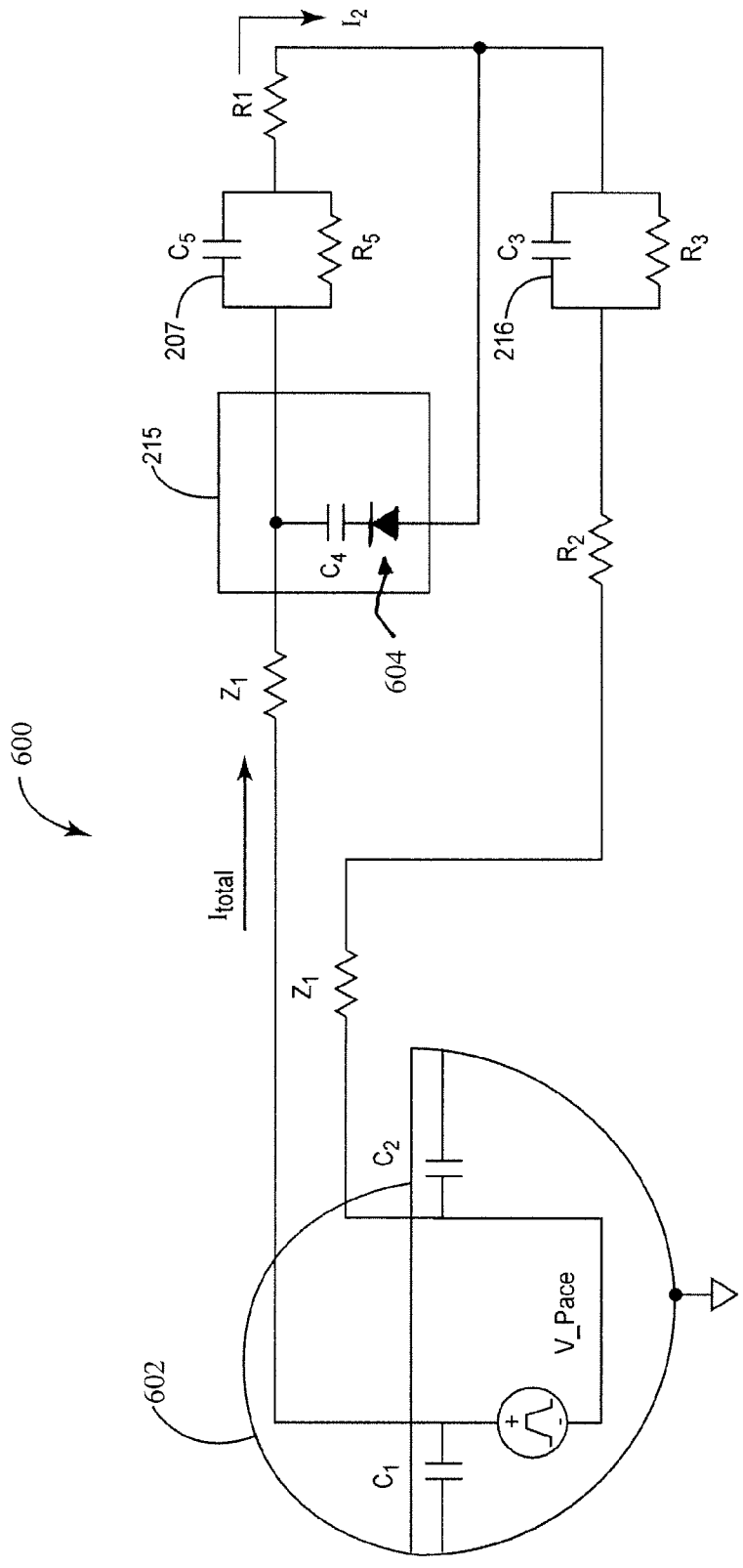

600
602
604
207
215
216
304c
R1
R2
R3
R5
C1
C2
C3
C4
C5
Z1
Z1
I2
Itotal
V_Pace

FIG. 13A

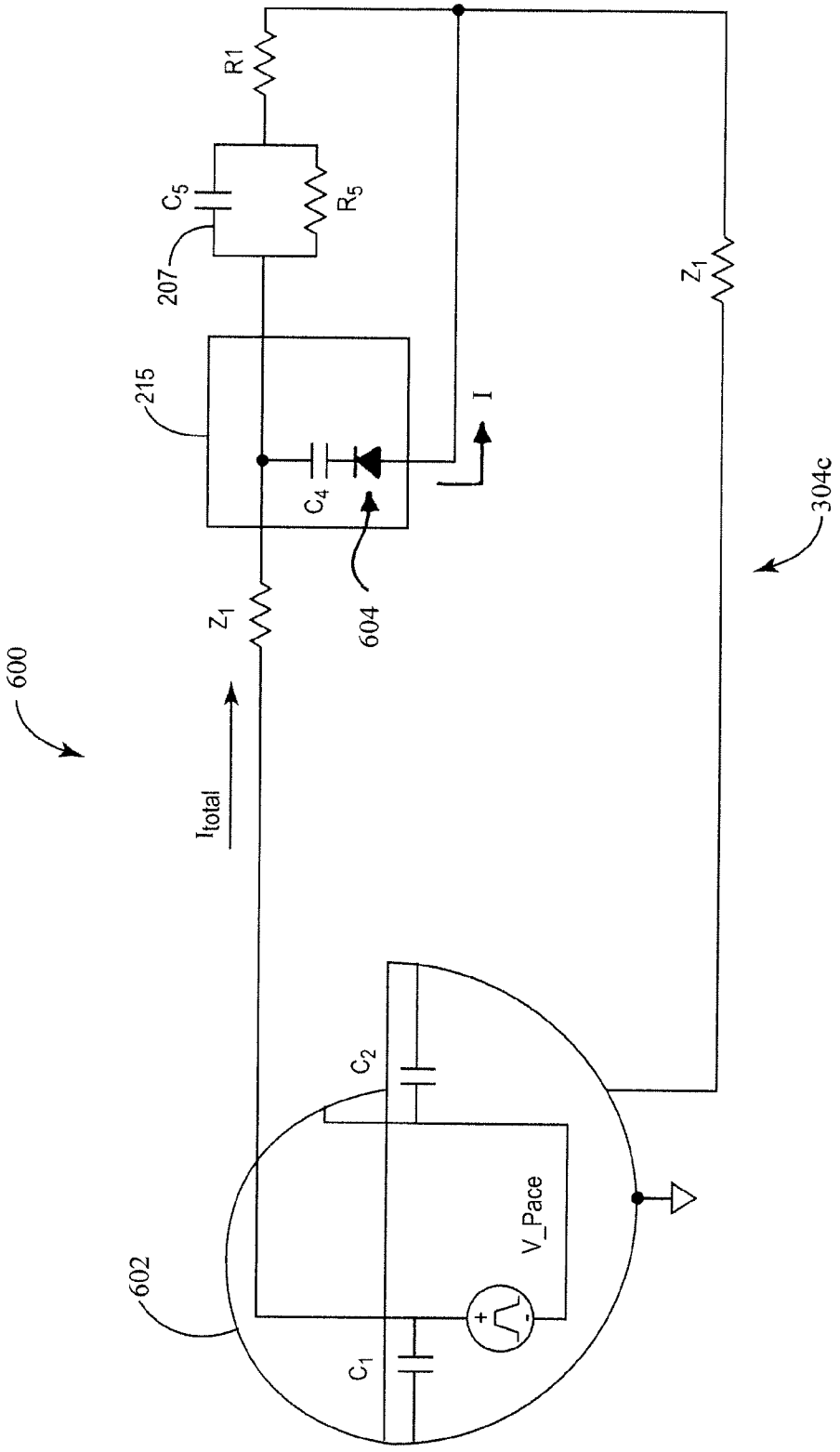


FIG. 13B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/042136

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/08

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, COMPENDEX, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/036865 A (MEDTRONIC INC [US]; REINKE JAMES D [US]; YANG ZHONGPING [US]; SOMMER J) 27 March 2008 (2008-03-27) abstract; figures 1-3,5,6,9 page 3, lines 5-11 page 3, line 20 - page 5, line 18 page 6, line 7 - page 7, line 27 page 8, line 29 - page 9, line 9	1,16
X	US 2006/271138 A1 (MACDONALD STUART G [US]) 30 November 2006 (2006-11-30) abstract; figures 1,2 paragraphs [0001], [0050] - [0063]	1,2,7, 16-18, 30-32
Y		3-6, 19-22, 33,34

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 June 2009	13/10/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Molina Silvestre, A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/042136

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	SHCHUKIN D G ET AL: "Layer-by-layer assembled nanocontainers for self-healing corrosion protection" ADVANCED MATERIALS 20060704 WILEY-VCH VERLAG DE, vol. 18, no. 13, 4 July 2006 (2006-07-04), pages 1672-1678, XP002533383 cited in the application the whole document	3-6, 19-22
Y	TOOHEY K S ET AL: "Self-healing materials with microvascular networks" Nature Materials Nature Publishing Group UK, vol. 6, no. 8, August 2007 (2007-08), pages 581-585, XP002533384 ISSN: 1476-1122 cited in the application the whole document	33,34
A	WU D Y ET AL: "Self-healing polymeric materials: A review of recent developments" PROGRESS IN POLYMER SCIENCE, PERGAMON PRESS, OXFORD, GB, vol. 33, no. 5, 4 March 2008 (2008-03-04), pages 479-522, XP022648873 ISSN: 0079-6700 [retrieved on 2008-03-04] cited in the application the whole document	1-7, 16-22, 30-34

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/042136

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

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

1. [X] Claims Nos.: 35-38
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7, 16-22 and 30-34

An electrode assembly with a self-healing or regenerative material comprising a dielectric layer, the dielectric layer having specific physical compositions or electrical properties (or a medical device system having such an electrode assembly).

---

2. claims: 8-15, 16 and 23-29

A medical device system adapted or configured to control the regeneration rate of a self-healing or regenerative material.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/042136

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008036865 A	27-03-2008	EP 2077896 A2	15-07-2009
		US 2007299490 A1	27-12-2007
US 2006271138 A1	30-11-2006	NONE	