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(54) **MRI CONDITIONALLY SAFE LEAD EXTENSION AND METHODS**

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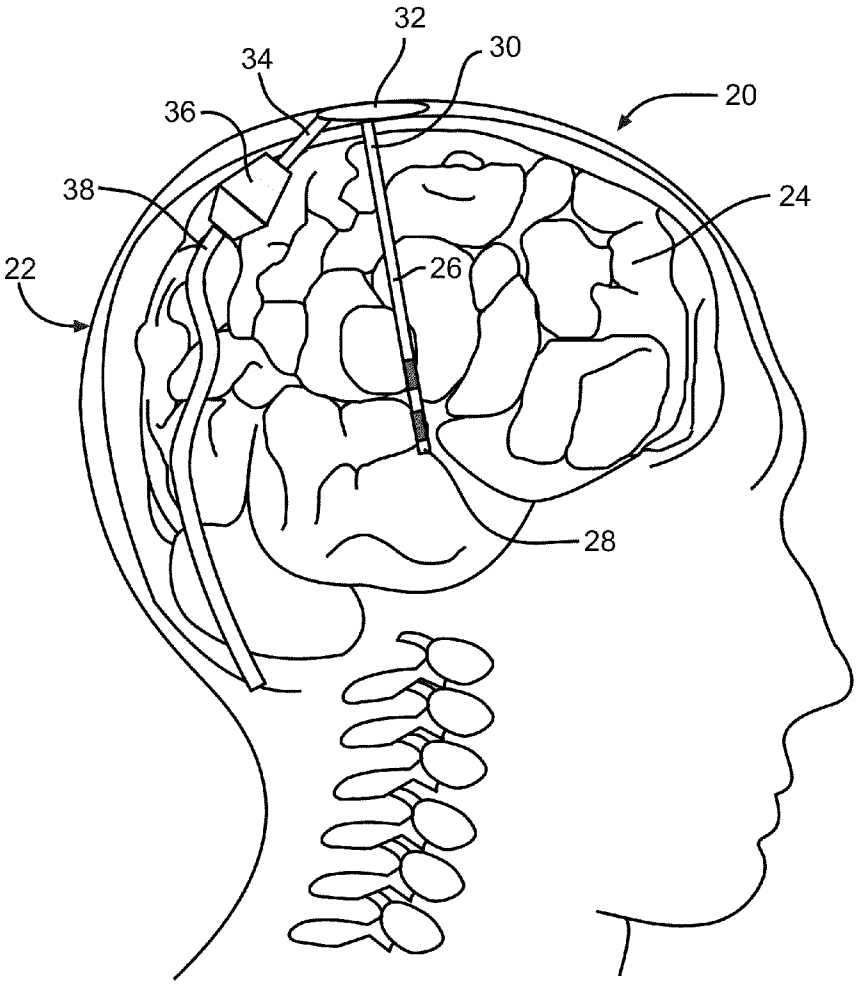
(57) **ABSTRACT**

Lead extensions, systems, and methods providing MRI compatible deep brain stimulation (DBS) and spinal cord stimulation (SCS) systems are described. Lead extensions are provided having band stop filters (BSFs) which resonate at a frequency expected from MRI systems to create a very high impedance which can effectively decouple the implanted lead from the lead extension proximal of the BSF and change the effective length. Changing the effective length can reduce the likelihood of undesirably heating tissue near the DBS/SCS electrodes during MRI. Some lead extensions include BSFs in a distal connector for coupling to the lead contacts. The BSFs can be included within a burr hole cap base which can also include a connector for connecting to the DBS lead. DBS and SCS leads having a sacrificial proximal portion and intermediate electrical contacts are also provided.



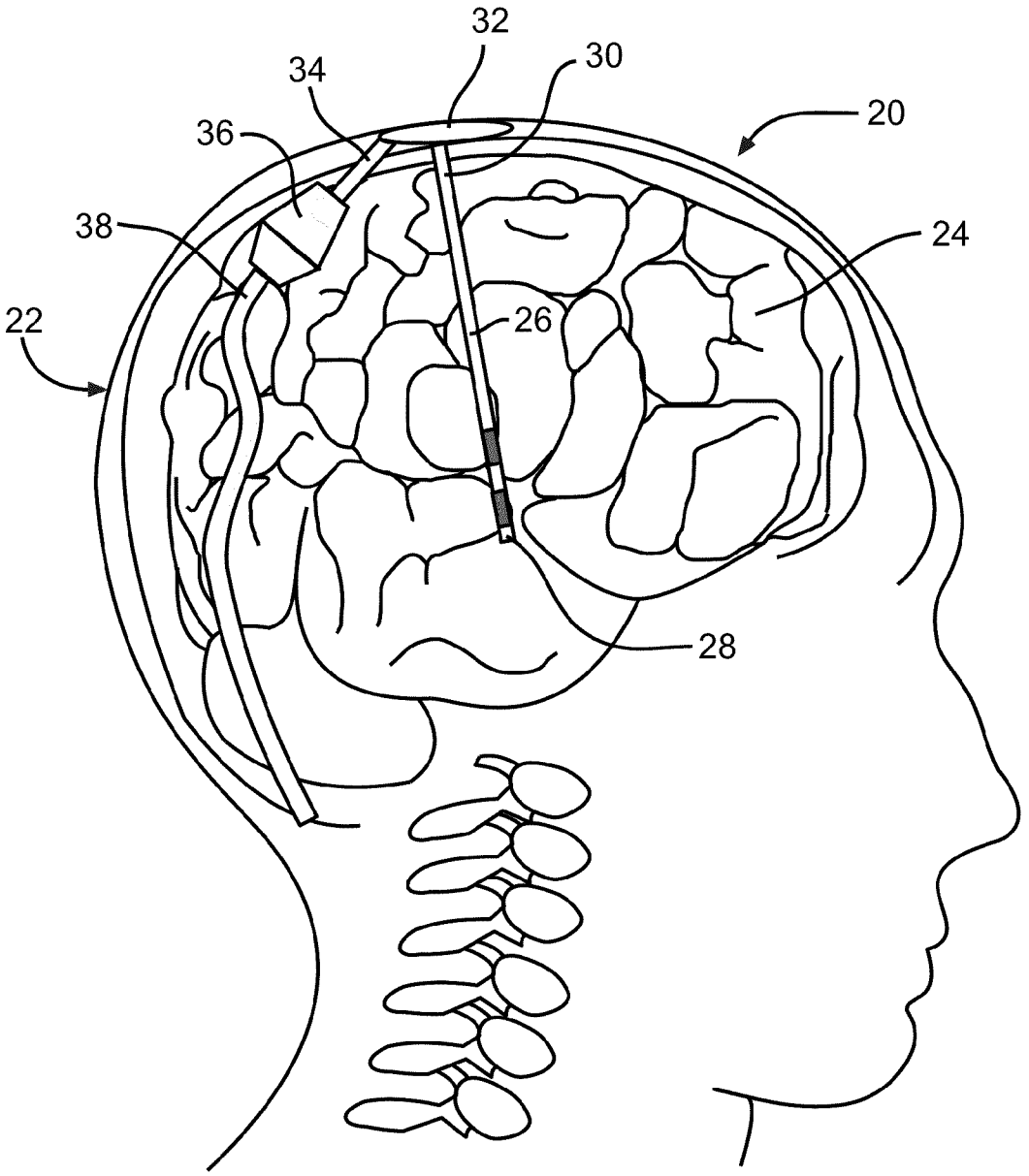


FIG. 1

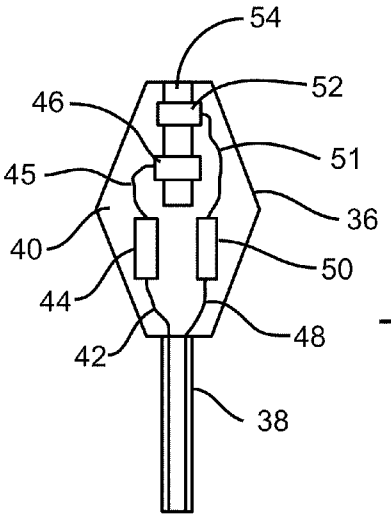


FIG. 2

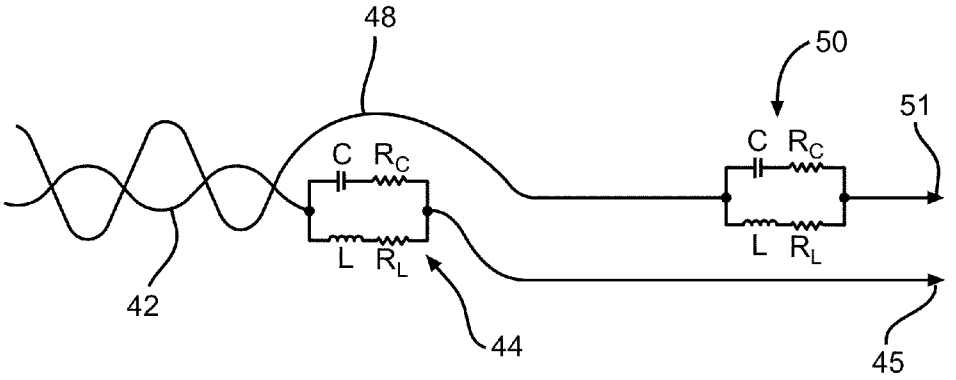


FIG. 3

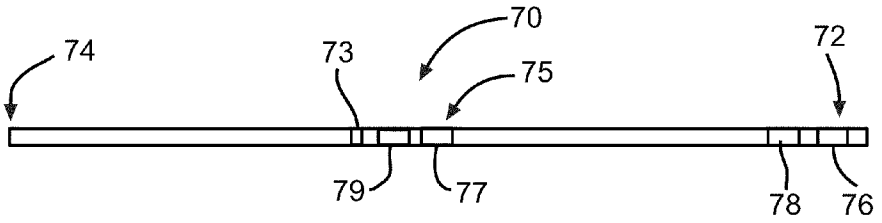


FIG. 4

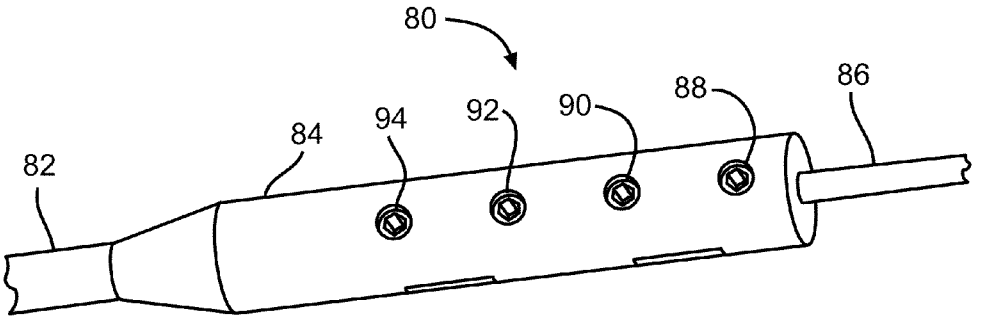


FIG. 5

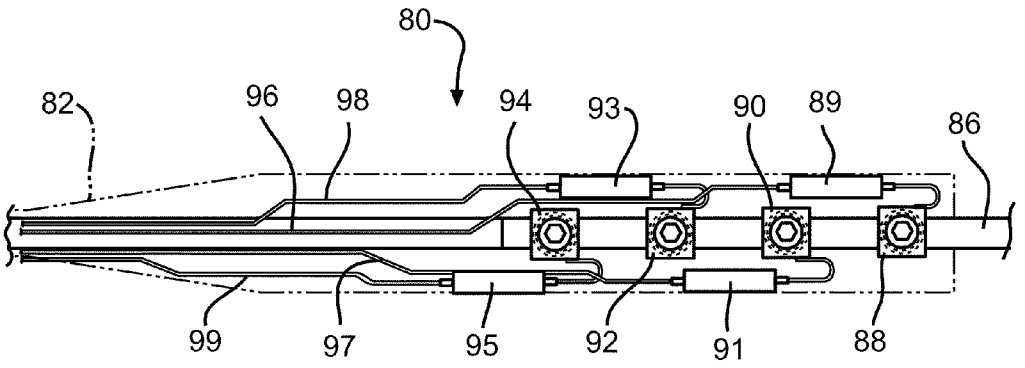


FIG. 6

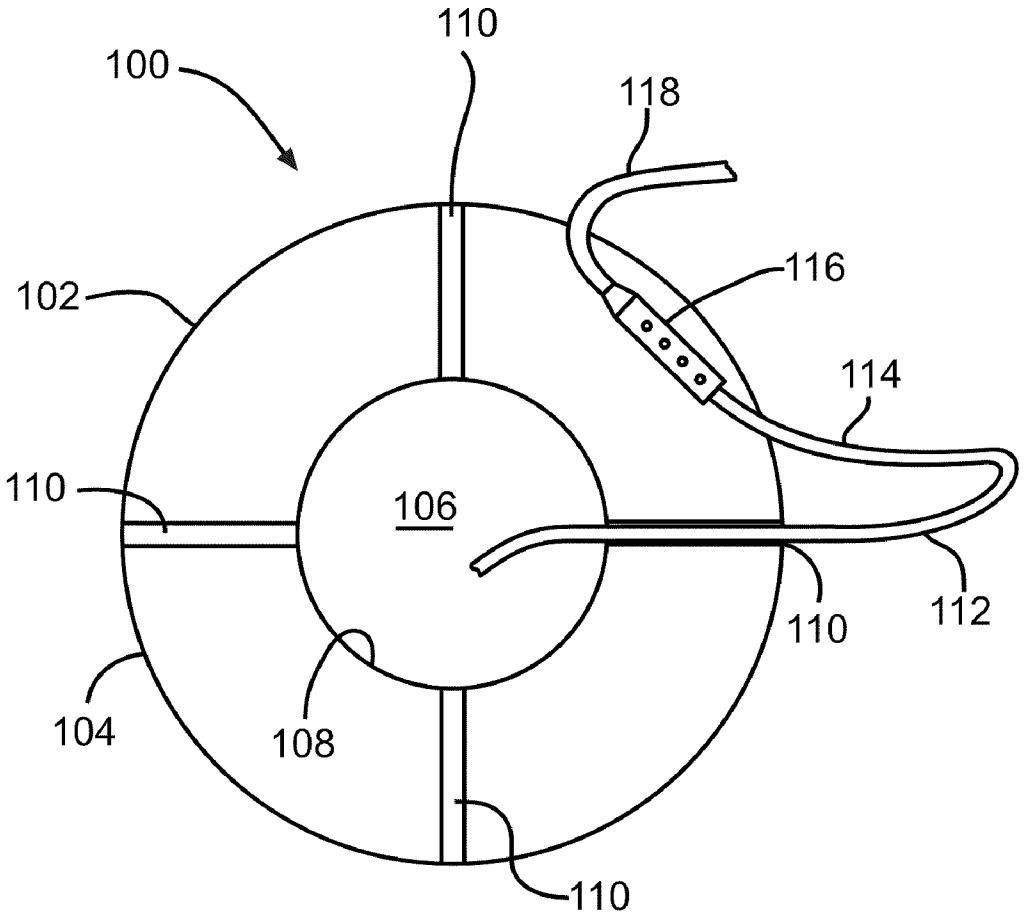


FIG. 7

MRI CONDITIONALLY SAFE LEAD EXTENSION AND METHODS

RELATED APPLICATIONS

[0001] This application is a non-provisional of U.S. provisional patent application No. 61/110,016, filed Oct. 31, 2008, herein incorporated by reference in its entirety.

BACKGROUND

[0002] MRI systems are well known to those skilled in the art and are well described in U.S. Pat. No. 7,363,090 (Halperin et al.). There are three types of electromagnetic fields used in an MRI unit. The first type is the main static magnetic field designated B_0 which is used to align protons in body tissue. The field strength varies from 0.5 to 3.0 Tesla in most of the currently available MRI units in clinical use. Some of the newer MRI system fields can go as high as 4 to 5 Tesla. It is a basic principle of physics that a magnetic field must either be time-varying as it cuts across the conductor, or the conductor itself must move within the magnetic field for currents to be induced. Thus, it is not likely (other than sudden system shut down) that the static MRI magnetic field can induce currents into a lead wire system.

[0003] The second type of field produced by magnetic resonance imaging is the pulsed RF field which is generated by the body coil or head coil. This is used to change the energy state of the protons and illicit MRI signals from tissue. The RF field is homogeneous in the central region and has two main components: (1) the magnetic field is circularly polarized in the actual plane; and (2) the electric field is related to the magnetic field by Maxwell's equations. In general, the RF field is switched on and off during measurements and usually has a frequency of 21 MHz to 64 MHz to 128 MHz depending upon the static magnetic field strength. The frequency of the RF pulse varies with the field strength of the main static field where: RF PULSED FREQUENCY in MHz=(42.56) (STATIC FIELD STRENGTH IN TESLA).

[0004] The third type of electromagnetic field is the time-varying magnetic gradient fields designated B_1 which are used for spatial localization. These change their strength along different orientations and operating frequencies on the order of 1 kHz. The vectors of the magnetic field gradients in the X, Y and Z directions are produced by three sets of orthogonally positioned coils and are switched on only during the measurements. In some cases, the gradient field has been shown to elevate natural heart rhythms (heart beat). This is not completely understood, but it is a repeatable phenomenon. The gradient field is not considered by many researchers to create any other adverse effects.

[0005] At the frequencies of interest in MRI, RF energy can be absorbed and converted to heat. The power deposited by RF pulses during MRI is complex and dependent upon the power (Specific Absorption Rate (SAR) Level) and duration of the RF pulse, the transmitted frequency, the number of RF pulses applied per unit time, and the type of configuration of the RF transmitter coil used. The amount of heating also depends upon the volume of tissue imaged, the electrical resistivity of tissue and the configuration of the anatomical region imaged. There are also a number of other variables that depend on the placement in the human body of the IPG and its associated lead wire(s). The routing of the lead and the lead length are also very critical as to the amount of induced current and heating that would occur.

[0006] The cause of heating in an MRI environment is twofold: (a) RF field coupling to the lead can occur which induces significant local heating; and (b) currents induced between the distal TIP and tissue during MRI RF pulse transmission sequences can cause local Ohms Law heating in tissue next to the distal TIP electrode of the implanted lead. The RF field of an MRI scanner can produce enough energy to induce lead wire currents sufficient to destroy some of the adjacent tissue. Tissue ablation has also been observed in pacing applications. The effects of this heating are not readily detectable by monitoring during the MRI.

[0007] PAD electrodes are very common in neurostimulator applications. For example, spinal cord stimulators or deep brain stimulators can include a plurality of PAD electrodes to make contact with nerve tissue. A good example of this also occurs in a cochlear implant. In a typical cochlear implant there would be sixteen RING electrodes that the physician places by pushing the electrode up into the cochlea. Several of these RING electrodes make contact with auditory nerves.

[0008] As previously mentioned, just variations in the lead wire length can significantly affect how much heat is generated. If one assumes, for example, a **3.0** Tesla MRI system, which would have an RF pulsed frequency of 128 MHz, there are certain implanted lead lengths that would couple efficiently as fractions of the 128 MHz wavelength. It is typical that a hospital will maintain an inventory of various leads and that the implanting physician will make a selection depending on the size of the patient, implant location and other factors. Accordingly, the implanted or effective lead wire length can vary considerably. There are certain implanted lead wire lengths that just do not couple efficiently with the MRI frequency and there are others that would couple very efficiently and thereby produce the worst case for heating.

[0009] Magnetic Resonance Imaging (MRI) systems are used to visualize internal body systems to a degree previously impossible. The use of MRI is contraindicated for many implanted electrical leads, as the leads may act as antennas, picking up the RF energy and converting that energy into heat at the distal end of the lead having the exposed electrodes in contact with the tissue. Some leads have been developed which have band stop filters (BSFs) included in the leads near the electrodes. The BSFs are provided to reduce the likelihood of heating tissue during an MRI procedure, making such procedures available to patients having implanted electrical devices. Such devices include pacemakers, cardioverters, and neurological stimulation devices. The size of the BSFs is often not an issue, due to the intended target site, the small number of lead wires, and/or the implantation techniques.

[0010] Deep Brain Stimulation (DBS) can be used to stimulate brain tissue deep within the brain. DBS can be used to treat Parkinson's disease, essential tremor, and epilepsy. The small diameter, fine stimulation leads would have to be substantially increased in profile to include BSFs. This increased profile would have to be pushed through the brain tissue to the target site. Such much larger stimulation leads would require substantially larger cannulas to advance the leads within. The larger cannulas would also have to be advanced through and deep into the brain. The larger size is undesirable and for these reasons the BSFs are not included in DBS leads.

[0011] Spinal Cord Stimulation (SCS) can be used to stimulate spinal cord tissue, typically from the epidural space. The SCS lead is typically introduced through a needle into the epidural space, and the needle removed over the lead once in place. Modern SCS leads may have several, small diameter

conductor wires contained within the lead body. The small diameter SCS leads would have to be substantially increased in profile to include BSFs. This increased profile would have to be pushed through the needle and epidural space, sometimes through a curved path, to the target site. Such much larger stimulation leads would require substantially larger needles and leads if having BSFs included in the lead body. The larger leads and needles are undesirable, and for this reason, the BSFs are also not included in SCS leads. SCS is well known in the art, and is discussed in U.S. Pat. No. 6,233,488.

[0012] When an MRI would be beneficial to, and given to most patients in a given medical situation, it may be denied to patients having DBS or SCS leads implanted. The treating physician may not want to incur the risk of heating the neurological tissue. The physician may balance the risk of tissue heating against the risk of not using the MRI, depending on severity of the medical reason for performing the MRI. The risk of possible tissue heating may not be worth the gain from the MRI.

[0013] The risk assessment is difficult, as the lead placement, travel path, length, orientation within the body relative to the MRI fields, and the nature of the tissue can all play a role in determining whether and how much tissue heating will occur. MRIs have been performed on DBS and SCS patients with no apparent ill effects. MRIs have been denied DBS and SCS patients due to the fear of ill effects.

[0014] What would be desirable are devices and methods providing deep brain stimulation and spinal cord stimulation while using MRI safe leads.

SUMMARY

[0015] Some embodiments of the present invention provide lead extensions, systems, and methods for MRI compatible deep brain stimulation (DBS) systems and spinal cord stimulation (SCS) systems. Lead extensions are provided having band stop filters (BSFs) which resonate at a frequency expected from MRI systems to create a very high impedance which can effectively decouple the implanted lead from the lead extension proximal of the BSF and change the effective length. Changing the effective length can reduce the likelihood of undesirably heating tissue near the DBS or SCS electrodes during MRI. Some lead extensions include BSFs in a distal connector for coupling to the lead contacts. The BSFs can be included within a burr hole cap base which can also include a connector for connecting to the DBS lead. DBS and SCS leads having a sacrificial proximal portion and intermediately disposed electrical contacts are also provided.

[0016] Some embodiments of the present invention provide resonant tank or band stop filters which can be placed at various locations along the active implantable medical device lead extension system, which also prevents current from circulating at selected frequencies of the medical therapeutic device. Some embodiment tank filters are designed to resonate at 64 MHz for use in an MRI system operating at 1.5 Tesla (or 128 MHz for a 3 Tesla system).

[0017] Some embodiments of the present invention include lead extensions for coupling to a lead where the lead has a lead distal region having at least one electrode thereon, a lead proximal region having at least one electrical contact thereon, and a lead length. The lead extension can include a lead extension body having a lead extension proximal region, a lead extension distal region, and at least one electrical conductor disposed within and extending between the lead extension proximal and distal regions. The lead extension can also have at least one band stop filter (BSF) including a capacitor in parallel with an inductor, with the parallel capacitor and inductor combination placed in series with each (or each and every one) of the electrical conductors somewhere between the lead extension proximal and distal regions. The values of capacitance and inductance can be selected such that the band stop filter is resonant around a selected frequency, for example the expected frequency of the MRI system to be encountered, for example, 64 MHz or 128 MHz.

[0018] In some such lead extensions, the BSF has a Q factor, and the overall Q of the BSF is selected to balance impedance at the selected frequency versus frequency band width characteristics. The BSF can be located a distance from the lead extension distal region adapted to reduce resonance with the MRI signal when used in combination with the lead length, in some embodiments. The distance from the BSF to the lead distal end when the lead and the lead extension are coupled together is substantially not equal to a fractional wavelength 1/n of the MRI system, where n is between 1 and 4. In one example, the distance from the BSF to the lead distal end when the lead and the lead extension are coupled together is less than about 15 cm. The lead extension can include a distal connector and the BSF can be included within the lead extension distal connector. The lead extension distal connector can include at least one insertion port for receiving the lead proximal region where the BSF is coupled to the insertion port.

[0019] In some lead extensions, the lead extension distal region includes a burr hole cap base for capping a burr hole, the burr hole cap base including an annular body disposed between a central aperture and an outer periphery, the body being MRI compatible. The burr hole cap base can also include at least one connector coupled to the body for electrically coupling to the lead proximal contact, wherein the BSF is mechanically coupled to the burr hole cap base.

[0020] Some embodiments of the present invention provide a lead for neuro stimulation (NS), the lead including a distal end and a proximal end having a first length therebetween, and a distal region having at least one electrode adapted for NS thereon. The lead can also have an intermediate region having at least one electrical contact thereon and disposed between the lead distal end and the lead proximal end, where a second length exists between the intermediate region and the lead distal end. At least one electrical conductor can extend between and be in electrical communication with the electrode and the electrical contact, where the first length is at least about twice the second length, and wherein the lead can be severed proximal of the electrical contact without compromising the NS functionality.

[0021] In some such leads, the intermediate region includes a visual indicia disposed proximal of the electrical contact indicating a location for cutting the lead after implantation. The intermediate region can include a region of preferential weakness disposed proximal of the contact indicating a location for severing the lead after implantation, where the region of preferential weakness may include a circumferential groove or scoring. Some leads have an outer diameter of less than about 2 mm and the first length is less than about 15 cm. The lead may have at least about 4 distinct conductor wires and an outer diameter of less than about 2 mm.

[0022] Some embodiments of the invention provide a burr hole cap base for capping a burr hole, the burr hole cap base including an annular body disposed between a central aper-

ture and an outer periphery, the body being MRI compatible. The base can have at least one connector coupled to the body for electrically coupling to at least one proximal contact of a DBS lead and at least one BSF electrically coupled to the at least one connector, the BSF including a capacitor in parallel with an inductor. Some bases include a lead feed through for feeding the lead from the central aperture to the outer periphery. The base can include a lead fixation structure for fixing position of the lead and inhibiting lead movement after fixation. The base body can include a lead feed through fixation structure for feeding the lead from the central aperture to the outer periphery and preventing movement of the lead at the feed through.

[0023] Embodiments of the present invention can also include methods for placing a neurological stimulation (NS) lead, some methods including advancing a tubular introducer to near a target tissue, advancing the NS lead to near the target tissue within the tubular introducer, and removing the tubular introducer over the NS lead. The methods can also include coupling a NS electrical contact to a lead extension distal electrical connector, in which the lead extension includes a band stop filter (BSF) in series with a lead extension electrical conductor.

[0024] In some such methods, the target tissue is brain tissue, the NS lead is a deep brain stimulation (DBS) lead, and the tubular introducer is a cannula. The lead extension electrical connector can be disposed within a burr hole cap base, such that the DBS lead extends through the burr hole cap base and the DBS lead proximal region couples to the burr hole cap base. In other such methods, the target tissue is spinal cord nerve tissue, the NS lead is a spinal cord stimulation (SCS) lead, and the tubular introducer is a hollow needle.

[0025] Some methods further include severing the NS lead proximal of the lead electrical contact after the tubular introducer has been removed over the NS lead. The length removed can be longer than the length remaining, in some methods. The lead extension can be configured such that the length from the BSF to the lead electrode is not near a substantial resonant wavelength of an expected MRI system, or is less than that wavelength, in various embodiments. Methods can also include electrically coupling a lead extension proximal region to a pulse generator. Performing an MRI including the target tissue after the lead extension with BSF has been coupled to the inserted lead is included in some methods. The MRI is performed prior to connecting the lead extension to an IPG in some embodiment methods. The target tissue can also be a peripheral nerve selected from the group consisting of a sacral nerve, occipital nerve, facial nerve, hypoglossal nerve, vagus nerve, and splanchnic nerve.

[0026] In various embodiment methods, the lead extension is configured such that the length from the BSF to the lead electrode is less than about 20 cm, 15 cm, 12 cm, and 10 cm. The lead extension is configured such that the length from the BSF to the lead electrode is less than about one-half wavelength or one-quarter wavelength of the expected MRI system. If the wavelength is about 46 cm (e.g. a 1.5 Tesla system), then the lengths would be less than about 23 and less than about 11-12 cm, respectively. If the wavelength is about 23 cm (e.g. a 3 Tesla system), the lengths would be less than about 11-12 cm, and less than about 5-6 cm, respectively.

[0027] Some embodiments of the present invention provide resonant tank or band stop filters which can be placed at various locations along the active implantable medical device lead extension system. These band stop filters prevent current from circulating at selected frequencies of the medical therapeutic device. For example, for an MRI system operating at 1.5 Tesla, the pulse RF frequency is 64 MHz (or 128 MHz for a 3 Tesla system). The band stop filters of the present invention can be designed to resonate at 64 MHz and thus create an open circuit in the implanted lead wire system at that selected frequency.

[0028] In some embodiments, the overall Q factor of the band stop filter is selected to balance impedance at the selected frequency versus frequency band width characteristics. More specifically, the Q of the inductor is relatively maximized and the Q of the capacitor is relatively minimized to reduce the overall Q of the band stop filter. The Q of the inductor is relatively maximized by minimizing the parasitic resistive loss in the inductor, and the Q of the capacitor is relatively minimized by raising its equivalent series resistance (ESR) of the capacitor (or by adding resistance or a resistive element in series with the capacitor element of the bank stop tank filter). This reduces the overall Q of the band stop filter in order to broaden its 3 dB points and thereby attenuate current flow through the lead wire along a range of selected frequencies. In IPG or external medical device applications, the range of selected frequencies includes a plurality of MRI pulsed frequencies. The capacitor Q can be raised in a controlled manner in the tank filter circuit in order to adjust its Q and adjust the band stop frequency width in the range of MRI pulsed frequencies.

[0029] The overall Q of the tank filter circuit may be reduced by increasing the Q of the inductor and reducing the Q of the capacitor. In this regard, minimizing resistive loss in the inductor maximizes the Q of the inductor, and raising the equivalent series resistance of the capacitor minimizes the Q of the capacitor. The net effect is to reduce the overall Q of the tank filter circuit which widens the band stop width to attenuate current flow through the lead wire along a range of selected frequencies. As discussed herein, the range of selected frequencies may include a plurality of MRI pulse frequencies.

[0030] Some of the embodiments described herein are also applicable to a wide range of other active implantable medical devices, including deep brain stimulators, spinal cord stimulators, cochlear implants, ventricular assist devices, artificial hearts, drug pumps, and the like. Some embodiments of the present invention can fulfill needs regarding reduction or elimination of undesirable currents and associated heating in implanted lead wire systems.

DESCRIPTION OF DRAWINGS

[0031] FIG. **1** is a transverse, cross-sectional view of a human head having a deep brain stimulation (DBS) lead implanted within, extending out through a burr hole cap, and coupled to an implantable pulse generator (IPG) through a lead extension having a band stop filter (BSF).

[0032] FIG. **2** is a schematic diagram of a two conductor lead extension connector having two band stop filters within.

[0033] FIG. **3** is a schematic diagram of two conductors having one band stop filter per lead conductor.

[0034] FIG. **4** is a side view of a stimulation lead having distal electrodes, intermediate contacts, and a removable proximal portion.

[0035] FIG. **5** is a fragmentary, perspective view of a lead extension distal connector receiving a lead proximal region, with the lead extension distal connector having band stop filters within.

[0036] FIG. **6** is a fragmentary, transverse, cross-sectional view of the lead extension connector and lead of FIG. **5**, showing the band stop filters within.

[0037] FIG. **7** is a highly diagrammatic top view of a burr hole cap base and lead extension connector having set screw blocks and band stop filters within, receiving a DBS lead proximal contact carrying region.

DETAILED DESCRIPTION

[0038] The embodiments described in this present application are intended to illustrate varies embodiments of the present invention and are not intended to limit the invention to those embodiments. The limitations are recited in the claims. All patents and published patent applications in the present application are to be understood as incorporated by reference unless noted otherwise.

[0039] FIG. **1** illustrates a human patient **20** having a skull **22** and a brain **24** within. A deep brain stimulation (DBS) lead **26** is shown inserted into brain **24** for a deep brain stimulation therapy. DBS lead **26** includes a lead distal end **28** having two electrodes in the example shown in FIG. **1**. DBS lead **26** is shown exiting the skull at **30** through a burr hole covered by a burr hole cap **32**. DBS lead **26** continues proximally to a DBS lead proximal region **34** which is coupled to a lead extension connector **36**. In the example shown, lead extension connector **36** is coupled to a lead extension distal region **38**. In many applications, DBS lead proximal region **34**, lead extension connector **36**, and lead extension distal region **38** are all tunneled outside of the skull but underneath the skin. In some applications, the lead extension can be tunneled down the neck and to an implantable pulse generator (IPG) for the deep brain stimulation therapy.

[0040] DBS implantation methods are well known to those skilled in the art. One explanation may be found in U.S. Patent Application Publication No. 2007/0233158. While methods for implanting DBS lead **26** need not be explained in great detail, a brief summary may be useful here. Prior to implantation, standard visualization methods including MRI's, X-rays, CAT scans, and the like can be performed. Often radiopaque markers called fuduciaries are secured to the patient's skull to provide fixed points of reference which will show up on the early visualization procedures and allow accurate points of reference and navigation during the actual implantation procedure. The location of the target region can be mapped out and the route planned ahead of time, using the results from the visualization procedures.

[0041] A stereotactic frame is typically secured to the patient's head, to fix movement of the devices relative to the head. A burr hole can be drilled through the skull, providing access to the brain for the DBS lead and other instruments. A burr hole cap base may then be put in place over the burr hole. In some methods, a small micro recording lead can be advanced to the target site and used to record brain signals to determine the proper location for implanting the DBS lead. The micro recording lead is often advanced within a stiffer and more pushable micro cannula and the micro recording lead pushed past the distal end of the cannula into the target tissue.

[0042] With the target tissue located, the micro recording lead can be withdrawn and replaced with a macro stimulation lead in some methods. The macro stimulation lead can also be advanced within a stiffer, more pushable macro cannula. The macro stimulation lead can be used to test stimulation of the target tissue. With the location better identified and partially tested, the macro cannula and macro lead can be withdrawn.

[0043] The stereotactic equipment can be used to advance a cannula over a desired path to the target tissue location. DBS lead **26** can be advanced together and/or within the cannula to approach the target tissue site. The DBS lead may have multiple wire conductors but yet preferably have a small profile to avoid displacing brain tissue as much as possible. Given the small desired size of the DBS lead, as previously mentioned, it is often undesirable to make the cannula and lead large enough to advance the band stop filters through the cannula to near the target tissue site. With the DBS lead implanted, the cannula can be withdrawn over the DBS lead, leaving the lead in place. The free, proximal end of the DBS lead carrying the contact electrodes also must fit through the cannula in most applications. With the free end of the DBS lead accessible, the lead proximal region may exit the burr hole through a central opening in a burr hole cap **32**. DBS lead proximal region **34** can then be electrically and mechanically coupled to a connector **36** which is electrically and mechanically coupled to the lead extension body. In some embodiments, band stop filters are included within the distal connector of the lead extension. In other embodiments, the band stop filters can be incorporated within the lead extension body itself, as the lead extension body does not have to be small enough to pass through the cannula. The lead extension body can be further tunneled under the scalp, down the neck, and to an implantable pulse generator (IPG) which can be located in a surgically formed pocket.

[0044] Burr hole cap **32** often includes an annular base portion which covers the edges of the burr hole itself, as well as a cap which fits into the central opening of the burr hole cap base, while allowing the lead to be fed through the burr hole base and/or cap.

[0045] FIG. **2** shows the lead extension connector **36** and lead extension distal region **38** of FIG. **1**. Lead extension connector **36** is shown in a highly diagrammatic, cutaway fashion. Lead extension **36** includes a body **40**, which can be formed of an MRI compatible material, for example, a plastic. In the example shown, the connector is adapted to couple two extension conductor wires to two conductor wires within the lead, which presumably has two distal electrodes. Lead extension **36** includes a first conductor or wire **42** coupled to a first band stop filter **44** which is coupled to a first receiving contact **46** through a first conducting wire **45**. Similarly, a second conductor or wire **48** is coupled to a second band stop filter **50** which is coupled to a second receiving contact **52** through a conducting wire **51**.

[0046] In the example shown, receiving contacts **46** and **52** form compressive metallic rings which are urged against a lead carrying external ring or band contacts as carried on the proximal region of a neurological stimulation lead. Lead extension connector **36** includes a lead receiving port **54** for receiving the proximal region of a neurological stimulation lead.

[0047] FIG. **3** shows in more detail the band stop filter of FIG. **2** having first band stop filter **50** coupled to first conductor **48** and a second band stop filter **44** coupled to second conductor **42**. First band stop filter **50** is coupled in series between first conductor **48** and the portion of the first conductor leading to the first lead electrode as indicated at **51**. Similarly, second band stop filter **44** is coupled in series with second conductor **42** and the second conductor portion leading to the second lead electrode as indicated at **45**.

[0048] In some embodiments, each and every conductor wire within the neurological stimulation lead extension includes a band stop filter. First band stop filter **50** is shown having a capacitor indicated by C in series with a non-ideal resistance indicated by R_C. Similarly, the band stop filter inductor is indicated by an L and is in series with the non-ideal resistance of the conductor indicated by R_L. The capacitor and inductor are coupled in parallel to form a so-called tank circuit or band stop filter. By selecting the proper values of the inductor and the capacitor, along with careful attention to the non-ideal real properties of the capacitor and the inductor, a band stop filter can be created as is well known now to those skilled in the art. At a frequency and wavelength expected from a typical MRI system, the band stop filters can be engineered to resonate at that frequency, creating a very high impedance and effectively breaking the electrical continuity of the lead, thereby shortening the effective length of the lead and substantially changing the RF resonant properties of the lead.

[0049] In some embodiments, the value of L is between about 1 and 100 nanohenries. The value of C may be between about 100 to 4000 picofarads.

[0050] MRI systems vary in static field strength from 0.5 Tesla all the way up to 3 Tesla with newer research machines going much higher. This is the force of the main static magnetic field. The frequency of the pulsed RF field associated with MRI is found by multiplying the static field in Teslas times 42.45. Accordingly, a 3 Tesla MRI system has a pulsed RF field of approximately 128 MHz.

[0051] The Q factor can be expressed using the equation $Q=f_r/\Delta f_{3\ dB}$, where f_r is the resonance frequency and $\Delta f_{3\ dB}$ is the bandwidth of the BSF. The bandwidth of the BSF can be taken as the difference between the two measured frequencies on either side of f_r at the 3 dB loss points as measured on an insertion loss chart. The resonance frequency is the average between these two frequencies on either side. As can be seen in this relationship, higher Q values result in a narrower 3 dB bandwidth.

[0052] In some BSFs, the Q of the inductor is relatively high and the Q of the capacitor is relatively low to select the overall Q of the band stop filter. The inductor can have a relatively low resistive loss and the capacitor has a relatively high equivalent series resistance. The overall Q of the band stop filter can be selected to attenuate current flow through the lead wire along a range of selected frequencies. In some embodiments, the range of selected frequencies includes a plurality of MRI pulsed frequencies.

[0053] If a lead electrode were located to the right of reference numeral **51** in FIG. **3**, and if the length of conductor shown was at a resonant frequency of the MRI system, the absorbed RF energy could generate heat at the distal electrodes. With band stop filter **50** in place, the effective length of the wire is shortened and the electrical continuity from the proximal portion of the wire to the left of the lead electrode is also disrupted by the greatly increased impedance of band stop filter **50** at the MRI frequency. While it would be ideal to have a band stop filter located deep in the brain near the distal electrode, as previously explained, this itself is less than desirable. Applicants have determined that while implanting band stop filters within the brain may not be feasible for most applications, locating the band stop filters soon after the lead exits the body can also be effective in substantially changing the effective length of the conductor and breaking the electrical continuity between the more proximal conductor regions and the more distal regions leading to the implanted distal electrode.

[0054] FIG. **4** shows another aspect of the present invention. A lead **70** is shown having a distal region **72**, a proximal region **74**, and an intermediate region **75** located in between the distal and proximal regions. In some embodiments, intermediate region **75** is located about halfway between the distal and proximal regions. In other embodiments, intermediate region **75** is located such that the distance between the proximal most electrical contact and the proximal end is greater than the distance from the proximal most electrical contact to the lead distal end. Distal region **72** includes a first electrode **76** and a second electrode **78**. Intermediate region **75** includes a first contact **77** and a second contact **79**. Electrodes **76** and **78** can be used for neurological stimulation, while contacts **80** and **82** can be used to couple to a lead extension.

[0055] A severing location **73** is also shown. In various embodiments, severing location **73** can include some visual indicia of the location, and/or a region of preferential weakness. In various embodiments, the region of preferential weakness can include circumferential scoring and/or perforations to promote severing at the desired severing location **73**. In use, and with possible reference to FIG. **1**, lead **70** can be advanced through a cannula to the target site in the brain, spinal epidural space, or other tissue. Intermediate region **75** and proximal region **74** may both extend proximally out of the cannula. Once the cannula is removed over lead **70**, the lead can be severed proximal of the proximal most electrical contact, for example, at indicated severing location **73**. In some embodiments, not requiring separate illustration, a set of corresponding proximal electrical contacts similar to contacts **77** and **79** can be provided in proximal region **74**. Such contacts can be used to stimulate and be in electrical communication with the distal electrodes **76** and **78**. Such electrode contacts in the proximal region could be used during the implantation process.

[0056] But for the severing of the lead, any lead extension would likely be coupled to the lead proximal region **74** as shown, and the length of the entire lead would be at least about twice the length of the implanted portion of the lead. This is because the lead must often be double the required length just to allow removing the cannula over the lead while maintaining control of the lead. Severing lead **70** can thus be used to attach band stop filters at a location much closer to the distal electrodes than would otherwise be possible. By shortening the lead in this way, the effective length of the RF antenna can be shortened and the RF energy absorbed by the lead extension length proximal of the band stop filters decoupled from the distal electrodes.

[0057] FIG. **5** illustrates one lead extension distal connector **80** according to the present invention. Connector **80** includes generally a body **84** and extends to a lead extension distal region **82**. The lead extension connector **80**, in the example shown, has received a lead proximal region **86** carrying four contacts (not shown in FIG. **5**). Each of the four lead electrical contacts can be contacted by the four connector block screws, indicated at **88**, **90**, **92**, and **94**. Devices for coupling lead electrode contacts to lead extenders are well-known in the art. Various devices including devices requiring tools to secure as shown in FIG. **5** and tool-less receiving contacts are also well known. In some embodiments, the lead extension distal connector can be simply a connector, with the band stop filters located proximal of the connector. In the embodiment illus-

trated, the band stop filters are incorporated as part of the lead extension distal connector, further illustrated in FIG. **6**.

[0058] FIG. **6** further illustrates lead extension connector **80**. Lead **86** has been inserted and secured by the four connector blocks **88**, **90**, **92**, and **94**, as previously described. The lead extension distal region **82** may be seen at left. The four lead electrical contacts are secured within the respective connector blocks. A first band stop filter **89** is coupled to first connector block **88** and extends through a first connector wire **96** to the remainder of the lead extension. A second band stop filter **91** is coupled to the second connector block **90** and extends through a second conductor wire **97** to the remainder of the lead extension body. A third band stop filter **93** is coupled to the third connector block **92** and extends through a third conductor wire **98** to the lead extension body. A fourth band stop filter **95** is coupled to the fourth connector block **94** and extends through a fourth conductor wire **99** to the remainder of the lead extension. As previously discussed, the connector blocks are replaced by tool-less connectors in some embodiments.

[0059] FIG. **7** illustrates a burr hole cap base **100** according to the present invention. Burr hole caps and bases are well known to those skilled in the art and are described in U.S. Pat. Nos. 4,328,813; 5,464,446; and 5,927,277 and U.S. Published Application No. 2007/0233158. Base **100** has an annular shape having a central opening or aperture **106**, an inner periphery **108**, an outer periphery **104**, and a body **102**. Several lead engaging, dressing, or fixation grooves **110** are shown in base **100**. Some embodiments have only one such engaging structure while others have more than one. In some embodiments, the width of the groove narrows as the lead extends outward from a central aperture **106**. In this way, the lead can be dressed, engaged, and effectively fixed with respect to translation within respect to base **102**. Lead engaging and fixation mechanisms and structures for burr hole caps are well-known in the art. In the embodiment illustrated, a lead extension distal connector **116** is coupled to the base body **102**. A portion of lead extension **118** is also shown, extending proximally from lead extension connector **116**. In use, deep brain stimulation lead **112** exits the burr hole through central aperture **106** and extends outward through a lead engaging structure **110**. The excess lead length may be dressed in various ways in various embodiments. In some embodiments, the base body may be rotated to dress excess lead around the periphery. In other embodiments, the lead engaging groups or structures may be selected from more than one in a location to take up a sufficient amount of excess lead. In many embodiments, lead extension **118** does not extend across the burr hole central aperture.

[0060] As shown in FIG. **7**, the lead proximal region **114** carrying the electrical contacts can be inserted into the lead extension connector **116**. With the lead proximal region thus secured, electrical continuity with the lead extension is obtained. In some embodiments, the band stop filters are included within the lead extension distal connector as previously described. In other embodiments, the band stop filters can be spread out more within the base body **102** as the space constraints may not be as great in the base as within the connector. Specifically, the connector blocks can be located further from the band stop filters if that is desired. In still other embodiments, the band stop filters can be located in and proximally further down the lead extension body. In some methods, the distance between the band stop filters and the distal region of the stimulation lead is selected to not be at a resonant or strong resonant wavelength of the expected MRI system. What is claimed is:

1. A lead extension for coupling to a lead, the lead including a lead distal region having at least one electrode thereon, a lead proximal region having at least one electrical contact thereon, and a lead length, the lead extension comprising:
- a lead extension body having a lead extension proximal region, a lead extension distal region, and at least one electrical conductor disposed within and extending between the lead extension proximal and distal regions;
- at least one band stop filter (BSF) including a capacitor in parallel with an inductor, the parallel capacitor and inductor combination placed in series with each of the electrical conductors somewhere between the lead extension proximal and distal regions, wherein values of capacitance and inductance have been selected such that the band stop filter is resonant around a selected frequency.

2. The lead extension of claim **1**, in which the parallel capacitor and inductor combination are placed in series with each and every one of the electrical conductors somewhere between the lead extension proximal and distal regions.

3. The lead extension of claim **1**, wherein the BSF has a Q factor, and the overall Q of the BSF is selected to balance impedance at the selected frequency versus frequency band width characteristics.

4. The lead extension of claim **1**, wherein the BSF is located a distance from the lead extension distal region adapted to reduce resonance with the MRI signal when used in combination with the lead length.

5. The lead extension of claim **1**, in which the distance from the BSF to the lead distal end when the lead and the lead extension are coupled together is substantially less than a half-wavelength of an expected MRI system selected from the group consisting of 1.5 and 3 Tesla MRI systems.

6. The lead extension of claim **1**, in which the distance from the BSF to the lead distal end when the lead and the lead extension are coupled together is less than about 15 cm.

7. The lead extension of claim **1**, wherein the lead extension includes a distal connector and in which the BSF is included within the lead extension distal connector.

8. The lead extension of claim **7**, in which the lead extension distal connector includes at least one insertion port for receiving the lead proximal region and in which the BSF is coupled to the insertion port.

9. The lead extension of claim **1**, wherein the lead extension distal region includes a burr hole cap base for capping a burr hole, the burr hole cap base including:
- an annular body disposed between a central aperture and an outer periphery, the body being MRI compatible;
- at least one connector coupled to the body for electrically coupling to the lead proximal contact; and
- in which the BSF is mechanically coupled to the burr hole cap base.

10. A lead for neuro stimulation (NS), the lead comprising:
- a distal end and a proximal end having a first length therebetween;
- a distal region having at least one electrode adapted for NS thereon;
- an intermediate region having at least one electrical contact thereon and disposed between the lead distal end and the lead proximal end;

the intermediate region and the lead distal end having a second length therebetween; and

at least one electrical conductor extending between and in electrical communication with the electrode and the electrical contact;

wherein the first length is at least about twice the second length,

wherein the lead can be severed close to and proximal of the electrical contact without compromising the NS functionality.

11. The lead of claim **10**, in which the intermediate region includes a visual indicia disposed proximal of the electrical contact indicating a location for cutting the lead after implantation.

12. The lead of claim **10**, in which the intermediate region includes a region of preferential weakness disposed proximal of the contact indicating a location for severing the lead after implantation.

13. The lead of claim **12**, in which the region of preferential weakness includes a circumferential groove.

14. The lead of claim **10**, in which the lead has an outer diameter of less than about 2 mm and the first length is less than about 15 cm.

15. The lead of claim **10**, in which the lead has at least about 4 distinct conductor wires including the at least one electrical conductor and an outer diameter of less than about 2 mm.

16. A burr hole cap base for capping a burr hole, the burr hole cap base comprising:

an annular body disposed between a central aperture and an outer periphery, the body being MRI compatible;

at least one connector coupled to the body for electrically coupling to at least one proximal contact of a DBS lead; and

at least one BSF electrically coupled to the at least one connector, the BSF including a capacitor in parallel with an inductor.

17. The burr hole cap base of claim **16**, in which the body includes a lead feed through for feeding the lead from the central aperture to the outer periphery.

18. A method for placing a neurological stimulation (NS) lead, the method comprising:

advancing a tubular introducer to near a target tissue;

advancing the NS lead to near the target tissue within the tubular introducer;

removing the tubular introducer over the NS lead; and

coupling a NS electrical contact to a lead extension distal electrical connector, in which the lead extension includes a band stop filter (BSF) in series with a lead extension electrical conductor.

19. The method of claim **18**, in which the target tissue is brain tissue, the NS lead is a deep brain stimulation (DBS) lead, and the tubular introducer is a cannula.

20. The method of claim **18**, in which the lead extension electrical connector is disposed within a burr hole cap base, such that the DBS lead extends through the burr hole cap base and the DBS lead proximal region couples to the burr hole cap base.

21. The method of claim **18**, in which the target tissue is spinal cord nerve tissue, the NS lead is a spinal cord stimulation (SCS) lead, and the tubular introducer is a hollow needle.

22. The method of claim **18**, further comprising severing the NS lead proximal of the lead electrical contact after the tubular introducer has been removed over the NS lead.

23. The method of claim **18**, in which the lead extension is configured such that the length from the BSF to the lead electrode is not a substantial resonant wavelength of an expected MRI system.

24. The method of claim **18**, further comprising electrically coupling a lead extension proximal region to a pulse generator.

25. The method of claim **18**, further comprising performing an MRI including the target tissue after the lead extension with BSF has been coupled to the inserted lead.

26. The method of claim **25**, in which the MRI is performed prior to connecting the lead extension to an IPG.

27. The method of claim **18**, in which the target tissue is a peripheral nerve selected from the group consisting of a sacral nerve, occipital nerve, facial nerve, hypoglossal nerve, vagus nerve, and splanchnic nerve

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