US 20120232632A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2012/0232632 A1

(43) Pub. Date: Sep. 13, 2012

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(54) MEDICAL IMPLANTABLE LEAD

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(21) Appl. No.: 13/504,452

(22) PCT Filed: Oct. 30, 2009

(86) PCT No.: PCT/SE09/00479

§ 371 (c)(1), (2), (4) Date: Apr. 26, 2012

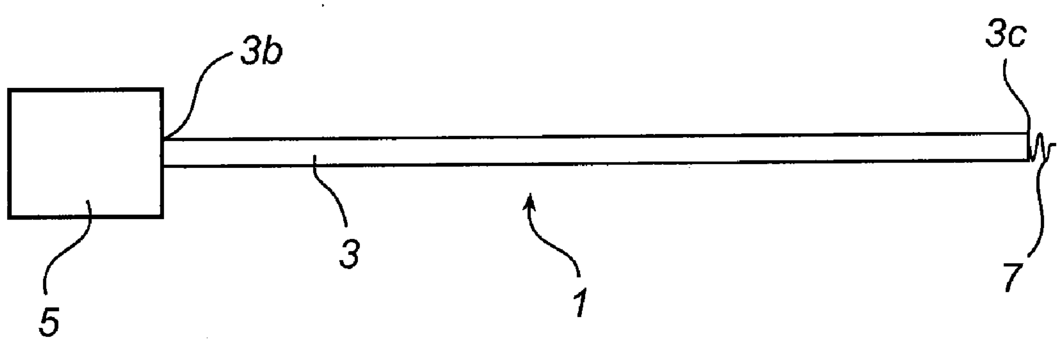
Publication Classification

(51) Int. Cl.
A61N 1/00 (2006.01)

(52) U.S. Cl. 607/116

(57) ABSTRACT

The present invention relates to a medical implantable lead having a coaxial structure, where an insulating tube arranged between an inner coil and an outer coil is provided with a periodically alternating capacitance along the length thereof in order to reduce lead tip heating during MRI scanning.



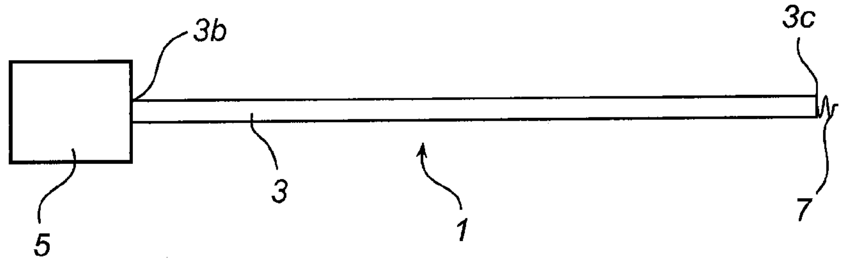


Fig. 1

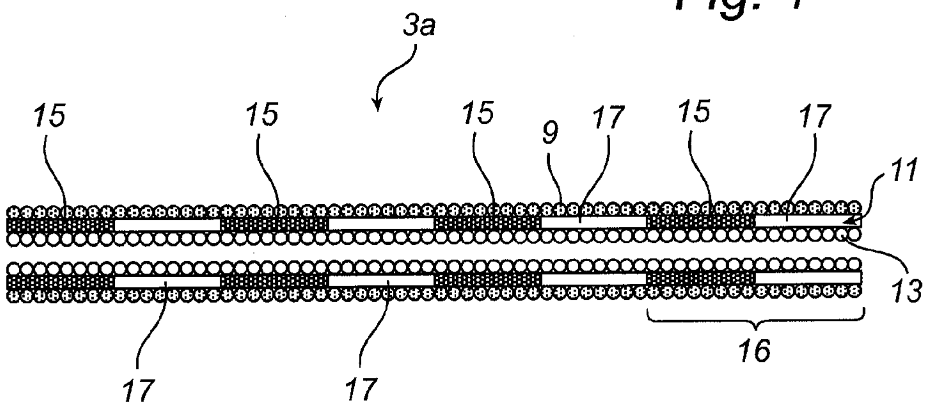


Fig. 2

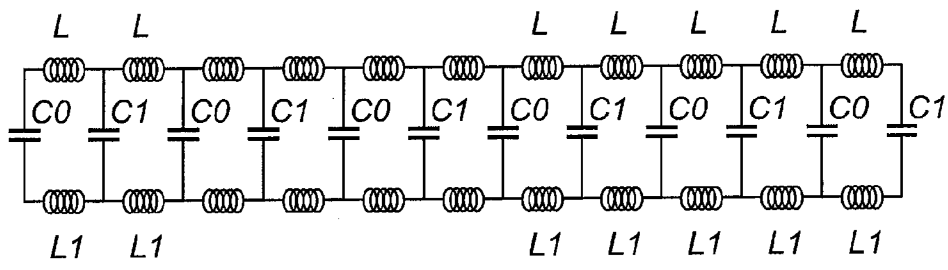


Fig. 3

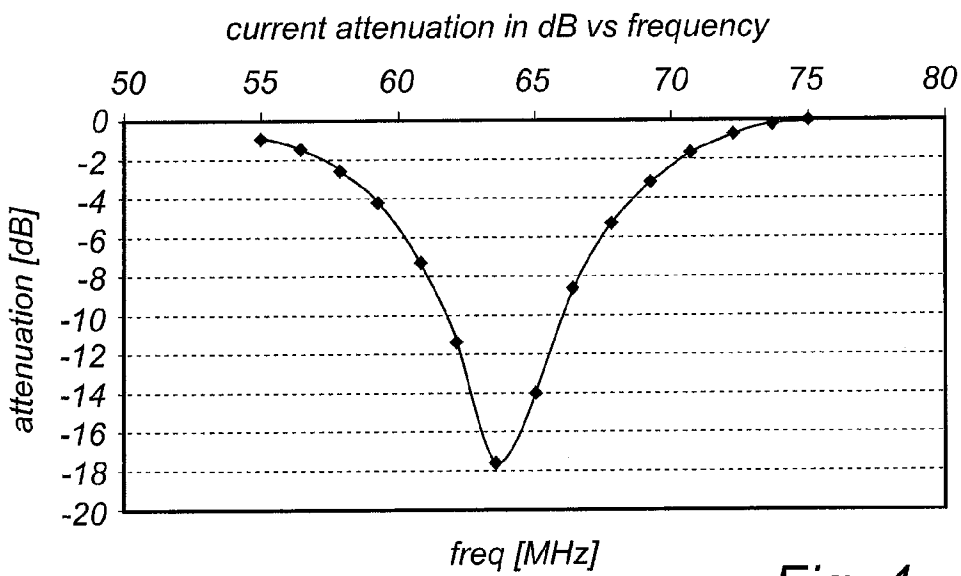


Fig. 4

Outer coil inductance [μH]	*1*	*0.9*	*0.7*	*1.2*	*2*
Inner coil inductance [μH]	*0.5*	*0.45*	*0.35*	*0.6*	*1*
Segment capacitance high [pF]	*10*	*12*	*16*	*8*	*4*
Segment capacitance low [pF]	*2.5*	*3*	*4*	*2*	*1*
Lead tip current at resonance frequency MHz [mA]	*20.0*	*16.7*	*13.3*	*16.5*	*20.4*

Fig. 5

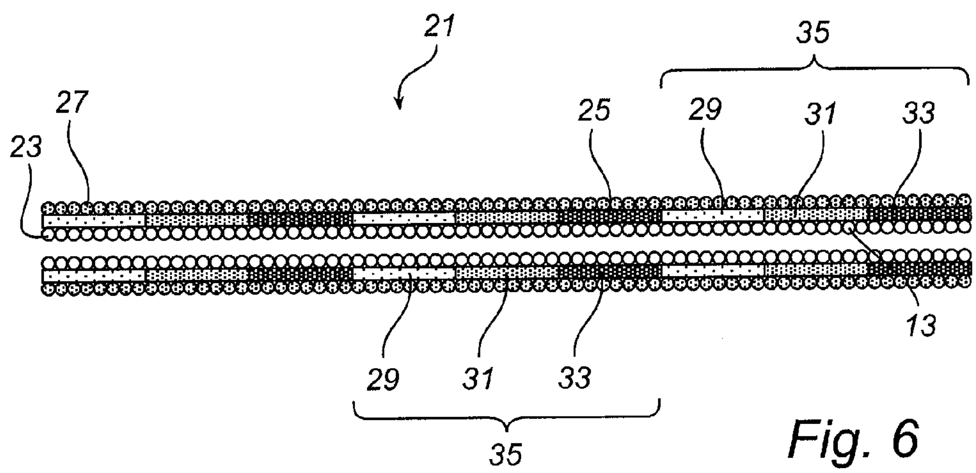


Fig. 6

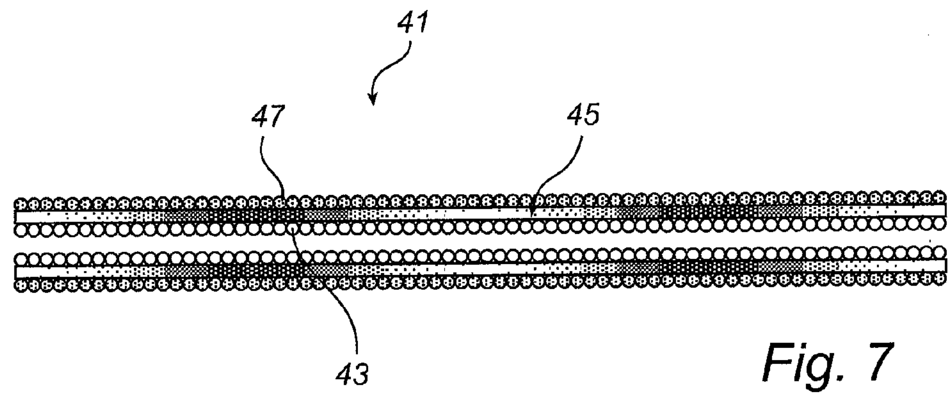


Fig. 7

MEDICAL IMPLANTABLE LEAD

FIELD OF THE INVENTION

[0001] The present invention relates to a medical implantable lead having an elongate coaxial arrangement of an outer coil, an inner coil and an intermediate insulating tube arranged between the outer coil and the inner coil.

BACKGROUND OF THE INVENTION

[0002] Magnetic Resonance Imaging (MRI) is of great use for generating an image of the internal tissues of a human body. However, for persons who have a medical implantable lead implanted in their body, there are problems with induced currents in the medical implantable lead causing, in turn, heating of the lead, in particular the distal tip of the lead. The MRI is based on Nuclear Magnetic Resonance (NMR) for protons of hydrogen nuclei. It is well-known that all nuclei have spin which are randomly oriented. When a magnetic field is applied, the proton spins become either parallel or anti-parallel, and the energy levels are split into a higher level for the anti parallel spin and a lower level for the parallel spin. Furthermore, the protons start precessing around the magnetic field direction with a precession frequency (Larmor frequency) which is proportional to the magnetic field, and with a precession angle, which is also called flip angle. If an external pulsed RF signal with Larmor frequency is applied, protons from the lower energy level with parallel spin will be excited to the higher energy level. This implies that the precession angle will change and all protons will precess in phase. After some time (in the order ms) the protons start to relax, that is the protons in the higher anti-parallel spin level will fall back to the lower parallel level, which implies that the precession angle falls back to the original value, and at the same time the protons will also de-phase. Both these processes will proceed with slightly different time-constants. The MRI takes advantage of the relaxation and time-constants to identify the substances in a human body. In-vitro MRI experiments have shown that the implanted lead acts like an antenna and receives the pulsed RF signal of the MRI scanning equipment. The reception of the RF energy results in an RF wave propagating along the lead and heating the pacemaker lead tip to an unacceptable level. Some other parts of the lead become heated as well, although not as much as the tip.

[0003] Referring to an in-vitro set up, where a particular gel is used to simulate human tissue, the mechanisms for the RF energy transfer are identified as follows. As mentioned above the precession frequency is proportional to the magnetic field, and more particularly at 42.58 MHz/T. Currently most MRI devices operate at 1.5 Tesla, while 3 Tesla MRI devices are expected to increase. Thus, the frequency of the RF pulses, or RF wave, produced in a 1.5T MRI device is about 64 MHz. The RF wave first passes through the boundary between the air and the gel. The RF wave undergoes a speed reduction from the speed in air v_0 to a speed in the gel (human body) v_1 due to the dielectric constant ($\in$) of the gel, where $v_1=v_0/\mathrm{sqrt}(\in)$. The wavelength λ is also reduced by the same factor, i.e. $\lambda_1=A_0/\mathrm{sqrt}(\in)$. The dielectric constant of the human tissue on average is in such an order that the resulting wave length in human tissue becomes close to the physical length of a typical medical implantable lead, e.g. in the order of half a meter. This transforms a pacemaker lead to a good antenna. The RF energy is picked up by the outer coil of the lead, and then transferred to the inner coil via the inter-coil capacitance. This coaxial structure of the lead in fact is a transmission line, and the potential difference along the lead and between the outer and inner coils cause the above-mentioned propagation. The RF energy is eventually transferred to the lead tip, causing heating of the tip.

[0004] This problem of lead tip heating has been addressed in prior art, such as in US 2008/0033497 A1, where different solutions have been suggested. According to one solution, the inner and outer coils are wound in opposite directions and they are interconnected at their ends. The purpose is to reduce the total current. However, a probable disadvantageous effect is that the current direction is determined by the incident wave phase and a different winding direction will not change the current direction. In fact, when studying the currents at a certain point they are always oppositely directed in the outer and inner coils irrespective of the winding direction. According to another solution, RF blocking circuits are inserted at half wavelength. This would work, but it is difficult to realize such a lead structure. According to yet another solution the lead coils are arranged such as to create resonance circuits. Such a resonance property, which is of a distributed kind, is sensitive to lead configuration, which can lower the impedance at RF frequency. This may work to a certain extent, but the outcome in each individual case is uncertain.

[0005] WO 2007/047966 also aims at providing a solution to the problem of tip heating, however in a lead structure where the conductors are not provided in a coaxial structure with inner and outer coils but arranged in parallel. Either the conductors are straight and parallel, individually and partially wound and parallel, or co-wound while still parallel. Capacitors are arranged to interconnect the conductors. The capacitors are arranged at regular or irregular distances from each other. By means of the capacitances a high impedance circuit is obtained, which appropriately tuned reduces the coupling of the pulsed RF signal to the lead. Furthermore, the high capacitance values mentioned in the WO document are most difficult to realize in a thin lead.

SUMMARY OF THE INVENTION

[0006] It is an object of the present invention to provide a lead structure that alleviates the above-mentioned drawbacks of the prior art and reduces the induced current of the lead due to the RF wave.

[0007] This object is achieved by a medical implantable lead according to the present invention as defined in claim **1**.

[0008] The invention is based on an insight that a periodic capacitive structure is capable of acting as a current reducer in a medical implantable lead subjected to a current inducing RF wave.

[0009] Thus, in accordance with an aspect of the present invention, there is provided a medical implantable lead, comprising an elongate coaxial arrangement of an outer coil, an inner coil and an intermediate insulating tube arranged between the outer coil and the inner coil, wherein the intermediate insulating tube has a periodically alternating capacitance along the length thereof.

[0010] Due to the alternating capacitance provided by the insulating tube the current induced by the RF wave in the lead will be substantially reduced, and thereby the heating of the lead tip will be negligible.

[0011] In accordance with an embodiment of the medical implantable lead, the intermediate insulating tube comprises a set of at least two segments, which set of at least two segments is repeated along the length of the intermediate insulating tube, and which segments have different capacitances, thereby providing the periodically alternating capacitance. Combining segments of different capacitances to form the intermediate tube provides for flexibility in choosing the capacitance values of the respective segments of each set. In an embodiment there are three segments in each set, i.e. three different capacitance values are repeated along the length of the intermediate tube.

[0012] In accordance with an embodiment of the medical implantable lead, the length of each segment is shorter than or equal to 1/10 of the total length of the intermediate insulating tube. This is true at least for tubes, and thus leads, having a length in the order of the wavelength of an RF wave that it is exposed to, which in turn is the case when the initially described problem of induced currents is at hand.

[0013] In accordance with an embodiment of the medical implantable lead, the segments are individual parts which are arranged in engagement with each other. This includes many different kinds of engagement, such as for instance the segments abutting on each other, and the segments being adhesively attached to each other.

[0014] In accordance with an embodiment of the medical implantable lead, a dopant is used to tailor the capacitance values of the segments. Here the intermediate insulating tube is made of silicone, where at least one segment in each set is doped with a dopant. An appropriate choice of the dopant is $BaTiO_4$.

[0015] In accordance with an embodiment of the medical implantable lead, the capacitance is varying continuously and periodically along the length of the intermediate insulating tube. In contrast to the embodiment where individual segments are mounted in a series, here the tube can be kept in one piece, while varying the capacitance in other ways along the length of the tube.

[0016] These and other aspects, features, and advantages of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The invention will now be described in more detail and with reference to the appended drawings in which:

[0018] FIG. **1** is a schematic side view of a medical implantable device;

[0019] FIG. **2** is a schematic longitudinal sectional view of a portion of an embodiment of a medical implantable lead according to the present invention;

[0020] FIG. **3** is an equivalent circuit diagram of the LC-structure of the lead in FIG. **2**;

[0021] FIG. **4** is a current attenuation diagram resulting from a simulation of an LC-structure with a periodically alternating capacitance;

[0022] FIG. **5** is a table illustrating the effect of parameter variations;

[0023] FIG. **6** is a schematic longitudinal sectional view of a portion of another embodiment of a medical implantable lead according to the present invention; and

[0024] FIG. **7** is a schematic longitudinal sectional view of a portion of yet another embodiment of a medical implantable lead according to the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0025] Referring to FIG. **1**, a typical implantable medical device **1** comprises an implantable lead and an electric unit, such as for instance a pacemaker, **5**. The implantable lead has a lead tip **7**, which is to be connected to body tissue.

[0026] A first embodiment of the medical implantable lead **3** according to the present invention comprises an elongate coaxial arrangement **3**_a_, a portion of which is schematically shown in FIG. **2**. The coaxial arrangement **3**_a_ extends between a proximal end **3**_b_ of the medical implantable lead **3**, where it is connected with the electrical unit **5**, using the coaxial arrangement to send signals to and/or receive signals from a desired part of the body, and a distal end **3**_c_ of the lead, where it is connected with the lead tip **7**, which interacts with the body tissue. Since this overall structure of a typical medical implantable lead is well known to the person skilled in the art, no further explanation thereof will be set forth here. The coaxial arrangement **3**_a_ comprises an outer coil **9**, an inner coil **13**, and an intermediate insulating tube **11**, arranged between the outer coil **9** and the inner coil **13**. The intermediate insulating tube **11** has a periodically alternating capacitance along the length thereof. Thereby it is possible to obtain a band-stop filter, wherein the capacitive intermediate insulating tube **11** interacts with the outer and inner coils **9**, **13**, which are inductive, to form an LC structure having band-stop filter characteristics, as will be further explained below. In this embodiment, the alternating capacitance is provided by individual segments **15**, **17** of tubular insulating material, which segments have one or the other of two different capacitances, a lower capacitance c_0 and a higher capacitance c_1. The structure of the intermediate insulating tube **11** can be regarded as consisting of a series of two segment sets, wherein each set of two segments **15**, **17** consist of a first segment **15** having the lower capacitance c_0 and a second segment **17**, having the higher capacitance c_1. Thus, the set of two segments **15**, **17** is repeated along the length of the intermediate insulating tube **11**, which means that the segments **15**, **17** alternately have the lower c_0 and the higher c_1 capacitance along the length of the tube **11**. The segments **15**, **17** are all of equal length, which is preferred although not necessary. As mentioned above, the segments **15**, **17** are individual parts, and they are arranged in engagement with each other. More particularly, the segments **15**, **17** abut on each other. However, other kinds of engagement are also possible, such as adhesive attachment, and the like. The length of each segment **15**, **17** preferably is no longer than about 1/10 of the total length of the intermediate insulating tube **11** for typical medical applications. Some criteria for dimensioning the coaxial arrangement **3**_a_ will now be described.

[0027] First it is important to point out that only the RF field components perpendicular to the axial direction of the medical implantable lead **3** contribute to the RF wave propagation in the lead **3**.

[0028] The coaxial nature of the medical implantable lead **3** implies that there are certain limitations for the energy propagation in the lead **3**. A coaxial structure is characterized by the per unit length inductance of the outer and inner coil and the per unit length inter-coil capacitance. Microwave theory tells us that the maximum speed v_t of a transmission line is 1/sqrt (l_u*c_u), where l_u is the series inductance per unit length and c_u is the parallel capacitance per unit length. In order to exemplify the LC-structure of the lead **3**, a typical pacemaker lead is considered. A typical total lead length for such a lead is approximately 0.5 m. Now assume that the unit inductance per meter is 20 μH and the unit capacitance per meter is 60 pF. Then,

$$v_t=1/(sqrt(l_u*c_u)=1/(20*10^{-8}*60*10^{-12})=0.28*10^8 \text{ m/s},$$

which is the maximum speed for a wave which can be transported through this transmission line.

[0029] In an in-vitro test set-up, as referred to above, using a gel to simulate body tissue, the speed of the wave (in the tissue) can be calculated easily.

$$V_g=c/sqrt(\in_r),$$

where v_g is the speed of the wave in gel,
c is the speed of light in vacuum and
$\in_r$ is the relative dielectric constant.

[0030] The relative dielectric constant of the gel is $\in_r=81$, which results in

$$V_g=3*10^8/sqrt(81)=0.33*10^8 \text{ m/s},$$

which is roughly equal to the calculated maximum wave speed v_t in the transmission line. Consequently, theoretically, the wave in the gel will not be able to propagate through the lead **3**, since its speed exceeds the calculated maximum speed of the transmission line. In practice, there will always be some leakage from the outer coil to the inner coil close still causing a current in the lead tip **7**.

[0031] The above example demonstrates that it is possible to reduce the energy of the propagating wave by making high inductive inner and outer coils, and high capacitive inter-coil insulation whereby the maximum allowable wave speed through the lead **3** is reduced. In practice, the capacitance per meter for a typical commercially available lead is about 100 pF so the 60 pF/m required is easily met. On the inductance side however, the unit inductance per meter is about 2 μH for a common 5-filar inner coil. The only way to achieve a high inductive inner coil is to make a 1-filar inner coil. This is, however, unacceptable from redundancy point of view. Besides, the torque transfer function will not be met.

[0032] The periodic capacitance structure according to the present embodiment, i.e. the intermediate insulating tube **11** having alternating low capacitive sections and high capacitive sections, can serve as a band-stop filter if realized with properly chosen parameters, and the required inductance values of the coils **9**, **13** are relatively low, and the required dielectric constants for c_0 and c_1 are reasonable. Thus, applying the periodic structure for heat reduction relaxes the requirement of high inductive coils, which would be difficult to meet.

[0033] According to an example, the lower capacitance c_0, for each lower capacitance segment **15**, was chosen to be $c_0=2.5$ pF, and the higher capacitance, for each higher capacitance segment **17**, was chosen $c_1=10$ pF. The length of the lead **3** was 0.52 m, and the number of segments was 13, i.e. each segment **15**, **17** was approximately 0.04 m long. The inner coil inductance was chosen $i_0=0.5$ pH, and the outer coil inductance was chosen twice thereof, i.e. $i_1=1.0$ pH. Twice the inductance in the outer coil than in the inner coil is a realistic relation for many kinds of medical implantable leads. Then a band-stop filter for a frequency range including the RF frequency of 64 MHz was obtained, i.e. the RF frequency used in a common 1.5 Tesla MRI scanner mentioned above. The attenuation of the lead tip current was about 18 dB at 64 MHz, see FIG. **4**. For a common lead a typical value of the total capacitance is 50 pF, which would result in approximately 4 pF per segment, which corresponds to the example value of the lower capacitance segments **15**. In order to achieve the higher capacitance segments **17** of 16 pF each, the same material as in the lower capacitance segments **15** was doped with a dopant, more particularly $BaTiO_4$. Such a dopant increases the relative dielectric constant of the material. In the present example, the capacitance of the higher capacitance segments **17** is increased by a factor **4** relative to the capacitance of the lower capacitance segments **15**, which means that the relative dielectric constant will have to be increased by a factor **16**. Such an increase is easy to obtain by means of an appropriate dopant.

[0034] Referring again to FIG. **4**, it shows a diagram of induced current versus RF frequency. The diagram was the result of a simulation on a circuit model of the above-exemplified LC structure, where the RF frequency was scanned from 55 MHz to 75 MHz. The simulation shows a maximum attenuation, 18 dB, of the induced current at approximately 64 MHz.

[0035] In order to exemplify variation of filter parameters of the band-stop filter, further simulations were made for inductance values of the outer coil ranging from 0.7 pH to 2 pH, and the inner coil inductance varying accordingly, keeping the relation between them; and for capacitance values of the higher capacitance segments ranging from 4 to 16 pF, and of the lower capacitance segments varying accordingly keeping the relation of 4 between them, as illustrated in FIG. **5**. For example, it can be seen that varying the inductances as well as the capacitances affect the outcome in terms of lead tip current at resonance frequency.

[0036] As mentioned above the section length should be about 1/10 of the RF wavelength at the lead, or shorter. It should be mentioned that also by varying the length of the segments the filtration result is affected, that is both the tip current and the frequency of minimum current vary with a varying segment length.

[0037] According to another embodiment of the medical implantable lead **21**, shown in FIG. **6**, the intermediate insulating tube **25**, coaxially arranged between an inner coil **23** and an outer coil **27**, is divided into segments **29**, **31**, **33** having three different capacitances. Each set of segments **35** consequently consists of three segments **29**, **31**, **33**. This structure could be arranged to achieve an even better effect than the two capacitance embodiment, but similarly it is more complex as regards the manufacture thereof.

[0038] According to another embodiment of the medical implantable lead **41**, shown in FIG. **7**, the intermediate insulating tube **45**, arranged between an inner coil **43** and an outer coil **47**, has a continuously varying capacitance along its length. Preferably, at least one minimum or one maximum capacitance is positioned between the ends of the tube **45**. The capacitance variation has been achieved by doping a basic material with a dopant such that a continuously varying concentration thereof has been obtained along the length of the tube **45**.

[0039] Above, embodiments of the medical implantable lead according to the present invention as defined in the appended claims have been described. These should be seen as merely non-limiting examples. As understood by a skilled person, many modifications and alternative embodiments are possible within the scope of the invention.

[0040] Thus, as explained by means of the embodiments above, by providing the intermediate insulating tube, positioned coaxially between the inner and outer coil of the lead, with a periodically alternating capacitance along the length thereof it is possible to achieve a band-stop filter that attenuates the RF energy transfer in the lead, and consequently reduces the heating of the lead caused by the RF energy.

1. A medical implantable lead, comprising an elongate coaxial arrangement of an outer coil, an inner coil and an intermediate insulating tube arranged between the outer coil and the inner coil, wherein the intermediate insulating tube has a periodically alternating capacitance along the length thereof.

2. A medical implantable lead according to claim **1**, wherein the intermediate insulating tube comprises a set of at least two segments, which set of at least two segments is repeated along the length of the intermediate insulating tube, and which segments have different capacitances, thereby providing the periodically alternating capacitance.

3. A medical implantable lead according to claim **2**, wherein the number of segments of each set is three.

4. A medical implantable lead according to claim **2**, wherein the length of each segment is shorter than or equal to 1/10 of the total length of the intermediate insulating tube.

5. A medical implantable lead according to claim **2**, wherein the segments are of equal length.

6. A medical implantable lead according to claim **2**, wherein the segments are individual parts which are arranged in engagement with each other.

7. A medical implantable lead according to claim **2**, wherein the intermediate insulating tube is made of silicone, where at least one segment in each set is doped with a dopant in order to provide a desired capacitance.

8. A medical implantable lead according to claim **7**, wherein the dopant is $BaTiO_4$.

9. A medical implantable lead according to claim **1**, wherein the capacitance is varying continuously and periodically along the length of the intermediate insulating tube.

10. A medical implantable lead according to claim **9**, wherein the capacitance variation is provided by a varying concentration of a dopant.

11. A medical implantable lead, comprising:

first and second electrodes;

a coaxially configured inner coil and outer coil, the inner coil being coupled to the first electrode and the outer coil being coupled to the second electrode;

an intermediate insulating tube arranged between the outer coil and the inner coil, the intermediate insulating tube having a plurality of segments doped with one or more dopants to provide a periodic alternating capacitance along the length of the insulating tube.

* * * * *