



US 20100204767A1

(19) **United States**

(12) **Patent Application Publication**
Zhao

(10) **Pub. No.: US 2010/0204767 A1**
 (43) **Pub. Date: Aug. 12, 2010**

(54) **SMALL CALIBER IMPLANTABLE BIOMETRIC LEADS AND CABLES FOR SAME**

Publication Classification

(51) **Int. Cl.**
A61N 1/05 (2006.01)
H01B 7/00 (2006.01)
 (52) **U.S. Cl.** **607/122; 174/113 R**
 (57) **ABSTRACT**

(75) **Inventor: Yong D. Zhao, Simi Valley, CA (US)**

Correspondence Address:
PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221 (US)

(73) **Assignee: PACESETTER, INC., Sylmar, CA (US)**

(21) **Appl. No.: 12/370,461**

(22) **Filed: Feb. 12, 2009**

Implantable medical leads have reduced diameter while providing for optimized mechanical and electrical properties, by reducing the diameters of the conducting cables used within the leads for sensing and delivery of therapeutic electrical stimulation. In an embodiment, conducting filaments within a cable have oval cross-sectional areas. Suitably orienting the oval filaments increases the contact surface between adjacent filaments, broadly distributing the pressure between filaments and reducing fretting fatigue, while the oval cross-sectional area also increases conductivity. In an embodiment, non-conducting coatings around filaments within a cable, or around groups of filaments organized into cable-layers, reduce fretting fatigue. In an embodiment, the cross-sectional area of filaments decreases as the filaments are positioned at increasing radial distances from the center of the cable. In an embodiment, the relative composition of various filament metals and/or alloys is varied in filaments at different radial distances from the center of the cable.

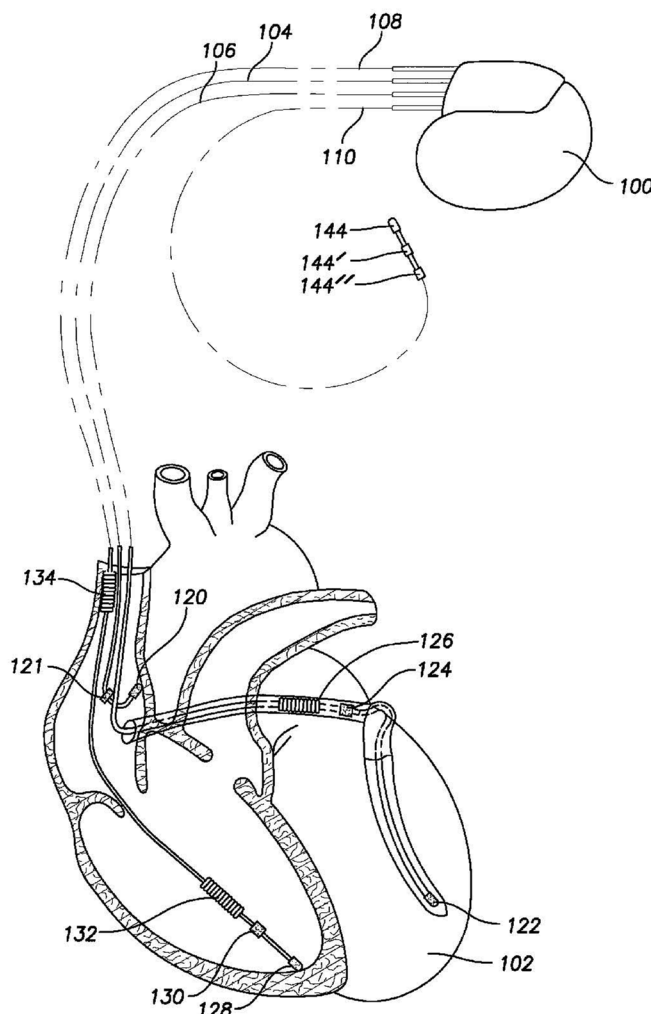


FIG. 1 shows an exemplary stimulation device 100 in electrical communication with a patient's heart 102 by way of three leads 104, 106, 108, suitable for delivering multi-chamber stimulation and shock therapy. The leads 104, 106, 108 are optionally configurable for delivery of stimulation pulses suitable for stimulation of autonomic nerves. In addition, the device 100 includes a fourth lead 110 having, in this implementation, three electrodes 144, 144', 144'' suitable for stimulation of autonomic nerves. This lead may be positioned in and/or near a patient's heart or near an autonomic nerve within a patient's body and remote from the heart. Of course, such a lead may be positioned epicardially or at some other location to stimulate other tissue.

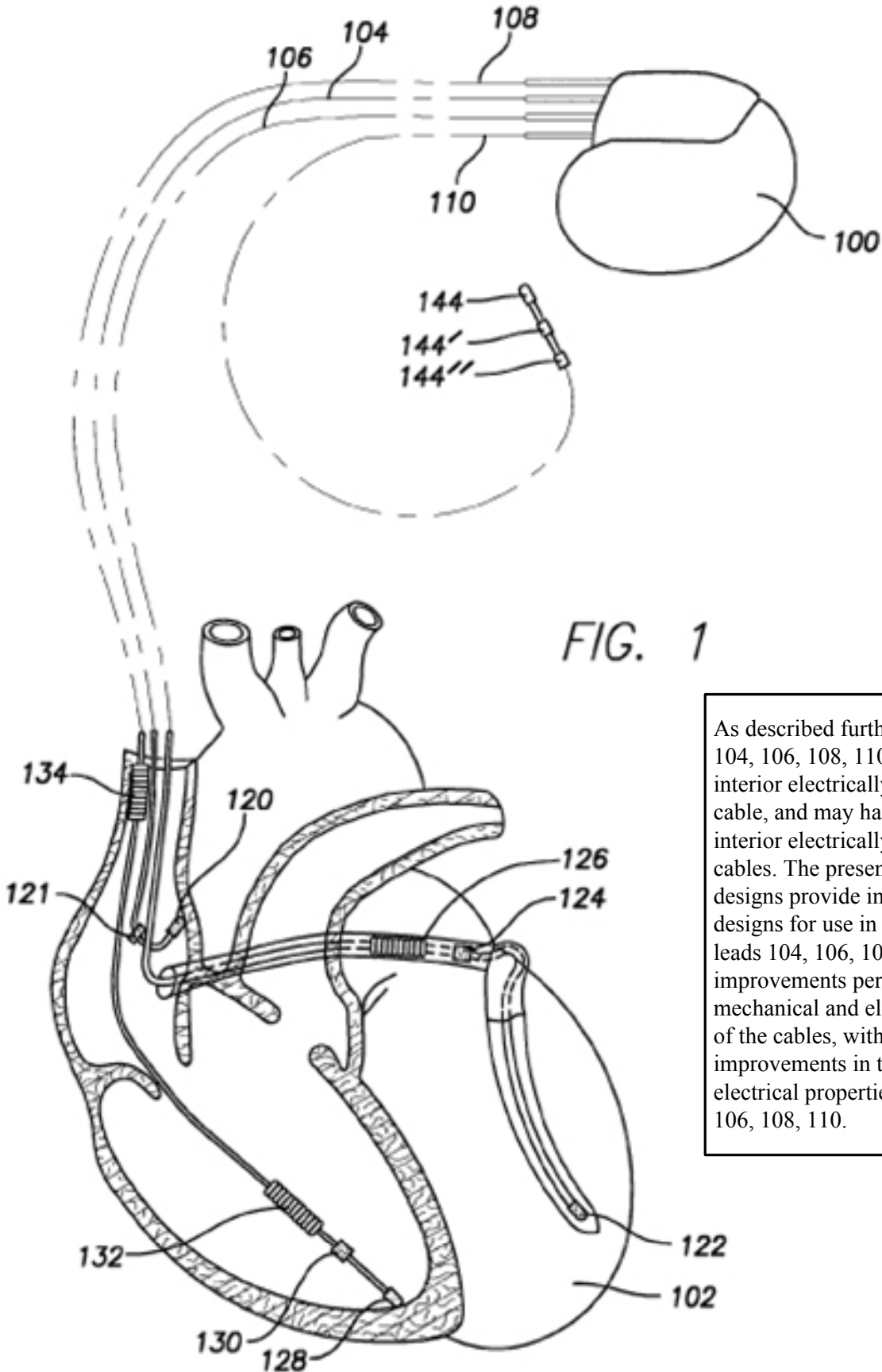


FIG. 1

As described further below... leads 104, 106, 108, 110 have at least one interior electrically conducting cable, and may have multiple interior electrically conducting cables. The present cable and lead designs provide improved cable designs for use in leads such as leads 104, 106, 108, 110. Such improvements pertain to both mechanical and electrical properties of the cables, with resulting improvements in the mechanical and electrical properties of leads 104, 106, 108, 110.

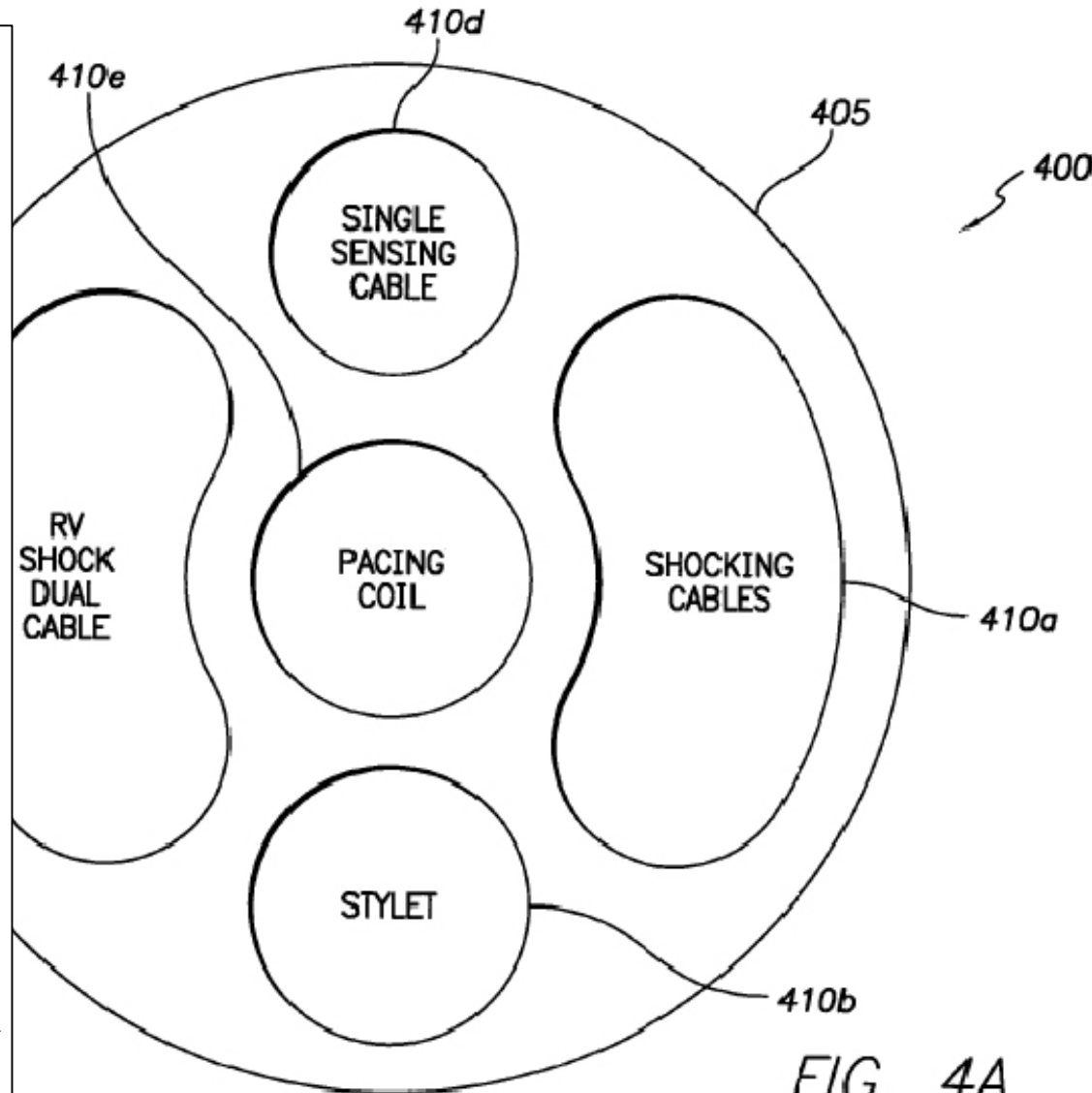
Below are definitions of some of the terms employed in this document.

Lead: Also known as a cardiac lead. An elongated, flexible tubular element, commonly though not necessarily with a circular cross-section orthogonal to the axis of elongation. A lead is composed of one or more cables, and a sheath which houses the cables, as defined further below. A lead has a proximal end and a distal end. The proximal end of the lead is designed to attach to an ICTD or other therapeutic or sensing device.

Cable: A cable is an electrically conducting element made from a conducting material (including for example and without limitation silver, copper, nickel, chromium, aluminum, iron, molybdenum, etc., and/or various alloys of these metals and other metals), typically running the full length or substantially the full length of an ICTD lead. The conducting elements of a cable (central core, cable-layers, and filaments, defined further below) are also composed of conducting elements...

Central Core: A central core is a continuous conducting element of a cable which runs substantially down the geometric center of the cable.

Cable-layer: A cable-layer is a conducting element of a cable which is exterior to the central core. A cable-layer may be wound around the central core. A cable-layer may be composed of one or more conducting filaments (defined below) which may be wound together in parallel, braided together, or otherwise be mechanically coupled to or immediately adjacent to each other.



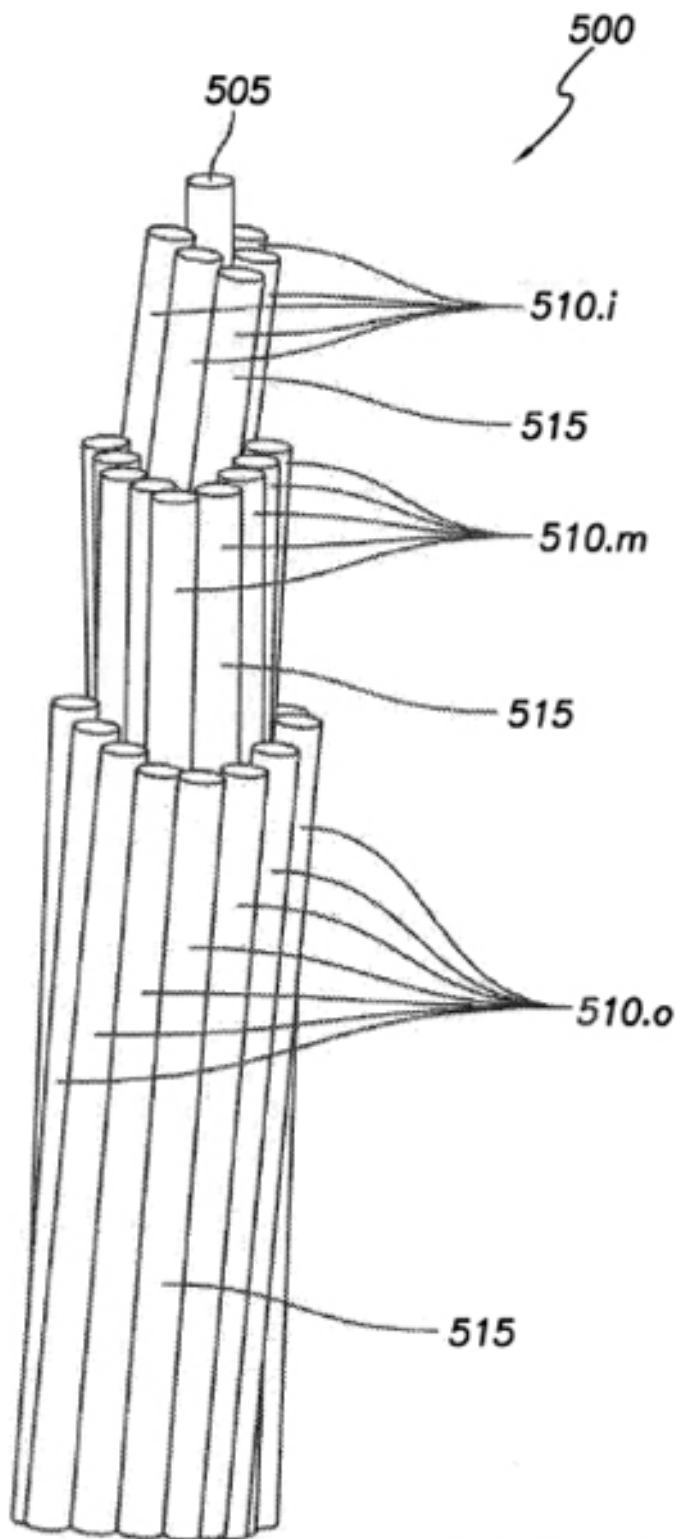
Filament (or synonymously in this document, a Wire): A filament or wire is a single, mechanically unitary thread of conducting material. While mechanically unitary, a filament may be composed of multiple materials, possibly in separate layers which are bonded to each other. For example, a filament may have an inner core of a first metal or metal alloy and an outer tube of a second metal or metal alloy, with the layers bonded to each other. Additional layers, and other composite arrangements of bonded, electrically conductive materials, may be possible as well.

Strand: A strand is an element of a cable in which multiple filaments are wound together, typically in a helical or spiral fashion. A strand may have multiple strand layers. Multiple strands may be wound together or otherwise conjoined to form a cable.

FIG. 4A

[0161] FIG. 5A illustrates an exemplary cable 500. Exemplary cable 500 has a central wire (or core) 505 which, in an embodiment, is a single wire or filament of a conducting material, such as a metal or a metal alloy. In an alternative embodiment, the central core may actually be comprised of multiple filaments which are wound together or otherwise mechanically coupled (not shown in FIG. 5A).

[0162] Surrounding central wire 505 is a cable-layer such as cable-layer 510.i which is an inner cable-layer, and which is composed of multiple filaments 515. The filaments 515 of cable-layer 510.i are wound around central core 505 in a helical fashion.



[0163] Surrounding inner cable-layer 510.i is a second cable-layer, namely a middle cable-layer 510.m, which is also composed of multiple filaments 515. Filaments 515 of cable-layer 510.m are wound around cable-layer 510.i, again in a helical fashion. Surrounding middle cable-layer 510.m is outer cable-layer 510.o which again is composed of multiple filaments 515, this time wound helically around middle cable-layer 510.m.

[0164] It will be noted in FIG. 5A that filaments 515 have a substantially circular cross-section as is commonly found in the art. Likewise, central core 505 has a substantially circular cross-section.

FIG. 5A

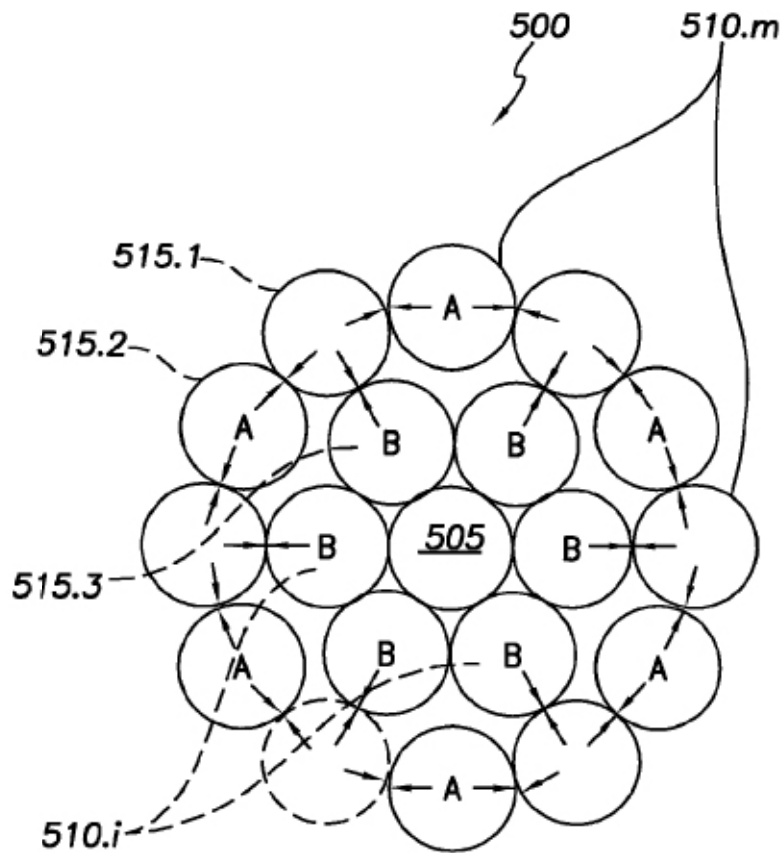


FIG. 5B

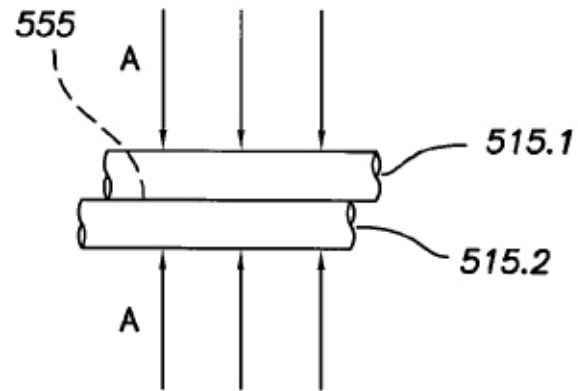


FIG. 5C

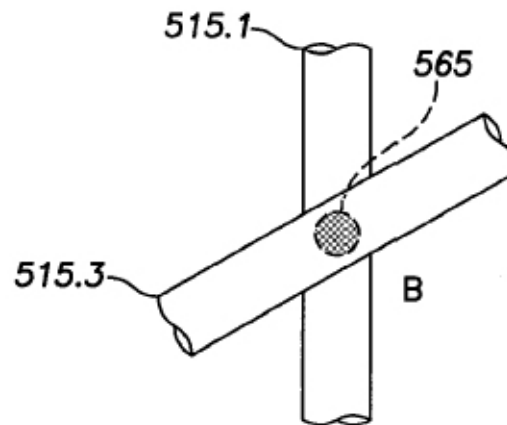


FIG. 5D

[0171] The contact point 565 between filaments 515.1 and 515.3 of adjacent cable-layers 510.m and 510.i is referred to as the point of Trellis contact between filaments 515.1 and 515.3. The overall configuration of filaments 515 in adjacent cable-layers 510 pressing against each other at Trellis contact point 565 is referred to as Trellis contact mode. Both line contact mode and Trellis contact mode ... are locations where fretting fatigue may occur.

[0172] Fretting fatigue is a wear phenomenon occurring between two surfaces having oscillatory relative motion of small amplitude. Fretting is generally associated with contact surfaces which are held together in some manner, often by a mechanical connection (such as clamping, or elements which are twisted or crimped together) and where the surfaces in contact are nominally at rest.

[0178] Fast fracture zone 525 takes approximately 10% or less of the total fatigue life. However, when the fatigue caused by pressure or force 526 reaches fast fracture zone 525, filament 515 has a high likelihood of experiencing fracture, that is, a complete break of the filament.

[0179] It is an advantage of the present cable and lead designs to modify both the structure of filament 515 and the interaction of filament 515 with the surrounding environment, such that pressure 526 on filament is less likely to reach the fatigue threshold. If the fatigue threshold is not reached, cycles of the fatigue life are not used up, and filament 515 is much less likely to experience fracture, or at least is likely to have a greatly prolonged life before fracture. The various elements disclosed in detail below may reduce the pressure experienced by filament 515 by anywhere from 30% to 90% lower as compared with existing designs.

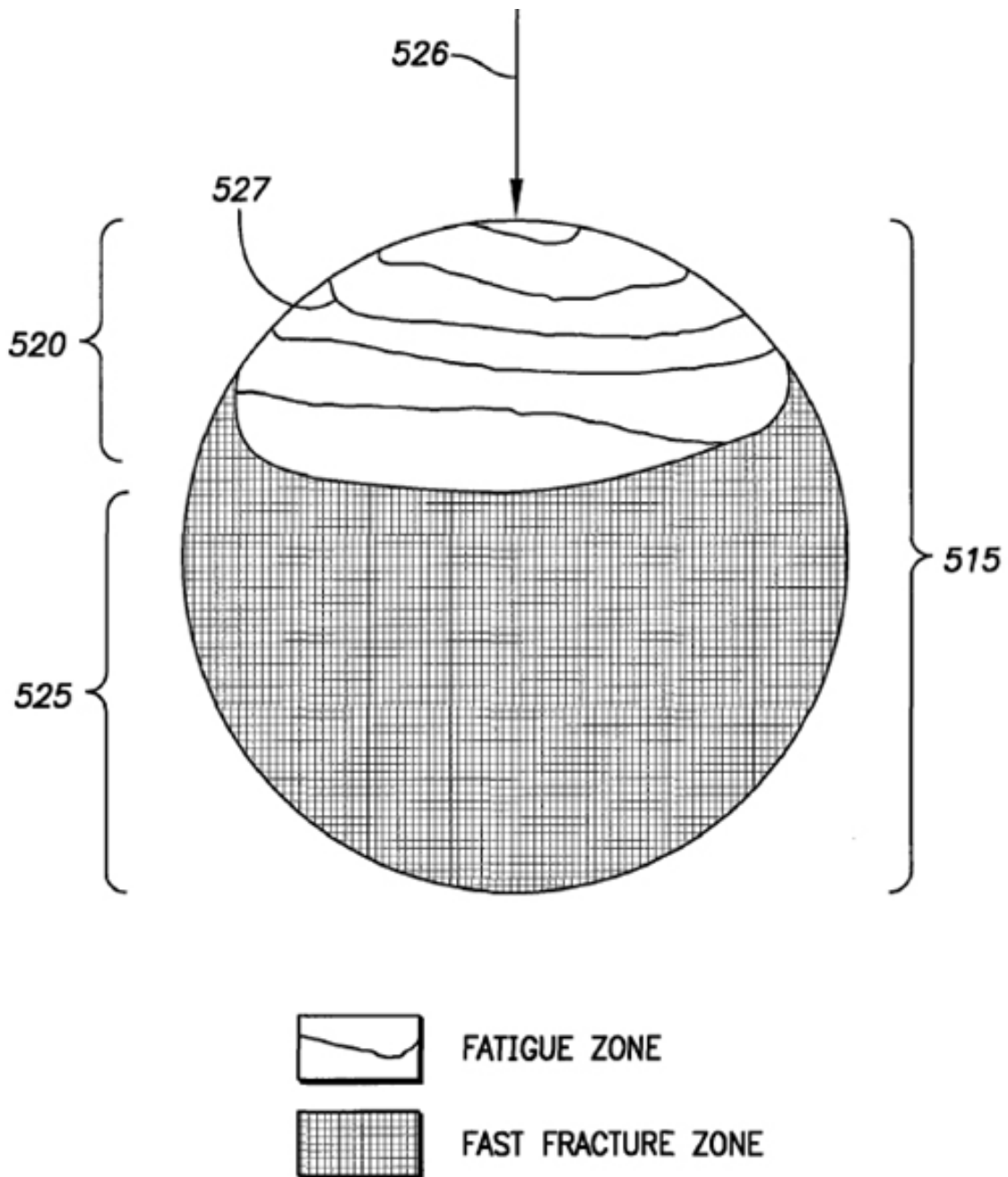
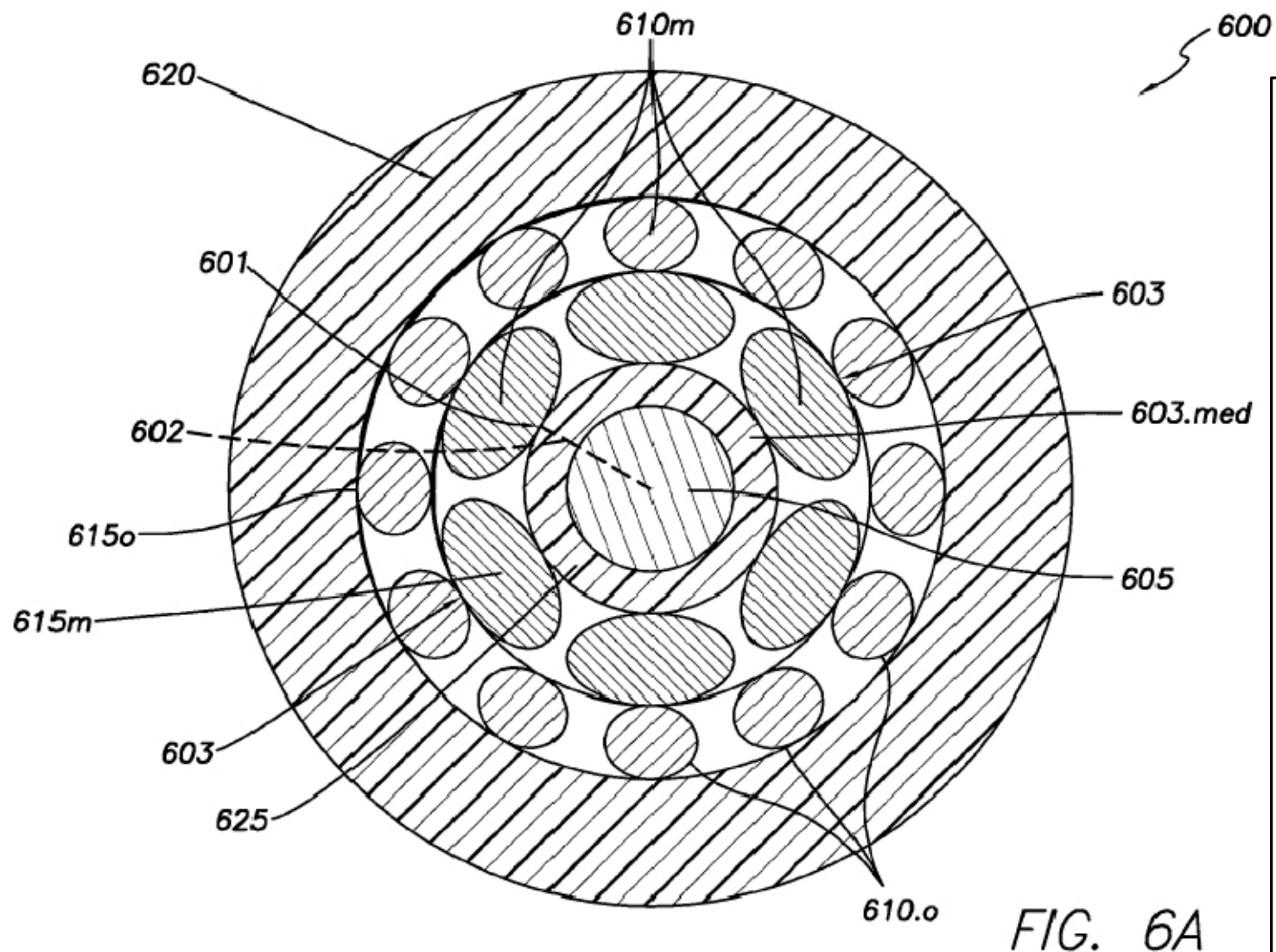


FIG. 5E

[0205] FIG. 6A illustrates an exemplary cable 600 configured for improved mechanical and electrical properties. Cable 600 has a central wire 605, a middle cable-layer 610.m, an outer cable-layer 610.o, a central wire coating 625, and a cable jacket 620.



[0206] [T]he filaments 615 of cable-layers 610 have a substantially oval cross-sectional shape. That is, exemplary filament 615.m of middle cable-layer 610.m has a substantially oval shape, and exemplary filament 615.o of outer cable-layer 610.o also has a substantially oval cross-sectional shape.

[0208] At locations 603 of parallelism between elongated surfaces of filaments 615.o and 615.m, the surfaces of filaments 615.o and 615.m are in contact. As a result of the contact between these elongated surfaces, the pressure between filaments 615 in adjacent cable-layers 610 is distributed over a wider contact surface area. As a consequence of distributing the pressure between the filaments over a wider contact surface area, the pressure per unit area is reduced on each filament 615. This ... results in decreased fretting fatigue, decreased structural damage to each filament 615, and therefore increased durability and lifetime for cable 600 as a whole.

FIG. 6A

[0215] FIG. 6B is another view of exemplary cable 600. This view illustrates the extended length of the cable and in addition illustrates the helical winding of filaments 615.o and 615.m.

[0216] Also shown in FIG. 6B is that central wire 605 has a 28% silver content. In FIGS. 6C and 6D (discussed further below) it is shown respectively that mid-layer cable-layer 610.m features filaments 615.m with 33% silver content and outer cable-layer 610.o features filaments 615.o with 41% silver content. The amount of silver content is exemplary only, and may vary in different embodiments. Further details of the filament metallic structure and content are presented below with respect to FIG. 10.

[0217] It is illustrated in FIG. 6B that alternate cable-layers 610 may be wound in alternate directions. For example, middle cable-layer 610.m may be left hand wound while outer cable-layer 610.o may be right hand wound.

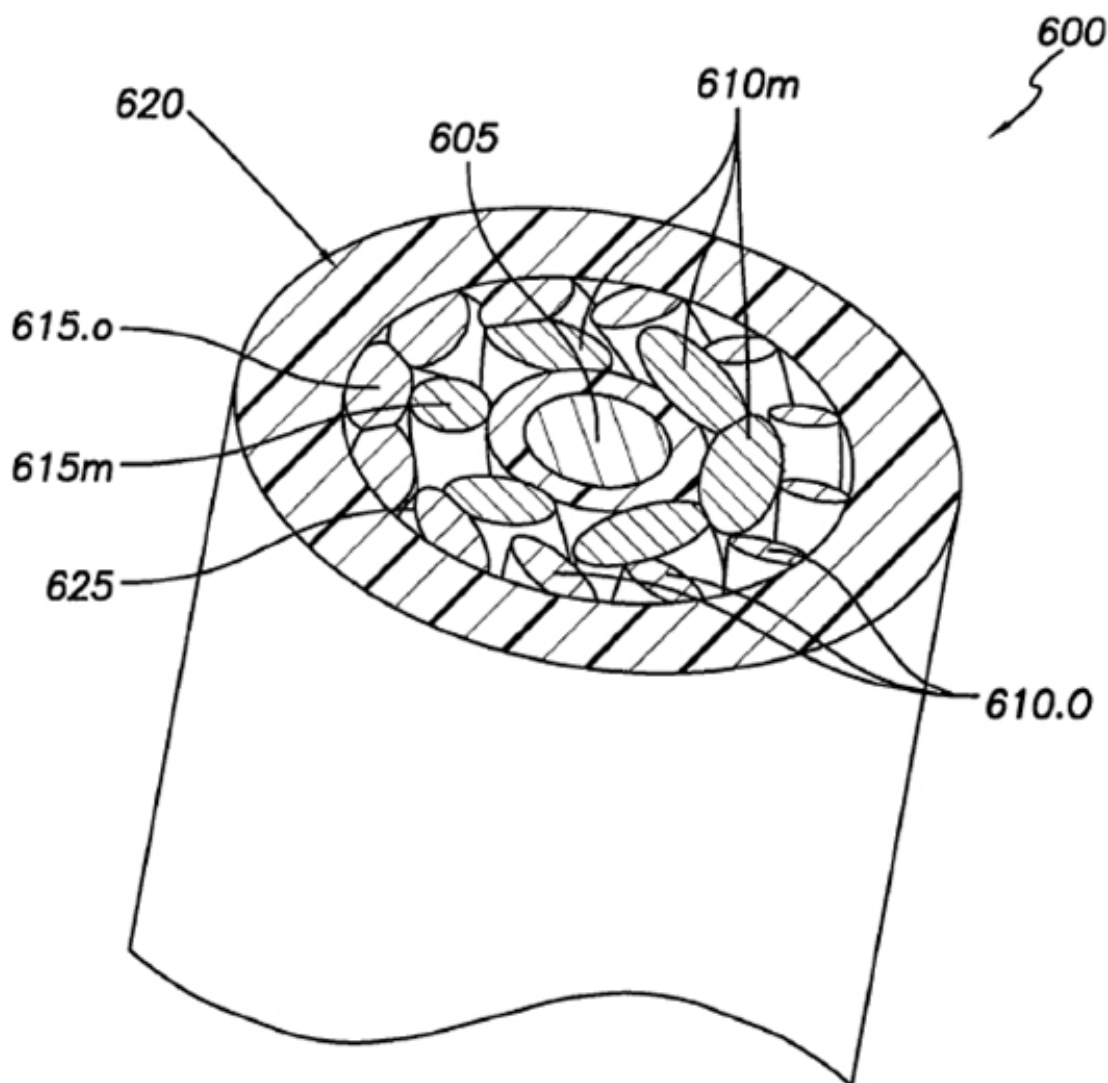


FIG. 6B

[0221] Notable, however, with exemplary cable 700 is that rather than central wire coating 625 (see FIG. 6) which is omitted in this configuration, filaments 715.m of middle cable-layer 710.m have individual filament coatings 730. These filament coatings 730 may be comprised of any number of polymers, such as that already enumerated above.

[0222] In addition, filament coating 730 serve to reduce fretting fatigue in multiple respects. Filament coatings 730 reduce fretting fatigue between middle filaments 715.m and central wires 705. Filament coating 730 also reduce fretting fatigue due to contact pressure between middle filaments 715.m and outer filaments 715.o. Filament coating 730 also reduce fretting fatigue between filaments 715.m of middle cable-layer 710.m.

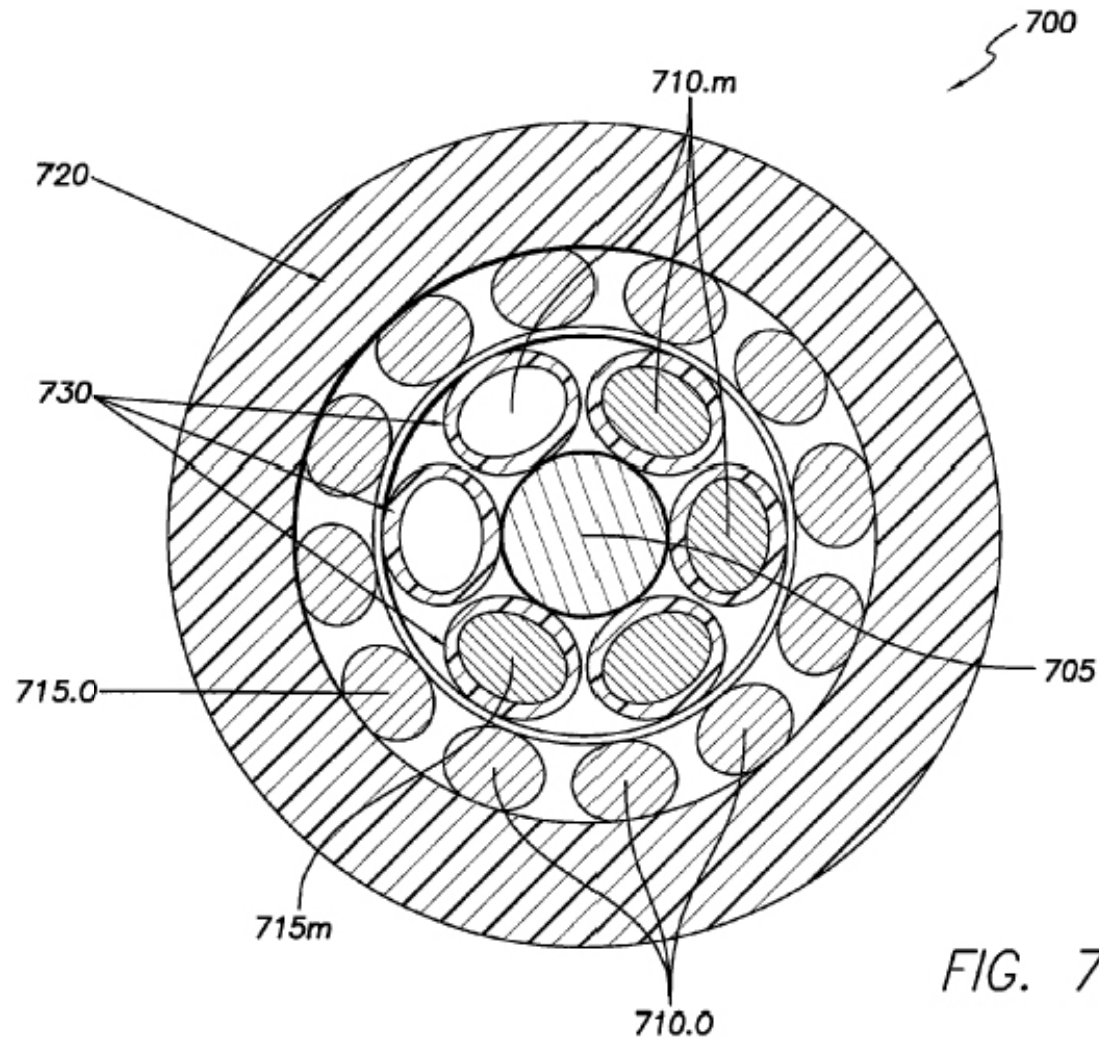


FIG. 7A

[0223] FIG. 7B is another view of exemplary cable 700 configured for improved mechanical and electrical properties. FIG. 7B shows elements which are substantially the same as the elements shown in cross-sectional view in FIG. 7A. In FIG. 7B a perspective view is offered, making clearer the windings of filaments 715.o and also the overall extension of exemplary cable 700.

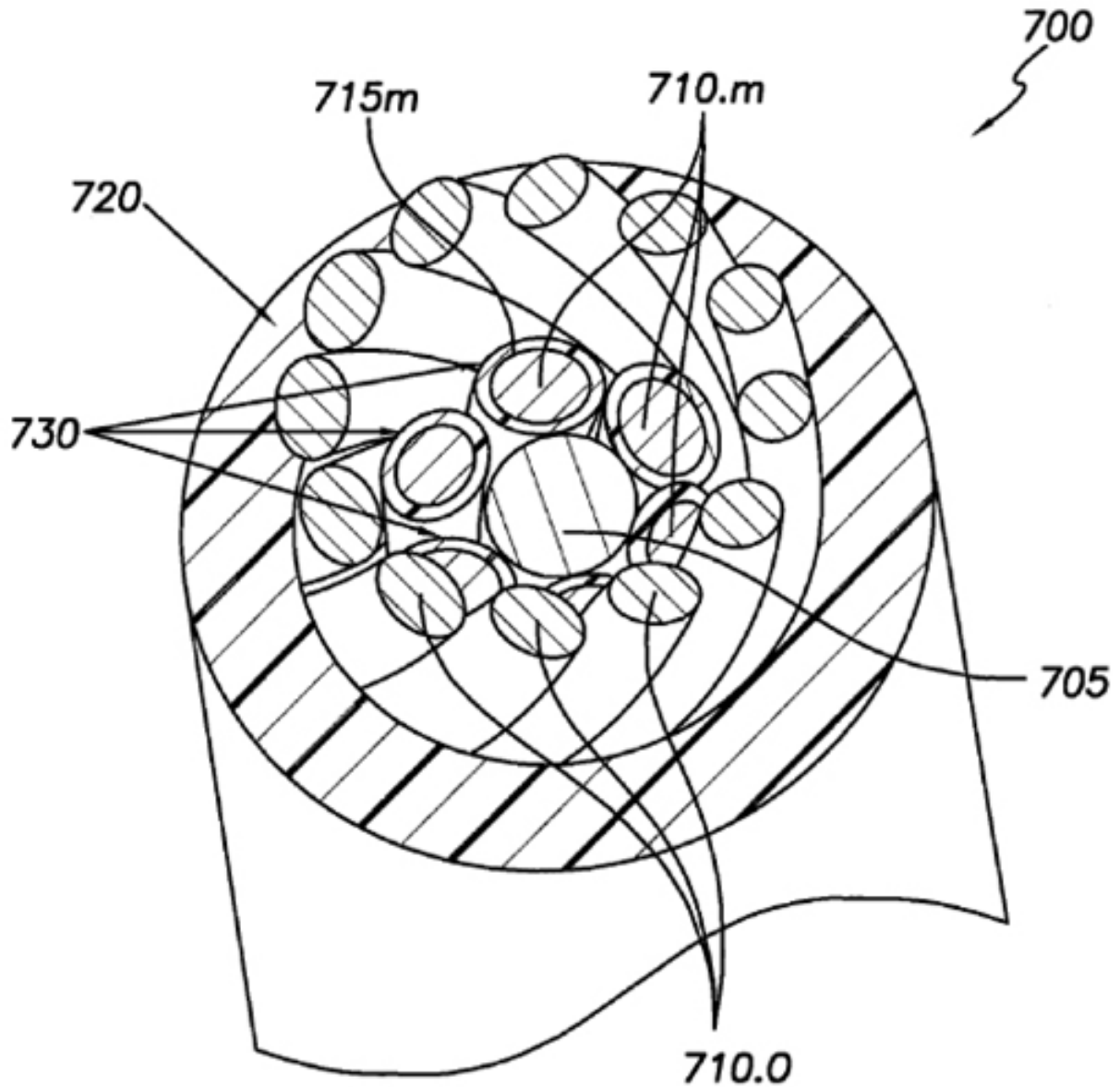
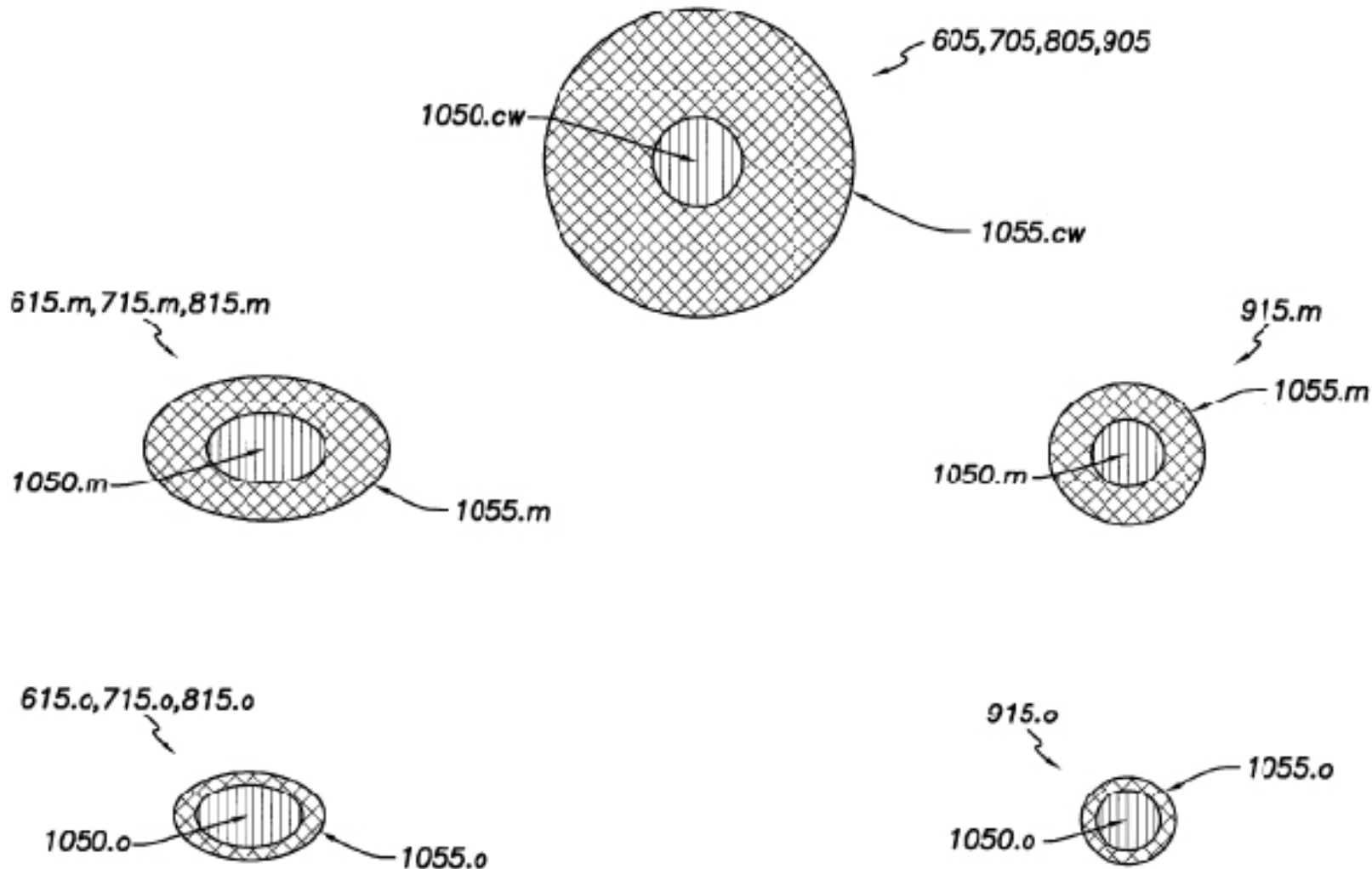


FIG. 7B

[0238] FIG. 10 illustrates cross-section view of several exemplary filaments 615/915 according to the present cable and lead designs. Each filament 615/915 has an exterior outer tubing 1055 which, as discussed immediately above, may be comprised of the alloy MP35N. Each filament also has a core 1050 running down the center and comprised of high purity silver.

[0239] [T]he cross-sectional area of a filament 615/915 may decrease with increasing distance from the center of cable 600/900. [C]entral wire 605/905 has a larger cross-sectional area than middle filaments 615.m/915.m. Similarly, middle filaments 615.m/915.m have a larger cross-sectional area than outer filaments 615.o/915.o.



[0248] [T]he choice of both materials for filament core material 1050 and filament tube 1055, as well as the relative percentages allocated between core 1050 and tube 1055, is generally selected such that the strength of the materials decreases from the center wire 605/905 to one or more middle layers 610.m/910.m to the outer layer 610.o/910.o, such that cable 600/900 as a whole will offer higher tensile strength but less flex/bending stiffness. Materials and relative percentages will also be chosen with a view towards reducing DC resistance and optimizing MRI compatibility.

FIG. 10

[0252] While not shown in rope cable 1100 of FIG. 11, persons skilled in the relevant arts will recognize that the elements, systems, and methods disclosed elsewhere herein... may be advantageously employed in other embodiments, for example in rope cable 1100. For example, strand filaments 1115 could be configured to have oval cross-sections, and the oval cross-sections oriented to maximize a contact area between strand filaments 1115 and central filament 1125, or to maximize a contact area between strand filaments 1115 and surrounding strand filaments of a second strand layer (not illustrated)....

[0253] Similarly, various types of polymer jackets could be employed around strand filaments 1115, ropes 1120, rope core 1105, rope layer(s) 1110, and/or central strand filament 1125 and/or elements thereof to reduce fretting fatigue between these elements. Similarly, the composition, for example (ratios of metals employed in construction) of strand filaments 1115 and/or central strand filament 1125 may be varied depending on radial distance from a central locus or based on other geometric or structural considerations, with the advantages already described above. Similarly, the cross-sectional area of strand filaments 1115, central strand filament 1125, and strands 1120 may be varied with radial distance from a central locus.....

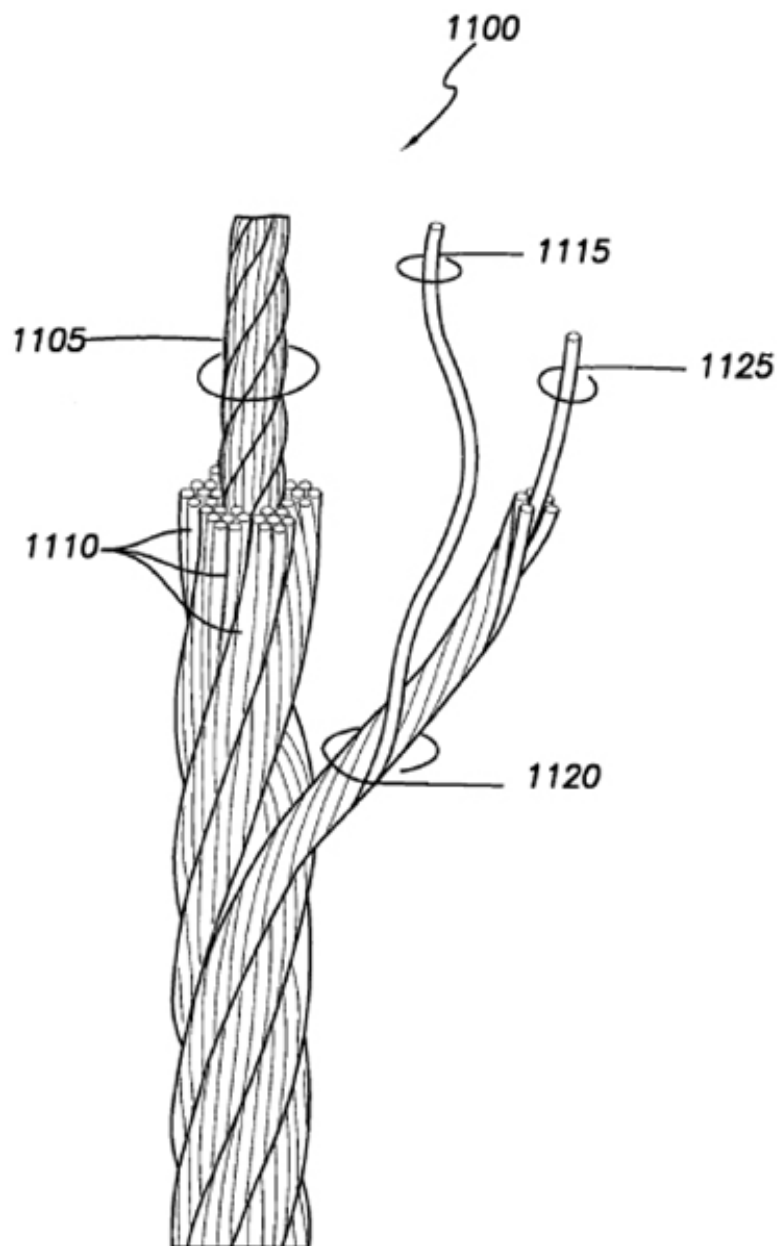


FIG. 11

**SMALL CALIBER IMPLANTABLE
BIOMETRIC LEADS AND CABLES FOR
SAME**

FIELD OF THE INVENTION

[0001] The present invention relates generally to implantable cardiac therapy devices, and more specifically to implantable leads for implantable cardiac devices.

BACKGROUND

[0002] Implantable cardiac therapy devices (ICTDs) enjoy widespread use for providing convenient, portable, sustained therapy for cardiac patients with a variety of cardiac arrhythmias. ICTDs may combine a pacemaker and defibrillator in a single implantable device. Such devices may be configured to provide ongoing cardiac pacing in order to maintain an appropriate cardiac rhythm. In addition, should the ICTD detect that the patient is experiencing an episode of ventricular fibrillation (or an episode of ventricular tachycardia), the ICTD can deliver appropriate defibrillation therapy.

[0003] Cardiac rhythm management (CRM) therapies require not only an ICTD, but also the placement of electrical leads threaded through blood vessels and typically into the heart itself. Patients with implanted electrical leads benefit from leads which exhibit optimized properties in terms of size (that is, minimal lead width or diameter), flexibility, strength, and reliability (including resistance to breaking), and various electrical properties such as low impedance (in order to carry large current loads).

[0004] With advances in both CRM therapy and ICTD technologies, the device implant pathway can become busy with three or more cables (for example, cables may be required for treating bradycardia, tachycardia, defibrillation, cardiac pacing, for standalone sensors, etc.). These multiple leads may need to be placed inside only one or two veins, which in turn benefit from smaller size leads to ensure adequate circulation through the blood vessels. Adding new sensor based diagnostic features, such as LAP (left atrial pressure), RVP (right ventricular pressure), and SvO₂ (blood oxygen sensor), requires creating additional space in the implant pathway or the lead body for the diagnostic circuits. Therefore, the addition of such sensors requires that the regular ICD lead diameter again must be reduced. Potential target drug delivery and target biological therapy delivery of tissues, cells, antibodies genes, etc. needs to be specifically delivered via a lead channel in the given vein with the new ICD leads. All of these therapeutic demands create requirements for the thinnest possible leads consistent with other lead requirements (flexibility, durability, low electrical resistance, and others).

[0005] With recent advances in cardiac therapies, alternative ICD lead implant sites are increasingly used. These include: the right ventricular outflow tract (ROT), the right ventricular (RV) high septum, and other sites in the right heart; and also the cardiac septum (CS), the great cardiac vein, and other areas of the left heart. To this end, the ICD leads must be robust and flexible for site specific positioning, and for ease of implantation through the torturous and complex implant pathways. ICTD leads also require improved acute and chronic stability at the desired site to reliably deliver the desired therapies for the entire design life of the system.

[0006] As is well known in the art, there are also different delivery methods to implant leads in the heart. The ICD lead should be compatible with traditional stylet delivery, and also be compatible with the emerging screw-driver stylet and/or slidable/steerable catheter, which benefits even more from a smaller size ICD lead.

[0007] Yet another aspect of lead design is enhanced lead removability, which becomes possible with leads that exhibit only minor fibrotic encapsulation. The degree of fibrosis engendered by a lead may be altered by optimized lead body materials and coatings, but here again a reduced electrical lead size contributes as well.

[0008] Yet another objective of lead design is MRI compatibility, which places specific requirements on the conductors for sizes, layout, insulation, etc.

[0009] The various operational requirements for ICTD leads, as specified above, create competing design requirements. In general, thinner leads contribute to flexibility and allow for maximum circulation within blood vessels. At the same time, it is known that fretting fatigue is the primary failure mode of a small-sized lead made of multiple filament wires; for example, the center filament wire is usually broken first in an existing 1×19 cable where all of the wires are of the same size. Further, smaller leads exhibit lower tensile strength. Also, when the lead size becomes smaller, the DC resistance of the cable increases, which in turn decreases the capability to carry large currents.

[0010] It will be noted that while implantable leads are essential in the field of cardiac rhythm management (CRM) therapies, they are employed in many other biomedical applications as well. For example, implantable leads have applications in neurology for treatment of Parkinson's disease, epilepsy, chronic back pain, and other conditions. Many of the requirements identified above, such as small size (i.e., being as thin as possible), flexibility, durability, and low resistance are requirements for these other applications as well.

[0011] What is needed, then, is an apparatus for an implantable lead for use with an ICTD, and for other implantable medical applications as well, with a smaller size lead which none-the-less exhibits optimized performance for implantation in relation to existing leads including, for example:

[0012] flexible bending but higher tension strength;

[0013] higher fatigue life;

[0014] stronger ability to resist kinking;

[0015] better electrical conductivity;

[0016] lower DC resistance to carry large current during cardiac shocking.

BRIEF SUMMARY

[0017] The cable and lead designs presented herein show optimal mechanical and electrical performances especially for applications such as ICTD leads. The present cable and lead designs are directed towards reducing the diameter of leads, while providing for optimized mechanical and electrical properties, by reducing the diameters of the conducting cables used within the leads for both sensing and delivery of therapeutic electrical stimulation.

[0018] The diameter of the conducting cables may be reduced via multiple strategies. In an embodiment of the present cable and lead designs, conducting filaments within the lead are configured to have oval cross-sectional areas. By suitably orienting the oval filaments within a cable, it is possible to increase the contact surface between adjacent filaments. The increased contact surface area broadly distributes

the pressure between filaments, resulting in reduced fretting fatigue. At the same time, the oval cross-sectional area increases conductivity and reduces DC resistance.

[0019] In an embodiment of the present cable and lead designs, suitable non-conductive coatings or jackets are employed around filaments within a cable, or around groups of filaments organized into cable-layers. The coatings or jackets reduce fretting fatigue, which enhances cable life and allows for the use of thinner filaments.

[0020] In an embodiment of the present cable and lead designs, the cross-sectional area of filaments used in a cable decreases as the filaments are positioned at increasing radial distance from the center of the cable. This configuration contributes to both structural strength and flexibility of the cable, while enabling a reduced cable diameter and maintaining optimized electrical properties.

[0021] In an embodiment of the present cable and lead designs, the relative composition of various metals and/or alloys of filaments in the cable is varied in relation to different radial distances of the filaments from the center of the cable. This configuration contributes both to structural strength and flexibility of the cables, while reducing cable diameter and maintaining optimized electrical properties.

[0022] Other and further features, advantages, and benefits of the present cable and lead designs will become apparent in the following description taken in conjunction with the following drawings. It is to be understood that the foregoing general description and the following detailed description are exemplary and explanatory but are not to be restrictive of the invention. The accompanying drawings which are incorporated in and constitute a part of this invention, illustrate only several of many possible embodiments of the invention, and together with the description, serve to explain the principles of the invention in general terms.

BRIEF DESCRIPTION OF THE DRAWINGS/FIGURES

[0023] The accompanying drawings, which are incorporated herein and form part of the specification, illustrate the methods and systems presented herein for conductor cable designs for small caliber leads for an ICTD. Together with the detailed description, the drawings further serve to explain the principles of, and to enable a person skilled in the relevant art(s) to make and use the methods and systems presented herein.

[0024] In the drawings, like reference numbers indicate identical or functionally similar elements. Further, the drawing in which an element first appears is typically indicated by the leftmost digit(s) in the corresponding reference number (e.g., an element numbered **302** first appears in FIG. **3**).

[0025] Additionally, some elements may be labeled with only a number to indicate a generic form of the element, while other elements labeled with the same number followed by another number or a letter (or a letter/number combination) may indicate a species of the element. For example, a generic filament of a cable may be labeled as **815**. A filament associated specifically with an inner cable-layer may be labeled as **815.i**, a filament associated with a middle cable-layer as **815.m**, and a filament associated with an outer cable-layer as **815.o**.

[0026] When referring to the figures, reference is sometimes made to a specific figure, for example, FIG. **5A**, FIG. **5B**, FIG. **6A**, FIG. **10**, etc. In other instances, especially where a group of figures illustrate different views and/or

different sub-elements of a common element, reference may be made for convenience to the group of figures by way of a common figure number. For example, a reference to “FIG. **6**” will be understood in this document as referring to all of, or to contextually pertinent aspects of, FIGS. **6A**, **6B**, **6C**, **6D**, and/or **6E** as appropriate, as well as to the disclosure associated with those figures. A reference to “FIGS. **6-9**” will be understood as referring to all of, or to contextually pertinent aspects of, FIGS. **6A-6E**, **7A-7C**, **8A**, **8B**, **9A**, and **9B**, as appropriate, as well as to the disclosure associated with those figures.

[0027] FIG. **1** is a simplified diagram illustrating an exemplary implantable cardiac therapy device (ICTD) in electrical communication with a patient’s heart by means of leads suitable for delivering multi-chamber stimulation and pacing therapy, and for detecting cardiac electrical activity.

[0028] FIG. **2** is a functional block diagram of an exemplary ICTD that can detect cardiac electrical activity and analyze cardiac electrical activity, as well as provide cardioversion, defibrillation, and pacing stimulation in four chambers of a heart.

[0029] FIG. **3** is a system diagram representing an exemplary computer, computational system, or other programming device which may be used to program an ICTD.

[0030] FIG. **4A** illustrates a cross-sectional view of an exemplary implantable ICTD lead according to an embodiment of the present cable and lead designs.

[0031] FIG. **4B** illustrates another cross-sectional view of the exemplary lead shown in FIG. **4A**.

[0032] FIG. **4C** illustrates another cross-sectional view of the exemplary lead shown in FIG. **4A** with a different set of dimensions than those shown in FIG. **4B**.

[0033] FIG. **4D** illustrates another cross-sectional view of the exemplary lead shown in FIG. **4A** with a different set of dimensions than those shown in FIG. **4B** or FIG. **4C**.

[0034] FIG. **4E** illustrates a cross-sectional view of another exemplary implantable ICTD lead according to the present cable and lead designs.

[0035] FIG. **4F** illustrates another view of the exemplary lead shown in FIG. **4E**.

[0036] FIG. **5A** illustrates an exemplary cable which may be part of a lead.

[0037] FIG. **5B** illustrates a cross-sectional view of the cable shown in FIG. **5A**.

[0038] FIG. **5C** illustrates a contact mode between two adjacent filaments which are part of a single cable-layer of a cable.

[0039] FIG. **5D** illustrates a contact mode between two filaments, each filament being part of a respective one of two adjacent cable-layers of a cable.

[0040] FIG. **5E** illustrates a fretting fatigue fracture morphology of a fine wire filament of a cable subjected to cyclic flex loading.

[0041] FIG. **6A** illustrates an exemplary cable configured for improved mechanical and electrical properties according to the present cable and lead designs.

[0042] FIG. **6B** illustrates another view of the exemplary cable shown in FIG. **6A**.

[0043] FIG. **6C** illustrates an exemplary cable-layer of the cable shown in FIG. **6A**.

[0044] FIG. **6D** illustrates another exemplary cable-layer of the cable shown in FIG. **6A**.

[0045] FIG. **6E** illustrates another view of the exemplary cable of FIG. **6A**.

[0046] FIG. 7A illustrates another exemplary cable configured for improved mechanical and electrical properties according to the present cable and lead designs.

[0047] FIG. 7B illustrates another view of the exemplary cable of FIG. 7A.

[0048] FIG. 7C illustrates another view of the exemplary cable of FIG. 7A.

[0049] FIG. 8A illustrates another exemplary cable configured for improved mechanical and electrical properties according to the present cable and lead designs.

[0050] FIG. 8B illustrates another view of the exemplary cable of FIG. 8A.

[0051] FIG. 9A illustrates another exemplary cable configured for improved mechanical and electrical properties according to the present cable and lead designs.

[0052] FIG. 9B illustrates another view of the exemplary cable of FIG. 9A.

[0053] FIG. 10 illustrates cross-sectional views of several exemplary filaments which may be part of a cable configured for improved mechanical and electrical properties according to the present cable and lead designs.

[0054] FIG. 11 illustrates an exemplary rope cable.

DETAILED DESCRIPTION

Overview

[0055] The following detailed description of systems and methods for conductor cable designs of small caliber ICTD leads for an implantable cardiac therapy device refers to the accompanying drawings that illustrate exemplary embodiments consistent with these systems and methods. Other embodiments are possible, and modifications may be made to the embodiments within the spirit and scope of the methods and systems presented herein. Therefore, the following detailed description is not meant to limit the methods and systems described herein. Rather, the scope of these methods and systems is defined by the appended claims.

[0056] It would be apparent to one of skill in the art that the systems and methods for conductor cable designs of small caliber ICTD leads for an implantable cardiac therapy device, as described below, may be implemented in many different embodiments of hardware, materials, construction methods, and/or the entities illustrated in the figures. Any actual hardware, materials, and/or construction methods described or illustrated herein is not limiting of these methods and systems. In addition, more than one embodiment of the present cable and lead designs may be presented below, and it will be understood that not all embodiments necessarily exhibit all elements, that some elements may be combined or connected in a manner different than that specifically described herein, and that some differing elements from the different embodiments presented herein may be functionally and structurally combined to achieve still further embodiments of the present cable and lead designs.

[0057] Thus, the operation and behavior of the methods and systems will be described with the understanding that modifications and variations of the embodiments are possible, given the level of detail presented herein.

[0058] It will be noted that while the exemplary embodiments presented below describe implantable leads, and cable conductors for use in the leads, used in the context of CRM therapies, the applications of the present cable and lead designs are not confined solely to leads employed for CRM therapies or to leads used in conjunction with ICTDs. For

example, the exemplary leads described herein, and other similar leads falling within the scope of the appended claims, may be employed in other biomedical applications as well. For example, the implantable leads may have applications in neurology for treatment of Parkinson's disease, epilepsy, chronic back pain, etc. The leads may have other biomedical applications as well, and due to their various advantages, such as small size (i.e., being as thin as possible), flexibility, durability, and low resistance, and may even find beneficial applications in non-medical or non-biological applications as well.

Exemplary Environment—Overview

[0059] Before describing in detail the methods and systems for conductor cable designs of small caliber ICTD leads for an implantable cardiac therapy device, it is helpful to describe an example environment in which these methods and systems may be implemented. The methods and systems described herein may be particularly useful in the environment of an implantable cardiac therapy device (ICTD).

[0060] An ICTD may also be referred to synonymously herein as a "stimulation device", emphasizing the role of the ICTD in providing pacing and shocking to a human heart. However, an ICTD may provide operations or services in addition to stimulation, including but not limited to cardiac monitoring.

[0061] An ICTD is a physiologic measuring device and therapeutic device that is implanted in a patient to monitor cardiac function and to deliver appropriate electrical therapy, for example, pacing pulses, cardioverting and defibrillator pulses, and drug therapy, as required. ICTDs include, for example and without limitation, pacemakers, cardioverters, defibrillators, implantable cardioverter defibrillators, implantable cardiac rhythm management devices, and the like. Such devices may also be used in particular to monitor cardiac electrical activity and to analyze cardiac electrical activity. The term "implantable cardiac therapy device" or simply "ICTD" is used herein to refer to any such implantable cardiac device.

[0062] FIGS. 1 and 2 illustrate such an environment.

Exemplary ICTD in Electrical Communication with a Patient's Heart

[0063] The techniques described below are intended to be implemented in connection with any ICTD or any similar stimulation device that is configured or configurable to stimulate nerves and/or stimulate and/or shock a patient's heart.

[0064] FIG. 1 shows an exemplary stimulation device **100** in electrical communication with a patient's heart **102** by way of three leads **104**, **106**, **108**, suitable for delivering multi-chamber stimulation and shock therapy. The leads **104**, **106**, **108** are optionally configurable for delivery of stimulation pulses suitable for stimulation of autonomic nerves. In addition, the device **100** includes a fourth lead **110** having, in this implementation, three electrodes **144**, **144'**, **144''** suitable for stimulation of autonomic nerves. This lead may be positioned in and/or near a patient's heart or near an autonomic nerve within a patient's body and remote from the heart. Of course, such a lead may be positioned epicardially or at some other location to stimulate other tissue.

[0065] As described further below in this document, exemplary leads **104**, **106**, **108**, **110** have at least one interior electrically conducting cable, and may have multiple interior electrically conducting cables. The present cable and lead designs provide improved cable designs for use in leads such as exemplary leads **104**, **106**, **108**, **110**. Such improvements

[0245] It should be further noted that elements of FIG. 10 are intended to illustrate relative dimensions, such as for example the relative percentages of silver compared with alloy in a central wire, a middle filament, and an outer filament, without necessarily being drawn exactly to scale. It will also be understood by persons skilled in the relevant arts that the relative percentages of core metal 1050 compared with tube metal 1055 may vary from that described above. In particular, in embodiments with only one layer of cable-layer 910 surrounding central wire 905, or with three or more layers of cable-layers 910 surrounding central wire 905, the percentages of silver in successive cable-layer(s) may vary from that described above.

[0246] In an embodiment, the percentage of silver in the core 1050 as compared with the percentage of alloy in the filament tube 1055 will progressively increase in filaments 615/915 working outwards from the central wire 605/905, through one or more middle cable-layers 610.m/910.m, towards an outermost cable-layer 610.o/910.o.

[0247] It should also be noted that the choice of silver for filament core 1050 and MP35N for tube 1055 is exemplary only. In alternative embodiments, other metals and/or alloys may be employed for core 1050, and other metals and/or alloys may be employed for tube 1055. Depending on the choice of material for core 1050 and tube 1055, the percentage of core material 1050 may decrease (rather than increase) working outwards from the central wire 605/905 towards an outermost cable-layer 610/910.

[0248] As already described above, the choice of both materials for filament core material 1050 and filament tube 1055, as well as the relative percentages allocated between core 1050 and tube 1055, is generally selected such that the strength of the materials decreases from the center wire 605/905 to one or more middle layers 610.m/910.m to the outer layer 610.o/910.o, such that cable 600/900 as a whole will offer higher tensile strength but less flex/bending stiffness. Materials and relative percentages will also be chosen with a view towards reducing DC resistance and optimizing MRI compatibility, as already described above.

Alternative Embodiments

[0249] Described above have been a number of exemplary embodiments 600/900 of cable conductors configured for improved mechanical and electrical performance in implantable biomedical leads. Referring again to FIGS. 6-10, such cables have comprised a central wire 605/905, cable layers 610/910, filaments 615/915 of the cable layers 610/910, and various coatings and jackets 620, 625, 720, 730, 820, 825, 920, 925, 930. Other elements, not shown or discussed, may be included as well, consistent with the present cable and lead designs.

[0250] Persons skilled in the relevant arts will appreciate that conducting cables may be designed and configured with various elements, such as wires 605/905, filaments 615/915, and other elements combined in a manner different than that illustrated and described above in FIGS. 6-10. FIG. 11, for example, illustrates an exemplary cable 1100 which, using terminology sometimes employed in the art, may be known as a rope cable 1100.

[0251] Rope cable 1100 may employ a plurality of strands 1120, where each strand may be comprised of multiple strand filaments 1115 which are wrapped or twisted together in a spiral or helical fashion, or otherwise coupled to each other. Strand filaments 1115 may, for example, be wrapped in spiral

or helical fashion around a central strand filament 1125. In turn, and as illustrated in FIG. 11, the plurality of strands 1120 may be wrapped in spiral or helical fashion around a rope core 1105 to form a rope layer 1110. While not shown in the figure, additional rope layers 1110 may be employed, each layer 1110 surrounding a layer 1110 interior to itself. The plurality of strands 1120 may also be bonded, coupled, or joined in some other fashion. Rope core 1105 may be a single, unitary wire, or may itself be comprised of multiple filaments conjoined or coupled in various manners.

[0252] While not shown in rope cable 1100 of FIG. 11, persons skilled in the relevant arts will recognize that the elements, systems, and methods disclosed elsewhere herein, in conjunction with other embodiments of the present cable and lead designs, may be advantageously employed in other embodiments, for example in rope cable 1100. For example, strand filaments 1115 could be configured to have oval cross-sections, and the oval cross-sections oriented to maximize a contact area between strand filaments 1115 and central filament 1125, or to maximize a contact area between strand filaments 1115 and surrounding strand filaments of a second strand layer (not illustrated), with the advantages already described above.

[0253] Similarly, various types of polymer jackets could be employed around strand filaments 1115, ropes 1120, rope core 1105, rope layer(s) 1110, and/or central strand filament 1125 and/or elements thereof to reduce fretting fatigue between these elements. Similarly, the composition, for example (ratios of metals employed in construction) of strand filaments 1115 and/or central strand filament 1125 may be varied depending on radial distance from a central locus or based on other geometric or structural considerations, with the advantages already described above. Similarly, the cross-sectional area of strand filaments 1115, central strand filament 1125, and strands 1120 may be varied with radial distance from a central locus or based on other geometric or structural considerations, with the advantages already described above.

[0254] More generally, persons skilled in the relevant arts will recognize that the elements disclosed herein may be combined in a variety of manners, in conducting cables of various configurations, to achieve some or all of the advantages described herein.

Conclusion

[0255] It is to be appreciated that the Detailed Description section, and not the Summary and Abstract sections, is intended to be used to interpret the claims. The Summary and Abstract sections may set forth one or more but not all exemplary embodiments of the present cable and lead designs as contemplated by the inventor(s), and thus, are not intended to limit the present apparatus and method and the appended claims in any way.

[0256] Moreover, while various embodiments of the present cable and lead designs have been described above, it should be understood that they have been presented by way of example, and not limitation. It will be apparent to persons skilled in the relevant art(s) that various changes in form and detail can be made therein without departing from the spirit and scope of the present cable and lead designs. Thus, the present cable and lead designs should not be limited by any of the above described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

[0257] In addition, it should be understood that the figures, which highlight the functionality and advantages of the present cable and lead designs, are presented for example purposes only. The architecture of the present cable and lead designs is sufficiently flexible and configurable, such that it may be constructed and utilized in ways other than that shown in the accompanying figures. Moreover, the steps, processes, methods, and/or construction techniques indicated in the exemplary system(s) and method(s) described above may in some cases be performed in a different order, or by combining elements in a different manner, than the order or manner described, and some steps may be added, modified, or removed, without departing from the spirit and scope of the present cable and lead designs.

[0258] Further, the purpose of the foregoing Abstract is to enable the U.S. Patent and Trademark Office and the public generally, and especially the scientists, engineers and practitioners in the art who are not familiar with patent or legal terms or phraseology, to determine quickly from a cursory inspection the nature and essence of the technical disclosure of the application. The Abstract is not intended to be limiting as to the scope of the present cable and lead designs in any way.

What is claimed is:

1. A cable comprising:
 - a conductive central core; and
 - at least one conductive cable-layer concentric with the central core and surrounding at least one of the conductive central core and a conductive cable-layer interior to itself;
 wherein:
 - each at least one conductive cable-layer is comprised of a plurality of conductive filaments, said filaments configured to provide an elongated contact area between the at least one conductive cable-layer and either the conductive central core or a second conductive cable-layer immediately interior to the at least one conductive cable-layer.
2. The cable of claim 1, wherein a conductive filament of the at least one conductive cable-layer has a substantially oval cross section.
3. The cable of claim 2, wherein:
 - the elongated contact area of the substantially oval cross section conductive filament is substantially parallel to a longer cross-sectional axis of the filament; and
 - the elongated contact area of the substantially oval cross section conductive filament is oriented such that the elongated contact area makes contact with at least one of the conductive central core or the second conductive cable-layer;
 wherein the substantially oval cross section conductive filament is configured to maximize a contact area between the at least one conductive cable-layer and at least one of the conductive central core or the second conductive cable-layer.
4. The cable of claim 1, wherein the cross sectional area of a filament of the plurality of conductive filaments progressively decreases with an increasing radial distance from the conductive central core, wherein:
 - the conductive central core has a cross sectional area that is greater than a cross sectional area of a filament in the cable-layers; and
 - each filament of a first cable-layer of the at least one conductive cable-layers has a cross-sectional area that is

greater than a cross sectional area of a filament of a cable-layer exterior to the first cable-layer.

5. The cable of claim 1, wherein the material composition of a filament progressively changes with an increasing radial distance from the conductive central core, the material composition determining a material strength of the filament, wherein:

- the conductive central core has a material strength that is greater than a material strength of each filament in the cable-layers; and

- each filament of a first cable-layer of the one or more cable-layers has a material strength that is greater than a material strength of a filament of a cable-layer exterior to the first cable-layer.

6. The cable of claim 5, wherein:

- the conductive central core and each filament of the at least one conductive cable-layer comprises an inner silver core and an outer alloy;

- the conductive central core has a lower percentage silver content of its inner silver core than a percentage silver content of the inner cores of the filaments in the at least one conductive cable-layer; and

- each filament of a first conductive cable-layer of the at least one conductive cable-layer has a lower percentage silver content of its inner silver core than percentage silver content of an inner core of a filament of a conductive cable-layer exterior to the first conductive cable-layer.

7. The cable of claim 6, wherein:

- the conductive central core has a silver content in a range of approximately 20% to 30%;

- each conductive filament of a first conductive cable-layer immediately surrounding the conductive central core has a silver content in a range of approximately 30% to 40%; and

- each conductive filament of a second conductive cable-layer immediately surrounding the first conductive cable-layer has a silver content in a range of approximately 40% to 60%.

8. The cable of claim 1, further comprising a non-conductive coating between at least one of:

- the conductive central core and a conductive cable-layer immediately surrounding the conductive central core; or
- a first conductive cable-layer of the at least one conductive cable-layer and an immediately adjacent second cable-layer of the at least one conductive cable-layer;

wherein:

- the non-conductive coating is configured to reduce a fretting fatigue at the elongated contact area while mediating and maintaining the elongated contact area.

9. The cable of claim 1, further comprising a non-conductive coating jacketing each filament of a least one cable-layer of the at least one conductive cable-layer, wherein the non-conductive coating is configured to minimize at least one of:

- a fretting at the area of contact between the cable-layer and either the conductive central core or a cable-layer immediately adjacent to itself; and

- a fretting fatigue at the area of contact between the plurality of filaments of the cable-layer.

10. A lead comprising:

- an extended exterior insulating body having a lumen; and
- a cable disposed within said lumen, said cable comprising: a conductive central core; and

at least one conductive cable-layer concentric with the central core and surrounding at least one of the conductive central core and a conductive cable-layer interior to itself;

wherein:

each at least one conductive cable-layer is comprised of a plurality of conductive filaments, said filaments configured to provide an elongated contact area between the at least one conductive cable-layer and either the conductive central core or a second conductive cable-layer immediately interior to the at least one conductive cable-layer.

11. The lead of claim **10**, wherein:

a conductive filament of the at least one conductive cable-layer has a substantially oval cross section; and the elongated contact area of the substantially oval cross section conductive filament is substantially parallel to a longer cross-sectional axis of the filament; and the elongated contact area of the substantially oval cross section conductive filament is oriented such that the elongated contact area makes contact with at least one of the conductive central core or the second conductive cable-layer;

wherein the substantially oval cross section conductive filament is configured to maximize a contact area between the at least one conductive cable-layer and at least one of the conductive central core or the second conductive cable-layer.

12. The lead of claim **10**, wherein the cross sectional area of a filament progressively decreases with an increasing radial distance from the conductive central core, wherein:

the conductive central core has a cross sectional area which is greater than a cross-sectional area of each filament in the cable-layers; and

each filament of a first cable-layer of the at least one conductive cable-layer has a cross-sectional area which is greater than a cross-sectional area of a filament of a cable-layer exterior to the first cable-layer.

13. The lead of claim **10**, wherein the material composition of a filament progressively changes with an increasing radial distance from the conductive central core, the material composition determining a material strength of the filament, wherein:

the conductive central core has a material strength which is greater than a material strength of each filament in the cable-layers; and

each filament of a first cable-layer of the one or more cable-layers has a material strength which is greater than a material strength of a filament of a cable-layer exterior to the first cable-layer.

14. The lead of claim **10**, further comprising a non-conductive coating between at least one of:

the conductive central core and the cable-layer immediately surrounding the conductive central core; or a first cable-layer and an immediately adjacent second cable-layer of the at least one conductive cable-layer;

wherein:

the non-conductive coating is configured to minimize a fretting fatigue.

15. The lead of claim **10**, further comprising a non-conductive coating jacketing each filament of a least one cable-layer of the at least one conductive cable-layer, wherein the non-conductive coating is configured to minimize at least one of:

a fretting fatigue at the area of contact between the cable-layer and either the conductive central core or a cable-layer immediately adjacent to itself; and a fretting fatigue at the area of contact between the plurality of filaments of the cable-layer.

16. An implantable system for delivery of cardiac therapy comprising:

an implantable cardiac therapy device (ICTD); and

a lead configured to be connected at a proximal end to said ICTD and configured to be attached at a distal end to a tissue of a patient;

wherein said lead comprises:

an extended exterior insulating body having a lumen; and a cable situated within said lumen, said cable comprising:

a conductive central core; and

at least one conductive cable-layer concentric with the central core and surrounding at least one of the conductive central core and a conductive cable-layer interior to itself;

wherein:

each at least one conductive cable-layer is comprised of a plurality of conductive filaments, said filaments configured to provide an elongated contact area between the at least one conductive cable-layer and either the conductive central core or a second conductive cable-layer immediately interior to the at least one conductive cable-layer.

17. A cable, comprising:

a conductive central core;

at least one conductive cable-layer concentric with the central core and surrounding at least one of the conductive central core and a conductive cable-layer interior to itself; and

a plurality of conductive filaments of the at least one conductive cable-layer;

wherein:

the cross sectional area of a filament of the plurality of conductive filaments progressively decreases with an increasing radial distance from the conductive central core, wherein:

the conductive central core has a cross sectional area which is greater than a cross-sectional area of a filament in the cable-layers; and

each filament of a first cable-layer of the at least one conductive cable-layers has a cross-sectional area which is greater than a cross-sectional area of a filament of a cable-layer exterior to the first cable-layer;

and;

the material composition of a filament progressively changes with an increasing radial distance from the conductive central core, the material composition determining a material strength of the filament, wherein:

the conductive central core has a material strength which is greater than a material strength of a filament in the cable-layers; and

each filament of a first cable-layer of the one or more cable-layers has a material strength which is greater than a material strength of a filament of a cable-layer exterior to the first cable-layer.

18. The cable of claim **17**, wherein a conductive filament of the at least one conductive cable-layer has a substantially oval cross section, wherein:

an elongated surface contact area of the substantially oval cross section conductive filament is oriented such that

the surface elongated contact area makes contact pressure with at least one of the conductive central core or the second conductive cable-layer.

19. The cable of claim 17, wherein:

the conductive central core and each filament of the at least one conductive cable-layer comprises an inner silver core and an outer alloy surrounding the inner silver core; the conductive central core has a percentage silver content of its inner silver core which is less than a percentage silver content of a filament in the at least one conductive cable-layer; and

each filament of a first conductive cable-layer of the at least one conductive cable-layer has a percentage silver content of its inner silver core which is less than a percentage silver content of a filament of a conductive cable-layer exterior to the first conductive cable-layer.

20. The cable of claim 17, further comprising a non-conductive coating between at least one of:

the conductive central core and a conductive cable-layer immediately surrounding the conductive central core;

a first conductive cable-layer of the at least one conductive cable-layer and an immediately adjacent second cable-layer of the at least one conductive cable-layer;

wherein:

the non-conductive coating is configured to reduce a fretting fatigue at the area of contact while mediating and maintaining the elongated contact area.

21. The cable of claim 17, further comprising a non-conductive coating jacketing each filament of a least one cable-layer of the at least one conductive cable-layer, wherein the non-conductive coating is configured to minimize at least one of:

a fretting fatigue between the cable-layer and either the conductive central core or a cable-layer immediately adjacent to itself; and

a fretting fatigue between the plurality of filaments of the cable-layer.

* * * * *