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(54) **Title:** MEDICAL ELECTRICAL LEAD

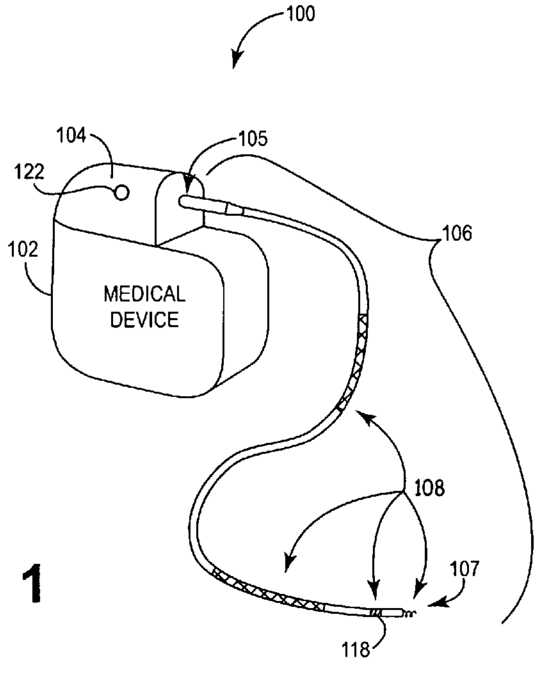

Fig. 1

(57) **Abstract:** A medical device lead is presented. The lead includes one or more jacketed conductive elements. The jacket comprises one or more covers. A first cover of expanded polytetrafluoroethylene (ePTFE) is in direct contact with the at least one conductive element. At least one conductive element and a ePTFE cover are coiled. The coiled conductive element can substantially retain its original coiled shape.

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MEDICAL ELECTRICAL LEAD

[0001] The present application claims priority and other benefits from U.S. Provisional Patent Application Serial No. 60/972,114 filed September 13, 2007, and Serial No. 60/973,479 filed September 19, 2007.

TECHNICAL FIELD

[0002] The disclosure relates to implantable medical devices and, more particularly, to implantable medical leads.

BACKGROUND

[0003] The human anatomy includes many types of tissues that can either voluntarily or involuntarily, perform certain functions. After disease, injury, or natural defects, certain tissues may no longer operate within general anatomical norms. For example, after disease, injury, time, or combinations thereof, the heart muscle may begin to experience certain failures or deficiencies. Certain failures or deficiencies can be corrected or treated with implantable medical devices (IMDs), such as implantable pacemakers, implantable cardioverter defibrillator (ICD) devices, cardiac resynchronization therapy defibrillator devices, or combinations thereof.

[0004] IMDs detect and deliver therapy for a variety of medical conditions in patients. IMDs include implantable pulse generators (IPGs) or implantable cardioverter-defibrillators (ICDs) that deliver electrical stimuli to tissue of a patient. ICDs typically comprise, inter alia, a control module, a capacitor, and a battery that are housed in a hermetically sealed container with a lead extending therefrom. It is generally known that the hermetically sealed container can be implanted in a selected portion of the anatomical structure, such as in a chest or abdominal wall, and the lead can be inserted through various venous portions so that the tip portion can be positioned at the selected position near or in the muscle group. When therapy is required by a patient, the control module signals the battery to charge the capacitor, which in turn discharges electrical stimuli to tissue of a patient through via electrodes disposed on the lead, e.g., typically near the distal end of the lead. Typically, a medical electrical lead includes a flexible elongated body with one or more insulated elongated conductors. Each conductor electrically couples a sensing and/or a stimulation electrode of the lead to the control module through a connector module. It is desirable to develop implantable medical electrical leads with new lead body subassemblies.

BRIEF DESCRIPTION OF DRAWINGS

[0005] Aspects and features of the present invention will be appreciated as the same becomes better understood by reference to the following detailed description of the embodiments of the invention when considered in connection with the accompanying drawings, wherein:

[0006] **FIG. 1** is a conceptual schematic view of an implantable medical device in which a medical electrical lead extends therefrom;

[0007] **FIG. 2** is a schematic view of a medical electrical lead;

[0008] **Fig. 3A** is a schematic view of a distal end of the medical electrical lead;

[0009] **Fig. 3B** is a cross-sectional view taken along plane A-A of the distal end of the medical electrical lead depicted in **Fig. 3A**;

[0010] **Fig. 4A** is a schematic view of a jacket that surrounds one or more conductive elements in a medical electrical lead;

[0011] **Fig. 4B** is a schematic sectional view of the jacket depicted in **Fig. 4A**;

[0012] **FIG. 5A** is a schematic view of an exemplary insulated conductive element;

[0013] **Fig. 5B** is a cross-sectional view of the insulated conductive element depicted in **Fig. 5A**;

[0014] **FIG. 6A** is a schematic view of an exemplary insulated multi-conductor element;

[0015] **FIG. 6B** is a schematic cross-sectional view of an exemplary insulated multi-conductor element depicted in **FIG. 6A**;

[0016] **FIG. 7A** is a schematic view of another exemplary insulated multi-conductor element;

[0017] **FIG. 7B** is a schematic cross-sectional view of an exemplary insulated multi-conductor element depicted in **FIG. 7A**;

[0018] **FIG. 8A** is a schematic view of an exemplary insulated multi-conductor element before its stretched;

[0019] **FIG. 8B** is a schematic view of an exemplary insulated multi-conductor element being stretched;

[0020] **FIG. 8C** is an exemplary insulated multi-conductor element in a relaxed position and returning to its original coiled shape;

[0021] **FIG. 9** is a schematic view of an exemplary insulated multi-conductor element wrapped around a tubular insulative element or a coil liner;

[0022] **FIG. 10A** is a schematic view of yet another exemplary insulated multi-conductor element wrapped around a mandrel;

[0023] **FIG. 10B** is a cross-sectional view of the insulated conductive element depicted in **FIG. 10A**; and

[0024] **FIG. 11** is a flow diagram for forming a coiled jacketed conductive element.

DETAILED DESCRIPTION

[0025] The present disclosure relates to a medical electrical lead that includes a lead body. The lead body comprises at least one elongated conductive element, such as a cable, surrounded by an elongated jacket. The jacket can include one or more covers. The jacket can be formed through an extrusion process directly over the conductive element, which reduces or eliminates diametrical expansion of the coiled conductive element which can occur due to elastic "springback" or stress relaxation of the coiled composite structure. A first cover comprises polyether ether ketone (PEEK) (PEEK) extruded directly over the conductive element. In one embodiment, the conductive element and the jacket, is then formed into a coil.

[0026] In one embodiment, the PEEK undergoes a molecular mobility process prior to or during introduction of the ePTFE over an elongated conductive element. Exemplary molecular mobility processes can include thermal annealing, stress relieving, or other suitable means for a material to achieve a more flexible molecular structure.

[0027] Thermal processing can involve exposing the composite structure to a controlled heating and cooling schedule. Suitable temperatures can depend upon the type of polymeric material and/or number of covers or layer(s) employed, to form a jacket, a composite jacket, or one or more longitudinal elements that can house conductive elements. PEEK, for example, can be thermally processed at about 130-200 degrees Celsius (°C). Thermal processing of PEEK onto an elongated conductive element causes the conductive element to substantially maintain a controlled pitch and diameter after coiling. For example, a conductive element such as a cable in a coil shape can substantially maintain up to about 99 percent of its original coil shape, after the conductive element has been released from, for example, a mandrel which is after a thermal processing has been performed. The final diameter and pitch of a coil shape is generally based upon the coil composite structure and its elastic “springback” or coil expansion from stress relaxation, the winding diameter/pitch, and the processing parameters used to set the coil shape. In one embodiment, a coiled cable is more resistant to flex fatigue compared to a linear or straight cable. Additionally, smaller coiled cable diameters are achieved through application of the principles described herein. In one embodiment, about 10 percent or more of a diameter reduction in the coiled conductive element is achieved through the principles described herein. In another embodiment, about 5 percent or more diameter reduction is achieved in the coiled conductive element through the principles described herein. In still yet another embodiment, about 2 percent or more diameter reduction is achieved in the coiled conductive element through the principles described herein. Smaller coiled cable diameters allow for smaller sized leads to be produced. Smaller sized leads can include 7 French or smaller. In another embodiment, smaller sized leads can include 6 French or smaller. In still yet another embodiment, smaller sized leads can include 5 French or smaller.

[0028] The principles described herein are applicable to all types of medical electrical leads. For example, the disclosure applies to cardiovascular leads (e.g. high voltage leads, low voltage leads etc.), neurological leads, or other suitable applications.

[0029] **FIG. 1** depicts a medical device system **100**. A medical device system **100** includes a medical device housing **102** having a connector module **104** (e.g. international standard (IS)-1, defibrillation (DF)-1, IS-4 etc.) that electrically couples various internal electrical components housed in medical device housing **102** to a proximal end **105** of a medical electrical lead **106**. A medical device system **100** may comprise any of a wide variety of medical devices that include one or more medical lead(s) **106** and circuitry coupled to the medical electrical lead(s) **106**. An exemplary medical device system **100** can take the form of an implantable cardiac pacemaker, an implantable cardioverter, an implantable defibrillator, an implantable cardiac pacemaker-cardioverter-defibrillator (PCD), a neurostimulator, a tissue and/or muscle stimulator. IMDs are implanted in a patient in an appropriate location. Exemplary IMDs are commercially available as including one generally known to those skilled in the art, such as the Medtronic CONCERTO™, SENSIA™, VIRTUOSO™, RESTORE™, RESTORE ULTRA™, sold by Medtronic, Inc. of Minnesota. Non-implantable medical devices or other types of devices may also utilize batteries such as external drug pumps, hearing aids and patient monitoring devices or other suitable devices. Medical device system **100** may deliver, for example, pacing, cardioversion or defibrillation pulses to a patient via electrodes **108** disposed on distal end **107** of one or more lead(s) **106**. Specifically, lead **106** may position one or more electrodes **108** with respect to various cardiac locations so that medical device system **100** can deliver electrical stimuli to the appropriate locations.

[0030] **FIG. 2** depicts lead **106**. Lead **106** includes a lead body **117** that extends from proximal end **105** to a distal end **107**. Lead body **117** can include one or more connectors **101**, and one or more jacketed conductive elements **112a-d.** A jacket (also referred to as a liner, longitudinal element, coating) extends along and longitudinally around the conductive elements **112a-d** and can serve to contain or mechanically constrain one or more conductive elements **112a-d**. A jacket can also insulate one or more conductive elements **112a-d**. Connector module **104** can contain connectors **122**, such as set screws, serve to electrically and mechanically connect conductive elements **112a-d** to ports (not shown) of connector module **104**. Conductive element **112c** (also referred to as a “conductor coil,” torque coil”, “distal tip conductor”) can extend to the distal end **107** and can optionally be coupled to a retractable and/or extendable helical tip. One or more conductive elements **112a,b** serve as, or are connected to, defibrillation coils **103a,b** that deliver electrical stimuli, when necessary, to tissue of a patient. Lead **106** can also include a conductive element **112d** that extends from the proximal end **105** to ring electrode **118** while another conductive element **112c** extends from proximal end **105** to tip electrode **120**.

[0031] Electrically conductive elements **112a-d** can include coils, wires, coil wound around a filament, cables, conductors or other suitable members. Conductive elements **112a-d** can comprise platinum, platinum alloys, titanium, titanium alloys, tantalum, tantalum alloys, cobalt alloys (e.g. MP35N, a nickel-cobalt alloy etc.), copper alloys, silver alloys, gold, silver, stainless steel, magnesium-nickel alloys, palladium, palladium alloys or other suitable materials. Electrically conductive element **112a-d** is covered, or substantially covered, longitudinally with a jacket **130** (also referred to as a liner, a longitudinal element, a longitudinal member, a coating, a tubular element, a tube or a cylindrical element). In yet another embodiment, each conductive element **112a-d** is surrounded by a tubular element, which can possess a circular or a non-circular cross-section. An outercover or outerjacket in a lead body **117** can exhibit a non-circular cross-section.

[0032] Typically, the outer surface of electrodes **108** such as the ring electrode **118**, the tip electrode **120**, and the defibrillation coils **103a,b** are exposed or not covered by a jacket **130** or liner so that electrodes **108** can sense and/or deliver electrical stimuli to tissue of a patient. A sharpened distal tip (not shown) of tip electrode **120** facilitates fixation of the distal end of helically shaped tip electrode **120** into tissue of a patient.

[0033] Referring to **FIGs. 3A-3B**, and **4A-4B**, lead body **117** can include one or more jackets **130** and one or more conductive elements **112a,b,d**. In one embodiment, lead body **117** comprises one or more jackets **130** disposed in another jacket **130**. In still yet another embodiment, lead body **117** comprises one or more jackets **130** with an outer cover **140** that surrounds the one or more jackets **130**.

[0034] Each jacket **130** can include one or more covers, as depicted in **FIGs. 4A-4B** with cross-sectional segment **128**. Each cover **146**, **148**, **150**, and **152** can comprise one or more layers of polymeric compounds. Numerous embodiments of jacket **130** or liner are summarized in Table 1 and described in greater detail below. The first embodiment listed in Table 1 relates to a jacket **130** formed of a first, second and third covers **144**, **146**, **148**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE (tape-wrapped, porous), commercially available from Zeus located in Orangeburg, South Carolina or C.R. Bard located in Tempe, AZ, is introduced over the first cover **144**. Porous ePTFE possesses a density of less than 2.2grams/cubic centimeters. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of PEEK is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, second, and third covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0035] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^0C to about 210^0C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0036] The second embodiment listed in Table 1 relates to a jacket **130** formed of a first, second and third covers **144**, **146**, **148**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE (tape-wrapped, porous) is introduced over the first cover **144**. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of ETFE is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, second, and third covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0037] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^0C to about 210^0C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0038] The third embodiment listed in Table 1 relates to a jacket **130** formed of a first, second covers **144**, **146**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE (tape-wrapped, porous) is introduced over the first cover **144**. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of PEEK is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, and second covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0039] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^0C to about 210^0C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0040] The fourth embodiment listed in Table 1 relates to a jacket **130** formed of a first, second and third covers **144**, **146**, **148**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE (tape-wrapped, nonporous) is introduced over the first cover **144**. Nonporous ePTFE possesses a density of about 2.2grams/cubic centimeters. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of PEEK is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, second, and third covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0041] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^0C to about 210^0C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0042] The fifth embodiment listed in Table 1 relates to a jacket **130** formed of a first, second and third covers **144**, **146**, **148**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE (tape-wrapped, nonporous) is introduced over the first cover **144**. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of ETFE is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, second, and third covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0043] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^0C to about 210^0C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0044] The sixth embodiment listed in Table 1 relates to a jacket **130** formed of a first, second and third covers **144**, **146**, **148**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE (tape-wrapped, nonporous) is introduced over the first cover **144**. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of EFEP is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, second, and third covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0045] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^0C to about 210^0C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0046] The seventh embodiment listed in Table 1 relates to a jacket **130** formed of a first, second covers **144**, **146**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE-FEP layered composite is introduced over the first cover **144**. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of PEEK is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, and second covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0047] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^{0}C to about 210^{0}C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0048] The eighth embodiment listed in Table 1 relates to a jacket **130** formed of a first, second and third covers **144**, **146**, **148**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE-FEP layered composite is introduced over the first cover **144**. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of ETFE is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, second, and third covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0049] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about

130^{0}C to about 210^{0}C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0050] The ninth embodiment listed in Table 1 relates to a jacket **130** formed of a first, second and third covers **144**, **146**, **148**. First cover **144** of PEEK can possess a thickness that ranges from about 0.0005 inches to about 0.0015 inches of extruded PEEK. In another embodiment, first cover **144** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. First cover **144** of PEEK is formed by extruding the PEEK over a conductive element **112a,b,d**. After the first cover **144** of PEEK has been formed, a second cover **146** of ePTFE-FEP layered composite is introduced over the first cover **144**. Second cover **146** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A third cover **148** of EFEP is introduced over the second cover **146** in which the third cover **148** can possess a thickness that ranges from about 0.00020 inches to about 0.001 inches. A composite structure is composed of the first, second, and third covers **144**, **146**, **148** respectively, over the conductive element **112a,b,d**. The composite structure is formed into a coil shape and then mechanically constrained, as previously described.

[0051] The composite structure then undergoes thermal annealing or stress relieving in a chamber. The temperature in the chamber is about 130^{0}C to about 210^{0}C for about 30 seconds to about 30 minutes to allow the polymeric material to form jacket **130** around conductive element **112a,b,d**. Thereafter, the mechanical constraint is removed.

[0052] Table 1, presented below, summarizes the various embodiments of jacket **130**.

[0053] **Table 1—Embodiments of jacket 130 that comprise one or more polymeric compounds**

No.	First Cover	Second Cover	Third Cover	N Co
1	PEEK	ePTFE (tape-wrapped, porous)	PEEK	
2	PEEK	ePTFE (tape-wrapped, porous)	ETFE	
3	PEEK	ePTFE (tape-wrapped, nonporous)		
4	PEEK	ePTFE (tape-wrapped, nonporous)	PEEK	
5	PEEK	ePTFE (tape-wrapped, nonporous)	ETFE	
6	PEEK	ePTFE (tape-wrapped, nonporous)	EFEP	
7	PEEK	ePTFE-FEP layered composite		
8	PEEK	ePTFE-FEP layered composite	ETFE	
9	PEEK	ePTFE-FEP layered composite	EFEP	

[0054] The insulated conductive element formed through jacket **130** over conductive element **112a,b,d** can be helically wrapped around a mandrel (not shown). After winding the insulated cable onto the mandrel and mechanically restraining this composite structure, the polymeric material over the conductive element (e.g. cable etc.) can be annealed to minimize springback and allow the conductive element (e.g. cable etc.) to retain its coiled shape. After being removed from the mandrel, the conductive element (e.g. cable etc.) retains its coiled shape.

[0055] Insulated conductive element **200** is depicted in **FIGs. 5A-5B**. Insulated conductive element **200** includes a conductive element **112a,b,d** (i.e. cable, coiled cable etc.) with a thin polymeric material **204** or cover that has been thermally processed (e.g. annealed etc.) to conductive element **112a,b,d**. Polymeric material **204** comprises a first and second covers **124a,124b**. Conductive element **112a,b,d** has an outer diameter of about 0.09 inches or less. In one embodiment, conductive element **112a,b,d** can be a 1x19 cable construction with filaments composed of MP35N/Ag core.

[0056] Referring to **FIGs. 6A-6B**, an insulated conductive element **300** is depicted that comprises a set of conductors **302a-c** (i.e. three conductors) and an insulative layer or cover **304**. Conductive element **300** such as a 1x19 cable MP35N/Ag core and has an outer diameter of about 0.055 inches. Insulative layer **304** comprises a layer of PEEK and a layer of ePTFE.

[0057] Referring to **FIG. 7A-7B**, insulated conductive element **400** comprises a set of conductors **402a-e** (i.e. five conductors) and an insulative layer or cover **404**. Conductive element **400** has an outer diameter of about 0.060 inches and is a 1x19 cable. Insulative layer **404** comprises a layer of PEEK and a layer of ePTFE.

[0058] Referring to **FIGs. 8A-8C**, jacketed conductive element **500** is shown as retaining its coiled shape despite being stretched. Conductive element **500** comprises a 1x19 cable construction with filaments composed of MP35N/Ag core with an insulative or jacketed layer, coating or cover. The insulative layer comprises a layer of PEEK and a layer of ePTFE. In one embodiment, each layer of PEEK and ePTFE is about 0.0008 inches or less. In one embodiment, each layer of PEEK and ePTFE is about 0.002 inches or less. Referring to **FIG. 8A**, insulated conductive element **500** is depicted in a relaxed position (**FIG. 8A**) over a mandrel. While over the mandrel, conductive element **500** is thermally annealed. Referring to **FIG. 8B**, insulated conductive element **500** is depicted in a stretched position. Thereafter, insulated conductive element **500** moves to a relaxed position after being stretched (**FIG. 8C**). The insulated conductive element **500** retains 99% or more of its original coiled shape. In another embodiment, insulated conductive element **500** comprises 95% or more of its original coiled shape.

[0059] Referring to **FIG. 9**, insulated conductive element **600** is helically wrapped around a coil liner 130. Insulated conductive element **600** comprises a set of jacketed conductors **602** (i.e. five conductors cable-coil). Referring to **FIG. 10A-10B**, insulated conductive element **700** is helically wrapped around a mandrel **702**. Insulated conductive element

700 comprises a set of conductors **702** (i.e. five conductors) and an insulative layer or cover.

[0060] **FIG. 11** is a flow diagram of an exemplary computer-implemented method or a manual process to form at least one cover of PEEK over the conductive element. At block **800**, a counter, x, is initiated to 1 in order to count the number polymer covers formed over a conductive element. At block **810**, a polymer is extruded (also referred to as introduced) over the conductive element. Polymers with high elastic modulus (i.e. stiffness) such as PEEK are preferred since PEEK can be annealed or stress relieved to increase crystallinity and set the coil shape in conductive element **112a-c**. At block **820**, the polymer cover can undergo an optional thermal process.

[0061] At block **830**, the counter, X, is incremented by adding 1 to the previous value of X. At block **840**, a determination is made as to whether a sufficient number of polymer covers have been formed over the conductive element. In this embodiment, a determination is made as to whether X=N where N equals the number of pre-selected covers to be added to the conductive element. If X does not equal N, the process control returns to block **810** to extrude the same or different polymer over the previous polymer cover. If x does equal N, then the process goes to block **850**, where the jacketed conductive element undergoes coiling, as previously described. If x does not equal N, the process returns to introducing another polymeric cover over the conductive element **112a-d**. If x does equal N, no additional polymer covers are introduced over the conductive element **112a-d**. At block **850**, the jacketed conductive element is formed into a coil. At block **860**, the coiled jacketed conductive element can undergo an optional thermal process. If the method is implemented on a computer, the number of polymeric covers formed over the conductive element and/or the types of polymeric material used for each cover can be displayed on a graphical user interface of a computer. The computer-implemented instructions are executed on a processor of a computer.

[0062] The description of the invention is merely exemplary in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the invention. Such variations are not to be regarded as a departure from the spirit and scope of the invention.

CLAIMS:

1. A medical electrical lead comprising:

a lead body that comprises one or more jacketed conductive elements;

wherein the jacket comprises a first and a second covers, the first cover of extruded polyether ketone (PEEK) directly contacts at least one conductive element and the second cover comprises ePTFE,

wherein the at least one conductive element retains up to about 95 percent of a coiled diameter associated with the at least one conductive element.

2. The medical electrical lead of claim 1 further comprising a third cover comprising one of PEEK, ethylene-tetrafluoroethylene (ETFE), and ethylene-tetraflouroethylene based copolymer (EFEP).

3. The medical electrical lead of claim 1 wherein the ePTFE comprising one of porous ePTFE, nonporous ePTFE, ePTFE-FEP layered composite.

4. The medical electrical lead of claim 1 wherein the at least one conductive element being a cabled coil that retains up to 90% of its coiled shape.

5. The medical electrical lead of claim 1 wherein the at least one conductive element being a cabled coil that retains up to 85% of its coiled shape.

6. The medical electrical lead of claim 1 wherein the at least one conductive element being a cabled coil that retains up to 80% of its coiled shape.

7. The medical electrical lead of claim 1 further comprising:

a second cover of polymeric material coupled to the first cover, the second cover comprises one of PEEK/ ethylene-tetrafluoroethylene (ETFE), PVDF/ETFE, ETFE, silicone, fluorinated ethylene propylene (FEP), perfluoroalkoxy (PFA), and perfluorinated ethylene propylene (EFEP).

8. The medical electrical lead of claim 1 further comprising:

a third cover of polymeric material coupled to the first cover, the second cover comprises one of PEEK/ETFE, ETFE, FEP, PFA, and EFEP.

9. A method of insulating a conductive element in a medical electrical lead comprising:

introducing an ePTFE over at least one conductive element;

coupling the at least one conductive element around a mandrel to form a coil shape in the at least one conductive element;

annealing the ePTFE over the at least one conductive element;

setting a coiled shape in the conductive element; and

removing the at least one conductive element from the mandrel.

10. The method of claim 9, wherein the ePTFE includes at least one of porous ePTFE and nonporous ePTFE.

11. The method of claim 9, wherein the at least one conductive element being a cabled coil that retains up to 99% of its coiled shape.

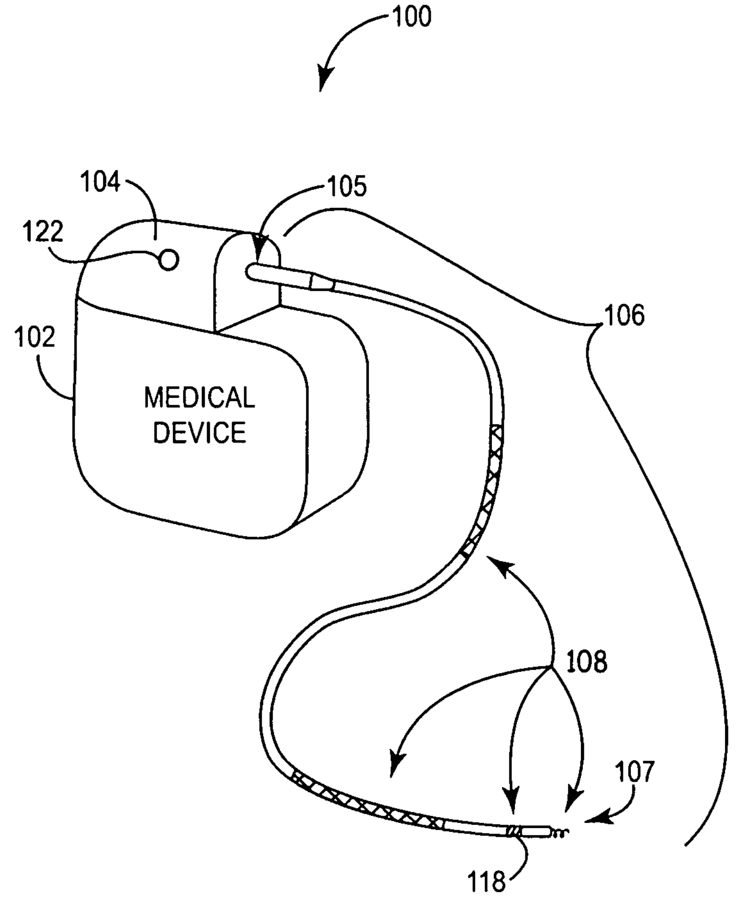

Fig. 1

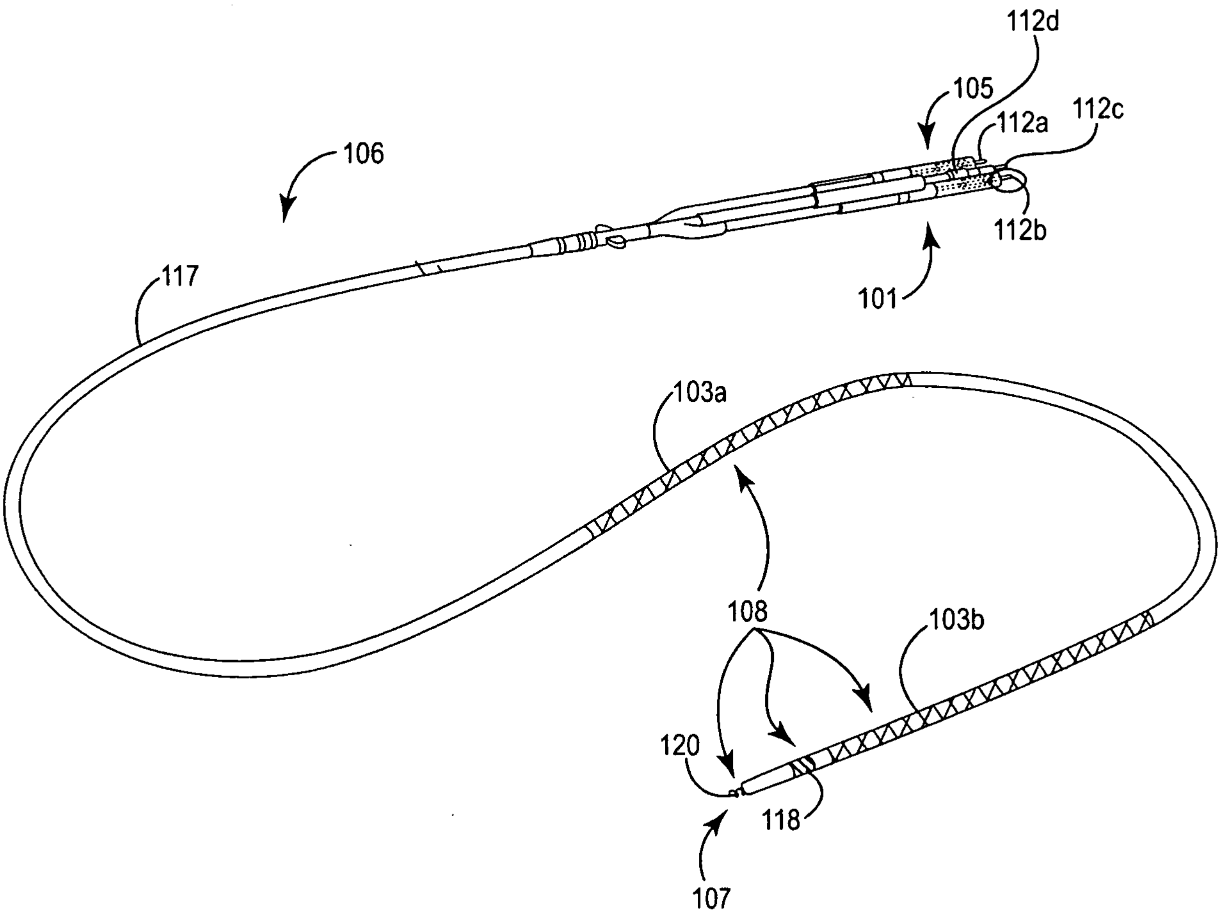

Fig. 2

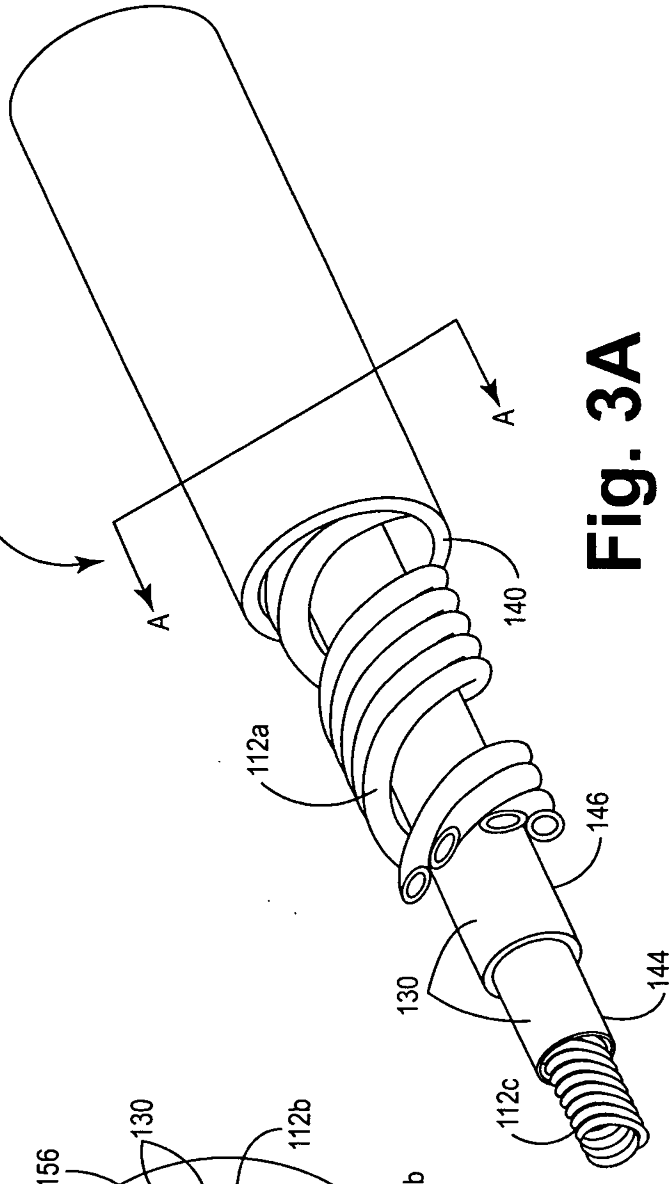
106
A
A
140
112a
146
130
144
112c

Fig. 3A

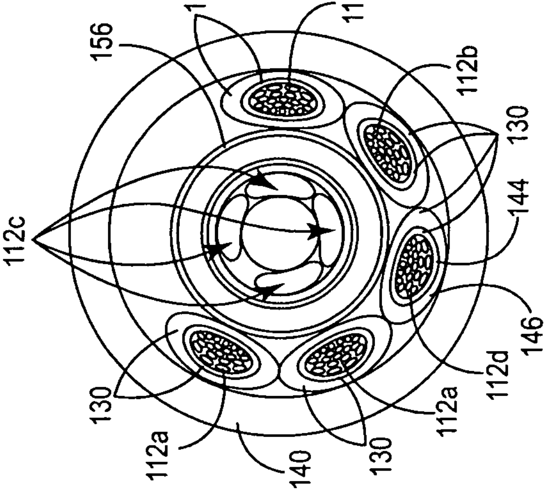
112c
156
130
112b
112b
130
144
146
112d
112a
130
140
112a
130

Fig. 3B

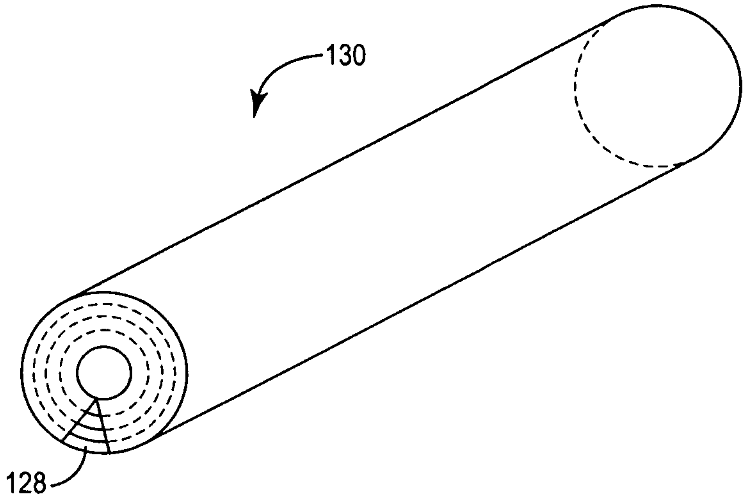

Fig. 4A

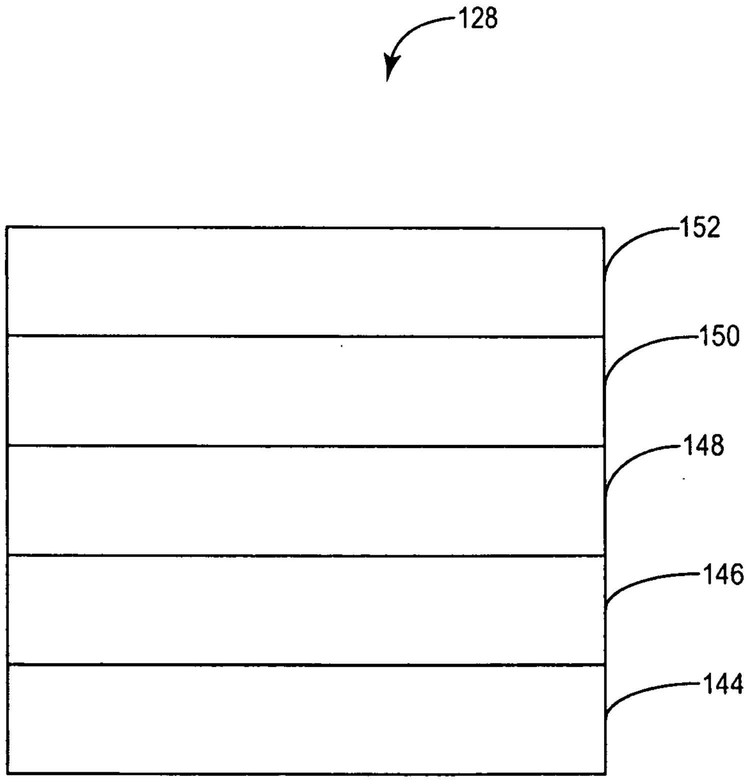

Fig. 4B

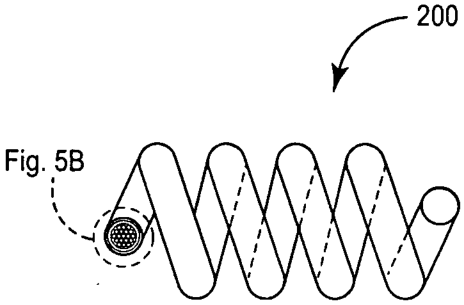

Fig. 5A

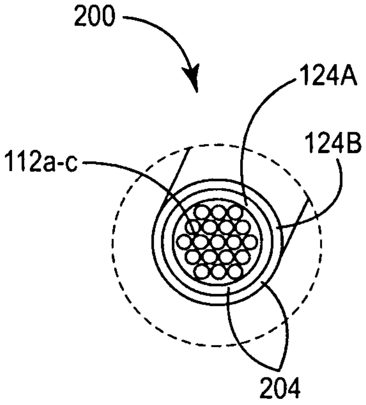

Fig. 5B

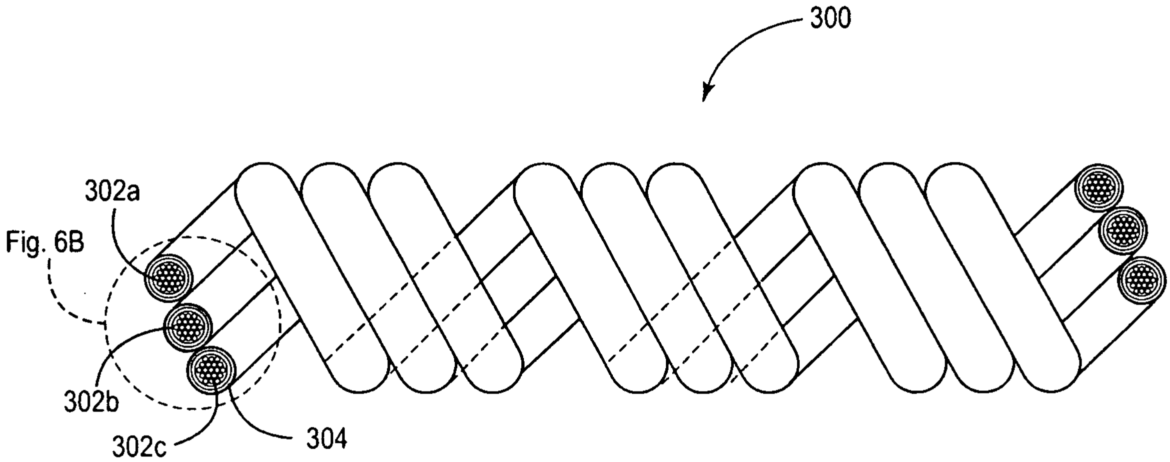

Fig. 6A

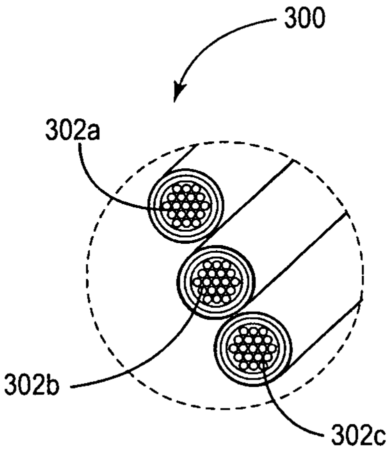

Fig. 6B

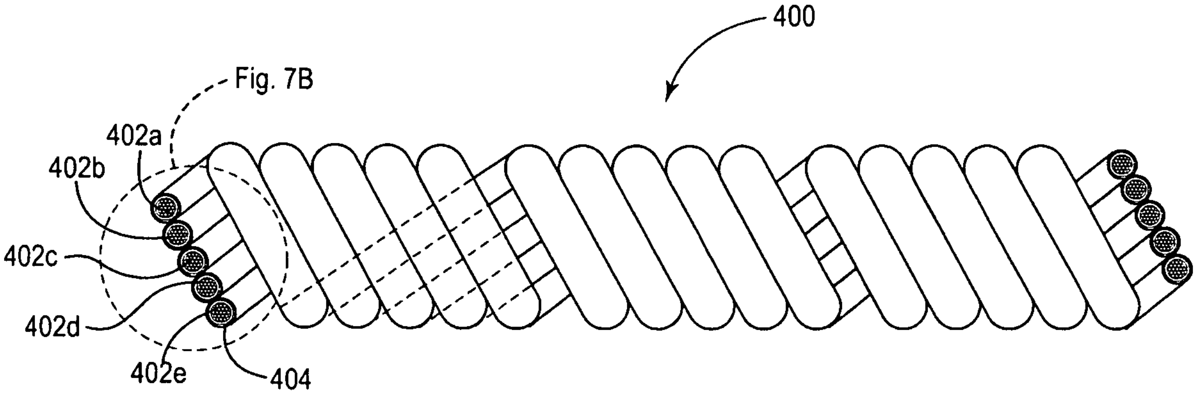
400
Fig. 7B
402a
402b
402c
402d
402e
404

Fig. 7A

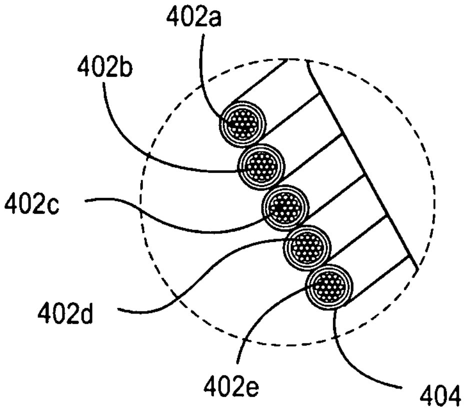
402a
402b
402c
402d
402e
404

Fig. 7B

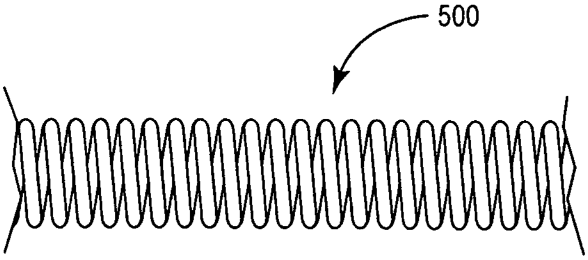

Fig. 8A

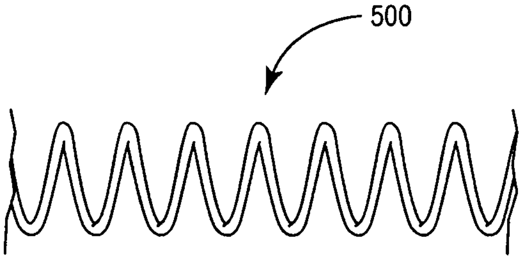

Fig. 8B

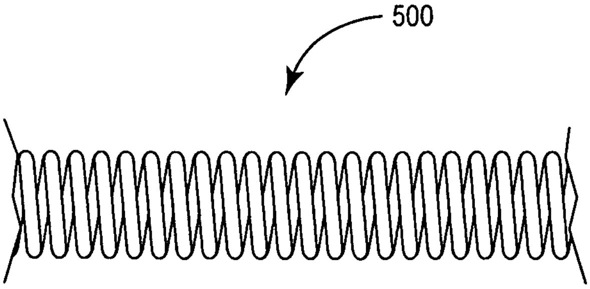

Fig. 8C

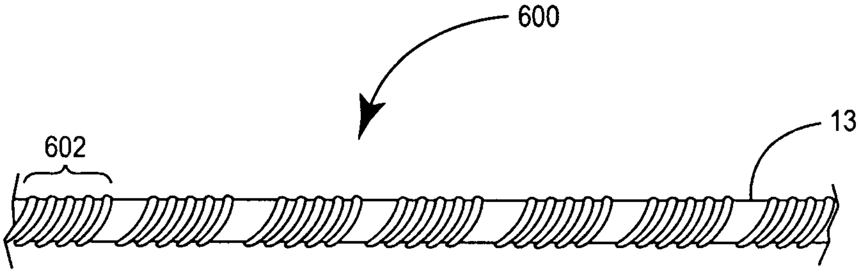

Fig. 9

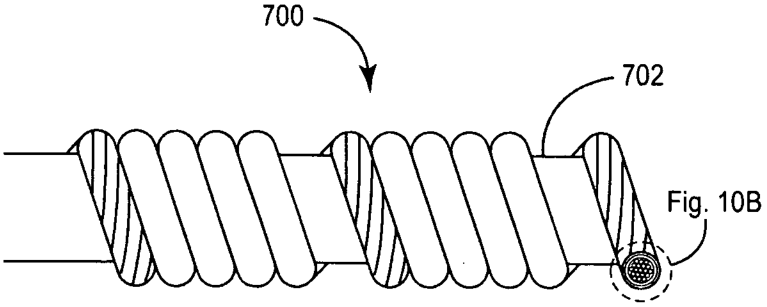

Fig. 10A

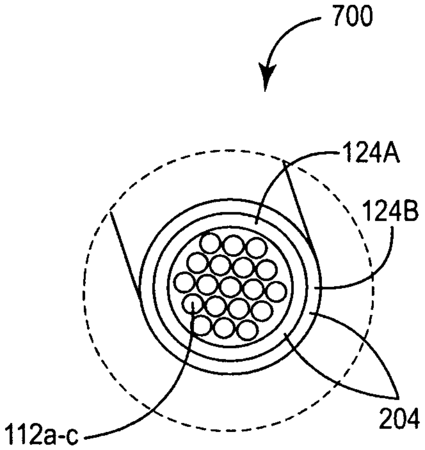

Fig. 10B

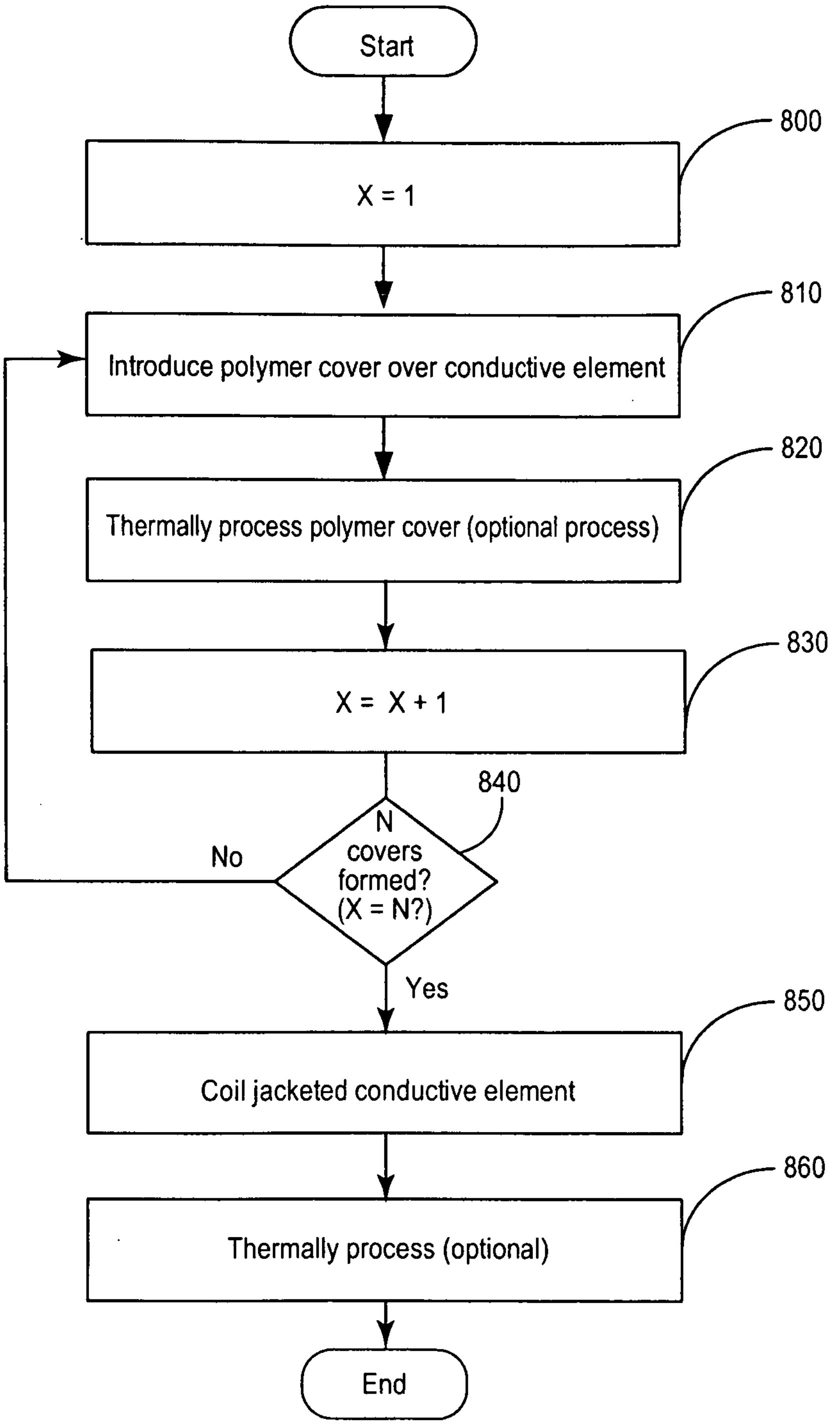
Start
800
X = 1
810
Introduce polymer cover over conductive element
820
Thermally process polymer cover (optional process)
830
X = X + 1
840
N covers formed? (X = N?)
No
Yes
850
Coil jacketed conductive element
860
Thermally process (optional)
End

Fig. 11