(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 November 2005 (24.11.2005)

PCT

(10) International Publication Number
WO 2005/110528 A1

(51) International Patent Classification[7]: A61N 1/05

(21) International Application Number:
PCT/US2005/010121

(22) International Filing Date: 25 March 2005 (25.03.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/841,070 6 May 2004 (06.05.2004) US
10/841,069 6 May 2004 (06.05.2004) US

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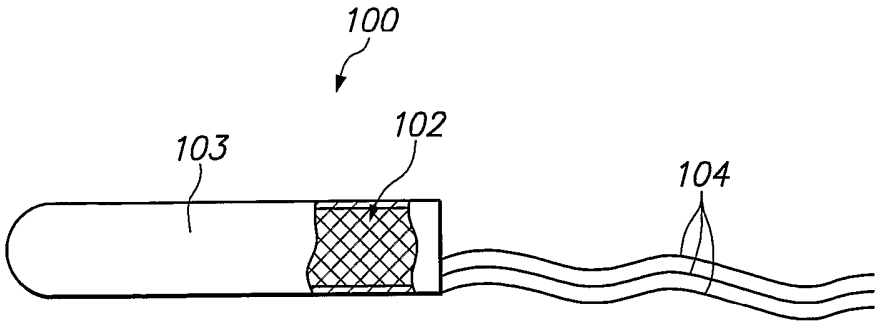
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTRAVASCULAR SELF-ANCHORING ELECTRODE BODY



(57) **Abstract:** An intravascular medical device comprises an expandable tubular body that includes an integrated resilient support structure that forms a plurality of electrically conductive regions to which lead(s) are coupled, and at least one electrically insulative element disposed between the conductive regions. The support structure may be skeletal in nature, e.g., formed of a mesh, braid, or coil. The conductive regions can be variously formed by the support structure. Alternately, the medical device may comprise an arcuate spring configured to be expanded into firm contact with the inner surface of a blood vessel, with at least one electrode associated with the arcuate spring. For example, the electrode(s) can be discrete elements that are bonded to the arcuate spring, electrically conductive layers disposed on the arcuate spring, or the arcuate spring, itself, can form the electrode(s). The inner surface of the arcuate spring may optionally be electrically insulative.

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INTRAVASCULAR SELF-ANCHORING ELECTRODE BODY

FIELD OF THE INVENTION

The invention relates to the intravascular delivery of medical devices into a patient, and in particular, the intravascular implantation of stimulation and/or recording electrode leads into a patient.

BACKGROUND OF THE INVENTION

There are certain circumstances in which it is desired to electrically stimulate tissue and/or record electrical signals received from such tissue via blood vessels. For example, U.S. Patent Application Ser. No. 10/744,319 describes a method of treating neurological disorders by intravenously delivering stimulation leads within the brain, thereby obviating the need to invasively create a burr hole in the cranium of the patient.

Despite the minimally invasive benefits provided by these types of procedures, it is preferable that thrombosis formation caused by the blockage of blood flow through a vessel be prevented. It is also preferable that the electrical energy delivered by the vessel implanted electrode lead be as efficient as possible. For example, when treating a neurological disorder using electrical energy, it is desirable that the magnitude of the electrical energy be sufficient to cause sub-threshold stimulation of the targeted brain tissue. Due to the relatively low resistance of blood versus the relatively high resistance of vessel walls, however, the electrical energy is likely to follow the path of least resistance, i.e., through the blood stream, rather than the vessel wall. The gain of the implanted stimulation device could be increased in order to overcome the power losses through the bloodstream.

Invariably, this may potentially cause poor sub-threshold stimulation of the target area, or worse, stimulation of a non-targeted region of the brain. Increasing the gain can also impact the system efficiency by reducing the battery life of the implanted stimulation source.

SUMMARY OF THE INVENTION

In one aspect of the invention, an expandable intravascular medical device is provided. In one embodiment, the device comprises an expandable tubular body which is cylindrical so that it can more easily conform to a blood vessel, although other body geometries are contemplated by the invention. The tubular body includes an integrated resilient support structure that forms a plurality of electrically conductive regions to which the lead(s) is coupled. The tubular body further includes at least one electrically insulative element disposed between the conductive regions. At least one lead is electrically coupled to the conductive regions. The conductive regions may be completely electrically isolated from each other, so that, e.g., as electrodes, they can be operated in parallel. In this case, a plurality of leads may be coupled to the respective conductive regions. Alternatively, the conductive regions may be serially connected. In this case, a single lead may be coupled to one of the conductive regions, which is in turn, connected to the other conductive regions in a serial manner.

In one embodiment, the support structure is skeletal in nature, e.g., it can be formed of a mesh, braid, or coil. The conductive regions can be variously formed by the support structure. For example, the support structure may comprise electrically conductive sub-structures that form the conductive regions. In this case, the sub-structures may be mechanically linked together by the insulative element(s), or they

can be directly linked together, and the insulative element(s) can take the form of insulative layer(s) disposed on one or more of the conductive sub-structures. As another example, the support structure can have a conductive core and insulative material disposed over portions of the conductive core. In this case, the exposed core portions form the conductive regions, and the unexposed core portions form the insulative element(s).

In another embodiment, the medical device comprises an electrode support structure, e.g., a non-tubular arcuate structure or a cylindrical member, which at least one electrode associated with the support structure. For example, the electrode(s) can be discrete elements that are bonded to the support structure, electrically conductive layers disposed on the support structure, or the support structure, itself, can form the electrode(s). A plurality of resilient spring loops laterally extending from the support structure. The electrode(s) may optionally be formed from the spring loops. The device further comprises at least one lead electrically coupled to the electrode(s). Alternatively, if there are a plurality of electrodes, a plurality of leads can be electrically coupled to the respective electrodes.

In yet another embodiment of the invention, an intravascular medical device comprises an elongated member and two resilient spring arms extending distally from the elongated member. The arms are configured to be laterally moved towards each other to place the medical device in a collapsed geometry, and configured to be laterally moved away from each into contact with an inner surface of a blood vessel to place the medical device an expanded geometry.

In one embodiment, the spring arms are pre-shaped to laterally move away from each other. The contact created between the respective arms and the blood vessel are sufficient to anchor the medical device within the blood vessel. The

medical device further comprises an electrode associated with the distal end of one of the spring arms. For example, the electrode can be a discrete element that is bonded to the spring arm, an electrically conductive layer disposed on the spring arm, or the distal end of the arcuate spring, itself, can form the electrode. The device may comprise another electrode associated with the distal end of the other of the spring arms. The device may further comprise a lead electrically coupled to the electrode. Alternatively, if there are two electrodes, a two leads can be electrically coupled to the respective electrodes.

In still another embodiment, the medical device comprises an arcuate spring configured to be expanded into firm contact with the inner surface of a blood vessel. The arcuate spring is non-tubular, i.e., it spans less than 360 degrees. In one embodiment, the arcuate spring spans greater than 180 degree. This allows the arcuate spring to more easily anchor the medical device to the inner surface of a blood vessel when expanded. The device further comprises at least one electrode associated with the arcuate spring. For example, the electrode(s) can be discrete elements that are bonded to the arcuate spring, electrically conductive layers disposed on the arcuate spring, or the arcuate spring, itself, can form the electrode(s). The device may further comprise at least one lead electrically coupled to the electrode(s). Alternatively, if there are a plurality of electrodes, a plurality of leads can be electrically coupled to the respective electrodes.

In yet another embodiment, the medical device comprises an arcuate structure with an inner electrically insulative surface. The arcuate structure may either be tubular or non-tubular. At least one electrode is associated with the arcuate structure. In one embodiment, at least a portion of the arcuate structure forms the electrode(s). In another embodiment, the arcuate structure has an outer

insulative surface, and the electrode(s) are disposed on the arcuate structure as a thin electrically conductive film. In either case, if the arcuate structure is resilient, the electrode(s) will be able to flex with the arcuate structure. In another embodiment, the arcuate structure is non-porous to enhance the electrical insulative nature of the arcuate structure. The device may further comprise at least one lead electrically coupled to the electrode(s). Alternatively, if there are a plurality of electrodes, a plurality of leads can be electrically coupled to the respective electrodes.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate the design and utility of embodiment(s) of the invention, in which similar elements are referred to by common reference numerals. In order to better appreciate the advantages and objects of the invention, reference should be made to the accompanying drawings that illustrate the embodiment(s), and in which:

Fig. 1 is a partially cutaway side view of an intravascular medical device constructed in accordance with one embodiment of the invention, wherein the medical device is particularly shown in a collapsed geometry;

Fig. 2 is a side view of the medical device of **Fig. 1**, particularly shown in an expanded geometry;

Fig. 3 is a cross-sectional view of the medical device of **Fig. 2**, taken along the **line 3-3**;

Fig. 4 is a side view of a modification of the medical device of **Fig. 2**, particularly shown in an expanded geometry;

Fig. 5 is a close-up view of the medical device of **Fig. 2**;

Fig. 6 is a close-up view of another modification of the medical device of **Fig. 2**, particularly shown in an expanded geometry

Fig. 7 is a side view of another alternative embodiment of the medical device of **Fig. 2**;

Fig. 8 is a close-up view of the medical device of **Fig. 7**, taken along the lines **8-8**;

Fig. 9 is a side view of a modification of the medical device of **Fig. 7**;

Fig. 10 is a plan view of an intravascular delivery kit used to deliver the medical device of **Fig. 1** into a patient;

Fig. 11 is a cross-sectional view of a delivery catheter used in the delivery kit of **Fig. 10**, taken along the **line 11-11**;

Fig. 12 is a cross-sectional view of another delivery catheter used in the delivery kit of **Fig. 10**, taken along the **line 12-12**;

Fig. 13 is a close-up side view of the electrode body of the medical device of **Fig. 1**, particularly showing the attachment of an electrolytic pusher wire used in the delivery kit of **Fig. 10**;

Fig. 14 is a partially cutaway side view of another intravascular medical device constructed in accordance with one embodiment of the invention, wherein the medical device is particularly shown in a collapsed geometry;

Fig. 15 is a perspective view of the medical device of **Fig. 14**, particularly shown in an expanded geometry;

Fig. 16 is a cross-sectional view of the medical device of **Fig. 1**, taken along the **line 16-16**;

Fig. 17 is a side view of the medical device of **Fig. 14** expanded within a blood vessel;

Fig. 18 is a cross-sectional view of the medical device and blood vessel of **Fig. 17** taken along the line **18-18**;

Fig. 19 is a perspective view of still another intravascular medical device constructed in accordance with one embodiment of the invention, wherein the medical device is particularly shown in a collapsed geometry;

Fig. 20 is a perspective view of the medical device of **Fig. 19**, particularly shown in an expanded geometry;

Fig. 21A is a side view of the medical device of **Fig. 19** expanded within a blood vessel;

Fig. 21B is a cross-sectional view of the medical device and blood vessel of **Fig. 21A** taken along the line **21B-21B**;

Fig. 22 is a perspective view of yet another intravascular medical device constructed in accordance with one embodiment of the invention, wherein the medical device is particularly shown in a collapsed geometry;

Fig. 23 is a perspective view of the medical device of **Fig. 22**, particularly shown in an expanded geometry;

Fig. 24A is a side view of the medical device of **Fig. 22** expanded within a blood vessel;

Fig. 24B is a cross-sectional view of the medical device and blood vessel of **Fig. 24A** taken along the line **24B-24B**;

Fig. 25 is a perspective view of yet another intravascular medical device constructed in accordance with one embodiment of the invention, wherein the medical device is particularly shown in a collapsed geometry;

Fig. 26 is a perspective view of the medical device of **Fig. 25**, particularly shown in an expanded geometry;

Fig. 27A is a side view of the medical device of **Fig. 25** expanded within a blood vessel;

Fig. 27B is a cross-sectional view of the medical device and blood vessel of **Fig. 27A** taken along the **line 27B-27B**;

Fig. 28 is a side view of another modification of the medical device of **Fig. 2,** particularly shown in an expanded geometry;

Fig. 29 is a side view of still another modification of the medical device of **Fig. 2,** particularly shown in an expanded geometry; and

Fig. 30 is a side view of yet another modification of the medical device of **Fig. 2,** particularly shown in an expanded geometry.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Referring to **Figs. 1-3**, an intravascular medical device 100 constructed in accordance with one embodiment of the invention will be described. The medical device 100 comprises an expandable/collapsible tubular electrode body 102, and a plurality of flexible conductive leads 104 electrically coupled to the electrode body 102. For the tubular body can either be continuous tubular structure or a structure that has a tubular profile, such as a coil. The electrode body 102 can be transformed from a collapsed geometry (**Fig. 1**) into an expanded geometry (**Fig. 2**). In its collapsed geometry, the medical device 100 can be intravascularly delivered to a target site within a vessel using a standard stent delivery apparatus. In order to maintain the medical device 100 in its collapsed geometry, a removable sheath or covering 103 is disposed over the collapsed electrode body 102. The sheath 103 may have one or more delivery wires (not shown) that can be pulled in order to remove the sheath 103 from the electrode body 102, thereby allowing the medical device 100 to be placed in its expanded geometry.

When the medical device 100 is in its expanded geometry, the electrode body 102 can be placed into firm contact with the target site and used to transmit to and/or receive electrical signals from the blood vessel and surrounding tissue, while minimizing blood occlusion. The leads 104, the proximal ends of which will extend from the intravascular access point in the patient (e.g., the femoral vein or jugular vein), are configured to be coupled to an implanted or external source and/or recorder of the electrical signals (not shown).

The electrode body 102 comprises a plurality of electrically conductive sub-structures 106 (in this case, three), which together, form an integrated support structure. In the illustrated embodiment, the conductive sub-structures 106 are self-expanding (i.e., they automatically expand in the absence of a radially compressive force). Alternatively, the conductive sub-structures 106 expand only in the presence of a radially expanding force, such with a stent balloon (not shown). In any event, once expanded, the rigidity of the conductive sub-structures 106 will allow them to remain in their expanded geometry until a radially compressive force is applied.

In the illustrated embodiment, the conductive sub-structures 106 are distinct in that they are separately formed, and then they are linked together to form the integrated structure. In the illustrated embodiment, the conductive sub-structures 106 are cylindrical structures that are axially aligned along the length of the electrode body 102. In this case, the conductive sub-structures 106 act as three ring electrodes that extend along the electrode body 102. Alternatively, as illustrated in **Fig. 4**, each conductive support structure 106 takes the form of semi-cylindrical structure that extends partially around the electrode body 102. In this case, two semi-circular conductive sub-structures 106 are linked together along the axis of the electrode body 102 to form an upper electrode and a lower electrode. In alternative

embodiments, the semi-cylindrical conductive sub-structures 106 can be further divided to create additional electrodes.

In any event, each conductive sub-structure 106 is skeletal in nature, and is formed by fashioning a wire or wires into an undulating shape, as illustrated in **Figs. 2** and **4**. Alternatively, the wire or wires can be fashioned into a mesh, braid, or coil to form the skeletal structure. Alternatively, each conductive sub-structure 106 may not be skeletal in nature, but rather may be composed of a resilient continuous material. The diameter of the wire used to make each conductive sub-structure 106 preferably has a diameter to provide a hoop strength to the conductive sub-structure 106 sufficient to hold the electrode body 102 in place within the selected blood vessel without moving as a result of the repetitive blood pulsing within the vascular system, but without distending the vessel wall.

In whichever manner fashioned, the material used to form each conductive sub-structure 106 is both biocompatible and electrically conductive. Preferably, such material is also radiopaque and allows for electrolytic detachable linkages to the proximal end of the electrode body 102, as will be described in further detail below. Suitable metals and alloys for the composition of the support structure include Platinum Group metals, especially platinum, rhodium, palladium, rhenium, as well as tungsten, gold, silver, tantalum, and alloys of these metals, such as a platinum/tungsten alloy. Each conductive sub-structure 106 can also be composed of a wide variety of stainless steels if some sacrifice of radiopacity can be tolerated. Certain super-elastic alloys, such as nickel/titanium alloys, nickel/titanium alloys, or nickel/aluminum alloys, can also be used. Especially preferred is the titanium/nickel alloy known as "nitinol," which is a very sturdy alloy that will tolerate significant flexing. If desired, the wire used to form the conductive sub-structure 106 can be

further coated with platinum-iridium, gold, or silver to improve its conduction properties, biocompatibility, and radiopacity. Each conductive sub-structure 106 can be coated with additives, such as a non-thrombogenic agent to prevent blood coating, or a therapeutic agent.

The portions of the conductive sub-structures 106 that are mechanically linked together (i.e., the loops 108 at the edges of the conductive sub-structures 106) are electrically isolated from each other. In the embodiments illustrated in **Figs. 2** and **4**, a plurality of electrically insulative elements 110 are connected between the loops 108, thereby mechanically linking, while electrically isolating, the conductive sub-structures 106, as illustrated in **Fig. 5**. Although the insulative elements 110 are shown in **Figs. 2, 4**, and **6** as single strands of material, the insulative elements 110 can have other shapes and forms, e.g., a loop or a hook. The insulative elements 110 can be composed of a suitably biocompatible and non-conductive material, such as silicone, nylon, Pebax®, polyimide, or urethane. The insulative elements 110 can be discrete elements that are bonded to the loops 108 of the respective conductive sub-structures 106 using a suitable material, such as silicone, Pebax®, and urethane, or can be formed by, e.g., microinjecting a non-conductive material, such as silicone, Pebax®, or urethane, between the loops 108. Preferably, the insulative elements 100 have sufficient axial rigidity to maintain the spatial separation between the sub-structures 106 to avoid electrical shorting.

Although each insulative element 110 is shown as only connecting a pair of loops 108 together, an insulative element 110 can connect a series of loop pairs. For example, **Fig. 28** illustrates an alternative electrode body 302 that electrically isolates the conductive sub-structures 106 with insulative tubular elements 310 that circumferentially extend around the electrode body 302. The tubular elements 310

can be integrated into a single tubular member, in which case, the conductive sub-structure 106 can be bonded to the exterior surface of the tubular member, or may be embedded into the tubular member. Alternatively, the tubular elements 310 may be formed between the respective conductive sub-structures 106 as discrete pieces, e.g., by injection molding insulative material between the sub-structures 106.

In the embodiment illustrated in **Fig. 28**, the tubular elements 310 are in contact with every portion of the conductive sub-structures 106. Alternatively, as illustrated in **Fig. 29**, another electrode body 402 comprises tubular elements 410 that are only formed between the loops 108 of the respective sub-structures 106. In this case, the substructures 106 can be bonded to the tips of the loops 108 using suitable means, such as an adhesive or melting, or the tubular elements 410 can be micro-injected between the loops 108. It should be noted that the tubular elements 310 and 410 illustrated in **Figs. 28** and **29** primarily exist to provide electrical insulation to the sub-structures 106, and do not significantly affect the radial spring force provided by the conductive sub-structures 106.

Fig. 30 illustrates an alternative electrode body 502 that electrically isolates the conductive sub-structures 106 with a plurality of insulative elements 510 that connect the loops 108 of a pair of conductive sub-structures 106 in a zig-zag shape. The zig-zagged insulative elements 510 can be made by, e.g., bonding or embedding the conductive sub-structures 106 onto or into an electrically insulative tubular member, similar to that shown in **Fig. 28**, and then etching away the insulative material to form the insulative elements 510.

In an alternative embodiment illustrated in **Fig. 6**, the loops 108 of the conductive sub-structures 106 are directly linked together. In this case, insulative elements 110 take the form of an insulative coating applied to one loop 108 of each

connected loop pair, thereby electrically insulating the directly linked conductive sub-structures 106 from each other. It should be noted that directly linking the conductive sub-structures 106 in this manner facilitates the retrievability of the electrode body 102. That is, since the loops 108 are tightly fitted together, snagging of the loops 108 as the electrode body 102 is pulled into a sheath is minimized.

As illustrated in **Fig. 3**, the electrode body 102 can optionally have a layer of insulative material 111, such as elastic or silicone, disposed on the inner surface of the conductive sub-structures 106. In this manner, if the electrode body 102 is used to convey stimulation energy, or otherwise transmit electrical signals, radially inward transmission of the electrical energy or signals through the blood is prevented, thereby efficiently focusing it radially outward into the vessel wall and surrounding tissue where it is needed.

In whichever manner the conductive sub-structures 106 are linked and electrically isolated, the leads 104 are connected to the electrode body 102 using suitable means, such as welding or soldering. Each lead 104 comprises an electrically conductive core with an outer insulative layer. The length of the lead 104 is preferably sized to extend from intravascular access point in the patient to the selected target site within the blood vessel where the electrode body 102 will be implanted. If the medical device 100 is to be connected to the implanted stimulator or recorder, the length of the lead 104 should be sized to extend from the implantation site of the stimulator and/or recorder to the selected target site when routed through the intravascular access point. For example, if the target site is in the patient's brain, the implantation site of the stimulator or recorder is in the chest region of the patient, and the intravascular access point is the patient's jugular vein, then the length of the lead 104 may be in the range of 50 cm to 100 cm. If, however,

the target site is in the patient's brain, the implantation site of the source or recorder is in the abdominal region of the patient, and the intravascular access point is the patient's femoral vein, then the length of the lead 104 may be in the range of 150 cm to 300 cm.

The leads 104 can be coupled to the electrode body 102 in a variety of manners to achieve different electrode functionalities. For example, in the illustrated embodiment, the leads 104 are coupled to the respective conductive sub-structures 106, so that the conductive sub-structures 106 are completely electrically isolated from one another. In this manner, the electrode body 102 can have a multiple-channel and/or multi-polar capability. That is, if operating as a multi-channel device, the conductive sub-structures 106 can simultaneously receive multiple signals (if connected to a recorder) or can simultaneously transmit multiple signals (if connected to a stimulation source). If operated as a multi-polar device, electrical signals can be transmitted between one or more conductive sub-structures 106 (as anodes) and one or more other conductive sub-structures (as cathodes). Of course, the conductive sub-structures 106 can be electrically combined to make a single-channel and/or monopolar device if the proximal ends of the leads 104 are electrically connected together at the stimulator and/or recorder. In an alternative embodiment, a single lead 104 can be coupled to one of the conductive sub-structures 106, preferably the proximal-most conductive sub-structure 106, in which case, the conductive sub-structures 106 can be electrically coupled together in series, e.g., by directly or indirectly electrically coupling a pair of respective loops 108 together.

It should be noted that electrode body 102 may alternatively have a wireless transmitter and/or receiver in order to provide the electrode body 102 with the

capability of wirelessly communicating with a remote stimulator and/or recorder. In this case, the leads will be routed from the electrodes on the electrode body 102 to the transmitter and/or receiver.

Although the previously described electrode body 102 has been described as having discrete conductive sub-structures, the electrode body 102 can be formed from a unibody support structure. In particular, **Fig. 7** illustrates an electrode body 122 that forms cylindrically-shaped electrically conductive regions 126 (delineated by the dashed line) extending around the electrode body 122, and electrically insulative regions 128 extending around the electrode body 102 between the conductive regions 126.

Like the previously described conductive sub-structures 106, the unibody support structure 124 is skeletal in nature and, in this case, is formed as a tubular mesh. The wires used to form the unibody support structure 124, however, comprises an electrically conductive core 130 and an insulative layer 132 disposed over the conductive core 130, as best shown in **Fig. 8**. The conductive regions 126 are formed by removing the insulative layer 132 from portions of the support structure 124 (in this case, cylindrical portions) in order to expose the underlying conductive core 130. Removal of the insulative layer 132 can be accomplished in any suitable manner, including mechanical, chemical, or laser etching. Thus, the exposed portions of the support structure 124 serve as the conductive regions 128, and the unexposed portions of the support structure 124 serve as the insulative regions 128. The electrically conductive leads 104 can be coupled to the electrode body 102 in the same manner described above, with the exception that the leads 104 are coupled to the conductive core 130 of the support structure 132.

The conductive and insulative regions 126/128 of the electrode body 102 can be formed into other shapes besides cylindrical shapes. For example, as illustrated in **Fig. 9**, the conductive regions 126 are formed as rectangular patches that are disposed about the electrode body 102. Thus, it can be appreciated that forming the electrode body 122 out of a unibody support structure in this manner provides great flexibility in providing various shapes and configurations of electrodes onto the body 122.

Referring to **Fig. 10**, an intravascular lead kit 150 arranged in accordance with one embodiment of the invention is illustrated. The kit 150 comprises the previously described medical device 100, a delivery catheter 152 configured for intravascularly delivering the medical device 100 into selected blood vessels within the patient's body, a guidewire 154 configured for guiding the delivery catheter 152 into the selected blood vessels, and a detachable pusher element 156 configured for deploying the medical device 100 from the delivery catheter 152 into a selected region within a blood vessel.

The pusher element 156 is mechanically coupled to the electrode body 102, and is axially rigid, so that the electrode body 102 can be introduced through the catheter 152, yet laterally flexible to allow the pusher element 156 to bend around the natural curves within the patient's vasculature. In the illustrated embodiment, the pusher element 156 can be selectively detached from the electrode body 102 (once properly placed) using an electrolytic arrangement.

In particular, as illustrated in **Fig. 13**, the pusher element 156 comprises an electrically conductive core wire 158 composed of a material that will electrolytically dissolve in an aqueous fluid medium, such as blood, saline solution, or other bodily fluid. Materials that are capable of electrolytically dissolving are steel, stainless

steel, nickel, and nickel/titanium alloys. The electrode body 102 may be suitably coupled to the distal end of the core wire 158 using means, such as crimping, soldering, or welding. The pusher element 156 further comprises an insulative sleeve 160 that, with the exception of a small sacrificial portion 162 just proximal to the mounted electrode body 102, covers the core wire 158. The length of the sacrificial portion 162 is preferably small. For instance, it may be as short as 0.010 inches, and typically no longer than 0.150 inches in length. The insulative sleeve 160 is composed of a material that will not decompose prior to the sacrificial portion 162 of the core wire 158. For example, the insulative sleeve 160 may be composed of polytetrafluoroethylene, fluoropolymers, polyurethane, parylene, polyethylene, polypropylene, polyethylene terephthalate, or other known suitable, typically polymeric, material. Thus, it can be appreciated that when electrical current is delivered through the core wire 158, while the distal end of the pusher element 156 is exposed to blood, the sacrificial portion 162 of the core wire 158 will disintegrate, thereby releasing the electrode body 102. Additional details regarding the use of pusher wires with electrolytic detachment means are disclosed in U.S. Patent No. 6,589,230.

In alternative embodiments, pusher wires with mechanical detachment mechanisms can be used to selectively detach the electrode body 102.

The delivery catheter 152 comprises an elongate, flexible, catheter body 164, and a delivery lumen 166 (shown in **Fig. 11**) extending the length of the catheter body 164. The delivery lumen 166 is sized to alternately receive a guidewire 154 and the medical device 100. The delivery catheter 152 further comprises a proximal adapter 168 suitably mounted on the proximal end of the catheter body 164. The proximal adapter 168 comprises a port 170 out which the guidewire 154 and medical

device 100. Alternatively, dedicated guidewire and electrode lead lumens, along with respective ports, can be provided.

The catheter body 164 is composed of a medically acceptable material, preferably a nondistensible polymer having the appropriate mechanical properties. Preferred materials include polyethylene, polyester, polypropylene, polyimide, polyvinyl chloride, ethylvinyl acetate, polyethylene terephthalate, polyurethane, Pebax®, fluoropolymers, silicone, and their mixtures and block or random copolymers. The catheter body 164 preferably has a relatively stiff proximal segment, which makes up between 70%-95% of the total length of the catheter body 164, and a relatively flexible distal segment, which makes up the remaining 5%-30% of the length of the catheter body 164.

The delivery lumen 166 of the catheter 152 preferably has a diameter of between 2-50 mils, but ultimately will be sized to allow the guidewire 154 and medical device 100 to be respectively introduced therethrough. Alternatively, as shown in **Fig. 12**, the catheter 152 may comprises separate lumens 168 and 170 for respectively receiving the guidewire 154 and medical device 100. The outer diameter of the catheter body 164 is preferably between 8-80 mils, but ultimately will be sized such that blood flow is not occluded within the smallest blood vessel through which the delivery catheter 152 will be introduced. For example, the vessel site may be within a small diameter vessel having a 2-5 mm diameter and accessible by way of a tortuous vessel path, which may involve sharp vessel turns and multiple vessel branches. In this case, the catheter 152 preferably has a small, flexible construction with a diameter of less than 40 mil, and preferably between 8-30 mils. The length of the catheter body 164 will typically be from 50-300 cm, depending on the total linear length of the blood vessels that the delivery catheter 152 must

traverse from its entry point into the patient's vasculature to the target delivery site of the electrode body 102.

Referring back to **Fig. 10**, the guidewire 154 may have any suitable construction for guiding the delivery catheter 152 to its intended site in the brain. Typically, the length of the guidewire 154 is at least about 10-50 cm longer than the length of the catheter 152, such that the distal end of the guidewire 154 can be extended several centimeters or more beyond the distal end of the delivery catheter 152, while allowing the proximal end of the guidewire 154 to be manipulated, such as by torqueing. The proximal end of the guidewire 154 is equipped with a handle 155 for applying torque to the wire during catheter operation. The guidewire 154 may optionally include radiopaque bands (not shown) for visualization under fluoroscopy. Additional details regarding the structure and dimensions of guidewires suitable for guiding catheters into the vasculature of the brain are disclosed in U.S. Patent No. 6,074,507.

It should be noted that the kit illustrated in **Fig. 10** is not the only manner in which the medical device 100 can be delivered to a vessel target site, but rather there are other means of delivering the medical device 100 into a vessel. For example, the medical device 100 can be delivered within a vessel by mounting the electrode body 102 around the distal end of a catheter, as disclosed in U.S. Patent Nos. 5,534,007 and 6,562,063.

Referring now to **Figs. 14-16**, an intravascular medical device 200 constructed in accordance with another embodiment of the invention comprises an expandable/collapsible electrode body 202, and a plurality of flexible conductive leads 204 electrically coupled to the electrode body 202. The electrode body 202

can be transformed from a collapsed geometry (**Figs. 14** and **16**) into an expanded geometry (**Fig. 15**).

In its collapsed geometry, the electrode body 202 can be intravascularly delivered to a target site within a vessel using a standard stent delivery apparatus. In order to maintain the electrode body 202 in its collapsed geometry, a removable sheath or covering 203 is disposed over the collapsed electrode body 202, as shown in **Fig. 14**. The sheath 203 may have one or more delivery wires (not shown) that can be pulled in order to remove the sheath 203 from the electrode body 202, thereby allowing the electrode body 202 to be placed in its expanded geometry, as shown in **Fig. 15**. In its expanded geometry, the electrode body 202 can be placed into firm contact with the target site and used to transmit electrical signals to and/or receive electrical signals from the blood vessel and surrounding tissue, while minimizing blood occlusion.

The electrode body 202 comprises an arcuate resilient spring 206 and a plurality of electrodes 208 (in this case, three) disposed on the spring 206. The resilient spring 202 is non-tubular, i.e., its arcuate shape spans less than 360 degrees. In this manner, unlike tubular electrode structures, the electrode body 202 is more adaptable to variously sized blood vessels. In addition, the transmitted and/or recorded electrical energy is more focused. Preferably, the arcuate shape of the arcuate spring 206 spans greater than 180 degrees, so that it is capable of being frictionally adhered to the inner surface of a blood vessel.

The spring 206 is pre-shaped to assume its arcuate shape in the absence of an external force, but can be collapsed, e.g., by rolling the spring 206. Thus, the electrode body 202 can be placed and maintained in its collapsed geometry by applying a compressive force on the spring 206 and placing it within the sheath 203.

In contrast, the electrode body 202 can be placed in its expanded geometry by releasing the compressive force to unfurl the spring 206, which naturally occurs when the sheath 203 is removed.

When expanded within a blood vessel, the resiliency of the spring 206 continuously urges it against the inner surface of the blood vessel with a force sufficient to hold the electrode body 202 in place within the selected blood vessel without moving as a result of the repetitive blood pulsing within the vascular system, but without distending the vessel wall. In the illustrated embodiment, the spring 206 is non-porous, but can alternatively be skeletal in nature, such as a coil, mesh, or braid. The surface of the arcuate spring 206 is preferably both biocompatible and electrically insulative. The arcuate spring 206 can be entirely composed of a resilient insulative material, such as polyimide, polytetrafluoroethylene (PTFE), Fluorinated Ethylene Propylene (FEP), polyethylene, or silicone, or can be composed of a core of electrically conductive material, such as one or more of the various materials from which the previously described conductive sub-structures 106 are composed, and an insulative layer disposed over the core.

In the illustrated embodiment, the electrodes 208 are applied to the spring 206 as a layer of highly electrically conductive and biocompatible material, such as gold, silver, or platinum. Deposition techniques include sputtering, vapor deposition, ion beam deposition, electroplating over a deposited seed layer, or a combination of these processes. Alternatively, the electrodes 208 may be discrete and flexible elements, such as mesh or braid, that is suitably bonded to the spring 206. In other alternative embodiments, the spring 206, itself, may form the electrodes 208. For example, any of the previously described techniques, such as forming electrodes

from electrically conductive sub-structures, or removing insulative material to expose portions of an electrically conductive core, can be used.

The leads 204, the proximal ends of which will extend from the intravascular access point in the patient (e.g., the femoral vein or jugular vein), are configured to be coupled to an implanted or external source and/or recorder of the electrical signals (not shown), as will be described in further detail below. The conductive leads 204, which are of similar construction and length as leads 104, are suitably coupled to the electrodes 208 using means, such as welding or soldering.

Using the delivery catheter 152, with the associated guidewire 154 and electrolytic pusher wire 156, the medical device 200 can be delivered to a target site 182 within a selected blood vessel in the same manner as that described above, so that the electrode body 202 is expanded into firm contact with the blood vessel 180, as illustrated in **Figs. 17** and **18**.

Referring to **Figs. 19** and **20**, an intravascular medical device 210 constructed in accordance with still another embodiment of the invention comprises an expandable/collapsible electrode body 212 and a plurality of flexible conductive leads 214 electrically coupled to the electrode body 212. The electrode body 212 can be transformed from a collapsed geometry (**Fig. 19**) into an expanded geometry (**Fig. 20**). In its collapsed geometry, the electrode body 212 can be intravascularly delivered to a target site within a vessel using a standard stent delivery apparatus. In its expanded geometry, the electrode body 212 can be placed into firm contact with the target site and used to transmit electrical signals to and/or receive electrical signals from the blood vessel and surrounding tissue, while minimizing blood occlusion.

The electrode body 212 comprises an arcuate structure 216, a plurality of electrodes 218 (in this case, three) disposed on the structure 216, and a plurality of resilient spring loops 215 mounted to the arcuate structure 216. The spring loops 215 can be mounted to the arcuate structure 216 in any suitable manner, including welding or soldering. The spring loops 215 are pre-shaped to extend laterally from the arcuate structure 216 in the absence of a compressive force, but can be collapsed, e.g., by applying a compressive force to the spring loops 215. Thus, the electrode body 212 can be placed in its collapsed geometry by applying a compressive force to hinge the spring loops 215, which naturally occurs when the electrode body 212 is introduced within the delivery catheter 152. In contrast, the electrode body 212 can be placed in its expanded geometry by releasing the compressive force in order to hinge the spring loops 215 into their laterally extending position, which naturally occurs when the electrode body 212 exits the delivery catheter 152. The resiliency of the spring loops 215 continuously urges the arcuate structure 216 against the opposing vessel wall into firm contact with the target site with a force sufficient to hold the electrode body 212 in place within the selected blood vessel without moving as a result of the repetitive blood pulsing within the vascular system, but without distending the vessel wall.

Like the previously described arcuate spring 206, the arcuate structure 216 is non-tubular, i.e., its arcuate shape spans less than 360 degrees, thereby providing the electrode body 212 with the same advantages as the electrode body 202. Unlike the previously described electrode body 202, however, the electrode body 212 can advantageously span less than 180 degrees, since the electrode body 212 need not have the capability, by itself, to adhere to the vessel walls. That is, the force applied by the spring loops 215 is sufficient to place the electrode body 212 firmly against

the vessel wall. In this manner, the electrode body 212 may be even more adaptable to a variety of blood vessel shapes, and the electrical stimulation and/or recording energy more focused, than that of the previously described arcuate electrode body 202.

Like the previously described arcuate spring 206, the surface of the arcuate structure 216 is preferably both biocompatible and electrically insulative, and thus can be constructed in a similar manner as the spring 206, with the exception that the arcuate structure 216 need not be resilient. Optionally, however, the arcuate structure 216 may be composed of a resilient material, so that it acts as a spring much like the resilient spring 206 of the electrode body 202. In this manner, the frictional engagement created by the resiliency of the spring, in addition to the lateral forces created by the resiliency of the spring loops 215, will place the electrodes 218 firmly in contact with the vessel wall.

The electrodes 218 can be composed of the same material and be disposed on the arcuate structure 216 in the same manner as the previously described electrodes 208. In addition to the electrodes 218, the resilient spring loops 215 can be composed of an electrically conductive material, so that they can also serve as electrodes. In this case, the spring loops 215 can be directly mounted to the electrodes 218. Alternatively, the spring loops 215 can act as electrodes, obviating the need for separate electrodes 218 on the arcuate structure 216.

The conductive leads 214, the proximal ends of which will extend from the intravascular access point in the patient (e.g., the femoral vein or jugular vein), are configured to be coupled to an implanted or external source and/or recorder of the electrical signals (not shown), as will be described in further detail below. The

conductive leads 214, which are of similar construction and length as leads 104, are suitably coupled to the electrodes 218 using means, such as welding or soldering.

Using the delivery catheter 152, with the associated guidewire 154 and electrolytic pusher wire 156, the medical device 210 can be delivered to a target site 182 within a selected blood vessel in the same manner as that described above, so that the electrode body 212 is placed into firm contact with the blood vessel 180, as illustrated in **Figs. 21A** and **21B**.

Referring to **Figs. 22** and **23**, an intravascular medical device 220 constructed in accordance with yet another embodiment of the invention comprises an expandable/collapsible electrode body 222 and a plurality of flexible conductive leads 224 electrically coupled to the electrode body 222. The electrode body 222 can be transformed from a collapsed geometry (**Fig. 22**) into an expanded geometry (**Fig. 23**). In its collapsed geometry, the electrode body 222 can be intravascularly delivered to a target site within a vessel using a standard stent delivery apparatus. In its expanded geometry, the electrode body 222 can be placed into firm contact with the target site and used to transmit electrical signals to and/or receive electrical signals from the blood vessel and surrounding tissue, while minimizing blood occlusion.

The electrode body 222 comprises an elongated cylindrical member 226, a plurality of electrodes 228 (in this case, three) disposed on the cylindrical member 226, and a plurality of resilient spring loops 225 mounted to the cylindrical member 226. The spring loops 225 can be mounted to the cylindrical member 226 in any suitable manner, including welding, soldering, or tying the spring loops 225 to the cylindrical member 226. Like the previously described spring loops 225, the spring loops 225 are pre-shaped to extend laterally from the cylindrical member 226 in the

absence of a compressive force, but can be collapsed, e.g., by applying a compressive force to the spring loops 225. The resiliency of the spring loops 225 continuously urges the cylindrical member 226 against the opposing vessel wall into firm contact with the target site with a force sufficient to hold the electrode body 222 in place within the selected blood vessel without moving as a result of the repetitive blood pulsing within the vascular system, but without distending the vessel wall.

The cylindrical member 226 can be composed of any flexible and insulative material, such as Pebax®, nylon, silicone, or urethane. In the illustrated embodiment, the electrodes 228 take the form of a ring electrodes that axially extend along the member 226. The electrodes 228 may be discrete elements that are mounted to the cylindrical member 226 in an interference relationship, or may be suitably formed on the cylindrical member 226 as a layer of material. The electrodes 228 may be composed of the same material as the previously described electrodes 208. Like the previously described spring loops 225, the resilient spring loops 225 can also be composed of an electrically conductive material in order to serve as electrodes, in which case, the spring loops 225 can be directly mounted to the electrodes 228, or alternatively, the spring loops 225 can act as electrodes, obviating the need for separate electrodes 228 on the cylindrical member 226.

The conductive leads 224, the proximal ends of which will extend from the intravascular access point in the patient (e.g., the femoral vein or jugular vein), are configured to be coupled to an implanted or external source and/or recorder of the electrical signals (not shown), as will be described in further detail below. The conductive leads 224, which are of similar construction and length as leads 104, extend through the cylindrical member 226 where they are suitably coupled to the electrodes 228 using means, such as welding or soldering.

Using the delivery catheter 152, with the associated guidewire 154 and electrolytic pusher wire 156, the medical device 220 can be delivered to a target site 182 within a selected blood vessel in the same manner as that described above, so that the electrode body 222 is placed into firm contact with the blood vessel 180, as illustrated in **Figs. 24A** and **24B**.

Referring to **Figs. 25** and **26**, an intravascular medical device 230 constructed in accordance with yet another embodiment of the invention comprises an expandable/collapsible electrode body 232 and a plurality of flexible conductive leads 234 electrically coupled to the electrode body 232. The electrode body 232 can be transformed from a collapsed geometry (**Fig. 25**) into an expanded geometry (**Fig. 26**). In its collapsed geometry, the electrode body 232 can be intravascularly delivered to a target site within a vessel using a standard stent delivery apparatus. In its expanded geometry, the electrode body 232 can be placed into firm contact with the target site and used to transmit electrical signals to and/or receive electrical signals from the blood vessel and surrounding tissue, while minimizing blood occlusion.

The electrode body 232 comprises a central support member 236, a pair of resilient spring arms 235 extending from the distal end of the support member 234, and a pair of electrodes 238 disposed on the distal ends of the respective spring arms 235. The support member 236 can be composed of any suitable rigid or semi-rigid insulative material, such as Pebax®, nylon, urethane, silicone, or polyimide.

The spring arms 235 can be mounted to the support member 236 in any suitable manner, including welding or soldering. The spring arms 235 are pre-shaped to laterally extend away from each other in the absence of a compressive force to place the electrode body 232, but can be collapsed, e.g., by applying a

compressive force to the spring arms 235. Thus, the electrode body 232 can be placed and maintained in its collapsed geometry by applying a compressive force to move the spring arms 235 towards each other, which naturally occurs when the electrode body 232 is introduced within the delivery catheter 152. A sheath (not shown) can be optionally used to maintain the electrode body 232 in its collapsed geometry as it is introduced through the delivery catheter 152. In contrast, the electrode body 232 can be placed in its expanded geometry by releasing the compressive force to allow the spring arms 235 to move away from each other, which naturally occurs when the electrode body 232 exits the delivery catheter 152. When the spring arms 235 expand against the vessel wall, they will create an anchoring force sufficient to hold the electrode body 232 in place within the selected blood vessel without moving as a result of the repetitive blood pulsing within the vascular system, but without distending the vessel wall.

In the illustrated embodiment, the electrodes 238 are discrete elements that are suitably bonded onto the resilient arms 235, although the electrodes 238 can be formed onto the spring arms 235 in other suitable manners. With the exception of their distal ends, the spring arms 235 are preferably coated with an electrically insulative material. Alternatively, the exposed distal ends of the spring arms 235 can act as electrodes, thereby obviating the need to bond separate discrete electrodes 238 onto the spring arms 235.

The conductive leads 234, the proximal ends of which will extend from the intravascular access point in the patient (e.g., the femoral vein or jugular vein), are configured to be coupled to an implanted or external source and/or recorder of the electrical signals (not shown), as will be described in further detail below. The conductive leads 234, which are of similar construction and length as leads 104,

extend through the support member 236 and are suitably coupled to the proximal ends of the spring arms 235 using means, such as welding or soldering.

Using the delivery catheter 152, with the associated guidewire 154 and electrolytic pusher wire 156, the medical device 230 can be delivered to a target site 182 within a selected blood vessel in the same manner as that described above, so that the electrode body 232 is placed into firm contact with the blood vessel 180, as illustrated in **Figs. 27A** and **27B**.

CLAIMS

1. An expandable intravascular medical device, comprising:

a tubular body including an integrated, electrically conductive, resilient support structure that forms a plurality of electrically conductive regions, the tubular body further including at least one electrically insulative element disposed between the conductive regions; and

at least one lead electrically coupled to at least one of the conductive regions.

2. The medical device of claim 1, wherein the at least one lead comprises a plurality of leads electrically coupled to the plurality of respective conductive regions.

3. The medical device of claims 1 o 2, wherein the support structure is skeletal.

4. The medical device of any of claims 1 - 3, wherein the support structure comprises electrically conductive sub-structures that form the conductive regions, the sub-structures being mechanically linked together by the at least one insulative element.

5. The medical device of claim 4, wherein the at least one insulative element comprises a strand.

6. The medical device of claim 4, wherein the at least one insulative element comprises a tubular element that extends around the periphery of the tubular body.

7. The medical device of claim 4, further comprising an electrically insulative tubular body to which the support structure is coupled, the at least one insulative element integrated within the tubular body.

8. The medical device of claim 1, wherein the support structure comprises electrically conductive sub-structures that form the conductive regions, the sub-structures being directly mechanically linked together, and at least one insulative element being an insulative layer disposed on one or more of the conductive sub-structures.

9. The medical device of claim 1, wherein the support structure includes an electrically conductive core and insulative material disposed over portions of the conductive core, wherein the exposed core portions form the conductive regions, and the unexposed core portions form at least one insulative element.

10. The medical device of claim 1, wherein the conductive regions are electrically isolated from each other.

11. The medical device of any of claims 1 - 10, wherein the tubular body is cylindrical.

12. An expandable intravascular medical device, comprising:

an expandable tubular body including a unibody support structure comprising an electrically conductive core, portions of which are exposed to form a plurality of electrically conductive regions and portions of which are covered within an insulative layer to form electrically insulative regions; and

at least one lead electrically coupled to at least one of the conductive regions.

13. The medical device of claim 12, wherein the at least one lead comprises a plurality of leads electrically coupled to the plurality of respective conductive regions.

14. The medical device of claims 12 or 13, wherein the support structure is skeletal.

15. The medical device of any of claims 12 -14, wherein the support structure is resilient.

16. The medical device of any of claims 12 -15, wherein the conductive regions are electrically isolated from each other.

17. The medical device of any of claims 12 -16, wherein the tubular body is cylindrical.

18. An expandable intravascular medical device, comprising:

a non-tubular arcuate spring;

at least one electrode associated with the arcuate spring; and

at least one lead electrically coupled to the at least one electrode.

19. The medical device of claim 18, wherein the arcuate spring spans greater than 180 degrees.

20. The medical device of claims 18 or 19, wherein the arcuate spring forms the at least one electrode.

21. The medical device of any of claims 18 - 20, wherein the at least one electrode comprises a plurality of electrodes, and the at least one lead comprises a plurality of leads electrically coupled to the respective electrodes.

22. An expandable intravascular medical device, comprising:

an arcuate structure having an inner electrically insulative surface;

at least one electrode associated with the arcuate structure; and

at least one lead electrically coupled to the at least one electrode.

23. The medical device of claim 22, wherein the arcuate structure is tubular.

24. The medical device of claims 22 or 23, wherein at least a portion of the arcuate structure forms the at least one electrode.

25. The medical device of any of claims 22 - 24, wherein the arcuate structure is non-porous.

26. The medical device of any of claims 22 - 25, wherein the arcuate structure has an outer electrically insulative surface on which the at least one electrode is disposed.

27. The medical device of claim 26, wherein the at least one electrode comprises an electrically conductive film.

28. The medical device of claim 22, wherein the at least one electrode comprises a plurality of electrodes, and the at least one lead comprises a plurality of leads electrically coupled to the respective electrodes.

29. The medical device of any of claims 22 - 28, wherein the arcuate structure is resilient.

30. The medical device of any of claims 22 - 28, further comprising a resilient support structure disposed on the outside of the arcuate structure.

31. An expandable intravascular medical device, comprising:

an electrode support structure;

at least one electrode associated with the support structure;

a plurality of resilient spring loops laterally extending from the support structure; and

at least one lead electrically coupled to the at least one electrode.

32. The medical device of claim 31, wherein the support structure is a non-tubular arcuate structure.

33. The medical device of claim 31, wherein the support structure is a cylindrical member.

34. The medical device of any of claims 31 - 33, wherein the support structure forms the at least one electrode.

35. The medical device of any of claims 31 - 33, wherein at least one electrode is formed by at least one of the spring loops.

36. The medical device of any of claims 31 - 33, wherein the at least one electrode comprises a plurality of electrodes, and the at least one lead comprises a plurality of leads electrically coupled to the respective electrodes.

37. An expandable intravascular medical device, comprising:

an elongated member;

two resilient spring arms extending distally from the elongated member, the arms configured to be laterally moved towards each other to place the medical device in a collapsed geometry, and configured to be laterally moved away from each into contact with an inner surface of a blood vessel to place the medical device an expanded geometry, wherein the contact created between the respective arms and the blood vessel are sufficient to anchor the medical device within the blood vessel;

an electrode associated with the distal end of one of the spring arms; and

a lead electrically coupled to the electrode.

38. The medical device of claim 37, further comprising another electrode associated with the distal end of the other of the spring arms.

39. The medical device of claim 38, further comprising another lead electrically coupled to the other electrode.

40. The medical device of any of claims 37 - 39, wherein the distal end of the one spring arm forms the electrode.

41. The medical device of any of claims 37 - 40 wherein the spring arms are pre-shaped to laterally move away from each other.

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FIG. 1

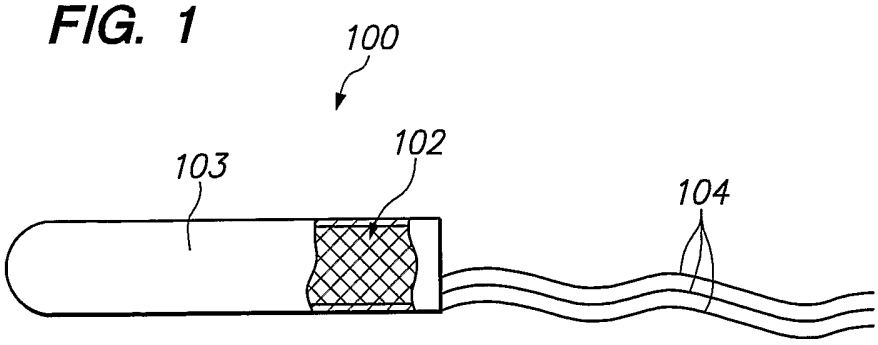


FIG. 2

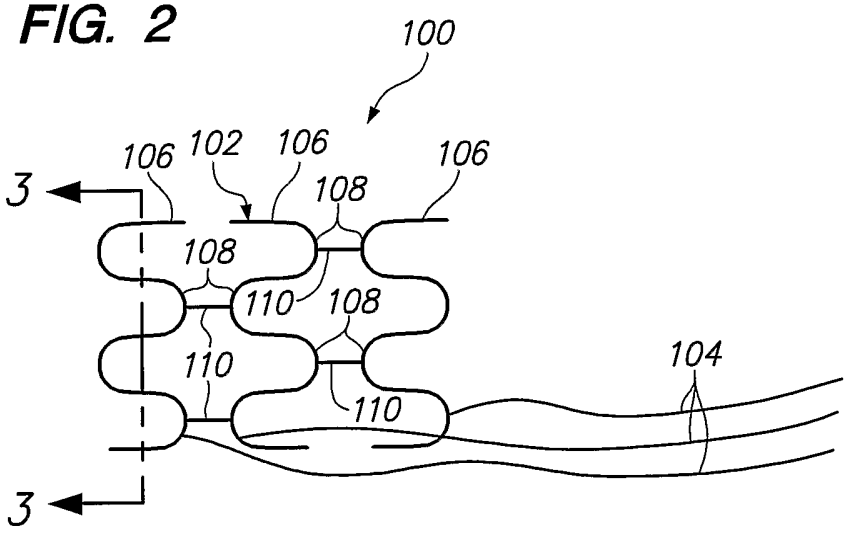


FIG. 3

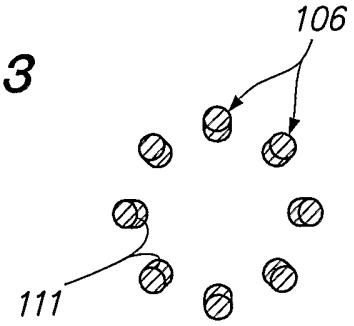


FIG. 4

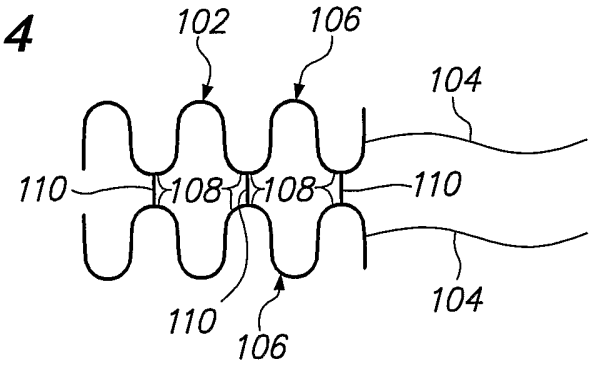


FIG. 5

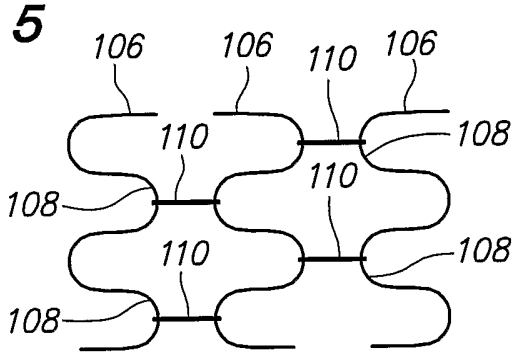


FIG. 6

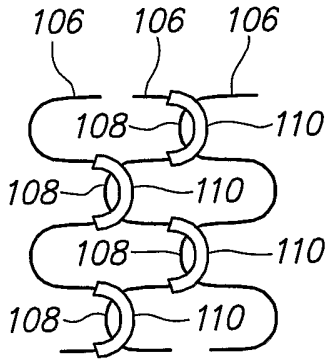


FIG. 7

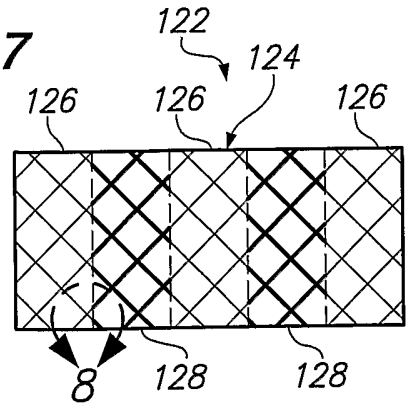


FIG. 8

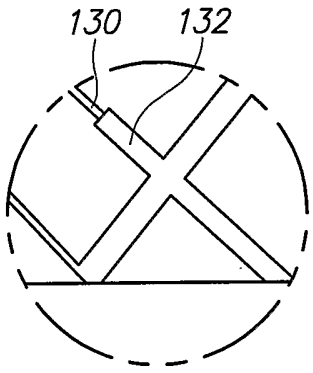


FIG. 9

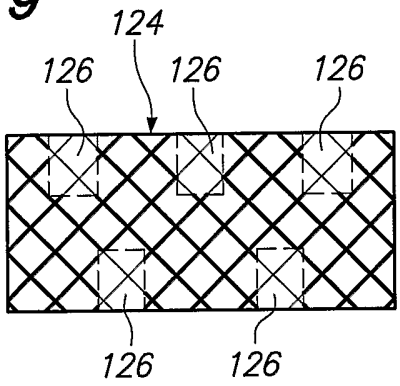


FIG. 10

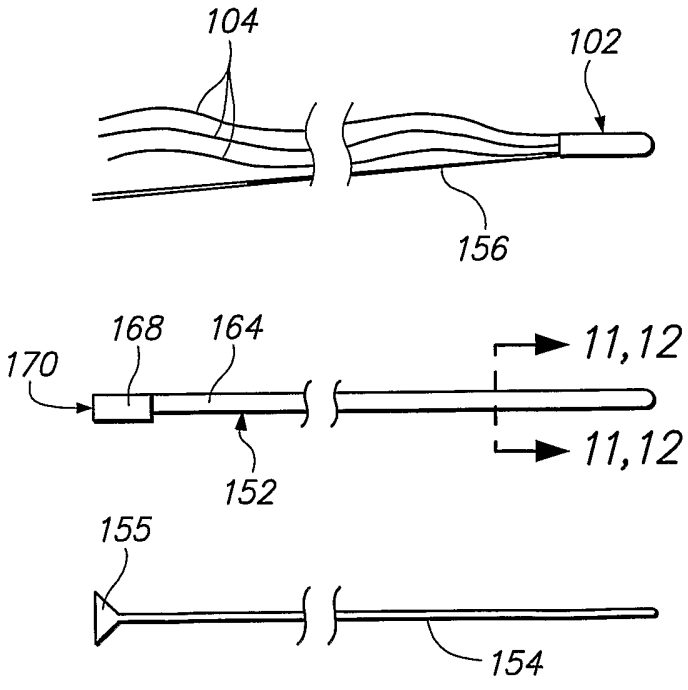


FIG. 11

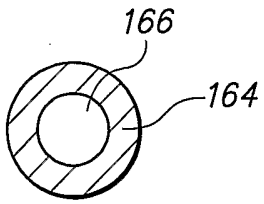


FIG. 12

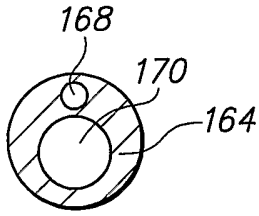


FIG. 13

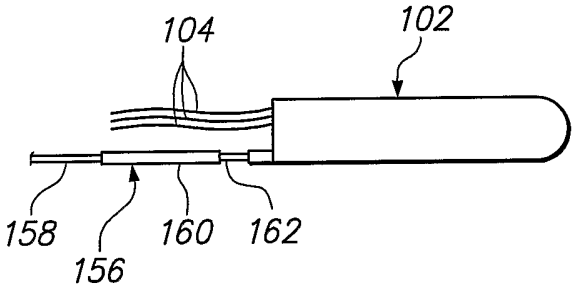


FIG. 14

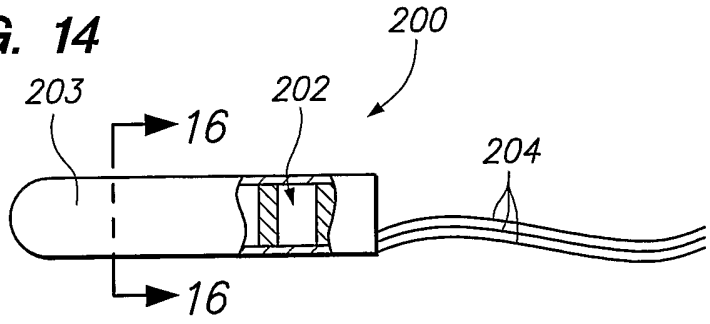


FIG. 15

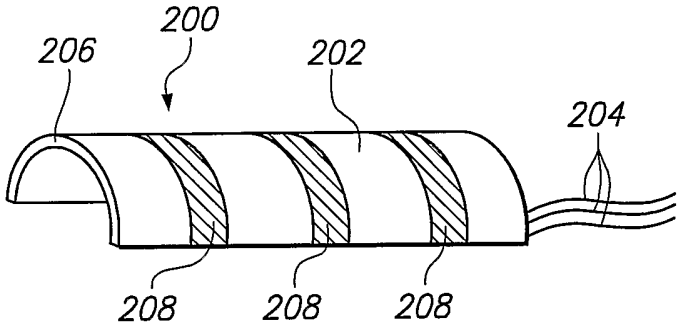


FIG. 16

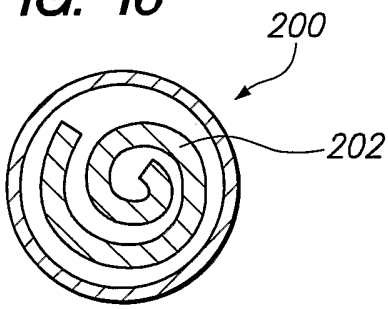


FIG. 17

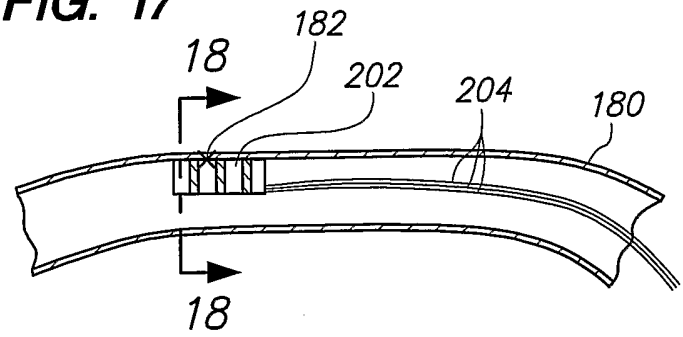


FIG. 18

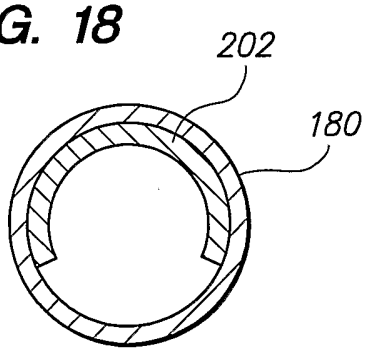


FIG. 19

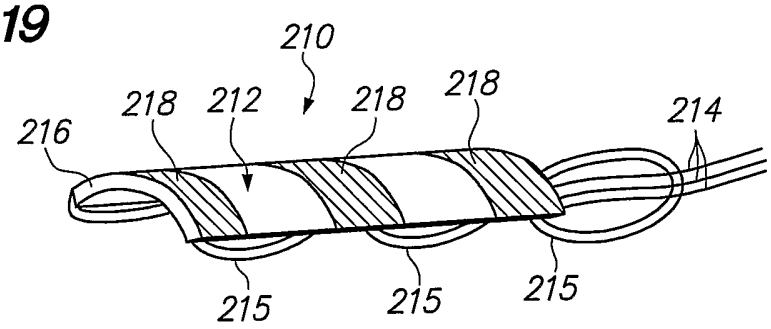


FIG. 20

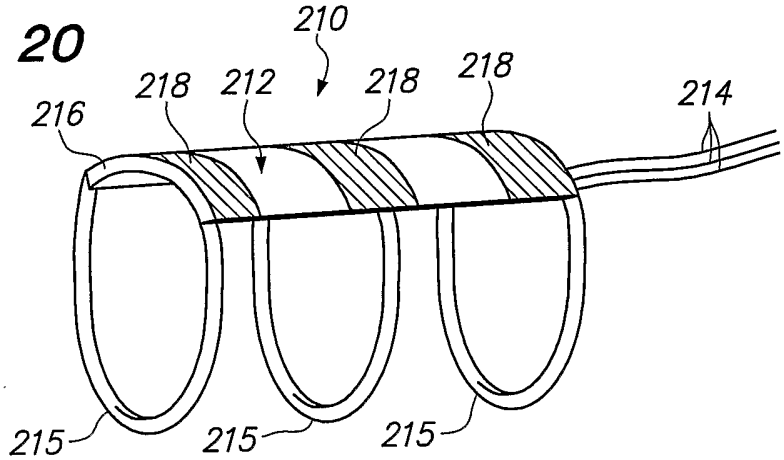


FIG. 21A

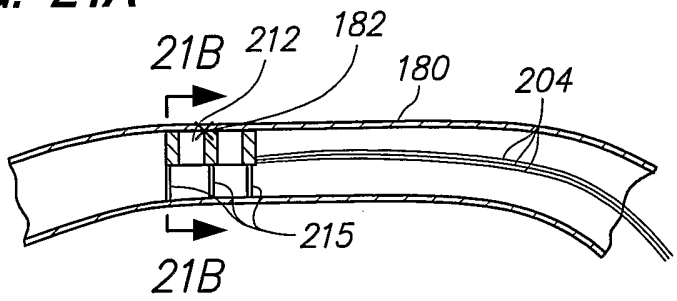


FIG. 21B

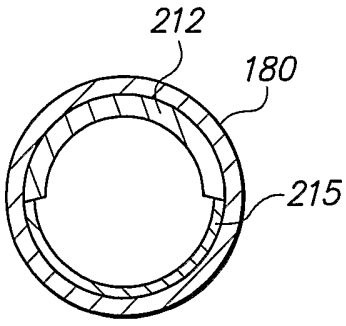


FIG. 22

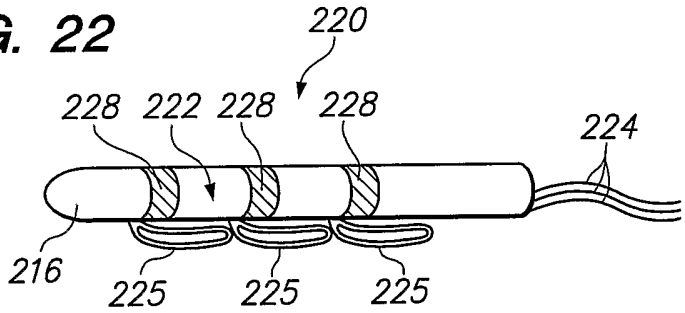


FIG. 23

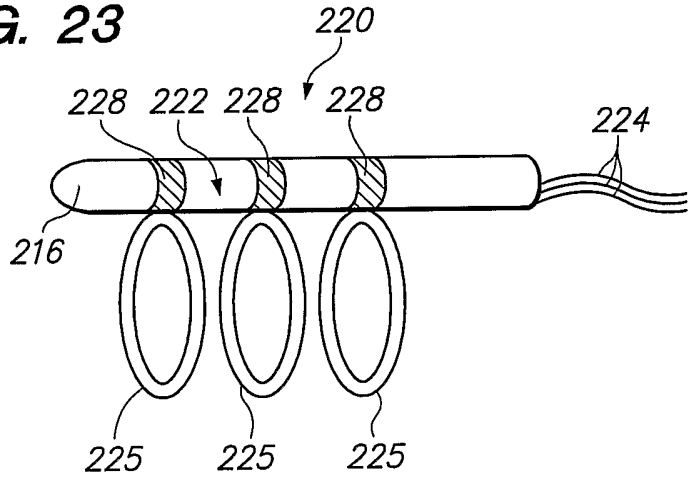


FIG. 24A

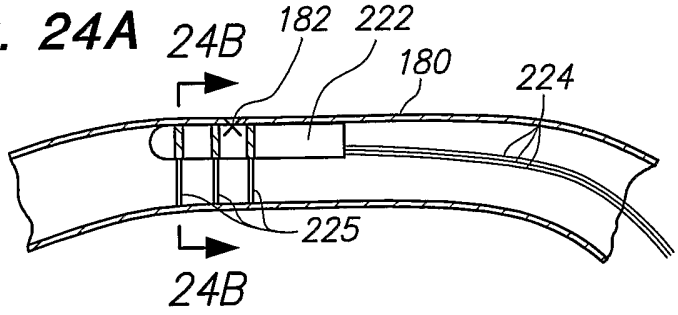


FIG. 24B

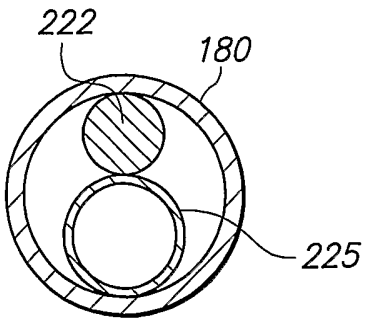


FIG. 25

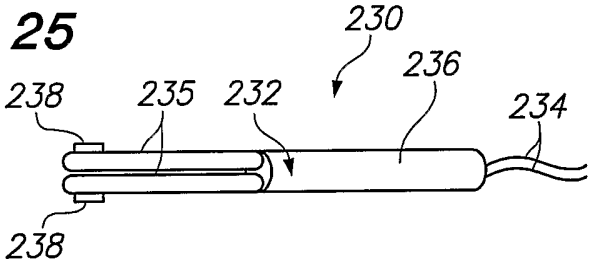


FIG. 26

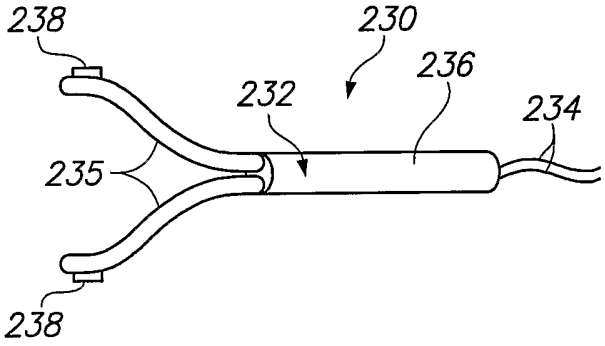


FIG. 27A

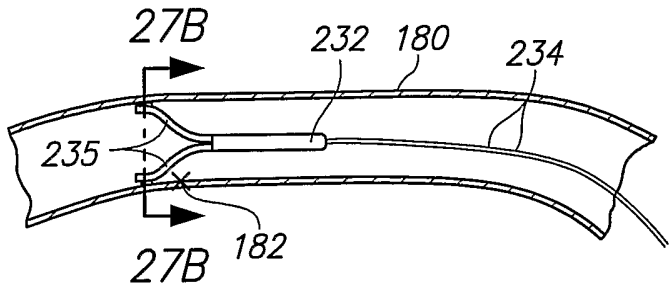


FIG. 27B

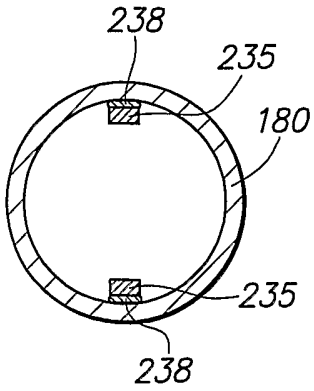


FIG. 28

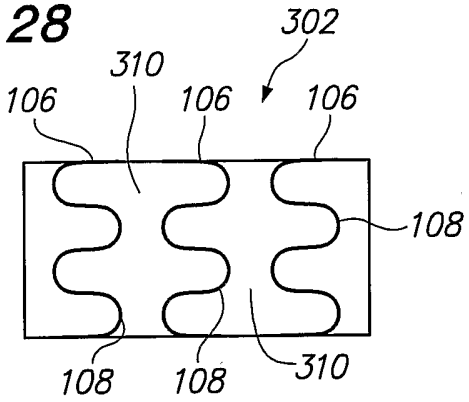


FIG. 29

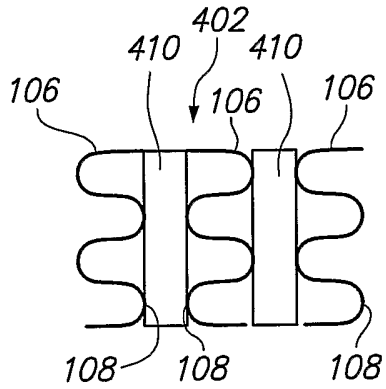
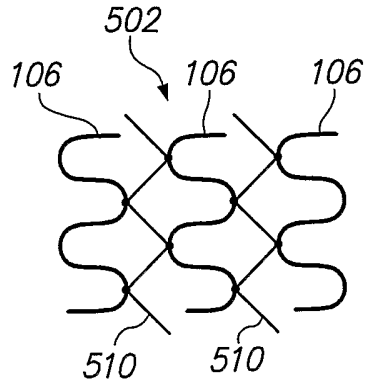


FIG. 30



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/010121

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/05

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 954 761 A (MACHEK ET AL) 21 September 1999 (1999-09-21) column 2, lines 18-60 column 3, line 31 - column 5, line 64; figures 3-5 -----	1-17, 22-24, 26,28-30
X	US 5 860 974 A (ABELE ET AL) 19 January 1999 (1999-01-19) column 1, line 31 - column 3, line 60 column 6, line 48 - column 7, line 20; figure 4 column 7, line 64 - column 8, line 9; figure 12 figure 27 ----- -/--	1-11, 18-34,36

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

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 June 2005	04/07/2005

Name and mailing address of the ISA	Authorized officer
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Inter nal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	US 6 136 021 A (TOCKMAN ET AL) 24 October 2000 (2000-10-24) column 3, line 15 - column 4, line 57; figure 14	22,23, 25,26,30
X	EP 0 861 676 A (MEDTRONIC CARDIORHYTHM) 2 September 1998 (1998-09-02) column 3, lines 40-56 column 9, lines 40-54; figure 9	37-41
X	US 5 782 239 A (WEBSTER, JR. ET AL) 21 July 1998 (1998-07-21) column 2, line 60 - column 3, line 50 column 4, line 47 - column 6, line 57; figures 1,2,4	1-4, 7-17, 22-26, 28-30, 37-41

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