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Friedman

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[54] **BODY IMPLANTABLE LEAD**

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[51] **Int. Cl.** **A61n 1/04**

[58] **Field of Search** ..... 128/418, 404, 419 P, 2.1 E, 128/2.06 E, 407, 408, 409, 410, 419 C

[56] **References Cited**

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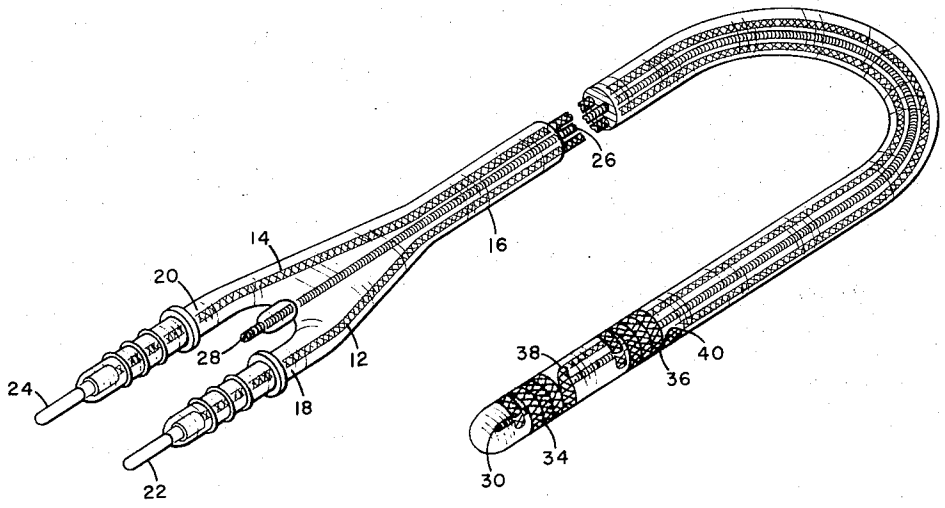
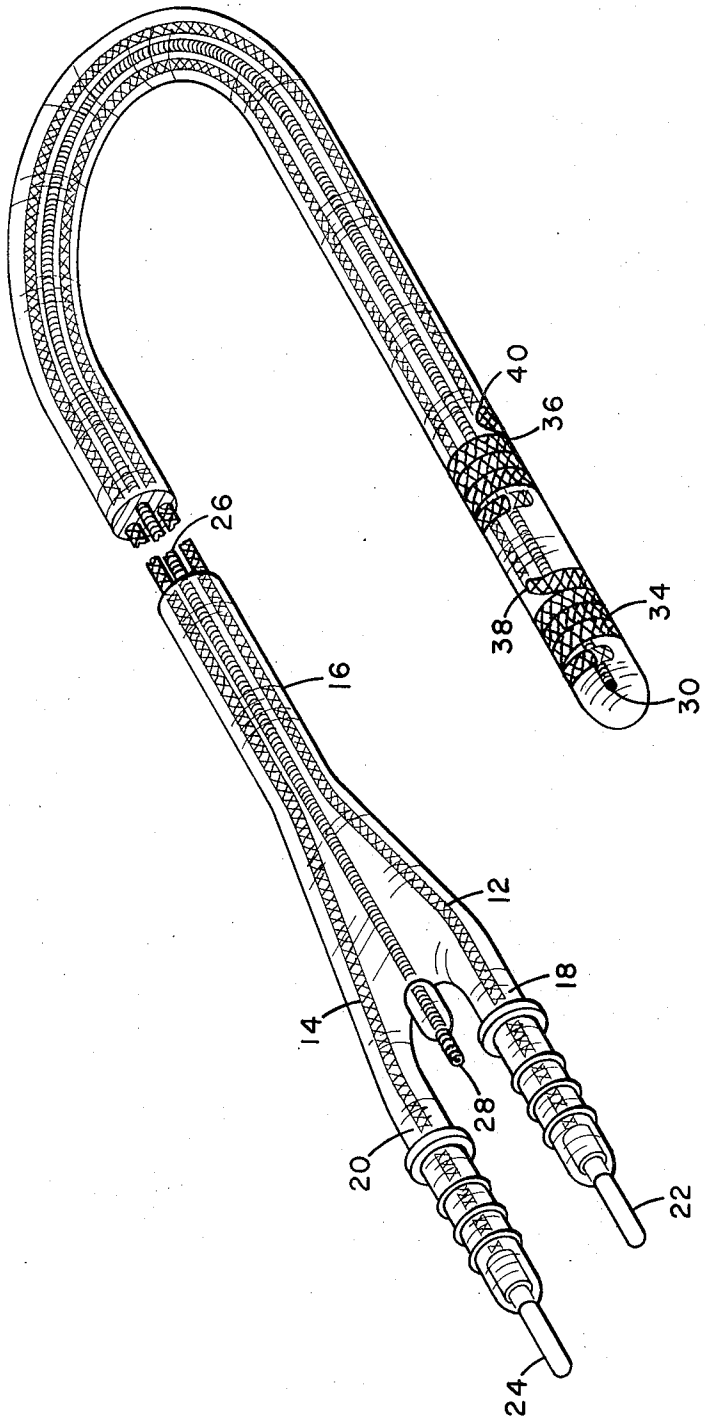
[57] **ABSTRACT**

A body-implantable, bipolar lead for insertion in and guidance through a body vessel to a desired location inside the body. The lead comprises a pair of electrical conductors adapted to be connected at their proximal end to a source of electrical energy. The conductors are substantially covered with a material substantially inert to body fluids and tissue. Tip and proximal electrodes spaced from one another are formed as an integral part of the corresponding conductor by at least a portion of the conductor projecting radially through the outer surface of the covering material and being at least partially exposed.

9 Claims, 1 Drawing Figure

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BODY IMPLANTABLE LEAD

BACKGROUND OF THE INVENTION

In the field of biomedical devices, various types of implantable stimulators have come into usage. One such stimulator is the cardiac pacemaker. These pacemakers generally employ one of two types of leads—myocardial or endocardial—for delivering the stimulating pulses from the pulse generator to the patient's heart. Myocardial leads have electrodes which are secured directly into cardiac tissue. Endocardial leads are passed intravenously to the heart and the electrodes are positioned so that the tip electrode is lodged in the apex of the right ventricle of the heart.

One problem which has existed with endocardial leads is the relationship of the electrical conductors and the electrodes. In prior art endocardial leads, the tip and proximal electrodes have been metal rings which are located on the outside of the inert material covering the conductors and bonded to the rings by soldering, welding, adhesive bonding or other bonding techniques. The difficulty with this is that with the contraction of the heart the bond between the conductors and electrodes is subjected to continual stress and thus apt to break. Also the covering material is apt to be broken by the edges of the rings thereby permitting body fluids to find their way inside the lead.

The present invention overcomes the disadvantages of the prior art by eliminating the use of metal rings for the tip and proximal electrodes. Also, the need for a bond between the conductor and the electrode is eliminated. The problem of leakage of body fluids into the lead over time is also substantially eliminated. The overall construction of the lead of the present invention is much more durable and reliable than those of the prior art.

SUMMARY OF THE INVENTION

The above advantages, features and objects of the present invention, as well as others, are accomplished by providing in a body-implantable, bipolar, endocardial lead comprising a pair of electrical conductors, means adapted to connect the proximal ends of the conductors to a source of electrical energy, means for permitting the lead to be inserted in and guided through a body vessel to a desired location inside the body, means for substantially covering the conductors with a material substantially inert to body fluids and tissue, and tip and proximal electrodes spaced from one another and connected to the distal ends of the corresponding conductors, the improvement being the formation of the tip and proximal electrodes as an integral part of the corresponding conductor by at least a portion of the conductor projecting through the outer surface of the covering means and being at least partially exposed to thereby form the tip and proximal electrodes respectively. In the preferred embodiment the exposed portion of each conductor is wrapped at least one turn around the covering means.

Other advantages, features and objects of the present invention will hereinafter become more fully apparent from the following description of the drawing, which illustrates a preferred embodiment of the present invention.

BRIEF DESCRIPTION OF THE DRAWING

The FIGURE shows a lead in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The FIGURE shows a body-implantable, bipolar, endocardial lead **10.** Lead **10** comprises a pair of electrical conductors **12** and **14** embedded in a covering **16.** Conductors **12** and **14** may, for example, be of the configuration and construction of the lead described in U.S. Pat. No. 3,572,344. However, it should be understood that any conductor configuration and construction compatible with body fluids and tissue may be used in the present invention. Covering **16** is made of a material which is substantially inert to body fluids and tissue, such as, for example, silicone rubber. Covering **16** is split into two legs **18** and **20** near the proximal end of lead **10.** Conductors **12** and **14** are connected to metal connectors **22** and **24** respectively which connectors are adapted to be connected to a source of electrical energy such as a pulse generator of a cardiac pacemaker. Conductors **12** and **14** and connectors **22** and **24** are made of materials which are substantially inert to body fluids and tissue and may, for example, be platinum or a platinum iridium alloy.

Also embedded in the covering **16** and extending from the juncture of legs **18** and **20** to close to the distal end of lead **10** is a closely wound helical coil spring **26** which is open at its proximal end **28** and crimped at its distal end **30.** Spring **26** defines a lumen into which a stylet (not shown) may be inserted. Insertion of a stylet makes lead **10** sufficiently rigid so that it may be inserted in and guided through a body vessel to a desired location inside the body. Once lead **10** is in its desired location inside the body, the stylet may be withdrawn.

Located at the distal end of lead **10** are a pair of spaced electrodes **34** and **36.** Electrode **34** is the tip electrode and is formed as an integral part of conductor **12.** Tip electrode **34** is formed by conductor **12** projecting through the outer surface of covering **16** at point **38** and being closely wrapped in a helical configuration away from electrode **36** for several turns about covering **16.** The turns of electrode **34** are terminated with the distal end of conductor **12** being embedded in covering **16.** The turns of electrode **34** are partially embedded in covering **16** so as to help maintain the turns in fixed position and prevent them from moving. Electrode **36** is the proximal electrode and is formed as an integral part of conductor **14.** Proximal electrode **36** is formed by conductor **14** projecting through the outer surface of covering **16** at point **40** and being closely wrapped in a helical configuration toward electrode **34** for several turns about covering **16.** The turns of electrode **36** are terminated with the distal end of conductor **14** being embedded in covering **16.** The turns of electrode **36** are partially embedded in covering **16** so as to help maintain the turns in fixed position and prevent them from moving.

When lead **10** is used as an endocardial lead for a pacemaker system, lead **10** is inserted transvenously and electrode **34** is wedged in the apex of the right ventricle. Although lead **10** has been described for use in conjunction with a cardiac pacemaker system, it should be understood that lead **10** may be used in other intra-

vascular applications, such as, for example, as a lead for a cardioversion or defibrillation system.

Although lead **10** has been shown and described as a bipolar lead, it could also have only one electrode for use with a monopolar system. Also, although the tip and proximal electrodes **34** and **36** have been shown in a wrapped configuration around covering material **16,** they could assume other configurations. An example of another configuration would be to have the electrodes just sections of conductors **12** and **14** partially embedded in and partially exposed along a section of covering material **16.**

It should be understood, of course, that the foregoing disclosure relates to only a preferred embodiment of the invention and that numerous modifications or alterations may be made therein without departing from the spirit and scope of the invention as set forth in the appended claims.

I claim:

1. A body implantable lead which comprises:

at least one electrical conductor means:

means for connecting said electrical conductor means to a source of electrical energy;

insulating means encapsulating and electrically insulating said conductor means, said insulating means being of a material which is substantially inert to body fluids and tissues; and

at least one electrode means partially embedded within the surface of said insulating means and helically wrapped and electrically exposed for at least one entire turn around the periphery of said insulating means for providing an electrical contact at all situs of said electrode means at the periphery of said insulating means, said electrode means being unitary with said conductor means, the terminus of said electrode means being totally embedded within said insulating means.

2. A body implantable lead which comprises:

a body member having an elongated central portion of substantially uniform cross section, a connector portion on the proximal end of said central protion and a tip portion on the distal end of said central portion, said body member being formed of an electrically insulating material which is substantially inert to body fluids and tissues;

first electrical conducting means embedded within said body member and originating at said body member connector portion for connection to an external device, said first electrical conductor means extending from said body member connector portion through said body member central portion to a point adjacent said body member tip portion whereat said first electrical conductor means projects through the surface of the body member central portion and is wrapped at least once around the periphery of said body member central portion while being partially embedded within its surface such that said first electrical conductor means is electrically exposed only at the location of said wrapping and is so exposed around the entire periphery of said body member central portion, the terminus of said first electrical conductor means being totally embedded within said body member; and

second electrical conductor means embedded within said body member and electrically insulated from said first electrical conductor means, said second electrical conductor means originating at said body member connector portion for connection to an external electrical device and extending from said body member connector portion through said body member central portion to a point spaced from the point at which said first electrical conductor means projects through the surface of said body member central portion whereat said second electrical conductor means projects through the surface of said body member central portion and is wrapped at least once around the periphery of said body member central portion while being partially embedded within its surface such that said second electrical conductor means is electrically exposed only at the location of said wrapping and is so exposed around the entire periphery of said body member central portion, the terminus of said second electrical conductor means being totally embedded within said body member.

3. The body implantable lead of claim **2** wherein the terminus of each of said first and second electrical conductor means are embedded within said body member at a point distal to the point at which the respective lead projects through the surface of said body member central portion.

4. The body implantable lead of claim **2** wherein said first and second electrical conductor means are helically wrapped around the periphery of said body member central portion in a direction away from said body member connector portion.

5. A body implantable lead which comprises:

first electrical conductor means;

second electrical conductor means;

means for connecting said first and second conductor means to a source of electrical energy;

insulating means encapsulating said first and second electrical conductor means and electrically insulating them from each other, said insulating means being of a material which is substantially inert to body fluids and tissues;

first electrode means unitary with said first electrical conductor means partially embedded within the surface of said insulating means and helically wrapped and electrically exposed for at least one entire turn around the periphery of said insulating means for providing an electrical contact at all situs of said electrode means at the periphery of said insulating means, the terminus of said first electrode means being totally embedded within said insulating means; and

second electrode means unitary with said second electrical conductor means spaced from said first electrode means and partially embedded within the surface of said insulating means, said second electrode means being helically wrapped and electrically exposed for at least one entire turn around the periphery of said insulating means for providing an electrical contact at all situs of said second electrode means at the periphery of said insulating means, the terminus of said second electrode means being totally embedded within said insulating means.

6. The body implantable lead of claim **5** wherein said insulating means covering said first and second electrical conductor means has a substantially uniform cross section in the region at which said first and second electrode means are partially embedded therein.

7. The body implantable lead of claim 6 wherein the helix formed by said first and second electrode means extend away from their respective unitary electrical conductor means.

8. The body implantable lead of claim 7 further comprising means extending substantially the entire length of said insulating means for guiding the lead through a body vessel and into a desired location inside the body,

said guiding means including means encapsulated in said insulating means and defining a lumin therethrough.

9. The body implantable lead of claim 5 wherein the helix formed by said first and second electrode means extend away from the respective unitary electrical conductor means.

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