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Black et al.

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(54) **IMPLANTABLE LEAD AND METHOD OF MANUFACTURE**

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(51) **Int. Cl.**[7] **A61N 1/05**
(52) **U.S. Cl.** **607/122**; 607/373
(58) **Field of Search** 607/116, 119, 607/122; 600/373–375, 381, 377

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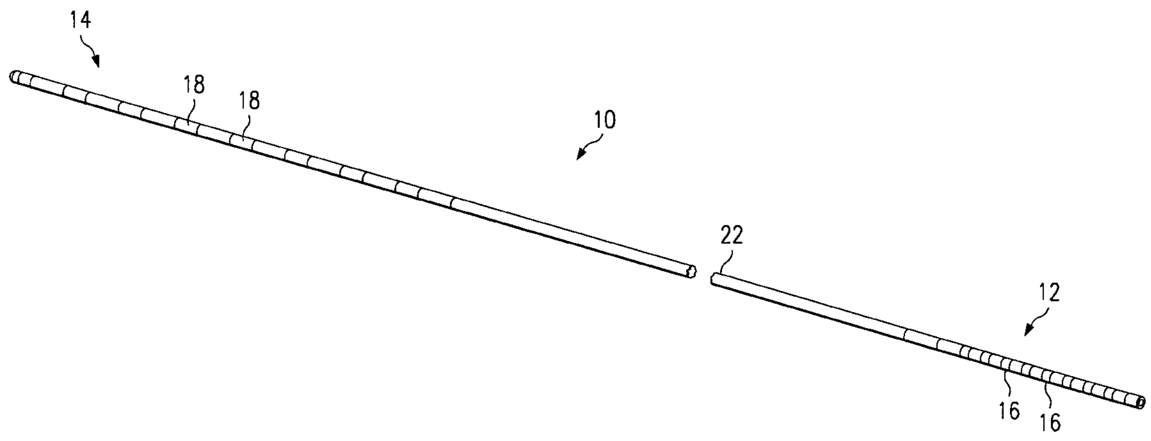
(57) **ABSTRACT**

An implantable, substantially isodiametric, low resistance implantable lead having at least one electrode positioned in a stimulation/sensing portion of the lead. At least the stimulation/sensing portion is unitized through partially surrounding and supporting insulation and conductive element (s) of the stimulation/sensing portion with a fused matrix of material having mechanical properties consistent with a body of the lead.

14 Claims, 3 Drawing Sheets



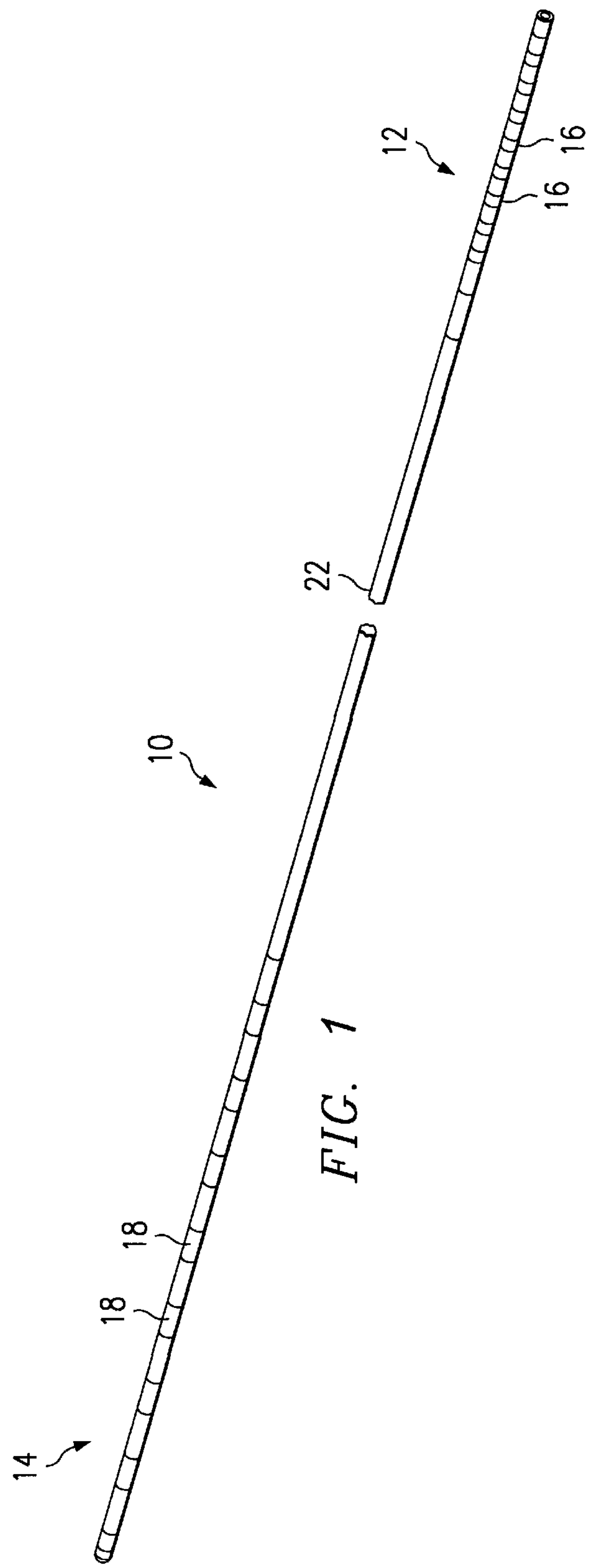


FIG. 1

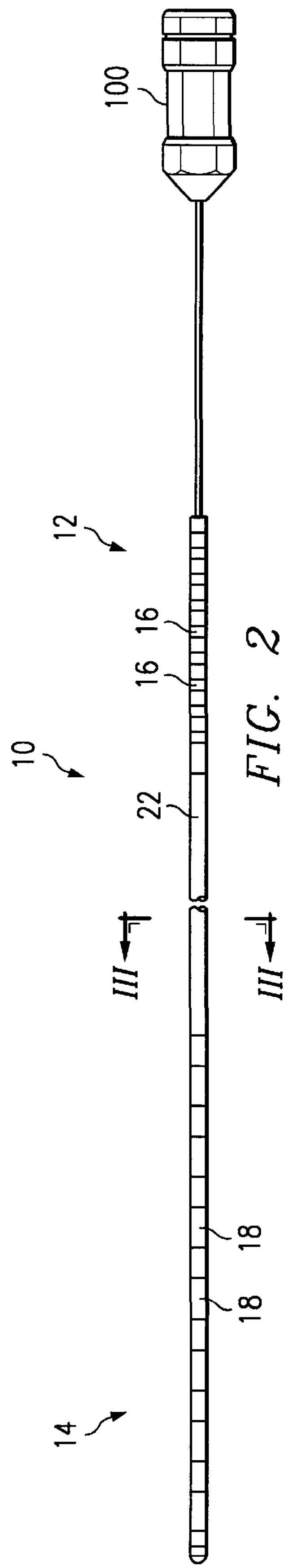


FIG. 2

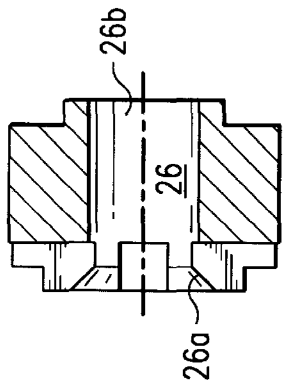


FIG. 6

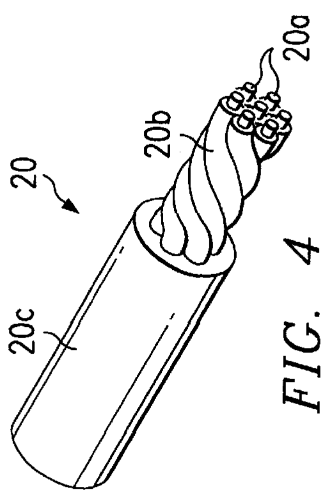


FIG. 4

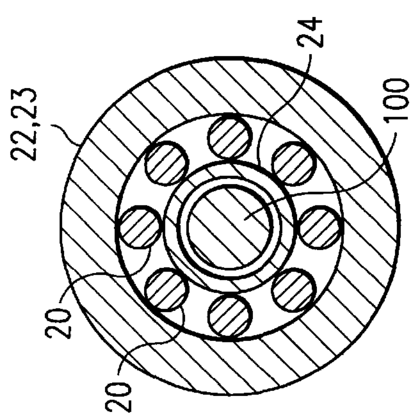


FIG. 3

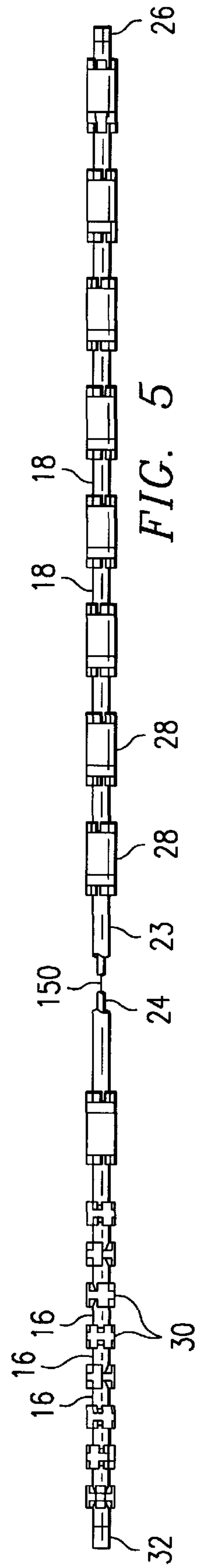


FIG. 5

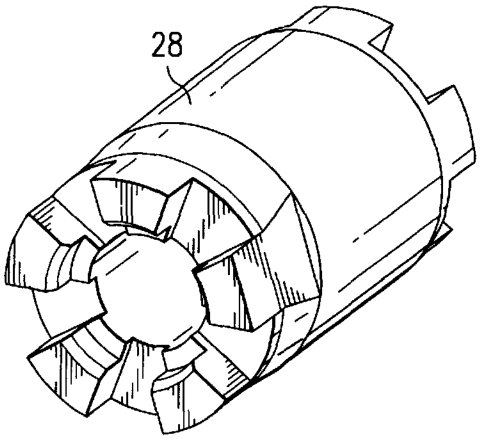


FIG. 7

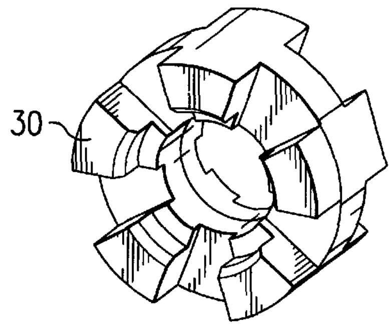


FIG. 8

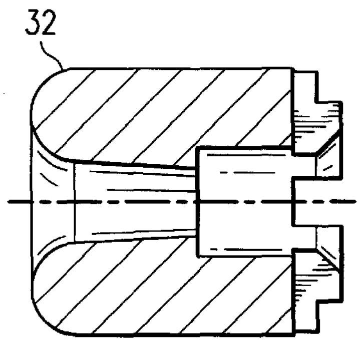


FIG. 9

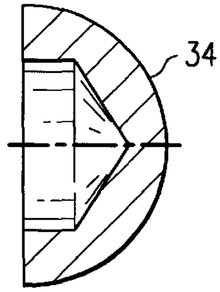


FIG. 10

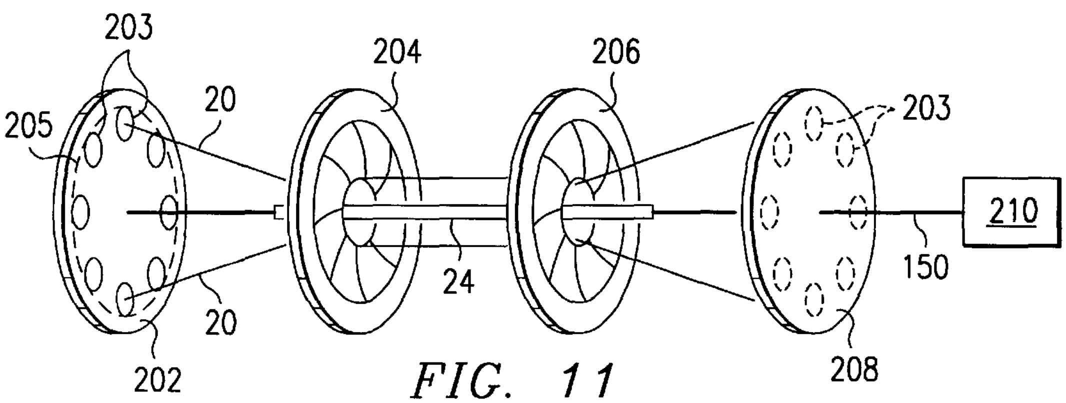


FIG. 11

IMPLANTABLE LEAD AND METHOD OF MANUFACTURE

BACKGROUND OF THE INVENTION

Implantable leads having ring electrodes can be used in a variety of applications, including delivery of electrical stimulation to surrounding tissue, neural or otherwise, as well as measuring electrical energy produced by such tissue. Whether serving in a stimulation capacity or a sensing capacity, such leads are commonly implanted along peripheral nerves, within the epidural or the intrathecal spaces of the spinal column, about the heart, and in the brain.

Notwithstanding the application, the common requirements for such implantable leads include flexibility, strength, and durability. The extent of such qualities, of course, is dependent upon the nature of the use, for example, temporary or permanent implantation. While material selection and certain construction techniques can be tailored to assist in meeting these prescribed characteristics, an overriding consideration in the design of such leads is achieving at least an isodiametric stimulation/pacing portion thereof.

The benefits of achieving desired levels of flexibility, strength, and durability are intuitive. The isodiametric characteristic is likely less obvious. Depending upon the application, an isodiametric lead can reduce the potential for damage to the lead during insertion (for example, when a lead is passed through an insertion needle to reach a patient epidural space) and/or placement, improve the ability of the lead to pass through tissue or a vascular system, and is more resistant to being immobilized by tissue growth at a permanent implantation site.

Differing techniques have been used to produce isodiametric leads. One such technique concerns adhering a plurality of elements (i.e., conductive electrodes, conductive terminals, and spacing insulative tubing material) to produce a generally integral body. Tubing material separates a stimulation/sensing portion (i.e., alternating insulative tubing material and electrodes) from a terminal portion (i.e., alternating insulative tubing material and terminals). The electrodes, terminals, and tubing are independently formed but are intended to be isodiametric. Understandably, dimension variances in any one element can result in a lead having a varying diameter.

Of further interest, to strengthen the plurality of element interfaces found in the stimulation/sensing portions and terminal portions of these leads, a composition, for example, medical grade epoxy, is injected within an interior of the leads in and about the stimulation/sensing portions and the terminal portions. While this technique does typically effect stabilization and strengthening of these critical regions, the end result can also be that these regions are too rigid and even brittle.

Other techniques include applying a ring electrode(s) about an exterior surface of insulative tubing that forms the main body of the lead. The insulative tubing may be prepared to receive the electrode, for example, milled to remove an amount of material substantially equal to the material thickness of the ring electrode. Alternatively, the insulative tubing may be unprepared, for example, a ring electrode is simply "crimped" to a diameter substantially equal to the otherwise unadulterated diameter of the tubing.

For all of the methods described above, a finished lead is still comprised of a plurality of independent components brought together in an effort to form an isodiametric cross-section. Element misalignment, inaccuracies in grinding, variances in electrode material thickness or individual ele-

ment dimensions, or over/under-crimping could respectively result in at least undesirable variances in lead diameter.

Accordingly, a need exists for a lead, as well as a method of fabricating such lead, that provides a requisite level of flexibility, strength, and durability, while further providing a true isodiametric body for at least the stimulation/sensing portion of the lead.

SUMMARY OF THE INVENTION

One aspect of the present invention is directed to an implantable lead including a lead body, having a distal end and a proximal end, whereas the lead body is formed of a material having prescribed mechanical properties. Extending from the distal end of the lead body, a first region includes a plurality of electrodes. A first insulative material, having mechanical properties consistent with the material of the lead body, separates adjacent electrodes. Extending from the proximal end of the lead body, a second region includes at least one terminal. A second insulative material, having mechanical properties consistent with the material of the lead body, separates adjacent terminals. A conductor couples each terminal to at least one corresponding electrode of the plurality of electrodes, wherein the conductor(s) extends along an interior passage defined by the lead body, first region, and second region. In addition to the at least one conductor, the interior passage of the first region is substantially filled with a third insulative material having mechanical properties consistent with the material of the lead body.

Another aspect of the present invention concerns a method of forming a substantially isodiametric lead. Specifically, such lead has a prescribed diameter and includes at least one electrode separated from at least one terminal by a lead body, wherein the at least one electrode is electrically coupled to the at least one terminal by a conductor passing through a passage defined by at least the lead body. The forming steps include assembling the at least one electrode and the at least one terminal relative to the lead body to form an assembly, including connecting the at least one electrode to the at least one terminal via the conductor. The assembly is subjected to an over-molding process that over molds the assembly with a first material to form an intermediate assembly. This first material is compatible with and has mechanical properties consistent with a material of the lead body. Ultimately, the intermediate assembly is processed to remove all material of the intermediate assembly in excess of the prescribed diameter.

An object of the present invention is to avoid the shortcomings of known leads and manufacturing techniques for the same.

Another object of the present invention is to provide a method of forming a lead having a true isodiametric body for at least the stimulation/sensing portion of the lead.

Another object of the present invention is to provide a lead having a true isodiametric body for at least the stimulation/sensing portion of the lead.

Another object of the present invention is to provide a lead having a low resistance from a terminal to a coupled electrode to reduce energy consumption during system operation.

Other aspects, objects, and advantages of the present invention will be apparent to those of ordinary skill in the art having reference to the following Specification together with the provided drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In reference to the following figures, like reference numerals and letters indicate corresponding elements:

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