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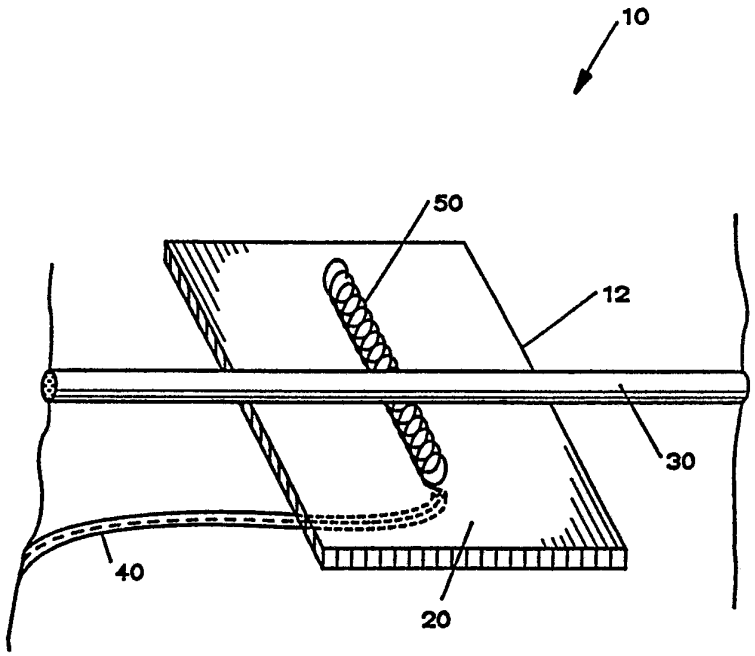
(54) Title: NERVE ELECTRODE WITH BIOLOGICAL SUBSTRATE



(57) Abstract

An electrode and method of making same characterized by a biological material used as a substrate. The electrode is used as a stimulation electrode, but could also be used to monitor electrical activity of neural tissues. The biological substrate is a chronically implantable material of treated human or animal tissue. The use of this material tends to prevent undue fibrosis and necrosis of the nerve tissue. An inner layer of a non-biological dielectric may be used to increase the resistivity of the structure. Similarly an inner layer of shielding material may also be used.

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NERVE ELECTRODE WITH BIOLOGICAL SUBSTRATE

CROSS REFERENCE TO RELATED APPLICATIONS

None.

BACKGROUND OF THE INVENTION

1. **Field of the Invention:** The present invention relates generally to electrode systems for stimulation or monitoring electrical activity in nerve tissue and more particularly relates to chronically implantable electrodes.

2. **Description of the Prior Art:** The use of electrodes to monitor electrical activity and stimulate body tissue is quite old. U.S. Patent No. 1,662,446 issued to R. H. Wappler teaches an early electrode system. The Wappler electrode is used for acute stimulation only, and is not implantable. An early stimulation electrode which is chronically implantable is taught by S. I. Schwartz, et al. in U.S. Patent No. 3,421,511. U.S. Patent No. 3,654,933 issued to Hagfors teaches an improved stimulation electrode for chronic implantation.

U.S. Patent No. 4,341,221 issued to Testerman teaches an improved electrode for chronic implantation. The Testerman electrode is suitable for monitoring electrical activity in nerve tissue. This electrode uses a substrate of silicone rubber or other material which is inert when chronically implanted. However, as with the other electrodes, the Testerman electrode does not prevent excess fibrotic growth.

SUMMARY OF THE INVENTION

The present invention produces a chronically implantable electrode suitable for stimulation or monitoring of electrical activity in nerve tissue. This electrode uses a substrate of biological tissue which has been properly treated to ensure long term resistance to excess fibrotic growth. An electrically conductive surface is attached to one side of the substrate. This side becomes the inside as the flexible

substrate is wrapped about the nerve to be monitored. The resistivity of the biological tissue is used to electrically insulate the exposed nerve tissue and electrically conductive surface in contact therewith. An electrically insulated conductor couples the electrically conductive surface with electronic circuitry.

For those applications requiring greater resistivity than the substrate can provide, additional layers can be added. Alternatively, a non-biological insulator of high dielectric constant can be interposed between two layers of the biologic material for increased resistivity.

A layer of a flexible conducting material may also be added between layers of the biological material to provide electrostatic and electromagnetic shielding. This shielding material may be grounded as necessary.

BRIEF DESCRIPTION OF THE DRAWINGS

Other features of the present invention and many of the attendant advantages will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

FIG. 1 is a plan view of an electrode of the present invention in position to be wrapped about a nerve;

FIG. 2 is a cross sectional cut away view of the layers of an alternate embodiment;

FIG. 3 is a cross sectional cut away view of the layers of a second alternative embodiment; and,

FIG. 4 is a plan view of an electrode of the present invention as chronically implanted.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is a plan view of an electrode 10 of the present

invention placed in proximity to a nerve 30. The electrode 10 has a substrate 12 to which is attached conductor 50 on one side 20. Conductor 50 is configured as a coil or other geometric shape which provides the desired surface area. Conductor 50 is electrically coupled to the distal end of insulated lead 40. The proximal end of lead 40 is coupled to electronic monitoring circuitry which is not shown.

Substrate 12 is of a sufficient size to conveniently wrap about nerve 30 with enough surface area to easily suture into place, without being so large as to be difficult to manage. Substrate 12 may be of a single layer as shown in this embodiment. It is made of a biological material which has been treated to enhance chronic implantability. A preferred material is porcine pericardium, although other biological materials may be used. The biological material is treated with a fixant such as glutaraldehyde.

The insulating properties of the resulting substrate 12 are moderate. Therefore, it may be desirable to use multiple layers of the biological material. A limitation of the use of such auxiliary layers is the desirability of a small and flexible substrate 12.

FIG. 2 is a cut away cross sectional view of an alternative embodiment of substrate 14. This embodiment provides greater resistivity with less bulk than can be achieved with multiple layers of biological material. In this embodiment, layers 22 and 24 are of the biological material. They are positioned on the exterior surfaces of substrate 14 to ensure that only the biological material is in contact with nerve 30 and other living body tissue.

Located between layers 22 and 24 is insulating material 26. This may be, without limitation, silicone rubber or other flexible material of high dielectric constant. Because insulating material 26 should be chosen of a chronically implantable material, it need not be covered at the edges by the biological material. However, it is desirable to cover

all of insulating material 26 to discourage any unnecessary fibrotic growth.

FIG. 3 is a cut away cross sectional view of a second alternative embodiment of substrate 16. Layers 22 and 24 are of the biological material as described in the embodiment of Fig. 2. Similarly, insulating layer 26 consists of the chronically implantable material of high dielectric constant of that embodiment. Layer 27 is a thin flexible metallic layer of a light conductive material. It is preferably of a biocompatible material, such as platinum, as a safety precaution. It also enables the substrate 16 to leave the edges of layer 27 uncovered by any of layers 22, 24, or 26 although it is desirable to do so as explained above. Layer 27 provides shielding of the electrical interface between nerve 30 and conductor 50. This shielding attenuates electrostatic and electromagnetic noise in the environment. Alternatively, layer 27 may be electrically coupled to ground as is appropriate.

FIG. 4 is a plan view of the electrode 10 as chronically implanted. This particular implantation technique is considered as representative only and should not be construed as limiting of the present invention. Those skilled in the art will readily be able to apply the present invention to other modes of implantation. Substrate 12 is wrapped about nerve 30 as shown. Permanent attachment is accomplished by creating excess flap 28 and applying sutures 29 as shown. The mechanical coupling of the distal end of insulating lead 40 to substrate 12 is sealed using medical adhesive 60.

Having thus described the preferred embodiments of the present invention, those of skill in the art will be readily able to apply the teachings found herein to other embodiments without departing from the scope of the claims hereto attached.

WE CLAIM:

1. An electrode comprising:

a. a substrate of a treated biological material;

b. a conducting surface attached to said substrate; and,

c. a lead electrically coupled to said conducting surface.

2. An electrode according to claim 1 wherein said substrate further comprises a plurality of layers of said treated biological material.

3. An electrode according to claim 2 wherein said substrate further comprises a layer of non-biological insulator of high dielectric constant located between said plurality of layers of said treated biological material.

4. An electrode according to claim 2 wherein said substrate further comprises a layer of shielding material located between said plurality of layers of said treated biological material.

5. An electrode according to claim 3 wherein said substrate further comprises a layer of shielding material located between said plurality of layers of said treated biological material.

6. A method of making an electrode comprising:

a. making a substrate by treating a biological material for chronic implantation;

b. attaching a conductor to a side of said substrate; and,

c. electrically coupling a lead to said conductor.

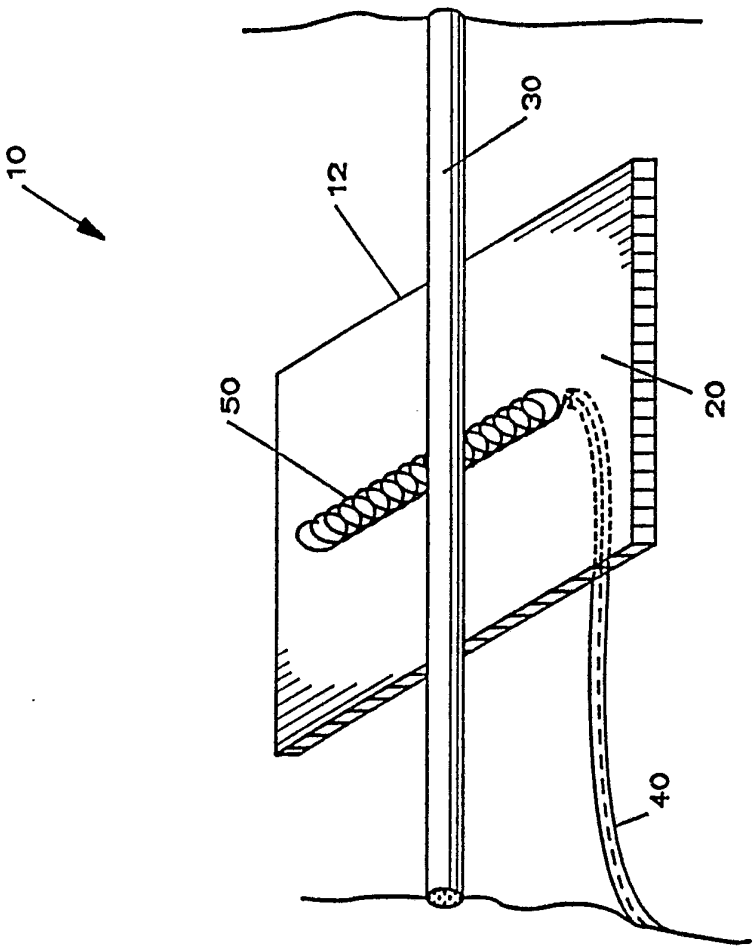

FIG. 1

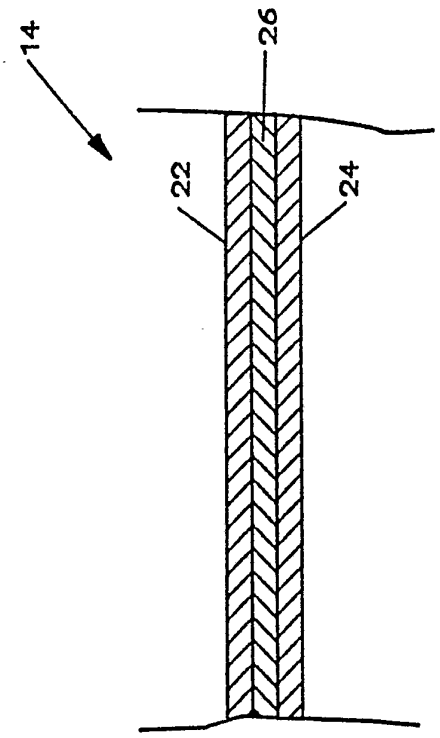

FIG. 2

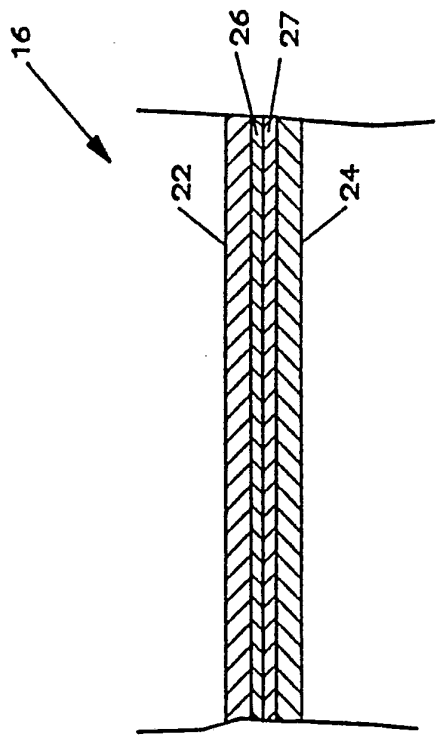

FIG. 3

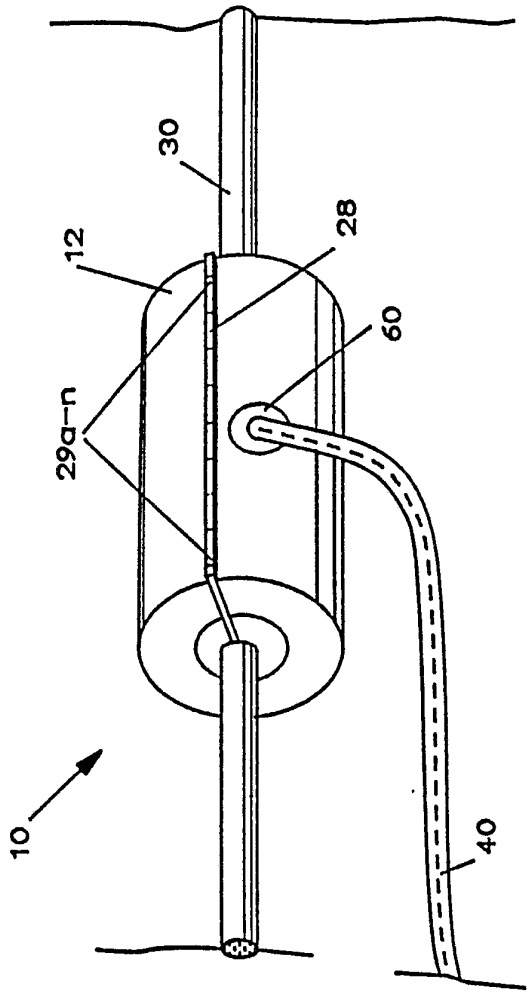

FIG. 4

INTERNATIONAL SEARCH REPORT

PCT/US 90/07089

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61N1/05

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61N ; A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X,.	US,A,4341221 (TESTERMAN) 27 July 1982 see column 1, line 32 (cited in the application)	1, 4-6
A	WO,A,8707825 (BYERS) 30 December 1987 see page 13, line 9 - page 15, line 2	1-3

° Special categories of cited documents :[10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
27 MARCH 1991	22.04.91
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	LEMERCIER D.L.L.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9007089
SA 43150

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4341221	27-07-82	None		
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		EP-A-	0272308	29-06-88
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