Jan. 14, 1969 S. I. SCHWARTZ ET AL 3,421,511

IMPLANTABLE ELECTRODE FOR NERVE STIMULATION

Filed Dec. 10, 1965 Sheet 1 of 2

FIG. 1

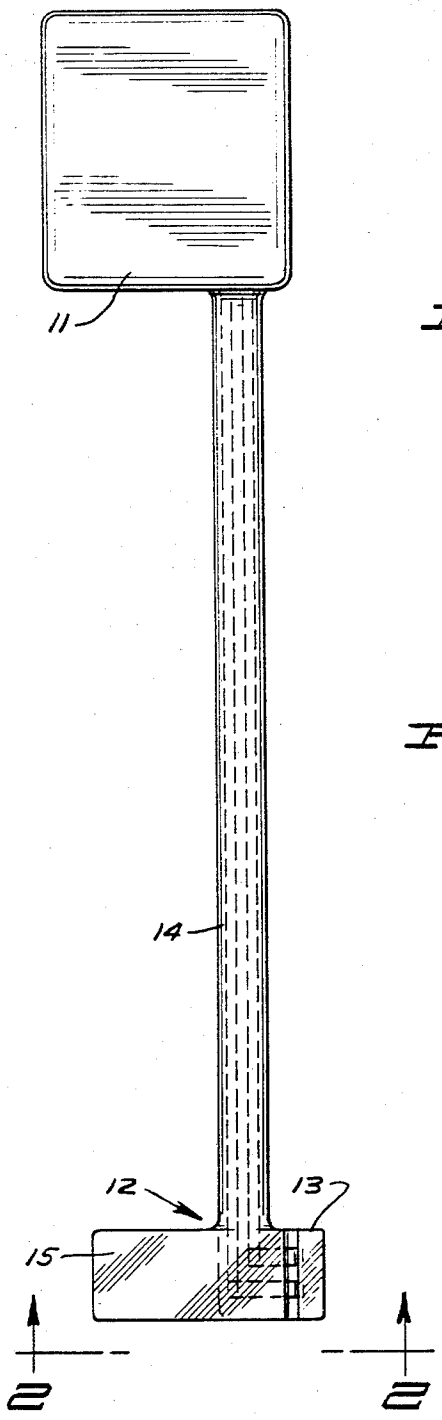


FIG. 2

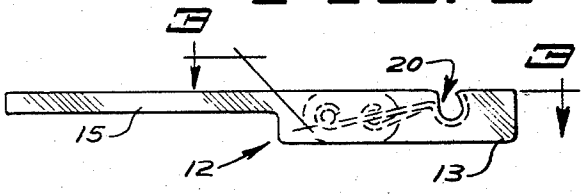


FIG. 3

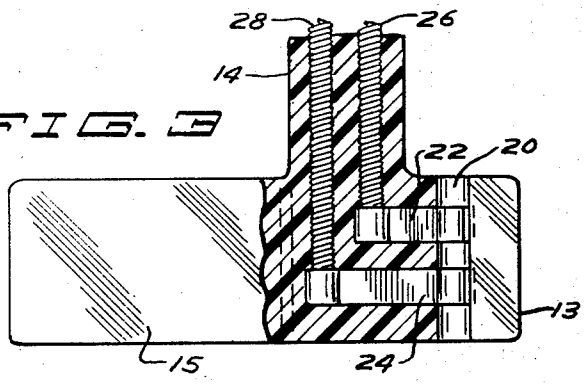
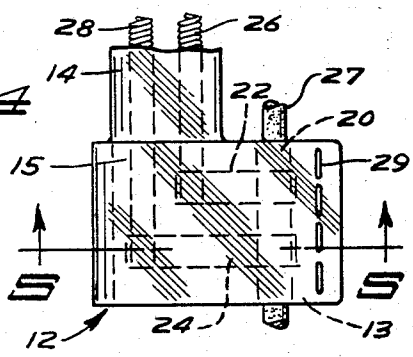


FIG. 4



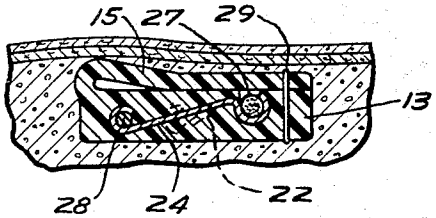


FIG. 5

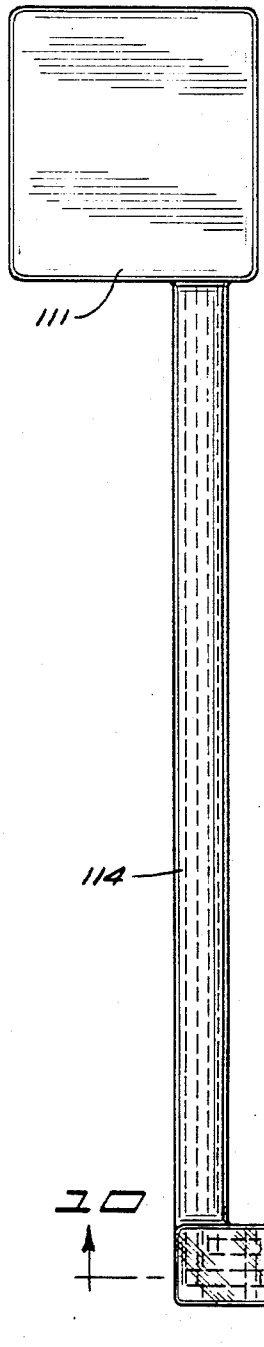
INVENTOR.
SEYMOUR I. SCHWARTZ
ROBERT C. WINGROVE
BY JAMES A. ANDERSON
Braddock+Burd
ATTORNEYS

Jan. 14, 1969 S. I. SCHWARTZ ET AL 3,421,511

IMPLANTABLE ELECTRODE FOR NERVE STIMULATION

Filed Dec. 10, 1965 Sheet 2 of 2

FIG. 6



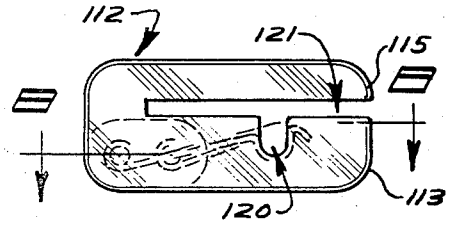


FIG. 7

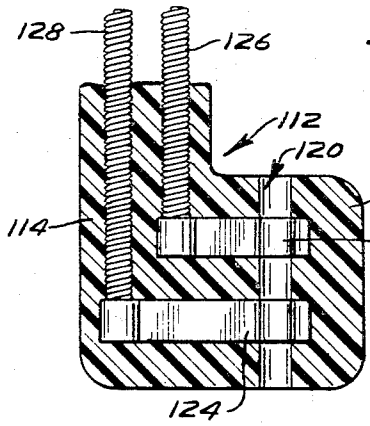


FIG. 8

FIG. 9

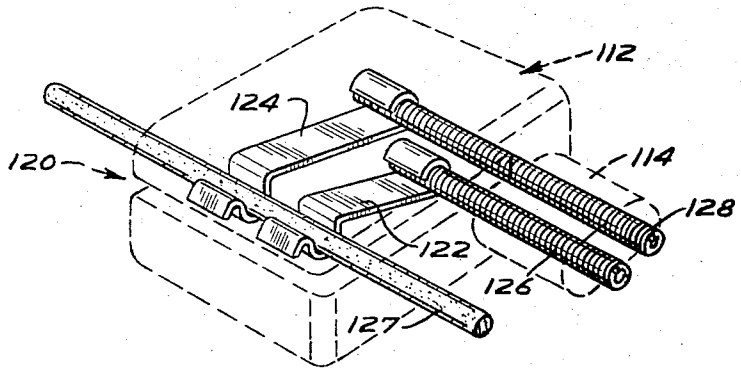
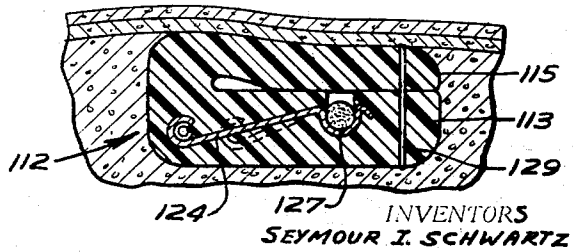


FIG. 10



INVENTORS
SEYMOUR I. SCHWARTZ
ROBERT C. WINGROVE
BY JAMES A. ANDERSON
Braddock+Burd
ATTORNEYS

United States Patent Office 3,421,511
Patented Jan. 14, 1969

3,421,511

IMPLANTABLE ELECTRODE FOR NERVE STIMULATION

Seymour I. Schwartz, Rochester, N.Y., Robert C. Wingrove, Minneapolis, Minn., and James A. Anderson, Burbank, Calif., assignors to Medtronic, Inc., Minneapolis, Minn., a corporation of Minnesota

Filed Dec. 10, 1965, Ser. No. 512,981
U.S. Cl. 128—418 2 Claims
Int. Cl. A61n 1/36

ABSTRACT OF THE DISCLOSURE

Electrode apparatus for connection to a nerve, having a pair of electrodes partially embedded within a substance inert to body fluids and tissue, the exposed portions of the electrodes lying in a groove generally conformed to the shape of the nerve for providing atraumatic egress of the nerve to the electrode, and including a further connected portion of the material inert to body food and tissue for covering the groove after the electrodes have been connected to space points on the nerve. Coiled leads are connected to the nerve, and are also encased in material inert to body foods and tissue.

This invention relates to medical apparatus, and more particularly to an implantable electrode for electrical stimulation of a single nerve within the body of an animal. The word animal is here used in its broad sense, including Homo sapiens.

Briefly described, the apparatus of this invention comprises a pair of electrodes almost entirely embedded within a substance, such as silicon rubber, which is inert to body fluids and tissue, and is thus suitable for implantation in the body of an animal. A pair of flexible leads are connected to the electrodes and may be used to connect the electrodes to an implanted or external source of electrical signal energy. The leads are also embedded in a substance which acts as an electrical insulator as well as being inert to body fluids and tissue. An exposed portion of each of the electrodes is formed to be connected to spaced points along a single nerve, to provide electrical stimulation of the nerve from the source of signal energy. The electrodes and the leads are also made of a material inert to body fluids and tissue, such as platinum or stainless steel. An extra member of the substance is provided, such as a flap, for tying down over the electrodes after they have been connected to the nerve.

The need for the apparatus of this invention is apparent upon consideration of such modern medical equipment as the carotid sinus nerve stimulator fully described in a co-pending application by Seymour I. Schwartz and Robert C. Wingrove, Ser. No. 397,899, entitled "Implantable Stimulator for Reducing Blood Pressure in Hypertensive Persons." In this co-pending application there is described the use of an implantable, artificial nerve stimulator, which provides electrical impulses for stimulation of the carotid sinus nerve to alleviate the problems of hypertensive animals.

Electrical impulses for major organs of the body of an animal may be transmitted to that organ by means of pointed electrodes which penetrate the body of the organ and indirectly make contact with a nerve network without damaging the organ. Such general stimulation is not effective where the impulse must be superimposed on one particular nerve and that nerve alone. The present structure is designed to allow transmission of an electrical impulse specifically and solely to a selected nerve, such as the carotid sinus nerve or the vagus nerve, by way of example.

In the drawings,

FIG. 1 is a view of a first embodiment of the invention as may be used with an implantable source of electrical signal energy;

FIG. 2 is a sectional view of FIG. 1 taken along the line 2—2 and showing a hinged flap which may be fastened over a nerve connected to the electrodes;

FIG. 3 is a sectional view of FIG. 2 taken along the line 3—3;

FIG. 4 is a plan view of the first embodiment of this invention showing the flap fastened over the electrodes connected to a nerve;

FIG. 5 is a sectional view of FIG. 4 taken along the line 5—5;

FIG. 6 is a view of a second embodiment of this invention also connected to the implantable source of electrical signal energy;

FIG. 7 is a sectional side view of the second embodiment of this invention showing the head of the second embodiment having a slot forming an upper and lower layer;

FIG. 8 is a sectional view of FIG. 7 taken along the line 8—8;

FIG. 9 is a perspective view of the second embodiment of this invention; and

FIG. 10 is a sectional view of the drawing of FIG. 6 taken along the line 10—10.

FIG. 1 discloses a first embodiment of this invention having a head indicated generally at **12**, including an electrode carrying member **13** and a flap member **15**. A lead carrying member or tail **14** is connected to head **12**. Tail **14** is also shown connected to an implantable source of electrical signal energy **11**.

FIG. 2 is a side view of head **12** showing a groove **20** in member **13**, and showing flap **15** folded over and connected to member **13**.

FIG. 3 discloses a pair of electrodes **22** and **24** partially encapsulated in member **13** and formed into the groove **20**. A pair of leads **26** and **28**, here shown as coiled lengths of an electrically conductive material, are connected, respectively, to electrodes **22** and **24**. Leads **26** and **28** are also encapsulated in the substance of tail **14**.

FIG. 4 discloses electrodes **22** and **24** connected to spaced points along a nerve **27** in groove **20**. Flap **15** is shown folded over to cover and thus insulate electrodes **22** and **24** and nerve **27** in groove **20**. Flap **15** is fastened to member **13** by use of sutures **29**.

FIG. 5 also discloses the nerve **27** as covered over by the flap **15** fastened to member **13** by sutures **29**.

FIG. 6 discloses a second embodiment of this invention having a head indicated generally at **112**, a tail **114** connected to head **112** and also connected to a source of electrical signal energy **111**.

FIG. 7 is a side view of head **112** disclosing a slot **121** cut in head **112** to form an upper layer **115** and a lower layer **113**. A groove **120** is shown in lower layer **113**.

FIG. 8 discloses a pair of electrodes **122** and **124** partially encapsulated in the substance of lower layer **113**, and partially formed to groove **120**. A pair of leads **126** and **128**, here shown as coiled lengths of an electrically conductive material, are connected, respectively, to electrodes **122** and **124**. Leads **126** and **128** are encapsulated in the substance of tail **114**.

FIG. 9 is a perspective view which discloses electrodes **122** and **124** connected to spaced points along the length of a nerve **127**.

FIG. 10 again shows nerve **127** within the groove **120** with upper layer **115** fastened to lower layer **113** by sutures **129**.

Since this invention comprises electrodes which are to be implanted within the body of an animal, it is necessary that the substance which comprises head **12** and **112** and

tail **14** and **114**, be inert to body fluids and tissue. Such a substance which has been successfully used is silicon rubber. It is also necessary that electrodes **22** and **24**, and **112** and **124**, which must connect directly to the outer wall of a nerve **27** or **127**, be of a material inert to body fluids and tissue and be not harmful to the outer wall of the nerve to which they are attached. Such a material which has been successfully used is platinum. Another material which may also be used is stainless steel. Leads **26** and **28**, and **126** and **128** must also be of a material inert to body fluids and tissue. It may be desirable, but is not mandatory that leads **26** and **28**, and **126** and **128**, be of the same material as electrodes **22** and **24**, and **122** and **124**.

The leads in the embodiments here shown are disclosed as being coiled lengths of a material, to facilitate ease of flexibility. This has proven to be a highly desirable type of lead structure, but it is not intended that this entire invention be limited to such a lead structure.

While it is necessary that a portion of electrodes **22** and **24**, and **122** and **124**, not be encapsulated in the substance of head **12** so that the electrodes may be connected to nerve **27** or **127**, it is highly undesirable to leave the electrodes exposed after connection to the nerve. To overcome this problem the embodiments of this invention provide either a flap **15** or an upper layer **115**. As shown in FIGS. 4 and 5, flap **15** may be folded over to cover electrodes **22** and **24** when they are connected to nerve **27**. Flap **15** is then fastened to member **13**, such as by sutures **29**. As shown in FIGS. 7, 9 and 10, upper layer **115** is separated from lower layer **113** only by the width of slot **121**. When electrodes **122** and **124** have been connected to nerve **127**, upper layer **115** may be fastened down upon them by means such as sutures **29**.

Groove **20** in member **13**, and groove **120** in lower layer **113**, are shaped generally to the configuration of nerves **27** and **127**, respectively, and also facilitate firm fastening and insulation of the connection of the electrodes to the nerves.

The sources of electrical signal energy **11** and **111**, shown in FIGS. 1 and 6, respectively, may be transistorized blocking oscillators powered by long life rechangeable batteries, which provide pulses at a predetermined frequency to the nerves **27** and **127**, respectively. Though the sources **11** and **111** shown here are implantable, that is, are encapsulated in a substance inert to body fluids and tissue for implantation in the body of an animal, it is not mandatory that the electrode apparatus of this invention be used with an implantable source of electrical signal energy. The tails **14** and **114**, including leads **26** and **28**, and **126** and **128**, respectively, may extend from within the body to a point external to the body, and be connected to any one of a number of sources of electrical signal energy. Also, the leads may extend to a circuit implanted in the body but powered from a source external to the body.

The electrode apparatus of this invention has been successfully implanted in a human being, and shown to be fully operable in providing electrical impulse stimulation to a carotid sinus nerve in one case and to a vagus nerve in a second case. In the various embodiments successfully used, silicon rubber was used as the substance to encapsulate the leads and electrodes. In at least one such embodiment the electrodes were made of platinum, while the leads were made of coiled lengths of stainless steel.

It is apparent from the foregoing description that the apparatus of this invention provides a noved structure for connection of a source of signal energy to a single nerve, to provide artificial stimulation of that nerve by timed electrical impulses from the source of signal energy. Further, the apparatus of this invention has been used and has been successful in alleviating medical problems of human beings.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. Electrode apparatus implantable in the body of an animal for stimulation of a single nerve comprising:

a housing of an electrically insulating substance substantially inert to body fluids and tissue, said housing having a head and a tail extending therefrom;

a slot in said head dividing a part of said head into an upper layer and a lower layer;

a groove in said lower layer adjacent said slot;

a pair of electrodes of an electrically conductive material substantially inert to body fluids and tissue, and encased in said head of said housing in spaced relation to one another;

a portion of each of said pair of electrodes formed to and fitted in said groove, said portions adapted to be connected to spaced points on a single nerve in the body of an animal;

said upper layer of said housing adapted to be fastened to said lower layer to hold and shield the single nerve in contact with said pair of electrodes;

a pair of leads of said material encased in said tail of said housing; and

each of said pair of leads connected to a different one of said pair of electrodes, for connecting said pair of electrodes to a source of signal energy for stimulating the single nerve.

2. Medical apparatus for implantation into the body of an animal comprising:

first and second electrodes of an electrically conductive material substantially inert to body fluids and tissue;

first and second leads of said material connected, respectively, to said first and second electrodes, and adapted to be connected to a source of electrical signal energy;

a first portion of said first and second electrodes and said first and second leads being encapsulated in a housing of an electrically insulating substance substantially inert to body fluids and tissue;

a second portion of said first and second electrodes adapted to be connected to spaced points along a single nerve in the body of an animal, for stimulation of the single nerve upon receipt of a signal from the source of signal energy; and

a further member of said substance flexibly connected to said housing for fastening over said second portion of said first and second electrodes when connected to the single nerve.

References Cited

UNITED STATES PATENTS

3,157,181	11/1964	McCarty	128—404
3,216,424	11/1965	Chardack	128—418

WILLIAM E. KAMM, *Primary Examiner.*