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Avery et al.

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[54] **ELECTRODE IMPLANT FOR THE NEURO-STIMULATION OF THE SPINAL CORD**

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[22] Filed: **Apr. 23, 1971**

[21] Appl. No.: **136,924**

[52] **U.S. Cl.** .....**128/418**, 128/419 R

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

[58] **Field of Search**.....128/2.06 E, 2.1 E, 404, 410, 128/411, 416, 417, 418, 419 C, 419 E, 419 R, DIG. 4

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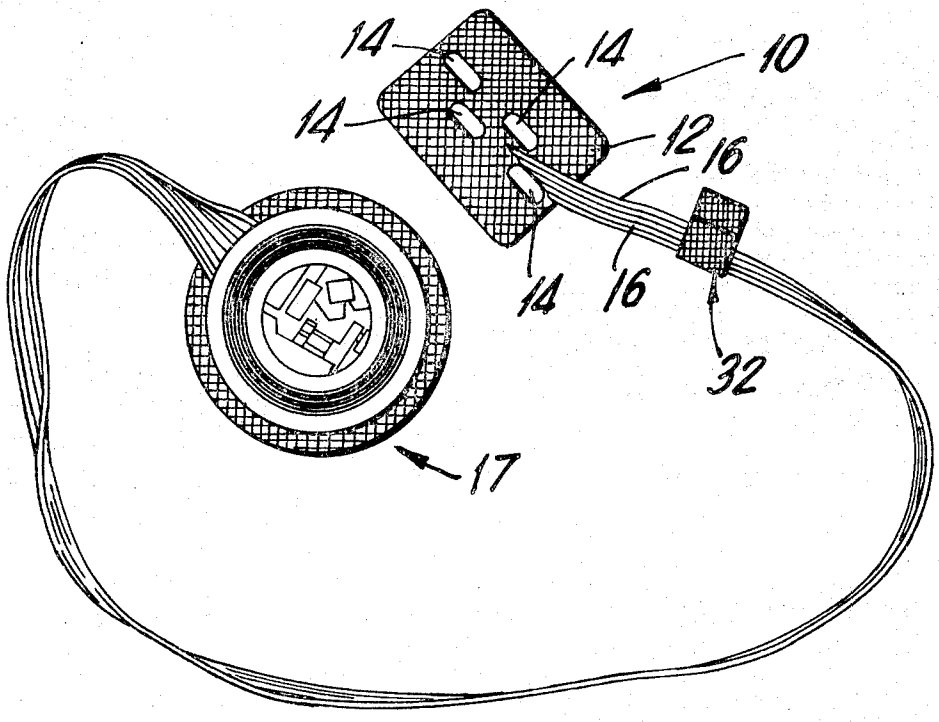
Attorney—Leonard H. King

[57] **ABSTRACT**

An improved implantable device for electrically stimulating a selected portion of the spinal cord is provided. A relatively thin and flexible strip of physiologically inert plastic is provided with a plurality of electrodes. Lead wires that are also encapsulated in the same physiologically inert plastic material are secured to the electrodes and extend therefrom at approximately the same angle as the spine's posterior process. A packing gland may be positioned about the lead wires to the electrodes to minimize leakage of spinal fluids.

11 Claims, 8 Drawing Figures



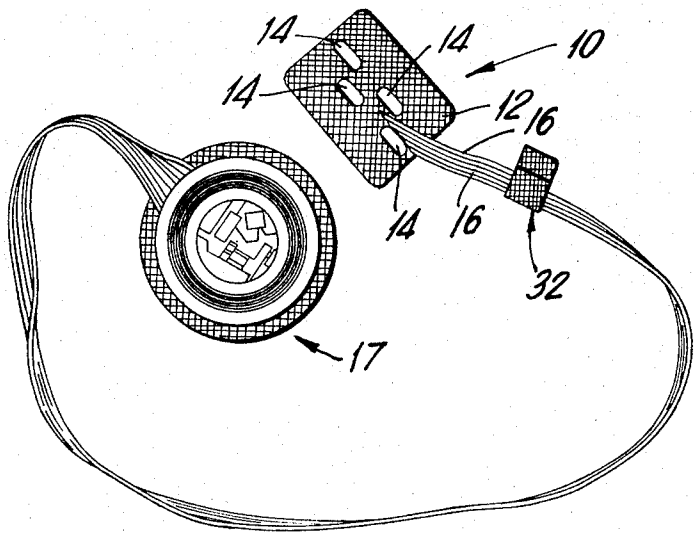


FIG. 1

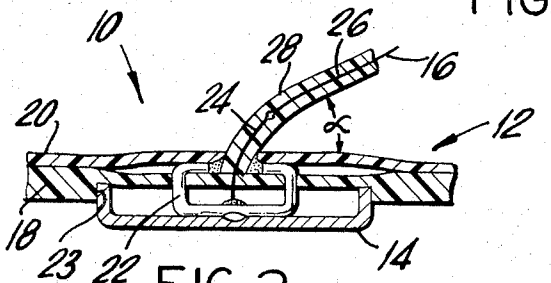


FIG. 2

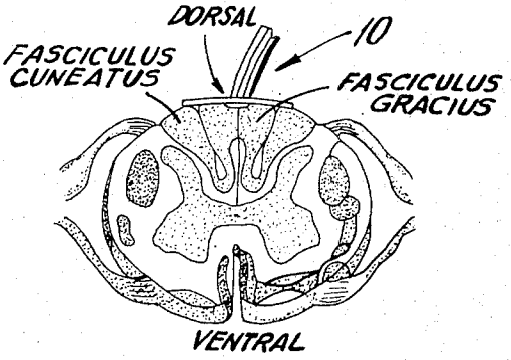


FIG. 3

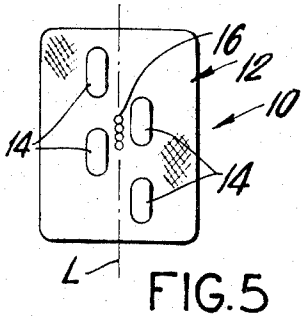


FIG. 5

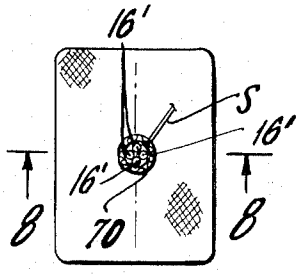


FIG. 7

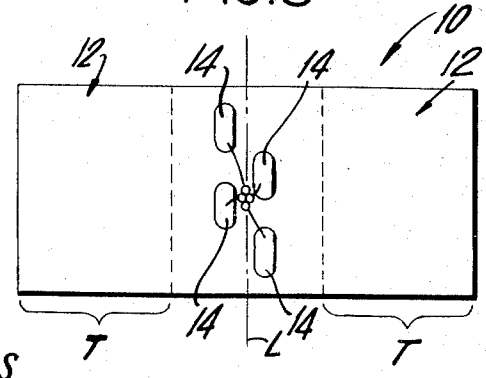


FIG. 4

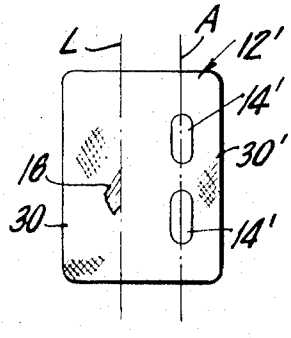


FIG. 6

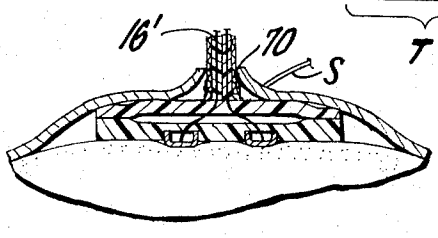


FIG. 8

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ELECTRODE IMPLANT FOR THE NEURO-STIMULATION OF THE SPINAL CORD

The aforementioned Abstract is neither intended to define the invention of the application which, of course, is measured by the claims, nor is it intended to be limiting as to the scope of the invention in any way.

This invention relates generally to neuro-stimulating implants and more particularly to an implant for electrical connection to the spinal cord.

BACKGROUND OF THE INVENTION

Neuro-stimulation has been applied to patients with severe pain states that are not relieved by traditional procedures and who require large doses of narcotics to control pain. After the first several implantations, it has become clear that those patients with some form of partial peripheral nerve injury resulting in "traumatic neuropathy" and who display the phenomenon of hyperpathia seem to respond most favorably to stimulation of the appropriate nerve. Similarly, patients with dysesthesias related to spinal cord dysfunction seem to respond best to stimulation of the dorsal column.

Implantable electrodes which have been used in the past to stimulate a portion of the spinal cord have been characterized by relatively large bulk. Normally the implant is sutured into place beneath the dura. However, with the prior art devices considerable pressure was thereby applied to the spinal cord. Further, the prior art devices of this class attempted to stimulate both the left and right-hand portions of the dorsal side of the spinal cord simultaneously.

The early use of the prior art implants proved to have several disadvantages in that they were too cumbersome and large to be placed neatly under the dura without causing undue pressure. The earliest models had to be removed due to the fact that they stressed the spinal cord so much that the patient became partly paralyzed in the lower extremity.

Another difficulty of the prior art structure was that the stimulation of the spinal cord was impeded or, in some cases, cut off entirely due to dislocation of the electrode from the cord caused by stretching and twisting of the torso.

The present invention overcomes the shortcomings of the prior art by using a relatively thin and flexible strip of physiologically inert plastic, such as Dacron reinforced silicone rubber. A plurality of electrodes are imbedded in two layers of the plastic material. The conductive leads, encapsulated in the physiologically inert plastic material, are electrically coupled into the electrodes and extend therefrom at an angle that is closely aligned to the spine's posterior process angle. In addition, construction of the present invention further minimizes the likelihood that the motion of the back or the muscles surrounding the implant will pull the electrodes away from the spinal cord and cause a cessation of stimulation by providing a physiologically inert plastic tie down clamp for the leads.

Accordingly, it is a primary object of the present invention to provide an improved neuro-stimulating implantable device.

It is another object of the present invention to provide an improved implantable device, particularly for the spinal cord, that will minimize the likelihood of the electrodes being detached or spaced inadvertently from the spinal cord as a result of movement of the patient.

It is a particular object of the present invention to provide an improved implantable device, as described above, wherein the leads that are coupled to the electrode are disposed at an angle substantially aligned with the spine's posterior process angle.

These and other objects, features and advantages of the invention will, in part, be pointed out with particularlity and will, in part, become obvious from the following more detailed description of the invention, taken in conjunction with the accompanying drawings, which form an integral part thereof.

BRIEF DESCRIPTION OF THE DRAWING

In the drawing:

FIG. 1 is a perspective view of an improved implantable nerve stimulating device fabricated in accordance with the teachings of the present invention;

FIG. 2 is an enlarged side elevational sectional view of the device shown in FIG. 1;

FIG. 3 is a cross-sectional view schematically illustrating the spinal column of a human being together with the present invention positioned thereon;

FIG. 4 is a schematic plan view illustrating another feature of the invention;

FIG. 5 is a plan view of a neuro-stimulating implantable device, as described above, with the leads removed in order to illustrate the relative position of the plurality of electrodes;

FIG. 6 is a plan view of an alternative embodiment of the present invention;

FIG. 7 is a plan view of an alternative lead arrangement; and

FIG. 8 is a cross-sectional elevational view taken along line 8—8 of FIG. 7.

Referring now to the drawings, and in particular to FIG. 1, there is shown an implantable device comprising the present invention. The neuro-stimulating implant **10** is comprised of a physiologically inert plastic body portion **12** fabricated from a material such as Dacron reinforced silicone rubber. A plurality of electrodes **14** are imbedded in the body portion **12** and a plurality of electrically conductive lead means **16** are suitably coupled to the electrodes **14**. As is well known in the art, the lead means **16** may be electrically coupled to an RF receiver **17** that may be remotely implanted.

Referring particularly to FIG. 2, it will be seen that the body portion **12** of the spinal cord implant **10** is comprised of first and second layers **18** and **20** of a physiologically inert plastic material such as that mentioned above, the layers **18** and **20** being suitably secured to each other, such as by heat sealing or the like. The electrodes **14**, which preferably are made of platinum, are secured to the plastic layer **18** by means of a platinum staple **22** that is welded to the electrode **14** and crimped about the plastic layer **18**. After crimping, the second plastic layer **20** is sealed to the first plastic layer **18**. It should be noted that the lead means **16** are comprised of a first platinum section **24** that is welded to the staple **22** and a second stainless steel section **26** that is welded to the platinum lead section **24**. A physiologically inert plastic material, such as described above, is used as a sleeve **28** about the lead means **16**.

FIG. 2 also illustrates a very important feature of the present invention. It will be noted that lead means **16**,

which are encased in the plastic sleeve **28**, are positioned at an angle α with respect to the plane of the body portion **12**. It has been found that molding the plastic sleeve at an angle that approximates the angle of the spinal process minimizes the likelihood of the implant being displaced away from the spinal cord due to movement of the patient's torso or stretching of the muscles. An acceptable average angle has been found to be within the angle of 15° to 45°, preferably about 30°.

Referring now to FIG. **3** which is a transverse cross-section of a typical spinal column, there is shown the implant **10** positioned on the dorsal side. It will be readily appreciated that the implant **10** can be laterally shifted or positioned to contact either the fasciculus cuneatus, the fasiculus gracilis, or both.

As shown in FIG. **4**, it is preferable that the lead means **16** are centered and that the body portion **12** extends on opposite sides of the longitudinal axis L and on opposite sides of the electrodes **14** for a distance that is somewhat greater than is actually required. Thus the surgeon may laterally shift the implant **10** to the optimum position and, after trimming away the unnecessary sections which are schematically designated as T, still have enough reinforced plastic material to apply sutures.

In one embodiment of this invention, as shown, for example, in FIG. **1**, strain relief tie down means **32** are provided. The tie down means **32** is comprised of a strip of physiologically inert plastic material similar to the body portion **12**. The strip **32** is wrapped around the lead means **16** remote from the body portion **12** and is then sutured in place. In this manner, the forces that are applied to the lead means **16** as a result of the patient moving his torso will not be transmitted to the body portion **12**.

FIG. **5** shows a preferred pattern for the electrodes **14**. It will be noted that the electrodes **14** are relatively close together and grouped about the longitudinal axis L of the implant **10**. This has been found to be preferable for bilateral spinal cord implants. In this instance the leads **16** are shown in a single row so that the dura need be spread only slightly to permit their exit.

An alternative embodiment of the present invention for placement on the spinal cord is illustrated in FIG.**6**. The electrodes **14'** are mounted on the body portion **12'**, as described above, but in tandem and on one side thereof. This construction provides means to stimulate only one side of the spinal cord. By way of example, the embodiment illustrated in FIG. **6** is in practice, 20 mm. from top to bottom and **15** mm. from the left edge to the right edge. The right-hand side of the electrodes **14** are spaced approximately 3½ mm. from the right-hand edge of the plastic body portion **12'**.

It will be noted that electrodes **14'** are off center with respect to the center line L on which the lead **16** extends. Thus it will be appreciated that although contact is made to the spinal cord along line A, the leads **16** are taken off the center of the dorsal column at line L, and yet there is enough material at portions **30** and **30'** to permit suturing.

It is important to minimize the size of the exiting lead length to minimize the cerebral spinal fluid leak from the dural incision. An alternative arrangement is shown in FIGS. **7** and **8** where the exiting leads **16'** are grouped within the minimum circumscribing circle. The lead sheaths have bonded to their surface for about three-eighths inch of their length fine fibers in the form of a felt which acts as a packing gland **70**. The surgeon gathers the dura about the "packing gland" employing a purse stitch S. The Dacron felt is receptive to the growth of tissue so that ultimately a non-porous seal is formed for the cerebral spinal fluids.

It has been found that the plastic sheet should be provided with recesses **23** as shown in FIG. **2** for receiving the cupped contact member. This is accomplished by molding the sheet between suitably shaped platens. Such molding techniques are well known and do not require further amplification. This arrangement serves to fix the contact element against rotation and also covers the sharp edge of the sheet metal contact button.

From the foregoing, it will be appreciated that an improved implant, particularly for the spinal cord, has been provided. By positioning the lead wires at an angle that corresponds with the angle of the spinal posterior process, the likelihood of inadvertent displacement of the implant by virtue of the movement of the patient's torso or flexing of the muscles is substantially minimized.

There has been disclosed heretofore the best embodiment of the invention presently contemplated. However, it is to be understood that various changes and modifications may be made by those skilled in the art without departing from the spirit of the invention.

What we claim as new and desire to secure by Letters Patent is:

1. An improved implant for the electrical stimulation of selected portions of the spinal cord of a human being, said implant comprising a relatively thin, physiologically inert plastic body portion having upper and lower surfaces, said body portion being substantially flat and sufficiently flexible so as to conform to the shape of the surface of the spinal column of a human being, a plurality of metallic electrodes secured to said body portion of said implant, said electrodes being adapted to be placed in contact with a selected portion of the spinal column of a human being, the contact surface of said electrodes being in a plane that is outward of the plane of said lower surface of said body portion of said implant and lead means coupled to said electrodes, said lead means being positioned at an angle of between 15° to forty-five degrees with respect to the plane of said body portion to thereby approximate the angle of the spine's posterior process for minimizing the likelihood of pulling the implant away from the spinal cord due to motion of the human's back or the muscles surrounding said implant, said lead means extending from said upper surface of said body portion opposed to said electrodes.

2. The implant in accordance with claim **1** wherein said angle is thirty degrees.

3. The implant in accordance with claim **1**, wherein said body portion extends laterally beyond said electrodes in at least one direction for defining an extension that is trimmable after said implant final location is determined.

4. The implant in accordance with claim **3** wherein said body portion extends laterally in two opposite directions beyond said electrodes.

5. The implant in accordance with claim 1 wherein said electrodes are arrayed in an alternating pattern on opposite sides of a longitudinal line defined by the juncture of said lead means and said body portion.

6. The implant in accordance with claim 1 wherein said electrodes are arrayed along a linear path that is laterally spaced from and substantially parallel to a longitudinal line defined by the juncture of said lead means and said body portion.

7. The implant in accordance with claim 1 wherein there is further included a recess in said body portion for receiving each of said electrodes.

8. An improved implant for the electrical stimulation of selected portions of the spinal cord, said implant comprising a physiologically inert plastic body portion, a plurality of metallic electrodes secured to said body portion, lead means coupled to said electrodes,said lead means being positioned at an angle of between 15° to 45° with respect to the plane of said body portion and strain relieving means comprising a physiologically inert strip wrapped around said lead means remotely from said body portion of said implant, said strain relieving means being adapted to be sutured in said remote location.

9. An improved implant for the electrical stimulation of selected portions of the spinal cord, said implant comprising a physiologically inert plastic body portion, a plurality of metallic electrodes secured to said body portion, lead means coupled to said electrodes, and strain relieving means comprising a physiologically inert strip wrapped around said lead means remotely from said body portion of said implant, said strain relieving means being adapted to be sutured in said remote location.

10. An improved implant for the electrical stimulation of selected portions of the spinal cord, said implant comprising a physiologically inert plastic body portion, a plurality of metallic electrodes secured to said body portion, lead means coupled to said electrodes, said lead means being positioned at an angle of between 15° to 45° with respect to the plane of said body portion of said implant and a packing gland surrounding said lead means at a position proximate said body portion of said implant for minimizing leakage of cerebral spinal fluid, said packing gland being comprised of a plurality of fibers bonded to said lead means.

11. An improved implant for the electrical stimulation of selected portions of the spinal cord, said implant comprising a physiologically inert plastic body portion, a plurality of metallic electrodes secured to said body portion and a packing gland surrounding said lead means at a position proximate said body portion of said implant for minimizing leakage of cerebral spinal fluid, said packing gland comprising a plurality of fibers bonded to said lead means.

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