

[54] **IMPLANTABLE NERVE STIMULATION ELECTRODE**

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Related U.S. Application Data

[63] Continuation of Ser. No. 46,085, June 15, 1970, abandoned.

[52] U.S. Cl. 128/418

[51] Int. Cl. A61n 1/04

[58] Field of Search..... 128/2.06 E, 2.1 E, 128/404, 410, 411, 416, 418, 419 C, 419 E, 419 P, DIG. 4, 2.05 F

References Cited

UNITED STATES PATENTS

[56] 3,654,933 4/1972 Hagfors..... 128/418

3,605,726	9/1971	Williams et al.....	128/2.05 F
2,943,628	7/1960	Howell.....	128/418
3,244,174	4/1966	Wesley et al.	128/418
2,047,308	7/1936	Chapman.....	128/418

OTHER PUBLICATIONS

Schaudinischky et al., "Medical & Biological Engineering," Vol. 7, pp. 341-343, 1969

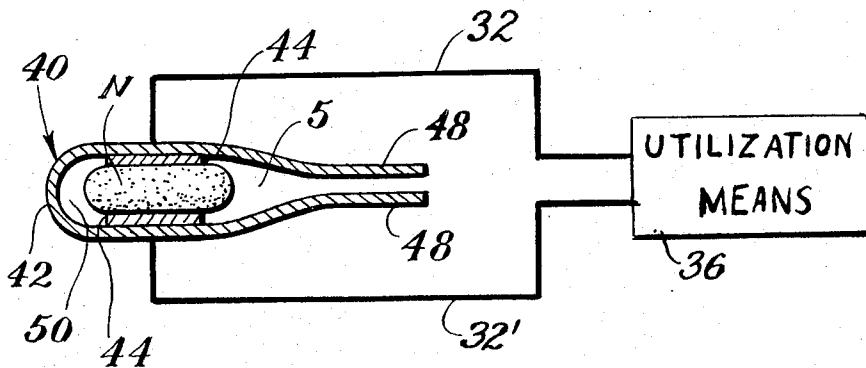
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ABSTRACT

[57] A relatively thin and flexible strip of inert plastic having electrodes and lead wires encapsulated therein is provided for implantation about a single nerve so that electrical stimuli may be applied thereto.

26 Claims, 13 Drawing Figures



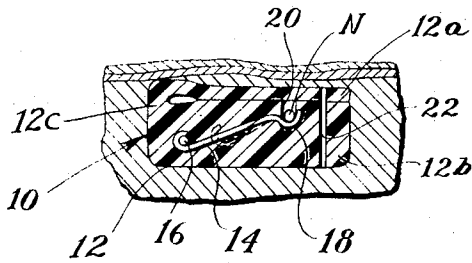


FIG. 1
(PRIOR ART)

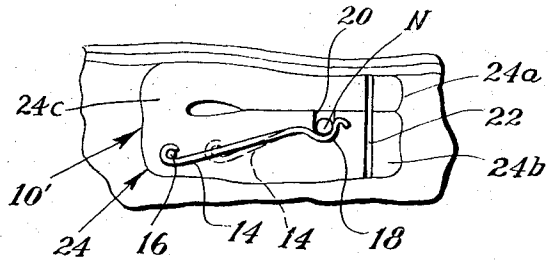


FIG. 2
(PRIOR ART)

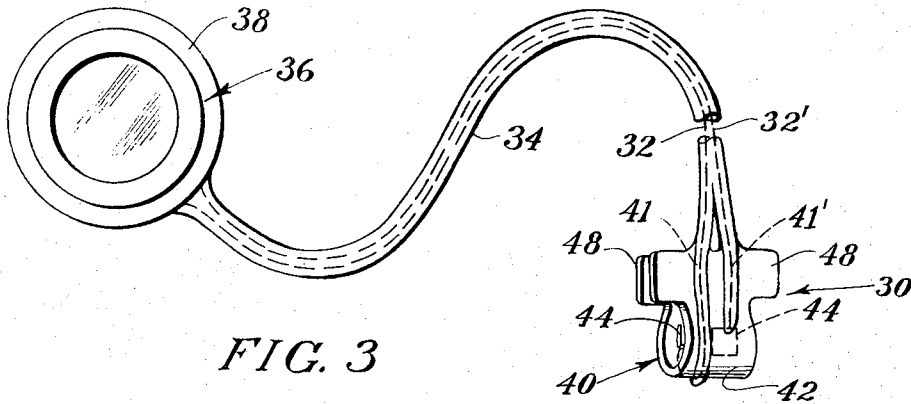


FIG. 3

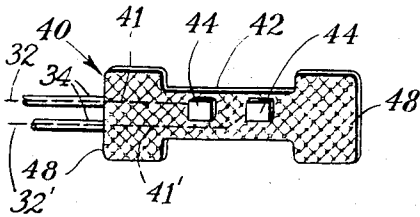


FIG. 4

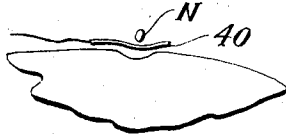


FIG. 5

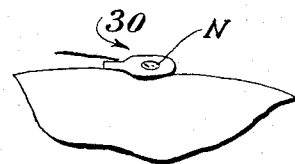


FIG. 6

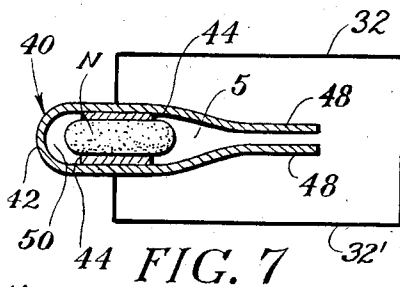


FIG. 7

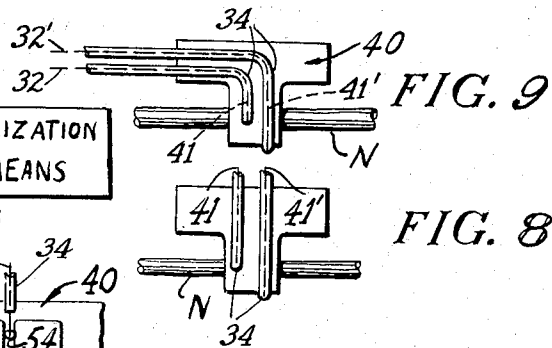


FIG. 8

FIG. 9

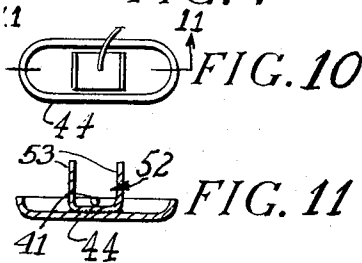


FIG. 10

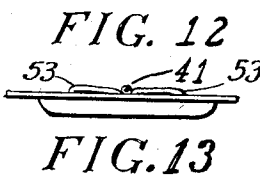


FIG. 12

FIG. 13

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IMPLANTABLE NERVE STIMULATION ELECTRODE

This is a continuation, of application Ser. No. 46,085 filed June 15, 1970, now abandoned.

This invention relates generally to the medical arts and more particularly to an improved device for electrically stimulating a single nerve.

BACKGROUND OF THE INVENTION

There are many different types of therapy that require surgical procedures wherein electrodes are implanted in the body for stimulating a selected nerve. Pain inhibition is an example of application wherein devices of the type that will subsequently be described are a particularly advantageous tool. A source of power electrically coupled to the electrode may also be implanted or an external source of power may be utilized. Regardless of the techniques that are used, it is absolutely essential that the body be able to tolerate the foreign object for extended periods of time.

U.S. Pat. No. 3,421,511, granted on June 14, 1969, to S. I. Schwartz et al. discloses the general type of device to which the present application is directed. A pair of arcuately formed electrodes are encapsulated within the relatively large block of an inert plastic. The nerve to be stimulated is deposited in the arcuate electrodes and an integral plastic flap is folded over the exposed nerve. Coiled lead wires that are similarly encased by the inert plastic couple the electrodes to a source of electrical signal energy.

While the foregoing patent does make a substantial contribution to the arts it still has some inherent shortcomings that limit its application. For example, the mass in which the electrodes are imbedded is relatively large. Accordingly, it is very difficult for the surgeon to slip the mass underneath the isolated nerve without introducing trauma. In practice it has been recognized that manipulation will inevitably result in trauma to the nerve. In some procedures the surgeon actually shakes the exposed nerve to induce trauma and thereby cancel out the effect of neuralgia.

Another serious shortcoming of the prior art device is the use of electrodes formed in an arcuate shape in transverse cross-section. Generally speaking many nerves are oval in transverse cross-section and not circular. Thus, in addition to requiring a more bulky mass for support purposes, the prior art structure may very well induce trauma by forcing the nerve to conform to the arcuate shape of the electrode. In this connection it will also be pointed out hereinafter that the prior art does not provide sufficient space about the nerve in the vicinity of the electrodes to permit the flow and circulation of nutrient bearing fluids.

The present invention overcomes the shortcomings of the prior art in a very efficient manner. A pair of substantially flat electrodes are secured to a surface of a relatively thin strip of a Dacron mesh reinforced silicone rubber strip. Each of the electrodes are coupled to a thin, flexible metallic lead wire that is similarly insulated and inert to body fluids and tissues. Using a suitable tool, the surgeon need only lift the nerve sufficiently to clear the thickness of the strip which is then deposited underneath the nerve with one of the electrodes in opposition thereto. The strip is then folded over the nerve so that the other electrode also makes light contact with the nerve and then the strip is sutured

in place. Tabs may also be provided on the strip to facilitate handling thereof during surgery.

It will be appreciated that, because the strip is relatively thin, the nerve is not likely to experience trauma due to excessive handling thereof. In addition, because the electrodes are substantially flat, they cannot distort the nerve. The combination of flat electrode means and a thin, flexible support therefor does not inhibit the normal flow of nutrients over the nerve. Provision of handling tabs also simplifies the surgical procedure.

Accordingly, it is a primary object of the present invention to provide an improved, implantable device for stimulating a single nerve by means of electricity.

It is an important object of this invention to provide an implantable device, as described above, having a substantially reduced bulk, as compared to the prior art.

Another object of this invention is to provide an implantable device, as described above, comprising a relatively thin, folded strip made of a material that is inert to body fluids and tissues wherein substantially flat electrode means are formed on a surface of the strip.

An advantage of this invention is that implantable strip described above may be slipped under and then secured by suture means about a single nerve without inducing a trauma therein.

A feature of this invention is the usage of thin, flexible wire leads encapsulated in insulating plastic members that are inert to body fluids and tissues.

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

DESCRIPTION OF THE DRAWING

In the drawing:

FIG. 1 is a transverse, cross-sectional elevational view of one embodiment of the prior art;

FIG. 2 is a transverse, cross-sectional elevational view of another embodiment of the prior art;

FIG. 3 is a perspective view of the present invention;

FIG. 4 is a developed, perspective view of one embodiment of this invention;

FIG. 5 is a schematic view illustrating positioning of the present invention beneath a single nerve;

FIG. 6 is another schematic view illustrating the present invention positioned about a single nerve;

FIG. 7 is an enlarged transverse cross-sectional view, partially schematic of the present invention;

FIG. 8 is a pictorial view showing the device of FIG. 4 wrapped about a nerve;

FIG. 9 is a view similar to FIG. 8 showing an alternative lead arrangement;

FIG. 10 is a plan view of a contact member;

FIG. 11 is a vertical section taken along line 11—11 of FIG. 10;

FIG. 12 is a top plan view showing the button of FIG. 10 assembled to a plastic member; and

FIG. 13 is a side elevational view of the assembly shown in FIG. 12.

The present invention can best be appreciated by a discussion of and a comparison with the prior art as represented by FIG. 1 and FIG. 2. The implant 10 is comprised of a relatively large mass 12 of an inert plastic material. Electrode 14 are molded integrally with

the plastic mass 12 and conductive leads 16 for coupling the implant 10 to a source of electrical energy are secured to one end of each of the electrodes 14. The opposite end of each of the electrodes 14 is formed with an arcuate recess 18 that is coincidental with a notch 20 formed in the lower portion of the plastic mass 12. A single nerve N is deposited in the notch 20 and the electrode recess 18.

It should be noted that the plastic mass 12 is defined by a relatively thin, upper section 12a and a relatively thick, lower section 12b, the two sections 12a and 12b being joined at one end by an integral hinge 12c. Initially the two sections 12a and 12b are side-by-side. After the device 10 is implanted and the nerve N is properly positioned the upper section 12a is folded over the lower section 12b and the two free ends thereof are secured to each other by sutures 22.

The structure 10' shown in FIG. 2 is substantially the same as that shown in FIG. 1 except that the plastic mass 24 is initially U-shaped in transverse cross-section and is defined by upper and lower sections 24a and 24b, respectively having substantially the same thickness. The sections 24a and 24b are joined to each other by integral hinge means 24c.

The prior art illustrated by FIG. 1 and FIG. 2 has several shortcomings. Perhaps the most obvious is the sheer bulk of the device. It will be readily apparent that because of their thickness it is extremely difficult to slip the lower sections 12a and 24a underneath the nerve N. In practice it would be necessary to lift the nerve N at least sufficiently to clear the lower section 12a or 24a thus causing severe trauma to the nerve N.

Still another shortcoming of the illustrated prior art is the shape preformed in both the electrode recess and the notch 20 formed in the lower sections 12a or 24a. Necessarily the nerve N must conform to the preformed shape. However, nerves are not necessarily circular in transverse cross-section. In fact, in vivo, nerves are generally oval in cross-section. This is a condition not recognized by the prior art. Thus, either incomplete contact will be made between the nerve N and the electrode recess 18 or the nerve N will be crimped thereby further inducing trauma.

By way of contrast, the present invention eliminates the aforementioned shortcomings in a very simple, yet efficient manner. Turning now particularly to FIG. 3, there is shown an implantable electrode 30 comprising the present invention. Conductive leads 32, 32' are a pair of spaced bundles of fine stainless steel filaments, each about 12 microns in diameter. Normally, about 50 to 450 such filaments are used in a bundle. For delicate work, say, in the vicinity of the eye, a lesser number of such filaments would be used, say, 60 to 90 filaments. The bundles are encapsulated in a physiological, inert plastic sheath 34 such as silicone rubber and serve to couple the electrode button 44 to a signal utilization means 36 similarly encapsulated in an inert plastic material that is reinforced with a Dacron mesh 38. Thus the entire assembly comprising the electrode 30, the sheath 34 and the signal receiving means 36 may be implanted in a human being without adverse side effects.

As shown in FIG. 4, for example, the electrode 30 is comprised of a relatively thin strip 40 between 0.009 inch and 0.025 inch thick made of a material that is inert to body tissues and fluids, for example a Dacron mesh reinforced silicone rubber of medical grade. The central or narrower section 42 of the strip 40 has a pair

of conductive electrodes 44 suitably secured on a surface thereof. Platinum has been found to be a satisfactory material for the electrodes 44 which are approximately 0.005 inch thick. Conductive lead wires 32, 32 couple the electrodes 44 to the signal receiving utilization means 36. In the preferred embodiment both ends 48 of the strip 40 are enlarged to provide a portion for the surgeon to grasp with a suitable tool.

From the foregoing it will be appreciated that only a minimum manipulation of the nerve N is required, as shown in FIG. 5, in order for the surgeon to slip the plastic strip 40 beneath the nerve N. Preferably, the electrode assembly 20 is molded in a U-shape with the enlarged ends 48 in spaced opposition to each other. The strip 40 is flattened prior to insertion, and then, when in place, is allowed to assume its original shape by its inherent memory so that the ends 48 may be secured to each, such as by sutures (not shown).

FIG. 7 illustrates an important advantage of this invention. Because the strip 40 is flexible it can readily conform to the generally oval shape of the nerve N instead of, as in the prior art, forcing the nerve to conform to the shape of the electrode. Further, the thin, flexible strip 40 provides spaces 50 on opposite sides of the nerve N for the flow of nutrients while still maintaining a maximum number of nerve fibers in contact with the electrodes 44. In this connection, it is important to note that only a very light "kissing" contact is made between the nerve N and the electrodes 44, owing in part to the integral hinge action of the central portion 42 of the strip 40.

In FIG. 8 there is shown covered leads 41, 41' extending in a direction perpendicular to the nerve N while in FIG. 9 the leads 41, 41' secured to the member 40 extend parallel to the nerve. The surgeon would of course choose the arrangement placing the least strain on the nerve. The covered leads 41, 41' are cemented to the member 40 by a suitable adhesive. It will be noted that they enter a common sheath 34.

The shape of the contact member 44 has been found to be important as it is essential to avoid the presence of sharp edges which could irritate or cut into the nerve. A preferred method of attachment is shown in FIGS. 10-13. A dish member 50 is provided with a staple 52 welded thereto. The staple, of the same platinum alloy as the member 50, is passed through the plastic member 40 and the legs 53 are bent over to secure the contact button 50 in place. Prior to this assembly the lead 41, 41' of a high tensile strength platinum alloy are welded to the staples 52 and passed through an opening 54 in member 40. A suitable construction for leads 41, 41' is a platinum-tungsten alloy containing, say, 15 - 30 percent of tungsten. Typically it may be composed of 16 strands each 0.001 inch in diameter formed in a braid. The short leads 41, 41', as shown in FIGS. 3 and 4 are then welded to the conductive leads 32 to 32' discussed earlier.

It is necessary to tailor the electrode size to match the nerve to which contact is made. Thus, for a 1 cm. nerve an electrode contact button 0.1 inch \times 0.075 inch \times 0.008 inch would be satisfactory; while, for a 1 mm. nerve a button 0.06 inch \times 0.04 inch \times 0.04 inch is suitable.

From the foregoing it will be evident that an improved, implantable device has been provided for electrically stimulating a single nerve. The device has substantially reduced bulk as compared to the prior art

structure and permits relatively simple insertion beneath a nerve with a minimum of trauma caused therein. The substantially flat electrodes which are positioned on an inert, flexible strip contact the nerve very lightly with spaces being provided on opposite sides of the nerve for the flow of nutrients thereabout.

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 thereto without departing from the spirit of the invention.

I claim:

1. A device implantable in a living body for the electrical stimulation of a single nerve, said device comprising:

- a. a relatively thin strip of flexible, electrically insulating material that is inert to body tissues and fluids;
- b. at least two substantially flat, electrically conductive electrode means secured to a surface of said strip, said electrode means comprising cup-shaped noble metal members with the edge of said cup-shaped members bearing against said strip of insulating material;
- c. a staple for securing each said electrode means to said strip of insulating material, said staple being welded to the inside of said respective cup-shaped member, said staples having legs crimped against the side of said strip of insulating material that is opposite to that to which said cup-shaped members are secured;
- d. first conductive lead means electrically and physically coupled to said electrode means and welded to said staples, said first conductive lead means being of relatively high tensile strength; and
- e. second conductive lead means secured to each said high tensile strength first lead means, said second conductive lead means comprising bundles of stainless steel filaments in the order of twelve microns diameter, said bundles containing from 50 to 450 filaments.

2. The device in accordance with claim 1 wherein said electrically insulating strip is molded in a U-shape with the ends thereof in spaced confronting relationship, said electrode means being on the inside surface of said shaped strip and in spaced opposition to each other.

3. The device in accordance with claim 2 wherein said ends of said strip are transversely enlarged with respect to the central portion of said strip.

4. The device in accordance with claim 2 wherein said strip is made of a plastic material that may be opened to a flat configuration and which is characterized by a built-in memory that will return the strip to said U-shaped configuration upon the release of pressure whereby a nerve positioned between the legs of said U-shaped strip will be contacted by said electrode means.

5. The device in accordance with claim 1 wherein said insulating material is a silicone rubber composition.

6. The device in accordance with claim 5 further comprising a material for reinforcing said silicone rubber.

7. A device adapted to be implanted within a living body and in contact with a single nerve for the electrical stimulation thereof, said device comprising:

a. a relatively non-elastic thin strip of flexible, electrically insulating material that is inert to body fluids and tissues, said strip being defined by a central, integral hinge section and two spaced apart ends contiguous with said central section, said strip being molded in a U-shape with the ends thereof in spaced confronting relationship;

b. at least two substantially flat, electrically conductive rigid electrode means secured to a surface of said strip in the central section thereof, said electrode means being on the inside surface of said strip in each leg of said U-shape and in spaced apart opposition to each other whereby a very light "kissing" contact is made between said electrode means and the nerve when said device is implanted; and

c. first conductive lead means electrically and physically coupled to said electrode means.

8. The device in accordance with claim 7 wherein said ends of said strip are transversely enlarged with respect to said central portion of said strip.

9. The device in accordance with claim 7 wherein said strip is made of a plastic material that may be opened to a flat configuration and which is characterized by a built-in memory that will return said strip to said U-shaped configuration upon the release of pressure whereby a nerve positioned between the legs of said U-shaped member will be contacted by said electrode means.

10. The device in accordance with claim 7 wherein said electrode means comprise cup-shaped noble metal members with the edge of said cup-shaped members bearing against said strip of insulating material.

11. The device in accordance with claim 7 wherein said insulating material is a silicone rubber composition.

12. The device in accordance with claim 11 further comprising a material for reinforcing said silicone rubber.

13. The device in accordance with claim 7 further including a staple for securing each said electrode means to said strip of insulating material, said staples being welded to the inside of said respective cup-shaped member, said staples having legs crimped against the side of said strip of insulating material that is opposite to that to which said cup-shaped members are secured.

14. The device in accordance with claim 13 wherein said first conductive lead means is of relatively high tensile strength and are welded to said staples.

15. The device in accordance with claim 14 further including second conductive lead means secured to each said high tensile strength first lead means, said second conductive lead means comprising bundles of stainless steel filaments in the order of twelve microns in diameter, said bundles containing from 50 to 450 filaments.

16. The device in accordance with claim 15 further including a physiologically inert sheath within which said second lead means are secured.

17. A device adapted to be implanted within a living body and in contact with a single nerve for the electrical stimulation thereof, said device comprising:

- a. a relatively non-elastic thin strip of flexible, electrically insulating material that is inert to body fluids and tissues, said strip being defined by a central, integral hinge section and two spaced apart ends contiguous with said central section;

- b. at least two substantially flat, electrically conductive rigid electrode means secured to a surface of said strip in the central section thereof whereby a very light "kissing" contact is made between said electrode means and the nerve when said device is implanted; and
- c. conductive lead means electrically and physically coupled to said electrode means.

18. The device in accordance with claim 17 wherein said strip is molded in a U-shape with the ends thereof in spaced confronting relationship, said electrode means being on the inside surface of said shaped strip in each leg of said U-shape and in spaced opposition to each other.

19. The device in accordance with claim 17 wherein said electrode means comprise cup-shaped noble metal members with the edge of the cups bearing against said strip of insulating material.

20. The device in accordance with claim 17, wherein said insulating material is a silicone rubber composition.

21. A device adapted to be implanted within a living body and in contact with a single nerve for the electrical stimulation thereof, said device comprising:

- a. relatively thin strip of flexible, electrically insulating material that is inert to body fluids and tissues, said strip being defined by a central section and two spaced apart ends contiguous with said central section, said strip being molded in a U-shape with the ends thereof in spaced confronting relationship;
- b. at least two substantially flat, electrically conductive cup-shaped noble metal electrode means secured to a surface of said strip in the central section thereof, the edge of said cup-shaped members bearing against said strip of insulating materials said electrode means being on the inside surface of said strip in each leg of said U-shape and in spaced

opposition to each other;

- c. a staple for securing each said electrode means to said strip of insulating material, said staples being welded to the inside of said respective cup-shaped member, said staples having legs crimped against the side of said strip of insulating material that is opposite to that to which said cup-shaped members are secured;
- d. first conductive lead means of relatively high tensile strength electrically and physically welded to said staples; and
- e. second conductive lead means secured to said high tensile strength first lead means, said second conductive lead means comprising bundles of stainless steel filaments in the order of 12 microns in diameter, said bundles containing from 50 to 450 filaments.

22. The device in accordance with claim 21 further including a physiological inert sheath within which said second lead means are secured.

23. The device in accordance with claim 21 wherein said ends of said strip are transversely enlarged with respect to said central portion of said strip.

24. The device in accordance with claim 21 wherein said strip is made of a plastic material that may be opened to a flat configuration and which is characterized by a built-in memory that will return said strip to said U-shaped configuration upon the release of pressure whereby a nerve positioned between the legs of said U-shaped member will be contacted by said electrode means.

25. The device in accordance with claim 21 wherein said insulating material is a silicone rubber composition.

26. The device in accordance with claim 25 further comprising a material for reinforcing said silicone rubber.

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