

- [54] **ELECTRICAL SPINAL CORD
STIMULATING DEVICE AND METHOD
FOR MANAGEMENT OF PAIN**
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- [73] Assignee: **Clinical Technology Corporation**,
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- [51] Int. Cl. **A61m 1/36**
- [58] Field of Search..... 128/419 R, 418, 404

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et al.

[57] **ABSTRACT**

Intractable pain that is transmitted by the spinal cord and sensed by the human body is suppressed by implanting an electrode carrying device near a nerve bundle in the spinal cord. The device is constructed of an electrical insulating substance inert to the body fluids and tissue and carries electrodes for supplying electric current to the spinal cord thereby suppressing the sensed quantity of pain. These electrodes are in aligned, spaced relationship with the alignment extending transversely of the nerve bundle. A switch may be positioned within the body and used to supply the current to certain of the electrodes in response to the quantity of pain sensed thereby controlling same by varying the area of the spinal cord affected.

7 Claims, 9 Drawing Figures

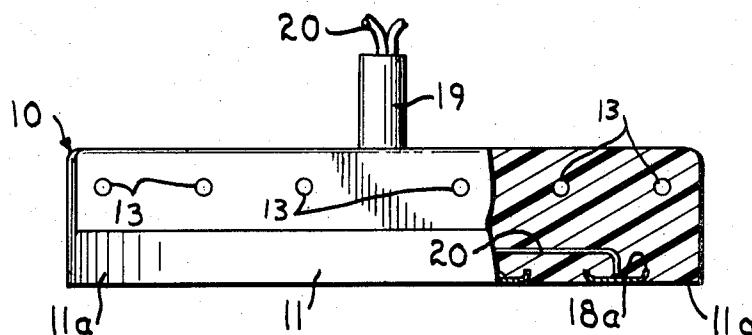


Fig. 1.

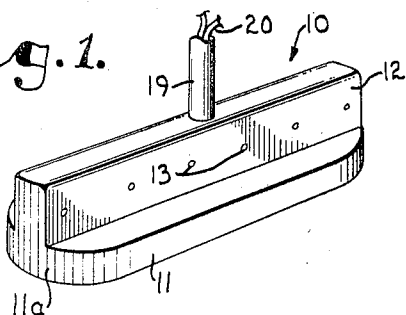


Fig. 2.

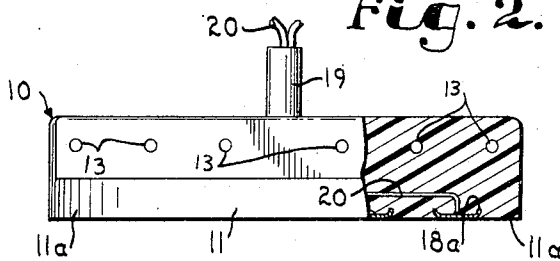


Fig. 4.

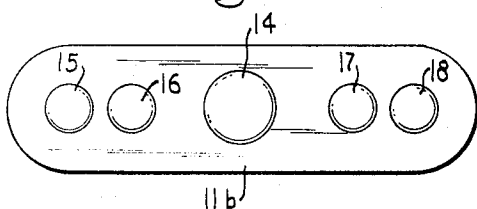


Fig. 3.

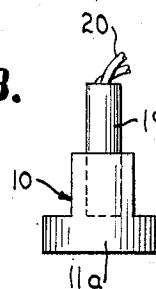


Fig. 5.

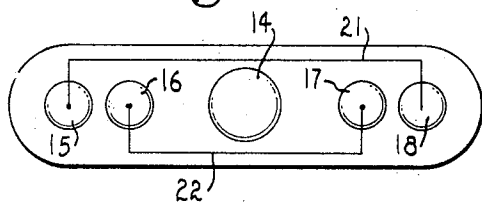


Fig. 6.

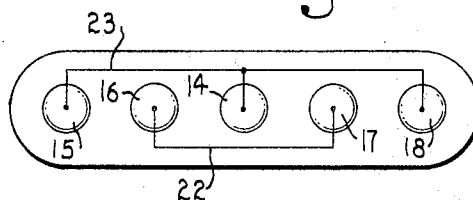


Fig. 7.

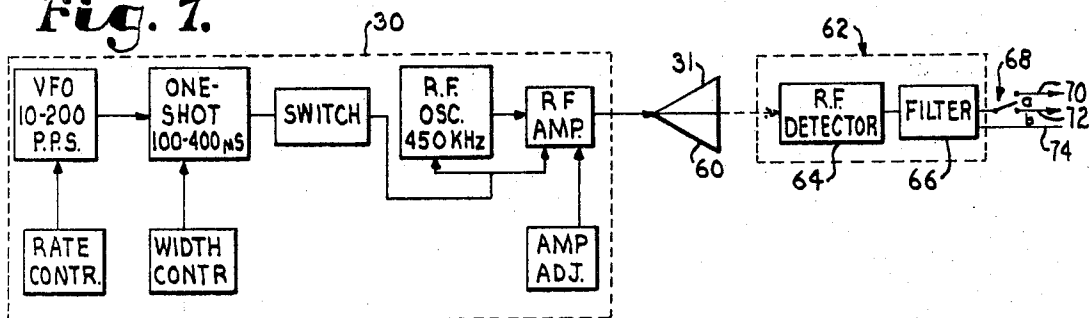


Fig. 8.

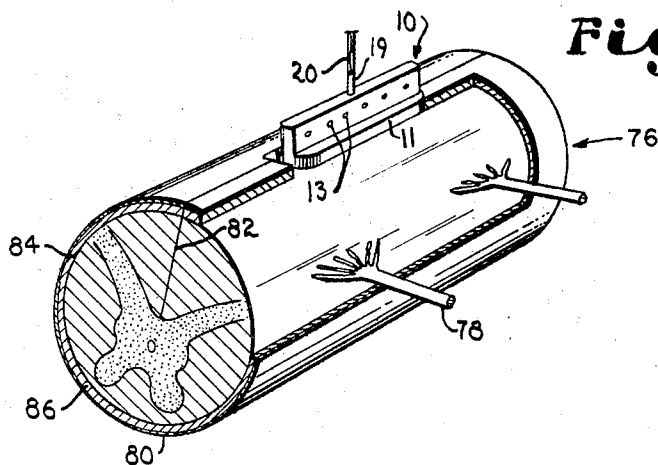
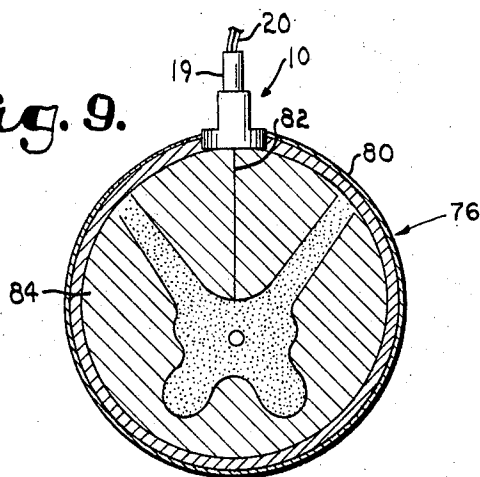


Fig. 9.



ELECTRICAL SPINAL CORD STIMULATING DEVICE AND METHOD FOR MANAGEMENT OF PAIN

BACKGROUND AND BRIEF DESCRIPTION OF THE INVENTION

Within the past several years rapid advances have been made in medical apparatus for controlling pain in which no single nerve fiber is responsible for the passing of the pain sense (intractable pain) by the human body. This apparatus normally involves the implantation of an electrode within the body to electrically stimulate the area of the spinal cord nearest the pain sensing nerve. The electrical stimulation of the spinal cord is analogous to the "gate control theory" of pain, and uses electrical energy to prevent the transmission of the sensed pain. That is, the pain relief which follows peripheral nerve stimulation according to the "gate control theory" is due to the inhibition of the small myelinated or unmyelinated fibers by electrically activating the large myelinated fibers. Prior to the use of this type apparatus, the only method of controlling intractable pain was through massive doses of "pain killing" drugs, which required larger doses as the pain became more intense. Also selective nerve surgery was possible but in both cases several undesirable effects were induced with a patient being unable to live a normal life.

The medical apparatus normally based on the "gate control theory" acts as an "on-off" switch. Stated another way, by activating the apparatus, the nerves will not pass any sensed signals on the length thereof. Still unexplained is the lasting effect of stimulation e.e., the lack of pain sensation continues for some time after turning the switch "Off." Further, motor function of the body may be adversely affected because of the total blocking of the nerve sensation. However, the utilization of such a device is still preferable to other known methods of managing intractable pain.

The present invention is an implantable electrode carrying device having five aligned electrodes carried thereon. This electrode alignment is positioned longitudinally on the spinal cord and transversely to the nerves entering the cord and carrying the sensed intractable pain. An electrical current is passed through certain ones of the electrodes, into a portion of the juxtaposed spinal cord area, and into another electrode acting as a ground. The passage of the current into the portion of the spinal cord (or selective tracks thereof) acts to block the sensed intractable pain and yet allow the passage of other sensation. Should the pain increase, current may be passed through certain other ones of the electrodes, into a larger portion of the passing nerve being stimulated, and onto the ground electrode. Accordingly, the volume of spinal cord being blocked by electric current is related to the pain being sensed by the body.

One of the primary objects of this invention is to provide unique device implantable in the spinal cord of an animal that will electrically stimulate a segment of the spinal cord to reduce sensed intractable pain in response to the amount of pain being sensed.

Another object of this invention is to provide a device of the character described having electrodes within a carrying member with the electrodes constructed so as to maintain a suitable current density in

proportion to the distance from the emitting electrodes.

A further object of this invention is to provide unique device to control the relative amount of sensed intractable pain without the necessity of directly contacting the nerve bundle passing said sensed intractable pain.

As a further object of the invention unique device is provided that is implantable and operable to be sutured to the spinal cord for maintaining the apparatus in its relative location with minimal adverse effects to the spinal cord.

Another object of this invention is to provide a unique electrode carrying member of such configuration as to be easily implanted within the body's spinal cord for the control of intractable pain.

These and other objects of the invention, together with the features of novelty appurtenant thereto, will appear in the course of the following description.

DETAILED DESCRIPTION OF THE INVENTION

In the accompanying drawings which form a part of this specification and are to be read in conjunction therewith and in which like reference numerals are employed to indicate like parts in various views:

FIG. 1 is a perspective view showing a form of an electrode carrying member embodying the present invention;

FIG. 2 is a front elevational view of the electrode carrying member of FIG. 1 with portions of the member being in section;

FIG. 3 is an end elevational view of the carrying member of FIG. 1;

FIG. 4 is a bottom plan view of a carrying member of the present invention showing the location and configuration of the electrodes thereon;

FIG. 5 is a view of the carrying member of FIG. 4 with a possible wiring interconnection between the electrodes being shown;

FIG. 6 is a view similar to FIG. 5 but an alternative electrode configuration and wiring interconnect;

FIG. 7 is a block diagram of a suitable circuit for providing the electrical current necessary for use with an electrode carrying member of the present invention;

FIG. 8 is a perspective view of the carrying member shown in FIG. 1 being implanted in the spinal cord and with certain portions of the spinal cord being shown in section; and

FIG. 9 is a side elevational view of the carrying member shown in FIG. 8 being implanted in the spinal cord.

Turning now more particularly to the drawings and with special reference to FIGS. 1-3, it is seen that the electrode carrying device is generally represented by the numeral 10. The device includes a flat elongated member 11 having rounded end portions 11a. A vertically oriented member 12 is integrally formed with the flat lower member 11 and substantially lies along the longitudinal center line of flat member 11. A plurality of apertures 13 will extend through the vertical portion 12 and will be utilized to properly locate the device when implanted. It is contemplated that the device will be constructed of a commercially available material such as silicone rubber and that it will not be rejected by the body when implanted therein.

The lower surface 11b (see FIGS. 4-6) of the device is generally oblong in shape and will have a center elec-

trode 14 fixedly located therein by a conventional molding process. It is contemplated that electrode 14 will be a disc shaped metallic member having a smooth outer surface and a fixed interconnect with a suitable electrical wire conductor described later. Four additional electrodes 15, 16, 17 and 19 are evenly disposed on either side of the center electrode 14 with electrode pair 15 and 16 being located on one side of the center electrode 14 while the pair 17 and 18 are located on the other. The latter four electrodes (in FIGS. 4 and 5) are smaller (approximately one half sized) in area and will be of the disc shape construction mentioned above with respect to electrode 14. As shown in FIG. 2, each electrode will also have its inner surface circumscribed by upturned rims 18a. These rims cooperate in the optimum locating and attaching the electrodes interiorly of lower surface 11b.

A flexible silicone rubber conduit 19 will extend through an aperture in the upper surface of the vertical member 12 of the device 10. Each one of the electrodes (14-18) may be interconnected with a separate conductor 20 (see FIG. 2) with the conductors bunched together and running out of the conduit 19. It should be noted that there are alternative ways in which the electrodes may be connected and that numeral 20 is used generally to designate a plurality of conductors which may interconnect with the electrodes. In the embodiment shown in FIGS. 4 and 5, the area of the center electrode 14 is constructed so that it is twice the size of the areas of the electrodes 15-18. Further the distance from electrode 14 to electrodes 16 and 17 is twice that between electrodes 15, 16, 17 and 18. This latter electrode configuration is used to concentrate current density along the center line of the unit.

An alternative conductor interconnection is shown in FIGS. 5 and 6. For example, the FIG. 5 representation indicates that the electrodes 15 and 18 may be bussed together by conductor 21 while the electrodes 16 and 17 are interconnected by conductor 22. Finally, the center electrode 14 and the two bus type connectors 21 and 22 will be interconnected with the leadin conductors 20 and are tied to the later described receiver.

In FIG. 6 it is indicated that electrodes 14, 15 and 18 may be interconnected by bus connectors 23 and further that the two electrodes 16 and 17 are again interconnected by bus 22. In the later embodiment, the two bus connectors 22 and 23 are again interconnected with the leadin conductors 20. Additionally, the size of all of the electrodes 14-18 in FIG. 6 are substantially equal and are therefore evenly distributed along the longitudinal center line of the lower surface 11b in order to obtain uniform current density. It has been found that the area of electrodes 16 and 17 may be made slightly larger than electrodes 14, 15, and 18 to equalize current density within the electrodes. In any event with the electrode configuration as shown in FIG. 6, this field will consist of four magnetic dipoles serving to concentrate currents in the dorsal region of the spinal cord, thereby avoiding unnecessary root pain which occurs with prior art devices. As suggested above, the electrode material will be chosen to provide a low electrical resistance (such as platinum) and will be of such a nature that it will not be rejected by adjacent body tissues. Additionally, all conductors passing through the conduit 20 and interiorly of the body will be insulated from each other and yet be flexible. Accordingly,

polytetrafluoroethylene may be used to coat the conductors which will eventually terminate in the receiver.

The actuating current is supplied to the device and by the circuitry shown in FIG. 7. As shown, a radio frequency transmitter generally indicated by the numeral 30 is used to transmit a rectangular pulse of approximately 250 milliseconds in width with a repetition rate of from 5 to 200 pulses per second. The radio frequency transmitter may be of a conventional design with the output of same being delivered to an antenna or output coil 31 and with the output signal emanating therefrom.

As indicated, the electrodes are interconnected with conductors which are in turn interconnected with a receiving device generally indicated by the numeral 62. The receiver 62 will include a receiver coil and RF detector 64 and a filter 66. The filtered output may be then delivered to reed switch 68. It is contemplated that this receiver, including the reed switch structure (if used) will be encapsulated and covered by a silicone rubber covering. The receiver is located under the skin and in such a position so as to be easily reached by the individual himself or certainly by an attending physician. In any event, when the signal is received by receiver 62, detected in 64 and filtered in 66, the resultant current flow will be through the reed switch 68 and out on either terminal 70 or 72 depending upon the location of the switch contact. Terminal 74 is considered to be the ground or neutral terminal and is usually interconnected with the current collecting or indifferent electrode in device 10.

The installation procedure would normally require a laminectomy involving the removal of the lamina of a vertebra with the electrode assembly 10 being placed under the dura in the spinal cord 76. It may be assumed for this discussion that the intractable pain sensed by the body is being transmitted along the nerve 78. The dura 80 of the spinal cord 76 is surgically separated and the device 10 positioned along the natural separation 82 of the spinal cord so that the center line of the device (through the centers of the electrodes 14-18) is substantially transversed to the longitudinal center line of nerve 78. The vertical height of the lower member 11 is selected so that it may be positioned between the dura 80 and the arachnoid 84 without discomfort. Also, the vertical height of the apertures 13 will be such that the device 10 may be sutured to the dura 80.

When the device shown in FIG. 4 is to be utilized, the conductors 20 of the electrode 14 passes through the device 10 and connects with terminal 74 (if the optional reed switch is used). Similarly, conductors will lead from the electrodes 15 and 16 and will tie in with switch terminals 70 and 72 respectively. With the reed switch in position so that its switch arm contact is interconnected with terminal 72, the electrode 16 will be energized with a current flow resulting from electrode 16, through the spinal fluid and to the center or return electrode 14. As a result, the current flow is suitable to suppress the intractable pain being passed through nerve 78. If the switch 68 is not used, then the conductors 20 connect directly with filter output.

If the pain is still present, switch 68 may be activated to move its contact to the terminal 70 position which interconnects with the appropriate conductor 20 to electrode 15. Since the distance from electrode 15 to the return electrode 14 is greater, an increased area of

the spinal cord is accordingly stimulated by the current flow between the terminals 15 and 14. As a result of the utilization of the end and the center electrodes (15 and 14), had, there is a greater capacity to block the pain. Should the intractable pain lessen, switch 68 may again be activated and the current will pass back through the terminal 72 and electrodes 16 and 14. Accordingly, the amount of blocking in response to the amount of pain sensed is controlled by area of nerve 78 being affected by the current flow therethrough. It should be pointed out that this embodiment will function equally well with electrodes 17 and 18 replacing the electrodes 15 and 16 described above.

The operation of the electrode configuration in FIG. 5 is similar to that described above except that conductor 22 is interconnected with terminal 72 while conductor 21 is interconnected with terminal 70. As a result, a greater spinal cord area is affected in the FIG. 5 embodiment than that disclosed in FIG. 4. Since more spinal cord area is controlled, the ability to block increased pain is likewise increased.

The FIG. 6 embodiment effectively eliminates the use of switch 68 in that conductor 22 could be interconnected with terminal 74 while conductor 23 could be connected with the terminals 70 or 72. Thus a pain sensed is again subjected to substantially the entire longitudinal dimension of the device when current is applied through the two above mentioned terminals.

Finally, it should be understood that the transmitter will include a suitable magnetic device to enable reed switch 68 to be controlled if such a switch is used. In other words, the switch arm of reed switch 68 will be movable from a location externally of the body. The transmitter will simply be placed over the implanted receiver so that the proper energizing and switch terminal selection is easily made in accordance with the degree of pain being experienced.

From the foregoing, it will be seen that this invention is one well adapted to attain all the ends and objects herein set forth, together with other advantages which are obvious and which are inherent to the structure.

It will be understood that certain features and sub-combinations are of utility and may be employed without reference to other features and subcombinations. This is contemplated by and is within the scope of the claims.

As many possible embodiments may be made of the invention without departing from the scope thereof, it is to be understood that all matter herein set forth or shown in the accompanying drawings is to be interpreted as illustrative and not in a limiting sense.

Having thus described my invention, I claim:

1. A method of suppressing pain by stimulating a preselected spinal cord level, said method comprising the steps of:

positioning at least three electrodes in a single row in at least a portion of said spinal cord substantially longitudinal to the length of said spinal cord along the natural separation of said spinal cord, generating electrical energy in a source of electric power, and electrically connecting said electrodes with the source of electric power, thereby establishing a plurality of electric dipoles having their fields oriented longitudinally with said spinal cord.

2. The method as in claim 1 including the step of

varying the area of said spinal cord being managed in accordance with the amount of pain sensed by the body.

3. The method as in claim 2 wherein said area varying step includes the step of providing electric current to preselected combinations of said electrodes.

4. A device for managing pain, said device being of the type that is implantable in the body within the spinal cord and adjacent a nerve transmitting intractable pain, said device including

an electrode carrying member constructed of electrical insulating material and of the type that will not be rejected by the body,

the electrode carrying member having a surface portion extending substantially perpendicular thereto, said perpendicular surface having a plurality of apertures defined therein, the perpendicular surface and the apertures facilitating the attachment of the electrode carrying member to said spinal cord, and the perpendicular surface facilitating post operative sealing of the dura incision,

a plurality of electrodes positioned longitudinally in a spaced apart relationship in said member with a surface of each of said electrodes being located substantially near the exterior of said member to enable electric current flow between said electrode, said surfaces of said electrodes having a predetermined portion surface area to achieve a preselected current density,

an electrical conductor extending from said electrodes, and

means for supplying electrical power to said conductors to thereby cause a current flow between said electrodes, thereby establishing electric fields oriented longitudinally along the spinal cord.

5. The combination as in claim 4 wherein said device includes an odd number of at least three electrodes, a center electrode, said center electrode having a larger area and operable to achieve a predetermined current density between said adjacent electrodes when a current flows between certain ones of said adjacent electrodes and said center electrodes.

6. The combination as in claim 5 including means for selectively supplying current to certain ones of said electrodes in accordance with the quantity of pain sensed, said selective current supplying means thereby permitting the controlling of pain by varying the area of said spinal cord being managed.

7. The combination as in claim 4 wherein said device comprises an odd number of electrodes arranged longitudinally in a spaced apart relationship,

a first group of electrodes connected together said first group being comprised of the first, third, and similarly odd numbered electrodes,

a second group of electrodes connected together, said second group being comprised of the second, fourth, and similarly even numbered electrodes, said first group and said second group operative to form an even number of longitudinally aligned electric dipoles when excited by said energy source, said device thereby concentrating electric current in preselected regions of the spinal cord to minimize unnecessary spinal cord current spread and root pain associated therewith.

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