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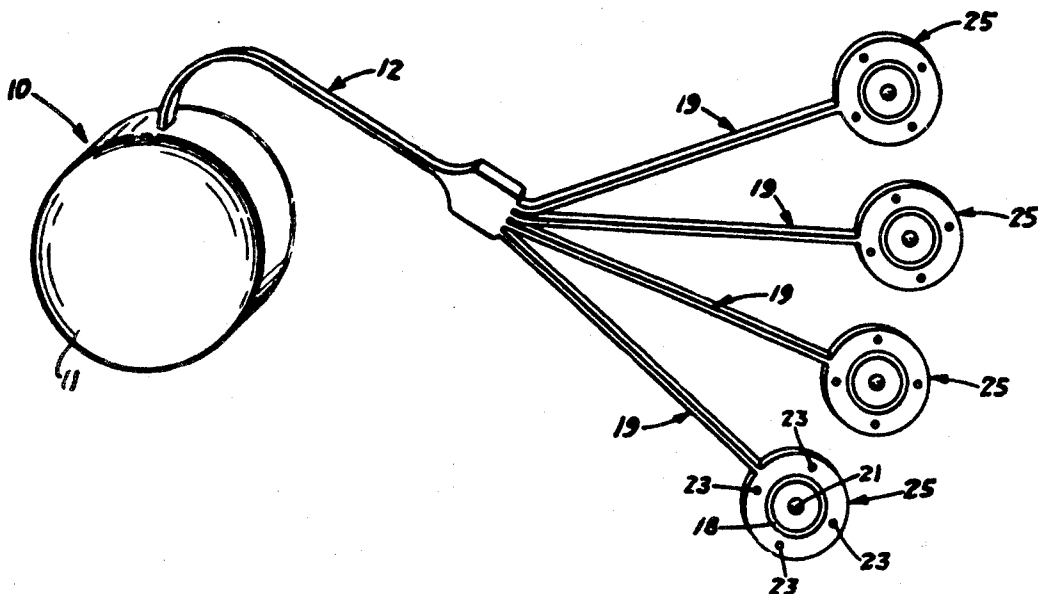
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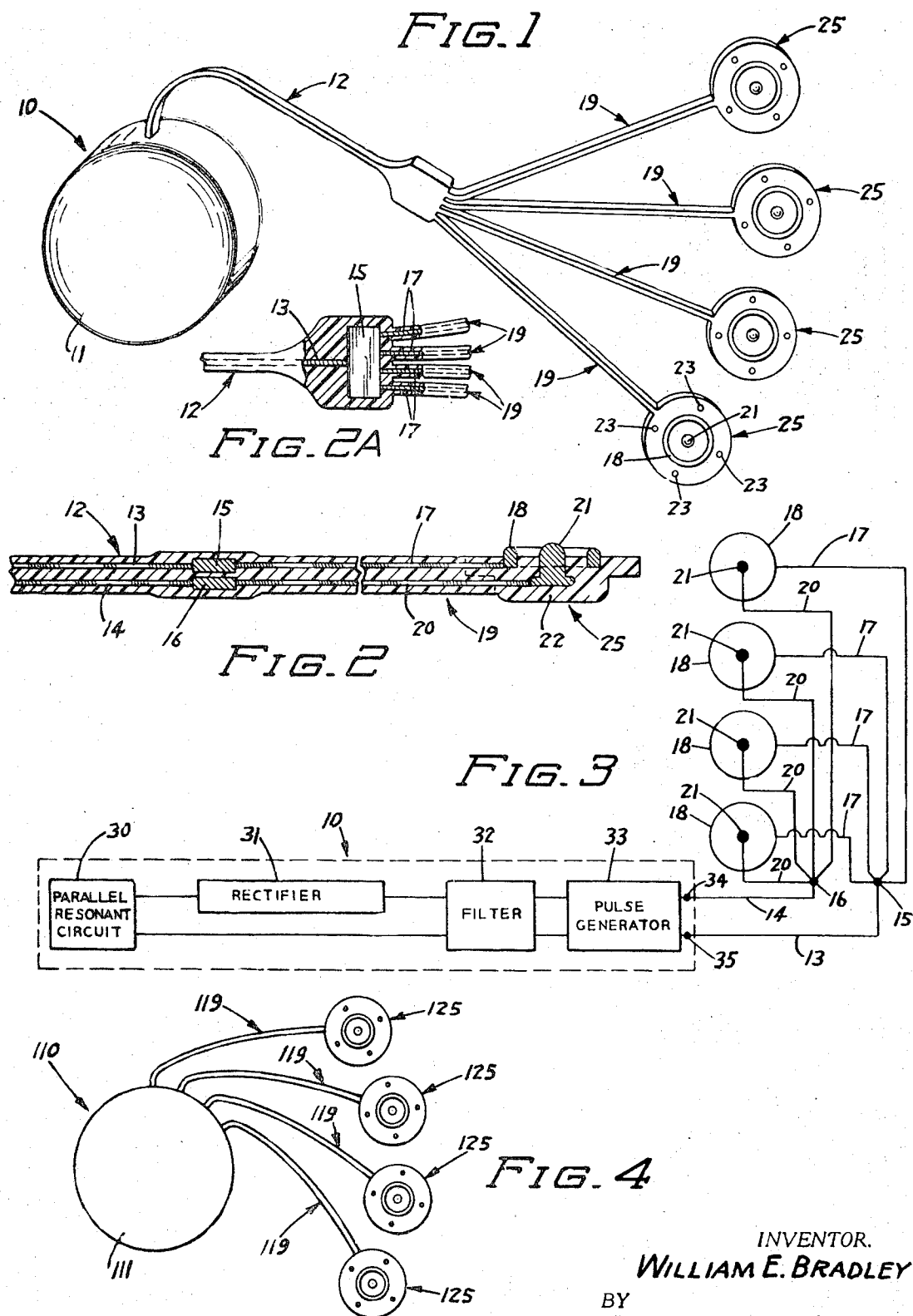
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[54] BLADDER STIMULATING METHOD
1 Claim, 5 Drawing Figs.

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128/418
[51] Int. Cl..... A61n 1/18
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—406, 410, 411, 416—422

ABSTRACT: An apparatus and method for implantation in the body of an animal to stimulate the bladder without stimulating nearby muscles, and the method of so stimulating the bladder. The electrode structure of the apparatus includes a first plurality of electrodes, each of which is surrounded by one of a second plurality of electrodes to limit the stimulation to a series of spaced spots.





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BLADDER STIMULATING METHOD**BACKGROUND OF THE INVENTION**

This invention relates to a method for artificially and electrically stimulating the bladder of persons who have lost the ability to voluntarily empty the bladder because of injury or disease.

This invention was made under a grant from the United States Government through the Department of Health, Education and Welfare.

This apparatus and method is an improvement over that described in my U.S. Pat. No. 3,236,240. It has been discovered that use of the apparatus there disclosed is not always completely satisfactory. That apparatus utilizes spaced apart electrodes to stimulate large areas of the bladder smooth muscle with volitionally generated electrical signals. It has been found that stimulation of such large areas sometimes results in stray electrical signals causing stimulation of nearby muscles in an undesired manner. Specifically, the stimulating signal causes the bladder to attempt to contract as desired but also causes contraction of the external sphincter, thereby inhibiting the evacuation of fluid from the bladder.

SUMMARY OF THE INVENTION

In order to overcome the above described prior art drawback, an improved method has been developed to stimulate a number of separated spots on the smooth muscle of the bladder with electrode structures that prevent stray signals from stimulating the sphincter or other nearby muscles in the pelvic floor. The method of the present invention utilizes a plurality of spaced first electrodes, connected in parallel, each of which is electrically guarded by a second electrode so that the stimulating signal is confined to small spots between each first electrode and the second electrode which guards it. The invention is more fully described in the drawing and detailed description which follow.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a perspective view of an implantable bladder stimulator according to the present invention;

FIG. 2 is a cross-sectional side view of a portion of the bladder stimulator electrode structure of FIG. 1;

FIG. 2A is a cross-sectional top view of a portion of the electrode structure of FIG. 1;

FIG. 3 is a schematic block diagram of a radio frequency responsive stimulation signal generating circuit which may be used to excite the bladder in accordance with the invention; and

FIG. 4 is a front view of a modified apparatus embodying the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIGS. 1, 2 and 2A, a stimulating signal generating means, generally designated 10, is encased in a sterilizable, inert, nonirritating and nontoxic protective and insulating mass 11, preferably of synthetic resinous material. Substances such as silicone rubber, silastic resins, tetrafluoroethylene polymers, vinyl chloride and the like, are suitable materials for use as the encasing or the encapsulating material. Pure natural rubber may also be used.

Extending outward from the signal generating means 10 is an encapsulated conductive lead structure, generally designated 12. Encapsulated lead structure 12 includes a pair of electrically conductive flexible leads 13 and 14 which are connected between the output of stimulating signal generating means 10 and a pair of buss bars 15 and 16, respectively. From buss bar 15, a plurality of flexible leads 17 extend to an exposed electrode structure, generally designated 25, with each lead 17 having one end connected to an annular electrode 18. From buss bar 16, a plurality of flexible leads 20 extend to exposed electrode structure 25 with each lead 20 having its free end connected to a circular electrode 21, which is positioned

inside of one of electrodes 18. The structures carrying leads 17 and 20 are generally designated 19.

Electrical leads 13, 14, 17 and 20 are constructed of any flexible good electrical conductor, but are preferably formed of an alloy of about 90 percent platinum and about 10 percent iridium. The leads may be flat or coiled as shown. Exposed electrodes 18 and 21 may be formed from any inert nontoxic and nonirritating electrically conductive material. Platinum or platinum-iridium alloys are preferred materials but other materials such as tantalum, gold, silver, and alloys of these metals or surgical grade stainless steel may also be used.

Conductive leads 13, 14, 17 and 20, buss bars 15 and 16, and portions of electrodes 18 and 21 are encased or encapsulated in inert, nontoxic material 22 which forms a unitary impervious coating with covering 11. Thus, only portions of electrodes 18 and 21 are exposed. Encapsulating material 22 performs the dual function of encapsulating the leads and supporting each of electrodes 18 in guarding relation to one of electrodes 21 so that the current path is confined to a small area between each electrode 21 and the electrode 18 which guards it.

The preferred exposed electrode structure, as shown in FIGS. 1 and 2, utilizes electrodes 21 having a circular surface which contacts the bladder muscle. Electrodes 18 are constructed so as to have an annular surface contacting the bladder muscle so as to entirely surround the circular area contacted by electrode 21. However, electrode 21 may contact an area in the shape of any geometrical FIG., and guarding electrode 18 may take the form of any closed geometrical FIG. which surrounds the area contacted by electrode 21. The diameter of the contact surface of annular guarding electrode 21 is preferably 1 centimeter or less so that several can readily be sutured to a collapsed human bladder. The contact area of electrode 18 is preferably small enough that substantially the entire area within the circle contacted by electrode 21 carries current.

Encapsulating material 22 has a series of holes 23 spaced around each guarded electrode structure. These holes are included for ease in suturing the electrode structures to the bladder wall at spaced apart locations. It has been discovered that from two to eight separate spots, and preferably four, should be stimulated to achieve satisfactory evacuation of the bladder of a human. When four structures are used, they are placed around the neck of the bladder at approximately equal intervals.

FIG. 3 discloses a block diagram of one electrical circuit which can be used to stimulate separated spots on the bladder or other body organ. Stimulating signal generating means 10 is shown containing a parallel resonant circuit 30 which is responsive to an externally generated, radio frequency, oscillatory signal. Resonant circuit 30 is connected through a rectifier 31 and filter 32 to a pulse generator or multivibrator 33. The output signal from pulse generator 33 appears across conductive leads 13 and 14.

In operation, stimulation signal generating means 10 responds to a radio frequency signal transmitted by an R-F oscillator transmitter, not shown. Since a transmitter may be, for example, a 450 kilohertz continuous wave transmitter. Parallel resonant circuit 30 can be composed of an inductor and a capacitor with the inductor acting as an antenna. Pulses of current generated in resonant circuit 30 are rectified by rectifier 31 and filtered by filter 32 to provide power for pulse generator 33 which has a pair of output terminals 34 and 35. Pulse generator 33 is preferably constructed to provide 10-30-volt peak pulses, with one millisecond pulse width, at the rate of 25 pulses per second into a 100 ohm load. The output signal from pulse generator 33 is A-C coupled to leads 13 and 14.

As shown in FIG. 3, it can be seen that the output of pulse generator 33 appears across electrodes 18 and 21 of each electrode structure. Since each of the electrodes 18 is tied to a common point or buss bar 15, they are all at substantially the same potential and substantially no current flows between the spaced apart electrode structures.

FIG. 4 is a modified bladder stimulator, according to the invention, wherein parts corresponding to those in FIGS. 1—3 are numbered one hundred greater. In FIG. 4, each electrode structure has separate leads which extend into encasing means 111. In this structure, more lead carrying structures exit from encasing means 111, but buss bars, like 15 and 16 of FIGS. 1 and 2, are not required. Elimination of the buss bars and direct connection of each of the leads to one of the output terminals of the pulse generator reduces cost substantially when platinum-iridium leads are used.

The embodiments described are only representative of many variations that are within the scope of the invention which is intended to be limited only by the scope of the following claims.

I claim:

1. A method of artificially stimulating activation of the bladder of an animal comprising the steps of: providing an electrical signal for artificially stimulating contraction of the smooth bladder muscle; stimulating four integral spaced locations adjacent the neck of the bladder; and limiting the stimulating signal path through the smooth muscle to that certain area defined substantially within each of the integral spaced locations to prevent undesired stimulation of other nearby muscles; and the stimulated area being substantially circular in each of the said locations.

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