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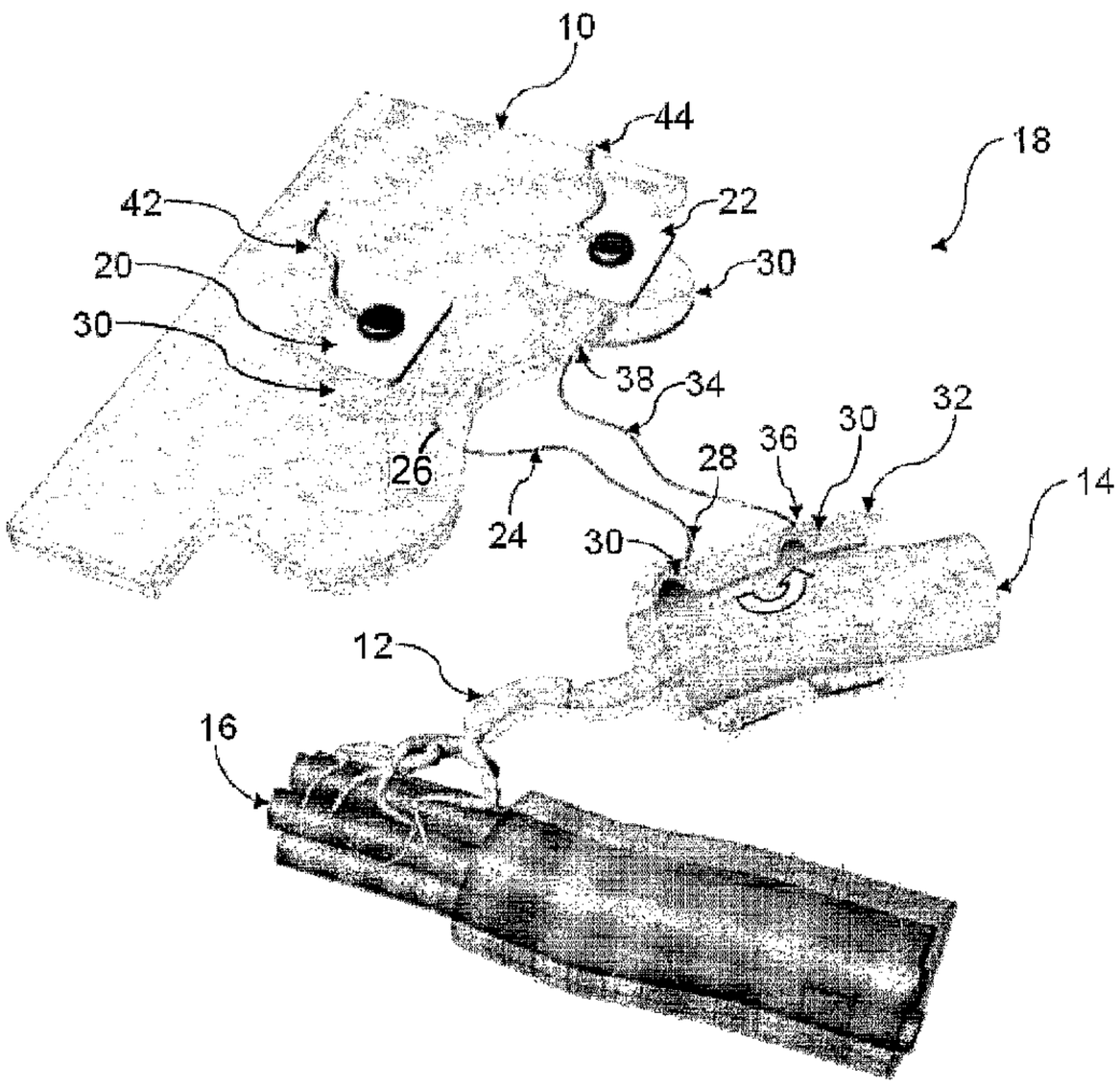
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(54) Titre : PROCEDE D'ACHEMINEMENT DE COURANT ELECTRIQUE A DES TISSUS CORPORELS VIA DES CONDUCTEURS PASSIFS IMPLANTES

(54) Title: METHOD OF ROUTING ELECTRICAL CURRENT TO BODILY TISSUES VIA IMPLANTED PASSIVE CONDUCTORS



(57) Abrégé/Abstract:
The invention provides an implant for electrically stimulating a target body tissue in a subject. The implant provides a conductive pathway for a portion of electrical current flowing between surface electrodes positioned on the subject's skin and transmits that current to the target body tissue. The implant has an electrical conductor of sufficient length to extend from subcutaneous tissue located below a surface cathodic electrode to the target body tissue. The conductor has a pick-up end which forms an electrical termination having a sufficient surface area to allow a sufficient portion of the electrical current to flow through the conductor, in preference to flowing through body tissue between the surface electrodes, such that the target body tissue is stimulated. The conductor also has a stimulating end which forms an electrical termination for delivering the current to the target body tissue. A system and method incorporating the implant are also provided.

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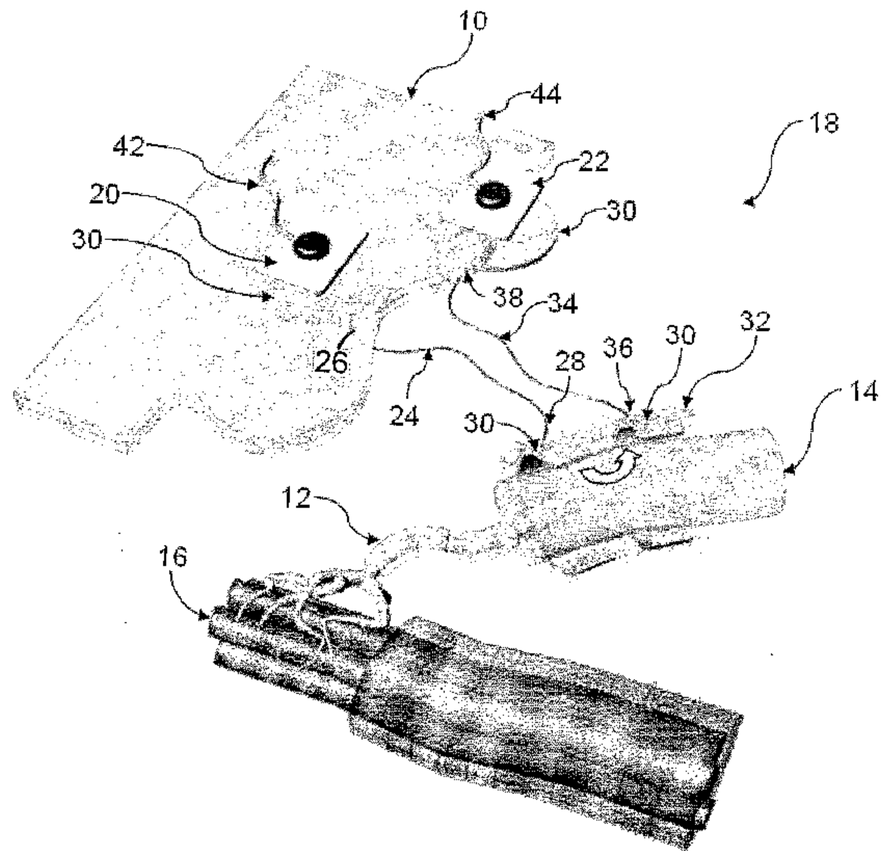
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(54) Title: METHOD OF ROUTING ELECTRICAL CURRENT TO BODILY TISSUES VIA IMPLANTED PASSIVE CONDUCTORS



(57) Abstract: The invention provides an implant for electrically stimulating a target body tissue in a subject. The implant provides a conductive pathway for a portion of electrical current flowing between surface electrodes positioned on the subject's skin and transmits that current to the target body tissue. The implant has an electrical conductor of sufficient length to extend from subcutaneous tissue located below a surface cathodic electrode to the target body tissue. The conductor has a pick-up end which forms an electrical termination having a sufficient surface area to allow a sufficient portion of the electrical current to flow through the conductor, in preference to flowing through body tissue between the surface electrodes, such that the target body tissue is stimulated. The conductor also has a stimulating end which forms an electrical termination for delivering the current to the target body tissue. A system and method incorporating the implant are also provided.

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METHOD OF ROUTING ELECTRICAL CURRENT TO BODILY TISSUES VIA IMPLANTED PASSIVE CONDUCTORS

FIELD OF THE INVENTION

The present invention relates to an implant, system and method for electrically stimulating a target body tissue in a subject.

BACKGROUND OF THE INVENTION

Electrically-excitable bodily tissues such as nerves and muscles may be activated by an electrical field applied between electrodes applied externally to the skin. Electric current flows through the skin between a cathode electrode and an anode electrode, eliciting action potentials in the nerves and muscles underlying the electrodes. This method has been used for many years in different types of stimulators, including transcutaneous electrical nerve stimulators (TENS) which relieve pain, therapeutic electrical stimulators which activate muscles for exercise purposes (Vodovnik, 1981), functional electrical stimulators which activate muscles for tasks of daily life (Kralj *et al.* (1989); United States Patent No. 5,330,516 to Nathan; United States Patent No. 5,562,707 to Prochazka *et al.*) and stimulators that promote regeneration of damaged bones.

A disadvantage of stimulation through electrodes attached to the body surface is that many non-targeted tissues may be co-activated along with the targeted tissues. This lack of selectivity often causes unwanted sensations and/or unwanted movements. Furthermore, tissues that lie deep within the body are difficult or impossible to stimulate adequately, because most of the electrical current flowing between the electrodes flows through tissues closer to the electrodes than the targeted tissues. Selectivity may be improved by implanting wires within the body that route electrical current from a stimulator to the vicinity of the targeted tissues. This method is used in cardiac pacemakers (Horch *et al.*, 2004), dorsal column stimulators (Waltz, 1997), deep brain stimulators (Benabid *et al.*, (1987) and sacral root stimulators (Brindley *et al.* (1982). Cuffs containing the uninsulated ends of the wires may be placed around peripheral nerves to restrict most of the current to the vicinity of the nerve and limiting the spread of current to surrounding tissues, thereby improving selectivity (Haugland *et al.*, (1999). Generally when wires are implanted, the stimulators, complete with an energy source, are also implanted (Strojnik *et al.*, 1987). Implanted stimulators are

expensive and often require a controller and/or power source external to the body. Batteries within the implanted stimulators need periodic replacement, entailing surgery.

In a minority of cases, stimulating wires are implanted in bodily tissues and led through the skin (percutaneously) to a connector attached to the surface of the body, to which an external stimulator is attached (Peckham *et al.*, (1980). External stimulators are much less expensive than implanted stimulators, but the percutaneous wires provide a conduit for infection and therefore require daily cleaning and maintenance. This has generally limited the use of percutaneous electrodes to short-term applications.

SUMMARY OF THE INVENTION

The present invention broadly provides an implant for electrically stimulating a target body tissue in a subject, the implant, once implanted, providing a conductive pathway for at least a portion of the electrical current flowing between surface cathodic and anodic electrodes positioned in spaced relationship on the subject's skin and transmitting that portion of the electrical current to the target body tissue, the implant comprising:

an electrical conductor of sufficient length to extend, once implanted, from subcutaneous tissue located below the surface cathodic electrode to the target body tissue, the electrical conductor having a pick-up end and a stimulating end and being insulated between its ends, the pick-up end forming an electrical termination having a sufficient surface area to allow a sufficient portion of the electrical current to flow through the conductor, in preference to flowing through body tissue between the surface cathodic and anodic electrodes, such that the target body tissue is stimulated, and the stimulating end forming an electrical termination for delivering the portion of electrical current to the target body tissue.

In another aspect, the invention provides a system for electrically stimulating a target body tissue in a subject comprising the above implant, together with

i) surface cathodic and anodic electrodes for making electrical contact with the subject's skin, and which, when positioned in spaced relationship on the subject's skin, for transmitting electrical current to the target body tissue; and

ii) a stimulator external to the subject's body, electrically connected to the surface cathodic and anodic electrodes, the stimulator supplying direct, pulsatile, or alternating current to the surface cathodic and anodic electrodes.

In yet another aspect, the invention provides a method for electrically stimulating a target body tissue in a subject comprising the steps of:

a) providing the above implant;

b) implanting the implant entirely under the subject's skin, with the pick-up end positioned in subcutaneous tissue located below the surface cathodic electrode, and the stimulating end positioned proximate to the target body tissue;

c) positioning the surface cathodic and anodic electrodes in spaced relationship on the subject's skin, with the surface cathodic electrode positioned over the pick-up end of the electrical conductor so the portion of the current is transmitted through the conductor to the target body tissue, and so that the current flows through the target body tissue and returns to the anodic surface electrode through body tissues or through an implanted electrical return conductor extending between the target body tissue and subcutaneous tissue located below the surface anodic electrode; and

d) applying direct, pulsatile or alternating electrical current between the surface cathodic electrode and the surface anodic electrode to cause the portion of the electrical current to flow through the implant sufficient to stimulate the target body tissue.

As used herein and in the claims, the terms and phrases set out below have the following definitions.

"Body tissue" is meant to refer to a neural tissue (in the peripheral or central nervous system), a nerve, a muscle (skeletal, respiratory, or cardiac muscle) or an organ, for example, the brain, cochlea, optic nerve, heart, bladder, urethra, kidneys and bones.

"Electrical current" is meant to refer to resistive, capacitive, or inductive current.

"Subject" means an animal including a human.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic three-dimensional view of an embodiment of the invention having an implanted electrical conductor, surface cathodic and anodic electrodes, and an implanted electrical return conductor.

Figure 2 is a side elevation view, in section, of an embodiment of the invention having an implanted electrical conductor and surface cathodic and anodic electrodes.

Figure 3 is a side elevation view, in section, of an alternate embodiment of the invention having an implanted electrical conductor, surface cathodic and anodic electrodes, and an electrical return conductor.

Figure 4 is a side elevation view, in section, of an alternate embodiment of the invention having two implanted electrical conductors, two surface cathodic electrodes, an anodic electrode, and an electrical return conductor.

DETAILED DESCRIPTION OF THE INVENTION

The invention broadly provides an implant for electrically stimulating a target body tissue in a subject. Once implanted, the implant provides a conductive pathway for at least a portion of the electrical current flowing between surface cathodic and anodic electrodes positioned in spaced relationship on a subject' skin, and transmits that portion of electrical current to the target body tissue. In further aspects, the invention provides a system and method incorporating the implant for electrically stimulating a target body tissue in a subject.

The subject can be an animal including a human. The body tissue can be a neural tissue (in the peripheral or central nervous system), a nerve, a muscle (skeletal, respiratory, or cardiac muscle) or an organ, for example, the brain, cochlea, optic nerve, heart, bladder, urethra, kidneys and bones. The invention can be applied to treat various conditions in which stimulation of any of these body tissues is required. Such conditions can include movement disorders (e.g., Parkinson's disease, tremor, cerebral palsy), muscular disorders (e.g., muscular dystrophy), incontinence (e.g., urinary bladder disorders), urinary retention, pain (e.g., migraine headaches, neck and back pain, pain resulting from other medical conditions), epilepsy (e.g., generalized and partial seizure disorder), cerebrovascular disorders (e.g., strokes, aneurysms), sleep disorders (e.g., sleep apnea), autonomic disorders (e.g., gastrointestinal disorders, cardiovascular disorders), disorders of vision, hearing and balance, and neuropsychiatric disorders (e.g., depression). The invention may also be used for promoting bone growth (as required, for example, in the healing of a fracture), wound healing or tissue regeneration.

The invention is described with reference to the drawings in which like parts are labeled with the same numbers in Figures 1 to 4. The invention is shown generally in Figure 1 which schematically illustrates portions of a subject's body tissues, including skin 10, a

nerve 12 with its overlying nerve sheath 14, and a muscle 16. Figure 1 also illustrates an implant indicated generally at 18, a surface cathodic electrode 20 and a surface anodic electrode 22. The implant 18 is provided for electrically stimulating a target body tissue, such as a nerve 12, in a subject. Once implanted, the implant 18 provides a conductive pathway for at least a portion of the electrical current flowing between the surface cathodic and anodic electrodes 20, 22.

When positioned in spaced relationship on the subject's skin 10, the surface cathodic and anodic electrodes 20, 22 make electrical contact with the skin 10 and transmit electrical current to the target body tissue. Surface cathodic and anodic electrodes 20, 22 can be selected from a conductive plate or sheet, a conductive gel electrode, a conductive rubber or polymer electrode that may be partially coated with an electrode paste or gel, or a moistened absorbent pad electrode. Self-adhesive hydrogel electrodes of the type used to stimulate muscles, with surface areas of 1 square centimeter or more are particularly effective. The positions of the surface cathodic and anodic electrodes 20, 22 on the skin 10 may vary, depending upon the location and nature of the target body tissue.

The implant 18 comprises an electrical conductor 24 of sufficient length to extend, once implanted, from subcutaneous tissue located below the surface cathodic electrode 20 to the target body tissue, for example nerve 12. The electrical conductor 24 can be formed from a metal wire, carbon fibers, a conductive rubber or other conductive polymer, or a conductive salt solution in rubber. Multistranded, Teflon®-insulated, stainless-steel wire conductors of the type used in cardiac pacemaker leads have been found to be particularly effective. The electrical conductor has a pick-up end 26 and a stimulating end 28, and is insulated between its ends 26, 28. The electrical impedance of the interface between the ends 26, 28 of the conductor 24 (when implanted) and the surrounding body tissue may be reduced by enlarging the surface area of the ends 26, 28. For that purpose, one or both of the pick-up and stimulating ends 26, 28 form electrical terminations 30 having sufficient surface areas for reducing the electrical impedance of the interface between the pick-up and stimulating ends 26, 28 of the electrical conductor 24 and the surrounding body tissues. Preferably, the pick-up end 26 forms a termination 30. The pick-up end 26 forms an electrical termination 30 which has a sufficient surface area to allow a sufficient portion of the electrical current to flow through the electrical conductor 24, in preference to flowing through body tissue

between the surface cathodic and anodic electrodes 20, 22, such that the target body tissue is stimulated. The stimulating end 28 also forms an electrical termination 30 for delivering the portion of electrical current to the target body tissue (i.e., nerve 12).

Terminations 30 should have sufficient surface area for providing high conductivity contact with body tissues, and lowering the electrical impedance between the body tissue and the conductor. If the surface area is minimal, the amount of current flowing through a conductor to the termination is reduced to an ineffective amount. The surface area required may thus be determined by a knowledge of the electrical impedance of the interface between the tissue and the terminations 30 at the receiving and stimulating ends 26, 28. Beneficial results have been obtained by making the surface area of metal terminations 30 at the ends 26, 28 about 0.5 square centimeters. The electrical impedance of each interface between tissue and terminations 30 at ends 26, 28 was then about 5 times the electrical impedance of all the subcutaneous tissue between surface electrodes 20, 22. A typical value of tissue impedance is 200 ohms. The impedance of the conductor itself is chosen to be very small, for example 5 ohms. In the example just given, the sum of the two interface impedances of the terminations 30 plus the conductor impedance was about 2000 ohms, that is to say about ten times the tissue impedance. Thus about 10% of the current applied between surface electrodes 20,22 flows through conductor 24 to the target tissue. In the case of the target tissue being a nerve 12 supplying a muscle 16, the amount of current between surface electrodes 20, 22 required to produce a useful muscle contraction of the target muscle 16 then remains below the threshold level of activation of nerve endings in the subcutaneous tissue immediately between surface electrodes 20, 22. This is a beneficial relationship, because it means that target muscles 16 can be activated with little or no local sensation under the surface electrodes 20, 22.

Terminations 30 of various shapes, materials and spatial arrangements can be used; for example, terminations 30 can provide an enlarged surface in the form of a coil, spiral, cuff, rod, or a plate or sheet in the form of an oval or polygon. As an example, Figure 1 illustrates a termination 30 as a plate or sheet in the form of an oval at the pick-up end 26 of the electrical conductor 24, and in the form of a cuff at the stimulating end 28. The cuff or a portion thereof can encircle or partially encircle the entirety or part of the nerve sheath 14 of the nerve 12. The cuff or a portion thereof can be positioned proximate to the nerve sheath

14, or the inner surface of the cuff or a portion thereof can directly contact the nerve sheath 14.

Beneficial results are obtained with stainless-steel plates or sheets in the form of an oval which is about 0.5 square centimeter in area and 1 mm thick, or made of metal foil and stainless-steel mesh and being about 0.5 square centimeter in surface area and 0.3 mm thick. For terminations 30 of conductors with nerve cuffs, nerve cuffs made of metal foil or stainless-steel mesh and being 0.5 to 1 square centimeter in surface area and 0.3 mm thick are suitable. Further, silastic elastomer cuffs ranging from 5mm to 15mm in length, 4 mm to 6mm inside diameter, and 1mm thick are suitable.

Terminations 30 can be formed from uninsulated ends 26, 28 of the electrical conductor 24, or from other conductive or capacitive materials. Terminations 30 can be formed by coiling, spiraling or weaving long, uninsulated lengths of the pick-up or stimulating ends 26, 28 to provide a sufficient surface. The surface area of the termination is thus "enlarged" relative to the surface area of a shorter length of the electrical conductor 24. This raises the effective surface area of the terminations 30 within a small space to provide higher conductivity contact with body tissues, and to lower the electrical impedance between the body tissue and the conductor 24 to allow current flow in the conductor in preference to in the body tissue. Sufficient current flow is thereby provided in the conductor 24 to stimulate the target tissue. Alternatively, prefabricated terminations 30 (for example, plates or sheets in the form of ovals or polygons) can be attached directly to the pick-up and stimulating ends 26, 28. Further, terminations 30 can be coated or modified with conductive materials to maximize the flow of electrical current through the target body tissue.

The spatial arrangement of the terminations 30 can be varied; for example, multiple terminations 30 can also be applied to different parts of a body tissue (Grill *et al.*, 1996). Advantageously, the terminations 30 themselves can be in the form of closely-spaced contacts enclosed within an embracing cuff 32 placed around the nerve 12. The embracing cuff 32 can be formed from conductive silicone rubber.

Electrical impedance may be further reduced by providing conductive or capacitive coatings, or an oxide layer on the terminations 30. The coating can be selected from a material whose structural or electrical properties improve the electrical conductance between the tissue and the conductor, for example, by providing a complex surface into which tissue

can grow (for example, a polymer such as poly-diethoxy-thiophene, or suitable oxide layers including tantalum and sintered iridium). In addition, the terminations 30 can have coatings which provide an anti-inflammatory, anti-bacterial or tissue ingrowth effect. The coating can be a substance selected from an anti-inflammatory agent, antibacterial agent, antibiotic, or a tissue ingrowth promoter.

Optionally, performance of the invention can be improved by implanting an electrical return conductor 34 of sufficient length to extend from the target body tissue to subcutaneous tissue located below the surface anodic electrode 22. The electrical return conductor 34 provides a low-impedance conductive pathway from the target body tissue to the surface anodic electrode 22, thereby concentrating the electric field through the target tissue. The electrical return conductor 34 can be formed from a metal wire, carbon fibers, a conductive rubber or other conductive polymer, or a conductive salt solution in rubber. The electrical return conductor 34 has a collecting end 36 and a returning end 38, and is insulated between its ends 36, 38. Both the collecting end 36 and the returning end 38 form electrical terminations 30 (as described above) for reducing the electrical impedance of the interface between the collecting end 36 and returning end 38 of the electrical return conductor 34 and the surrounding body tissues. The collecting end 36 forms an electrical termination 30 (shown in Figure 1 in the form of a cuff), which has a sufficient surface area to allow a portion of the electrical current delivered to the target body tissue to return through the electrical return conductor 34 in preference to returning through body tissue. The returning end 38 forms an electrical termination 30 (shown in Figure 1 as a plate or sheet in the form of an oval) which returns the electrical current to the surface anodic electrode 22 via the subcutaneous tissue and skin underlying the surface anodic electrode 22.

A power source 40 (shown in Figures 2-4) provides operating power to a stimulator (not illustrated) which is external to the subject's body. The stimulator is electrically connected to the surface cathodic and anodic electrodes 20, 22 to supply electrical current to the surface cathodic and anodic electrodes 20, 22. The current can be resistive, capacitive, or inductive current, depending on the net impedance encountered between the electrodes 20, 22. The stimulator can supply direct, pulsatile or alternating current between the surface cathodic and anodic electrodes 20, 22 to cause the portion of the electrical current to flow through the implant 18 sufficient to stimulate the target body tissue.

Exemplary pulse parameters of electrical current flowing between the surface cathodic and anodic electrodes 20, 22 are as follows: biphasic current pulses, 30 pulses per second, each phase 200 microseconds in duration, and a peak current per pulse ranging from 0.7 to 2 milliampere. Beneficial results can be obtained with rectangular, feedback-controlled current pulse waveforms, although other waveforms and modes of control of current or voltage have also been found to give satisfactory results. The inventor has discovered that between 10% and 20% of the current flowing between the surface electrodes 20, 22 is propagated through an implanted conductor 24, even when there is no electrical return conductor 34. The type of current may be dependent upon the application for which the invention is intended; for example, continuous current would be applied, rather than pulsatile current, when the target body tissue is bone and promotion of bone growth is desired.

Although most of the electrical current flows through the body tissues in proximity to the surface cathodic and anodic electrodes 20, 22, there is flow of electrical current through the electrical conductor 24, nerve 12, and electrical return conductor 34. As shown in Figure 1, the surface cathodic electrode 20 is positioned over the pick-up end 26 of the electrical conductor 24, so that a portion of the current is transmitted through the conductor 24 to the target body tissue, and current flows through the target body tissue and returns to the anodic surface electrode 22 through body tissues. This can also be achieved through the implanted electrical return conductor 34 extending between the target body tissue and subcutaneous tissue located below the surface anodic electrode 22.

The complete electrical path of the portion of the electrical current is as follows: cathodic wire 42, surface cathodic electrode 20, skin 10, termination 30 (as a plate or sheet), pick-up end 26, electrical conductor 24, stimulating end 28, termination 30 (in the form of a cuff), nerve sheath 14, nerve 12, termination 30, collecting end 36, electrical return conductor 34, returning end 38, termination 30, skin 10, surface anodic electrode 22 and anodic wire 44. The pulses of electrical current elicit action potentials are conducted along nerve 12 to muscle 16, causing it to contract.

As an example, Figure 2 illustrates the invention for use in the treatment of a movement disorder requiring stimulation of the median nerve 46. The median nerve 46 innervates most of the flexor muscles in front of the forearm, most of the short muscles of the thumb, and the short muscles of the hand. A subject's arm 48 is illustrated with the implant

18 implanted in the forearm. The electrical conductor 24 is illustrated with its pick-up end 26 forming a termination 30 (as a plate or sheet in the form of an oval) for receiving the electrical current from the surface cathodic electrode 20. The stimulating end 28 forms a termination 30 (in the form of a cuff) for delivering the electrical current to the median nerve 46. A surface anodic electrode 22 is positioned on the skin 10. A flow of electrical current from the power source 40 is supplied via cathodic wire 42 into the skin 10 at the surface cathodic electrode 20 and the surface anodic electrode 22 via anodic wire 44. The electrical current flows through the termination 30, the pick-up end 26, the electrical conductor 24, the stimulating end 28, a portion of the median nerve 46, the tissue between stimulating end 28 and surface anodic electrode 22 including the skin underlying electrode 22, the surface anodic electrode 22, anodic wire 44 and the power source 40, thus completing the electrical circuit. Some of the current flowing between the stimulating end 28 and the surface anodic electrode 22 passes through the target body tissue (in this example, median nerve 46), thereby causing the muscle 16 of the arm 48 to be stimulated.

As a further example, Figure 3 again illustrates the invention for use in the treatment of a movement disorder requiring stimulation of the median nerve 46. However, in addition to the components shown in Figure 2, Figure 3 illustrates an electrical return conductor 34. The electrical circuit is essentially the same as that described for Figure 2, with the exception that after flowing through the stimulating end 28 and the median nerve 46, the electrical current flows through termination 30, the collecting end 36, the electrical return conductor 34, the returning end 38, termination 30, the surface anodic electrode 22, anodic wire 44 and the power source 40, thus completing the electrical circuit. Advantageously, the electrical return conductor 34 acts to collect electrical current flowing through the target body tissue (i.e., median nerve 46) from the electrical conductor 24 and provides a low impedance pathway back to the surface anodic electrode 22, thereby concentrating the electric field through the target body tissue (i.e., median nerve 46).

As yet a further example, Figure 4 illustrates a plurality of implants 18 for electrically stimulating more than one target body tissue independently or in unison. Each implant 18 is implanted entirely under the subject's skin 10 and is of a sufficient length to extend to a different target body tissue. The presence of multiple implants 18 necessitates positioning of a plurality of surface cathodic electrodes 20, and one or more surface anodic electrodes 22

appropriately relative to the implants 18 to stimulate the different target body tissues independently or in unison. Figure 4 illustrates the invention for use in the treatment of a movement disorder requiring stimulation of the median nerve 46 and the radial nerve 50. The radial nerve 50 innervates extensor muscles on the back of the arm and forearm, the short muscles of the thumb, and the extensor muscles of the index finger. Two separate surface cathodic electrodes 20 are each electrically connected via two separate cathodic wires 42 to a stimulator (not illustrated) operated by the power source 40. Electrical current is transmitted to the two separate electrical conductors 24, one of which extends to the median nerve 46, and the other to the radial nerve 50. An electrical return conductor 34 extends from the target tissue (i.e., below the median nerve 46) to subcutaneous tissue located below one surface anodic electrode 22.

The electrical path of the current is as follows: cathodic wire 42, the surface cathodic electrodes 20, the skin 10, termination 30, the pick-up end 26, the electrical conductor 24, the stimulating end 28, termination 30, the median nerve 46 and/or radial nerve 50, termination 30, collecting end 36, electrical return conductor 34, returning end 38, termination 30, surface anodic electrode 22, anodic wire 44, and power source 40. The median nerve 46 and radial nerve 50 can be stimulated either independently by pulsatile electrical current to provide firstly, a flexion or upward position of the wrist and finger closing (via the median nerve 46), then secondly, extension or downward position of the wrist and finger extension (via the radial nerve 50). Alternatively, the median nerve 46 and radial nerve 48 can be stimulated simultaneously for example, to straighten the hand (i.e., position the wrist horizontally).

The invention thus provides several advantages including a means of "remote" stimulation, that is the surface cathodic and anodic electrodes 20, 22 do not have to be positioned over target body tissues. Remote target body tissues, such as nerves 12, can be stimulated from closely spaced surface cathodic and anodic electrodes 20, 22, by routing current through separate electrical conductors 24 simultaneously to several remote target body tissues.

Further, greater selectivity is provided in stimulating target body tissues. The electrical conductor 24 extends to a specific target body tissue, or multiple electrical conductors 24 can extend to multiple target body tissues. Stimulation is thus specific to the target body tissues, and stimulation of non-target body tissues is avoided. As an electrical

conductor 24 of sufficient length is used to reach target body tissues, stimulation of target body tissues which are positioned deep within the body or organs such as the muscles, brain, cochlea, optic nerve, heart, bladder, urethra, kidneys and bones, can be achieved.

Stimulation is reproducible at will. The electrical conductor 24 is passive and can remain permanently implanted with the pick-up end 26 under the skin 10 beneath the site at which the surface cathodic electrode 20 would be placed, and the stimulating end 28 positioned proximate to the target body tissue. To the inventor's knowledge, difficulty has been encountered in positioning surface electrodes accurately to obtain acceptable selectivity of stimulation of body tissues. The inventor has discovered that surprisingly, the invention requires far less accuracy in positioning of the surface cathodic and anodic electrodes 20, 22; consequently, stimulation of body tissues is more accurately reproducible.

Further, the invention avoids problems inherent in other forms of stimulation. The conductors (i.e., electrical conductor 24, electrical return conductor 34) do not emerge through the skin, thus reducing the risk of infection which may arise with percutaneous devices. There is no need to construct an implant housing its own stimulator, signal generator or power source, or to provide radio-frequency or other telemetric command signals through the skin.

As is known to those skilled in the art, the electric currents delivered by a pulse generator to a plurality of electrodes 20, 22 may be independently controlled with the use of an interleaved pulse train. This comprises a sequence of stimulus pulses of different amplitudes, the pulses separated in time by a few milliseconds and delivered to each electrode in turn, the sequence as a whole being repeated at a rate such as 30 times per second. The amplitudes of the pulses flowing through each electrode may thereby be controlled independently.

A plurality of surface electrodes 20, 22 may be fabricated on a single non-conductive substrate to form an electrode array that may be conveniently attached to the skin 10 in one manoeuvre. Similarly, the plurality of terminations 30 of implanted conductors 24 may be fabricated on a substrate to form an array. By matching the physical layout of the surface electrode array to that of the implanted terminations array, a good spatial correspondence of surface and implanted conductors may be achieved in a convenient and reproducible manner. Surface electrode arrays in which the conductivity of each element of the array may be

independently controlled could also be used to adjust the conductivity between the surface electrodes and the terminations in an implanted array.

It will be apparent to one skilled in the art that modifications may be made to the illustrated embodiment without departing from the spirit and scope of the invention as hereinafter defined in the claims.

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Prochazka, A. (2003) Method and apparatus for controlling a device or process with vibrations generated by tooth clicks. International Patent Application Publication No. WO 2004/034937, published October 16, 2003.

All publications mentioned in this specification are indicative of the level of skill in the art to which this invention pertains. All publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference. Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity and understanding it will be understood that certain changes and modifications may be made without departing from the scope or spirit of the invention as defined by the following claims.

WHAT IS CLAIMED IS:

1. An implant for electrically stimulating a target body tissue in a subject, the implant, once implanted, providing a conductive pathway for at least a portion of the electrical current flowing between surface cathodic and anodic electrodes positioned in spaced relationship on the subject's skin and transmitting that portion of the electrical current to the target body tissue, the implant comprising:

an electrical conductor of sufficient length to extend, once implanted, from subcutaneous tissue located below the surface cathodic electrode to the target body tissue, the electrical conductor having a pick-up end and a stimulating end and being insulated between its ends, the pick-up end forming an electrical termination having a sufficient surface area to allow a sufficient portion of the electrical current to flow through the conductor, in preference to flowing through body tissue between the surface cathodic and anodic electrodes, such that the target body tissue is stimulated, and the stimulating end forming an electrical termination for delivering the portion of electrical current to the target body tissue.

2. The implant according to claim 1, wherein the implant further comprises:

an electrical return conductor of sufficient length to extend, once implanted, from the target tissue to subcutaneous tissue located below the surface anodic electrode, the return conductor having a collecting end and a returning end and being insulated between its ends, the collecting end forming an electrical termination having a sufficient surface area to allow a portion of the current delivered to the target body tissue to return through the return conductor in preference to returning through body tissue, and the returning end forming an electrical termination that returns the electrical current to the surface anodic electrode via the subcutaneous tissue and skin underlying that electrode.

3. The implant according to claim 1 or 2, wherein one or both of the conductor and return conductor is formed from a metal wire, carbon fibers, a conductive rubber or other conductive polymer, or a conductive salt solution in rubber.

4. The implant according to claim 3, wherein the terminations on one or both ends of the conductor and return conductor provide an enlarged surface in the form of a coil, a spiral, a cuff, a rod, or a plate or sheet in the form of an oval or polygon.

5. The implant according to claim 4, wherein one or more of the terminations are formed from uninsulated ends of the conductor or return conductor, or from other conductive or capacitive materials.

6. The implant according to claim 5, further comprising a conductive or capacitive coating, or oxide layer on one or more of the terminations.

7. The implant according to claim 5, further comprising a coating on one or both of the terminations for providing an anti-inflammatory, an anti-bacterial or a tissue ingrowth effect, the coating being a substance selected from the group consisting of an anti-inflammatory agent, an antibacterial agent, an antibiotic, and a tissue ingrowth promoter.

8. A system for electrically stimulating a target body tissue in a subject comprising:

i) surface cathodic and anodic electrodes for making electrical contact with the subject's skin, and which, when positioned in spaced relationship on the subject's skin, for transmitting electrical current to the target body tissue;

ii) a stimulator external to the subject's body, electrically connected to the surface cathodic and anodic electrodes, the stimulator supplying direct, pulsatile, or alternating current to the surface cathodic and anodic electrodes; and

iii) an implant for picking up a portion of the electrical current flowing between the surface cathodic and anodic electrodes and transmitting that portion of the electrical current to the target body tissue, the implant comprising an electrical conductor of sufficient length to extend, once implanted, from subcutaneous tissue located below the surface cathodic electrode to the target body tissue, the electrical conductor having a pick-up end and a

stimulating end and being insulated between its ends, the pick-up end forming an electrical termination having a sufficient surface area to allow a sufficient portion of the electrical current being applied to flow through the conductor, in preference to current flowing through body tissue between the surface cathodic and anodic electrodes, such that the target body tissue is stimulated, and the stimulating end forming an electrical termination for delivering the portion of electrical current to the target body tissue.

9. The system according to claim 8, further comprising an electrical return conductor of sufficient length to extend, once implanted, from the target tissue to subcutaneous tissue located below the surface anodic electrode, the return conductor having a collecting end and a returning end and being insulated between its ends, the collecting end forming an electrical termination having a sufficient surface area to allow a portion of the current delivered to the target body tissue to return through the return conductor in preference to returning through body tissue, and the returning end forming an electrical termination that returns the electrical current to the surface anodic electrode via the subcutaneous tissue and skin underlying that electrode.

10. The system according to claim 8, comprising comprising implanting a plurality of implants as defined in claim 8 for electrically stimulating more than one target body tissue independently or in unison, each implant being implanted entirely under the subject's skin and being of a sufficient length to extend to a different target body tissue, and positioning a plurality of surface cathodic and one or more surface anodic electrodes appropriately relative to the implants to stimulate the different target body tissues independently or in unison.

11. The system according to claim 8, 9 or 10, wherein the conductor is formed from a metal wire, carbon fibers, a conductive rubber or other conductive polymer, or a conductive salt solution in rubber.

12. The system according to claim 11, wherein the terminations on one or both of the pick-up end or stimulating end provide an enlarged surface in the form of a coil, a spiral, a cuff, a rod, or a plat or sheet in the form of an oval or polygon.

13. The system according to claim 12, wherein the surface cathodic and anodic electrodes comprise a conductive plate or sheet, a conductive gel electrode, a conductive rubber or polymer electrode that may be partially coated with an electrode paste or gel, or a moistened absorbent pad electrode.

14. The system according to claim 12, wherein the terminations can be formed from uninsulated ends of the conductor itself, or from other conductive or capacitive materials.

15. The system according to claim 12, further comprising a conductive or capacitive coating, or oxide layer on one or both of the terminations.

16. The system according to claim 12, further comprising a coating on one or both of the terminations for providing an anti-inflammatory, an anti-bacterial or a tissue ingrowth effect, the coating being a substance selected from the group consisting of an anti-inflammatory agent, an antibacterial agent, an antibiotic, and a tissue ingrowth promoter.

17. A method for electrically stimulating a target body tissue in a subject comprising the steps of:

a) providing an implant to act as a conductive pathway for at least a portion of the electrical current flowing between surface cathodic and anodic electrodes positioned in spaced relationship on the subject's skin and transmitting the portion of the electrical current to the target body tissue, the implant comprising an electrical conductor of sufficient length to extend, once implanted, from subcutaneous tissue located below the surface cathodic electrode to the target body tissue, the electrical conductor having a pick-up end and a stimulating end and being insulated between its ends, the pick-up end forming an electrical termination having a sufficient surface area to allow a sufficient portion of the electrical current to flow through the conductor, in preference to flowing through body tissue between the surface cathodic and anodic electrodes, such that the target body tissue is stimulated, and the stimulating end forming an electrical termination for delivering the portion of electrical current to the target body tissue;

b) implanting the implant entirely under the subject's skin, with the pick-up end positioned in subcutaneous tissue located below the surface cathodic electrode, and the stimulating end positioned proximate to the target body tissue;

c) positioning the surface cathodic and anodic electrodes in spaced relationship on the subject's skin, with the surface cathodic electrode positioned over the pick-up end of the electrical conductor so the portion of the current is transmitted through the conductor to the target body tissue, and so that the current flows through the target body tissue and returns to the anodic surface electrode through body tissues or through an implanted electrical return conductor extending between the target body tissue and subcutaneous tissue located below the surface anodic electrode; and

d) applying direct, pulsatile or alternating electrical current between the surface cathodic electrode and the surface anodic electrode to cause the portion of the electrical current to flow through the implant sufficient to stimulate the target body tissue.

18. The method according to claim 17, further comprising the return conductor entirely under the subject's skin, the return conductor comprising sufficient length to extend, once implanted, from the target tissue to subcutaneous tissue located below the surface anodic electrode, the return conductor having a collecting end and a returning end and being insulated between its ends, the collecting end forming an electrical termination having a sufficient surface area to allow a portion of the current delivered to the target body tissue to return through the return conductor in preference to returning through body tissue, and the returning end forming an electrical termination that returns the electrical current to the surface anodic electrode via the subcutaneous tissue and skin underlying that electrode.

19. The method according to claim 17, further comprising implanting a plurality of implants as defined in claim 17 for electrically stimulating more than one target body tissue independently or in unison, each implant being implanted entirely under the subject's skin and being of a sufficient length to extend to a different target body tissue, and positioning a

plurality of surface cathodic and one or more surface anodic electrodes appropriately relative to the implants to stimulate the different target body tissues independently or in unison.

20. The method according to claim 17, 18 or 19, wherein the conductor is formed from a metal wire, carbon fibers, a conductive rubber or other conductive polymer, or a conductive salt solution in rubber.

21. The method according to claim 20, wherein the terminations on one or both of the pick-up end or stimulating end provide an enlarged surface in the form of a coil, a spiral, a cuff, a rod, or a plate or sheet in the form of an oval or polygon.

22. The method according to claim 21, wherein the surface cathodic and anodic electrodes comprise a conductive plate or sheet, a conductive gel electrode, a conductive rubber or polymer electrode that may be partially covered with an electrode paste or gel, or a moistened absorbent pad electrode.

23. The method according to claim 21, wherein the terminations can be formed from uninsulated ends of the conductor itself, or from other conductive or capacitive materials.

24. The method according to claim 21, further comprising a conductive or capacitive coating, or oxide layer on one or both of the terminations.

25. The method according to claim 21, further comprising a coating on one or both of the terminations for providing an anti-inflammatory, anti-bacterial or growth effect, the coating being a substance selected from the group consisting of an anti-inflammatory agent, an antibacterial agent, an antibiotic, and a tissue ingrowth promoter.

26. The method according to claim 17, 18 or 19, wherein the body tissue is selected from a neural tissue in the peripheral or central nervous system, a nerve, a muscle or an organ.

27. The method according to claim 17, 18 or 19, wherein stimulation of the body tissue is conducted to treat a condition selected from the group consisting of a movement disorder, a muscular disorder, incontinence, urinary retention, pain, epilepsy, a cerebrovascular disorder, a sleep disorder, an autonomic disorder, a disorder of vision, hearing or balance, and a neuropsychiatric disorder, to promote bone growth or wound healing, or to promote tissue regeneration.

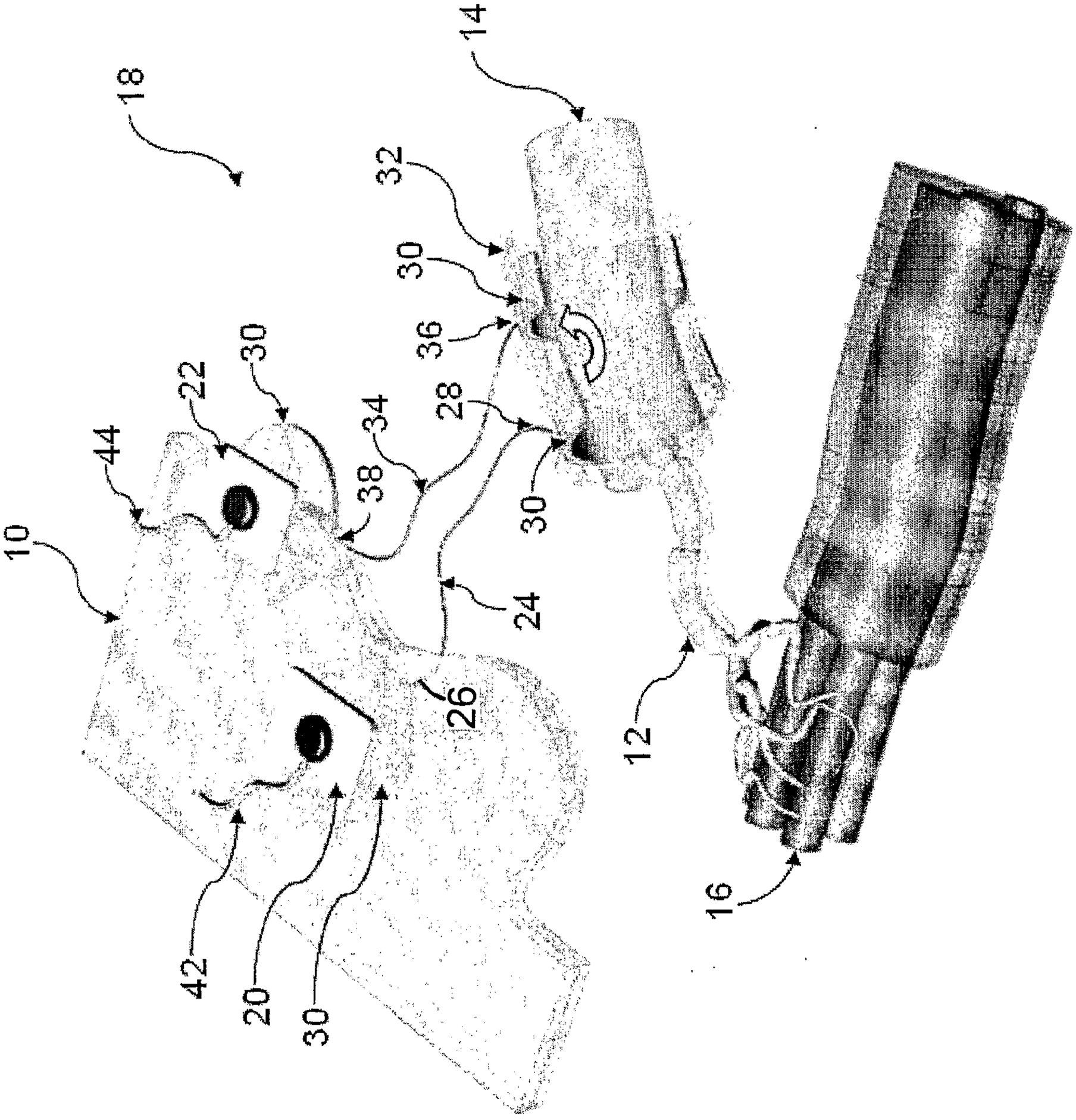


FIGURE 1

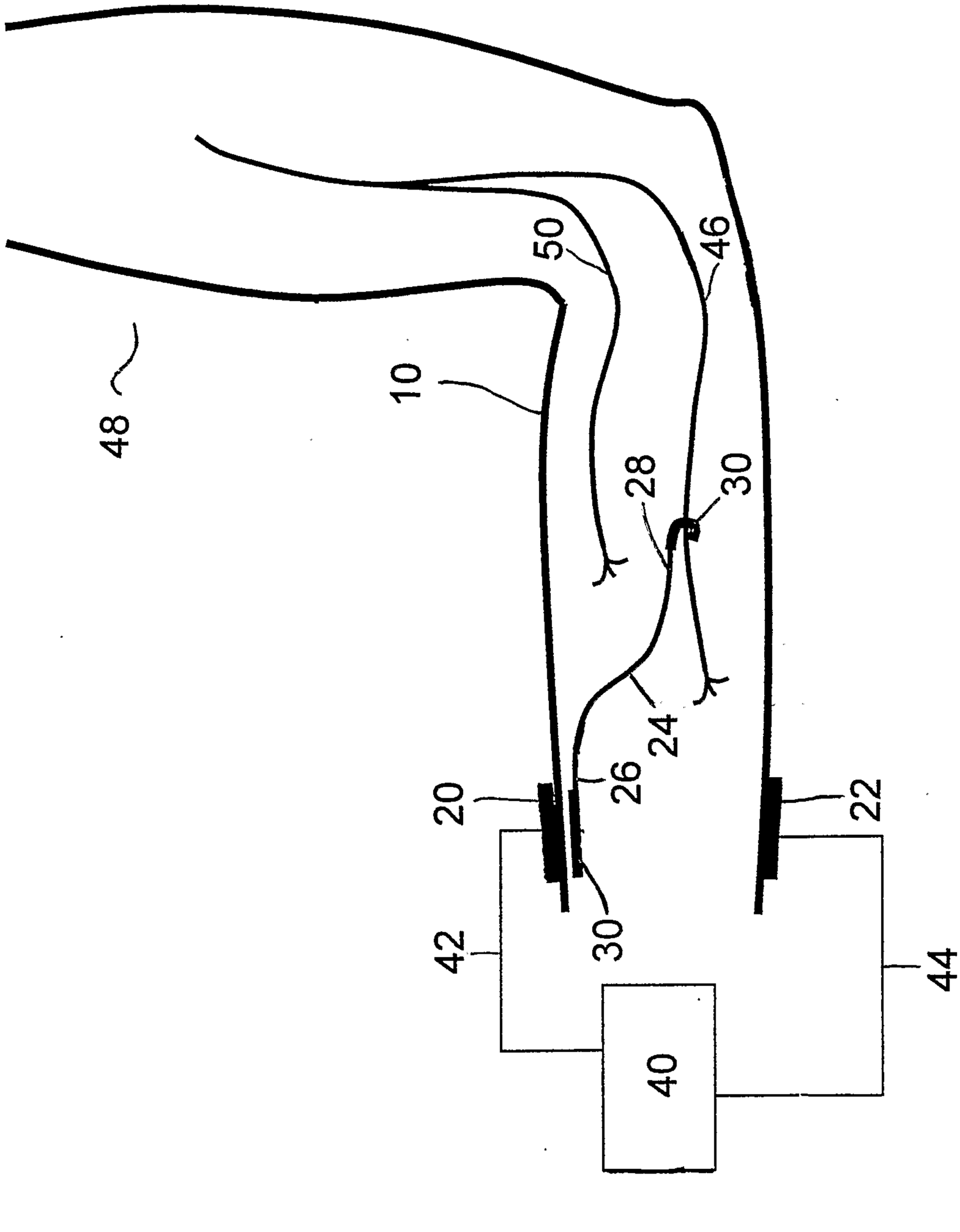


FIGURE 2

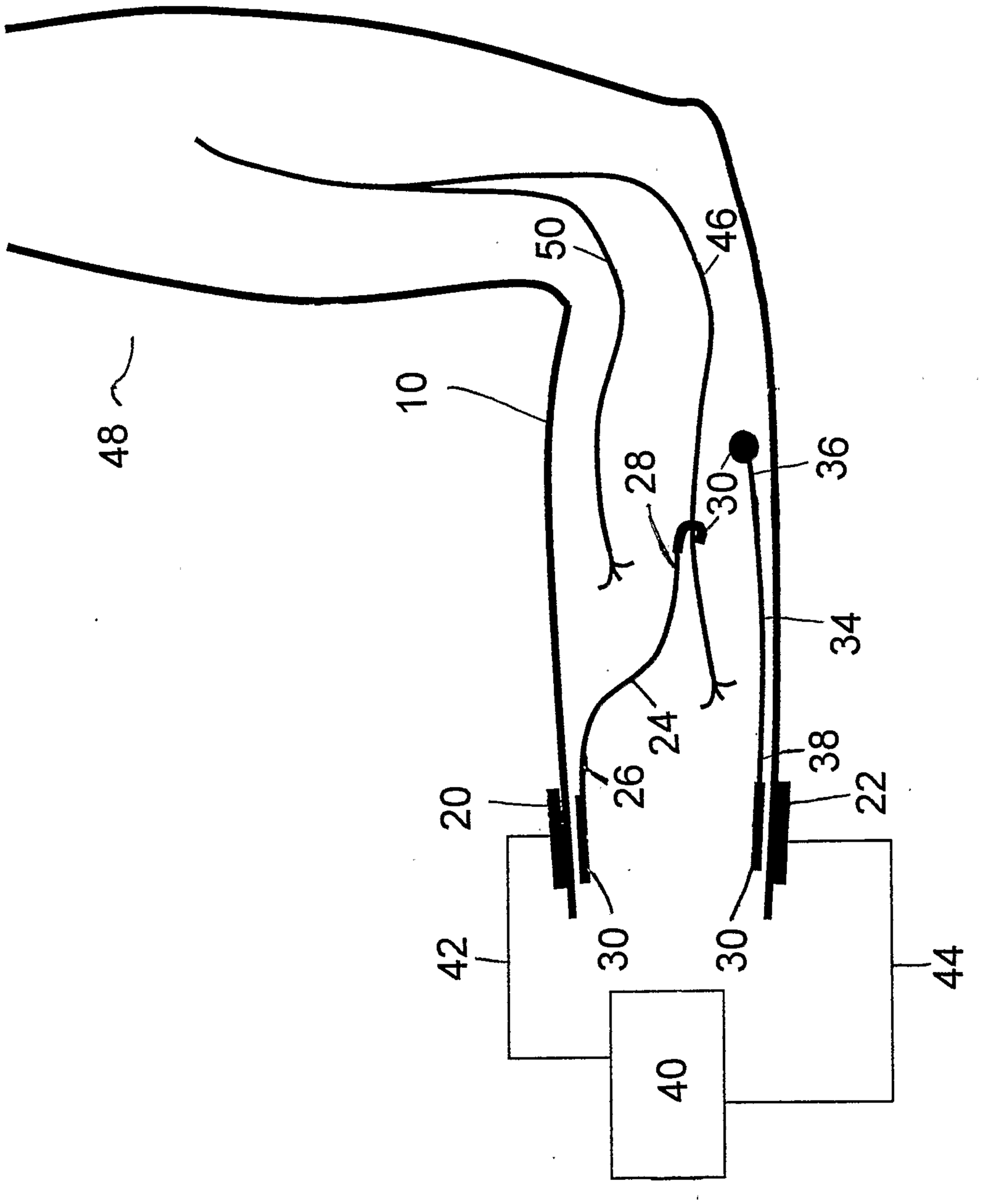


FIGURE 3

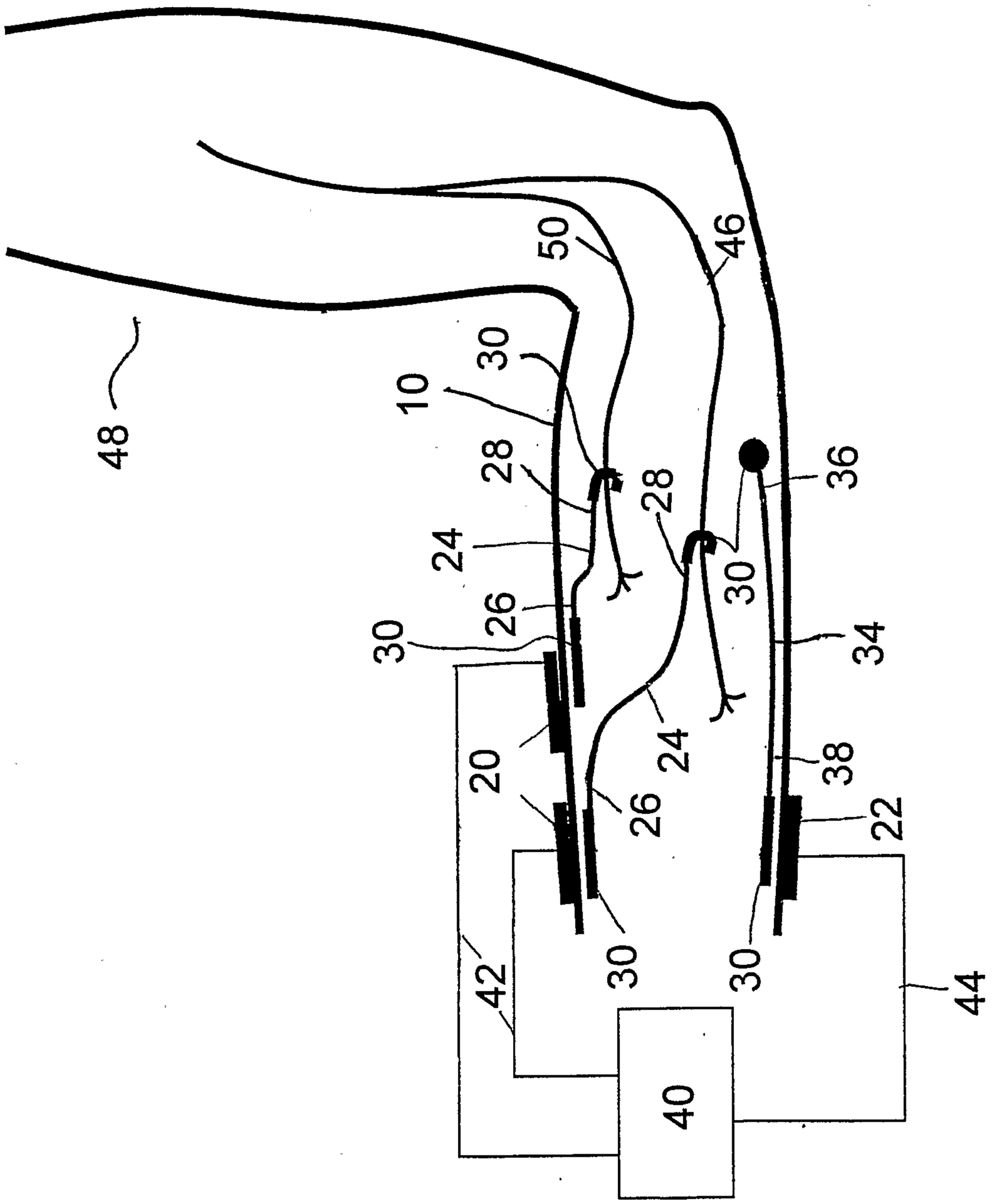
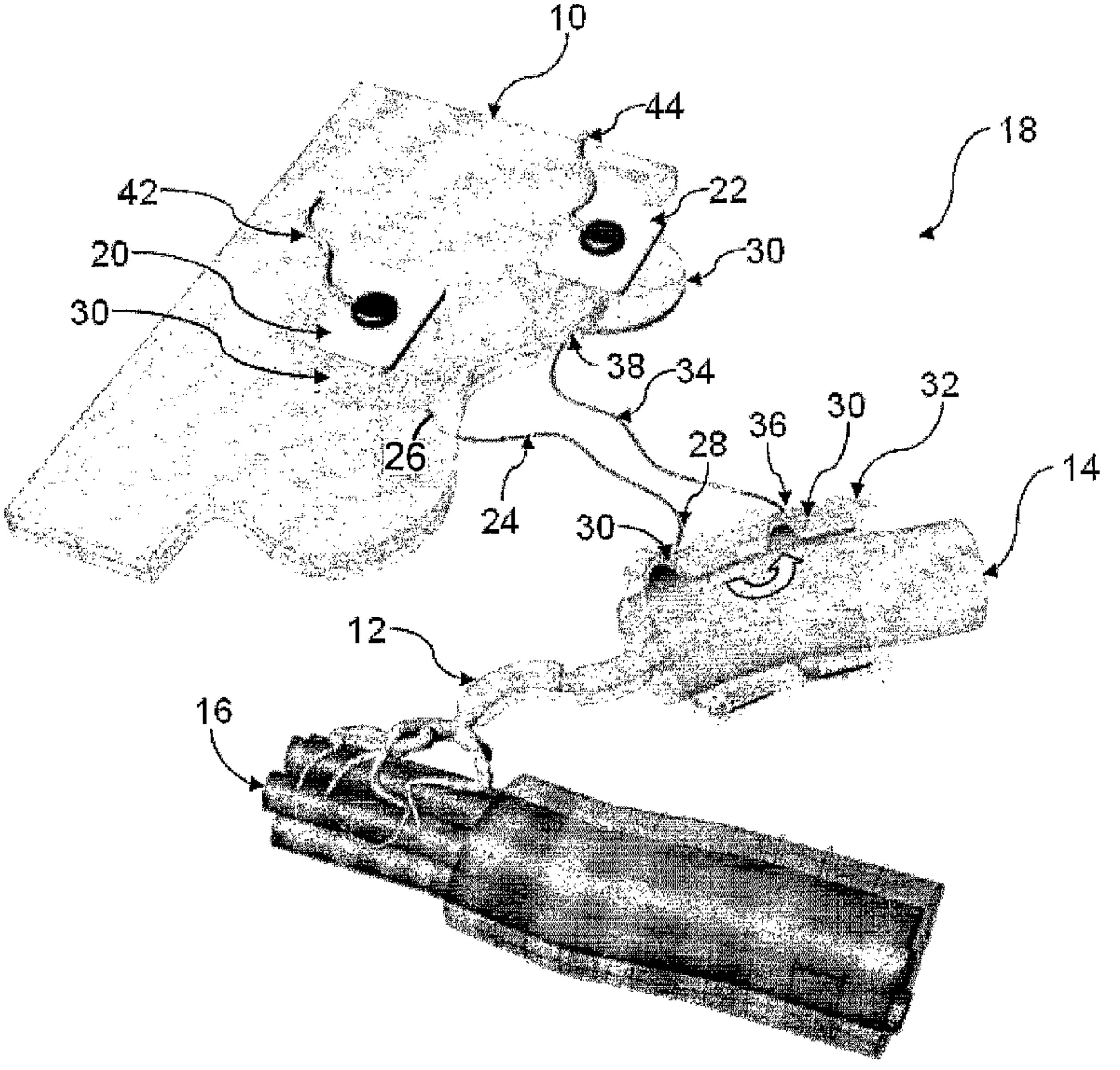


FIGURE 4


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