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(54) **Title:** NEURAL STIMULATION DELIVERY DEVICE WITH INDEPENDENTLY MOVEABLE DELIVERY STRUCTURES

(57) **Abstract:** The present invention relates to a neural stimulation delivery device to deliver electrical and/or chemical stimulation to target sites in the central and peripheral nervous system. The device generally includes a tubular body defining a plurality of ports along the longitudinal axis thereof, a plurality of delivery structures insertable in the body, and a control mechanism in communication with the plurality of delivery structures to independently move each of the plurality of delivery structures through a respective one of the plurality of ports with respect to each other of the plurality of delivery structures. The ability of each delivery structure to be independently moveable through a respective port allows each delivery structure to be selectively advanced or retracted independent of the movement of another delivery structure.

NEURAL STIMULATION DELIVERY DEVICE WITH INDEPENDENTLY MOVEABLE DELIVERY STRUCTURES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to Provisional U.S. Application No. 60/353,705, filed February 1, 2002, which is incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates to a device for electrically and/or chemically stimulating neural tissue.

BACKGROUND OF THE INVENTION

Electrical stimulation of neural tissue is becoming an increasingly preferred form of therapy for various neurological conditions and disorders. Such therapy provides distinct advantages over surgical lesioning techniques, which are still being used to affect disorders and conditions such as Parkinson's disease, essential tremors and dystonia. In particular, unlike surgicial lesioning techniques, electrical stimulation is a reversible and adjustable procedure that provides continuous benefits as the patient's disease progresses and the patient's symptoms evolve.

Electrical stimulation of neural tissue to affect a particular neurological condition is typically performed by implanting near a specific site of neural tissue a device including an electrical lead having one or more electrodes. The lead is coupled to a signal generator that delivers electrical energy through the electrodes to the neural tissue stimulating an increase, decrease, or block of neuronal activity to directly or indirectly affect the neurological condition. In order to perform this procedure effectively, a practitioner must position the electrical stimulation device in such a way to modulate the desired volume of neural tissue and to minimize stimulating unwanted adjacent neural tissue, which could create undesirable side effects. Such precise targeting to focus stimulation towards a specific location sub-serving the desired function to be modulated requires enormous time and effort. Furthermore, often times the stimulation must be adjusted or redirected after the initial surgery as a result of sub-optimal placement, lead migration, disease progression, inefficacious treatment, undesirable side effects, neural plasticity, or histological changes of tissue surrounding the stimulation device.

With present multi-contact electrode devices, it is hard to overcome these problems since it is difficult to redirect stimulation after the initial surgery even though limited readjustments can be made by selecting a different contact combination, pulse rate, pulse width or voltage. Stimulation devices have been described to purportedly address the deficiencies of these multi-contact electrode devices, but none provide an optimal alternative. For example, U.S. Patent Publication 2002/018317 describes a directional brain stimulation lead assembly including a lead body and an insulating member defining one or more windows that selectively expose portions of electrodes carried by the lead body to produce a directional stimulation current field. Because of the configuration of the electrodes, however, the distance of electrical stimulation in the radial direction is limited. Therefore, the lead assembly may not be able to effect therapy to neural tissue sites located outside the assembly's radius of stimulation. U.S. Patent No. 6,353,762 describes a device including electrical leads inserted into a cannula and projecting outward at the distal end of the cannula. Because the leads only project from the distal end of the cannula, the area over which stimulation can be provided is limited. For example, if it is desired to stimulate a new neural tissue site located superior or inferior to the original stimulation site, the device's position must be readjusted to raise or lower the device so that the leads are positioned in a location adjacent to this new neural site. Such readjustment may require a second surgery if the decision to reposition the device is made after the initial surgery, thereby increasing the risk of bleeding and damage to surrounding neural tissue and increasing the cost of the overall therapy.

Therefore, there is an unmet need for a versatile neural stimulation delivery device that allows for varying directions, distances, and degrees of stimulation to sufficiently reduce the time, cost, and risk of electrical stimulation of neural tissue.

SUMMARY OF INVENTION

The present invention discloses a stimulation delivery device to stimulate neural tissue generally including a plurality of independently moveable delivery structures. The delivery structures may provide electrical stimulation in which case the delivery structures are leads or leads having delivery elements that are electrodes disposed thereon. The leads are, in turn, coupled to a signal generator. Alternatively or in addition, the delivery structures may provide chemical stimulation in which case the delivery structures are catheters defining delivery elements that are drug ports. The catheters are, in turn, coupled to a drug pump. The delivery structures may non-destructively stimulate any type of neural tissue including any areas of the central nervous system and peripheral nervous system such as the brain, spinal cord, and peripheral nerves. Although the device of the present invention is particularly adapted for deep brain stimulation, the device may be implanted epidurally, subdurally, intracranially, or cortically.

In particular, one embodiment of the present invention provides a stimulation delivery device for stimulating neural tissue including a body having a proximal end and a distal end and defining a plurality of ports along a longitudinal axis thereof between the proximal end and the distal end of the body. The device also includes a plurality of delivery structures insertable within the body, each of the plurality of delivery structures independently moveable through a respective one of the plurality of ports. In a preferred embodiment, the device also includes at least one delivery element disposed on the body.

Another embodiment of the present invention provides a stimulation delivery device for stimulating neural tissue comprising a body having a proximal end and a distal end, the body defining an annular arrangement of a plurality of ports between the proximal end and the distal end of the body about a plane transverse to the longitudinal axis of the body. The device further includes a plurality of delivery structures insertable in the body, each of the plurality of delivery structures independently moveable through a respective one of the plurality of ports.

Another embodiment of the present invention provides a stimulation delivery device for stimulating neural tissue comprising a body having a proximal end and a distal end, the body defining a semi-annular arrangement of a plurality of ports between the proximal end and the distal end of the body about a plane transverse to the longitudinal axis of the body. The device further includes a plurality of delivery structures insertable in the body, each of the plurality of delivery structures independently moveable through a respective one of the plurality of ports.

Another embodiment of the present invention provides a stimulation delivery device for stimulating neural tissue comprising a body having a proximal end and a distal end and defining a plurality of ports at the distal end thereof. The device further includes a plurality of delivery structures insertable within the body, each of the delivery structures independently moveable through a respective one of the plurality of delivery structures.

Another embodiment of the present invention provides a stimulation delivery system for stimulating neural tissue comprising a stimulation delivery device and a control mechanism. The stimulation delivery device comprises a body having a proximal end and a distal end and defining a plurality of ports along the longitudinal axis thereof between the proximal end and the distal end of the body. The stimulation delivery device further comprises a plurality of delivery structures insertable within the body. The control mechanism is in communication with the plurality of delivery structures to independently move each of the plurality of delivery structures through a respective one of the plurality of ports.

BRIEF DESCRIPTION OF DRAWINGS

The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus are not limitative of the present invention, and wherein:

FIG. 1 is a diagrammatic view of a patient in which an embodiment of a device according to the present invention has been implanted.

FIG. 2 is a cross-sectional view of the brain showing one placement of an embodiment of a device according to the present invention.

FIG. 3 is a partial interior view of an embodiment of a device according to the present invention.

FIG. 4 depicts alternative deployments of a device according to the present invention.

FIG. 5 is a schematic view of an alternative embodiment of a device according to the present invention.

FIG. 6 is a cross-sectional view of the device of FIG. 5 along lines I-I.

FIG. 7 is a top plan view of an alternative embodiment of a device according to the present invention.

FIG. 8 is a partial side view of an alternative embodiment of a device according to the present invention.

FIG. 9 is a cross-sectional view of the device of FIG. 8 along lines II-II.

FIG. 10 is a cross-sectional view of an alternative embodiment of a device according to the present invention.

FIG. 11 is a cross-sectional view of an alternative embodiment of a device according to the present invention.

FIG. 12 is a cross-sectional view of an alternative embodiment of a device according to the present invention.

FIG. 13 is a partial side view of an alternative embodiment of a device according to the present invention.

FIG.14 is a partial side view of an alternative embodiment of a device according to the present invention.

FIG. 15 is a partial interior view of an alternative embodiment of a device according to the present invention.

FIG.16 is a partial side view of the device of FIG. 15.

FIG. 17 depicts alternative deployments of a device according to the present invention.

FIG. 18 is a perspective view of a control mechanism according to the present invention.

FIG. 19 is a perspective view of a control mechanism according to the present invention.

FIG. 20 is a top view of a control mechanism according to the present invention.

FIG. 21 is a side view of a component of a control mechanism according the present invention.

FIG. 22 is a side view of a component of a control mechanism according to the present invention.

FIG. 23 is a perspective view of a component of a control mechanism according to the present invention.

FIG. 24 is a cross-sectional view of a device according to the present invention implanted in the brain of a patient and attached to a control mechanism according to the present invention.

FIG. 25 is a partial interior view of an alternative embodiment of a device of the present invention.

FIG. 26 depicts alternative deployments of the device of FIG. 25.

DETAILED DESCRIPTION OF INVENTION

The present invention relates to a neural stimulator delivery device with independently moveable delivery structures. As illustrated diagrammatically in FIG. **1**, device **10** may be implanted in brain **B** of patient **P** to modulate a neural tissue target site of brain **B** to affect a neurological condition. As illustrated schematically in FIG. **2**, in a preferred system, device **10** is implanted within a target site of brain **B** and coupled to a therapy delivery device **500**, such as a pulse generator or drug pump to produce electrical or chemical stimulation pulses that are sent to device **10** to electrically or chemically stimulate the target site. A connector **510**, which is an insulated conductor in the case of electrical stimulation, couples therapy delivery device **500** to device **10**. Therapy delivery device **500** is, in turn, implanted in the abdomen or any other part of a patient **P**'s body.

With respect to general features and aspects of device **10** itself, referring to FIG. **3**, device **10** includes a body **20** having a proximal end **400** and a distal end **410** and defines a plurality of ports **30** along the longitudinal axis **y** thereof between proximal end **400** and distal end **410**. Device **10** also includes a plurality of delivery structures **40** that are insertable within body **20**. In the case of electrical stimulation, delivery structures **40** may either be leads that are electrically conductive and function as electrodes or delivery structures **40** may be leads having delivery elements **50**, which are electrode, disposed thereon. In the case of chemical stimulation, delivery structures **40** are catheters that define delivery elements **50**, which are drug ports.

A control mechanism **100** is in communication with the plurality of delivery structures **40** to independently move each of the plurality of delivery structures **40** through a respective one of the plurality of ports **30** with respect to each other of the plurality of delivery structures **40**. The ability of each delivery structure **40** to be independently moveable through a respective port **30** allows each delivery structure **40** to be selectively advanced and retracted through the respective port **30** independent of the movement of another delivery structure **40**. Such independent moveability of each delivery structure **40** consequently allows a practitioner to modify the locus of stimulation in a multitude of directions and to increase or decrease the volume of neural tissue to be stimulated, in part, as a function of the number of delivery structures **40** advanced. For example, as illustrated in FIG. **4A**, if only the neural tissue adjacent to port **30a** is desired to be stimulated then delivery structure **40a** can be solely advanced through port **30a**. As illustrated in FIG. **4B**, if it is determined that such stimulation is inefficacious or produces ill side effects, and the locus of stimulation is desired to be redirected to the neural tissue adjacent port **30b** then delivery structure **40a** can be retracted through port **30a** and delivery structure **40b** can be solely advanced through port **30b**. Alternatively, as illustrated in FIG. **4C**, if both the neural tissue adjacent to port **30c** and **30b** are desired to be stimulated, then delivery structure **40c** and delivery structure **40b** can both be advanced through respective ports **30c** and **30b**. Furthermore, as illustrated in FIG. **4D**, if a greater volume of neural tissue is desired to be stimulated, such as the neural tissue adjacent to each port **30a-d**, then delivery structures **40a-d** can all be advanced through ports **30a-d**. The present invention contemplates any combination of independent movement of delivery structures **40** depending on the location and volume of the particular neural tissue site(s) desired to be stimulated. All these positional readjustments can be made by advancing or retracting the desired delivery structure **40** or the desired combination of delivery structures **40** without having to extend or retract the overall position of device **10**, although device **10** is capable of such a positional readjustment.

Although the present invention envisions any arrangement of ports **30** along the longitudinal axis **y**, referring to FIG. **5-7**, in a preferred embodiment of the present invention, device **10** includes a first portion **60** containing a plurality of ports **30** and a second, different portion **70** containing a plurality of ports **30**. Referring to FIG. **6** first portion **60** and second portion **70** may each contain a plurality of ports **30** arranged annularly in a plane transverse to longitudinal axis **y** of body **20** (first portion **60** only shown). A first set **80** and a second set **90** of a plurality of delivery structures **40** are, in turn, extendable through the respective plurality of ports **30**. Although first portion **60** and second portion **70** may contain any number of ports, each port separated by any number of degrees, in a preferred embodiment, first portion **60** and second portion **70** have four ports each and the ports are situated 90 degrees apart from each other in the same annular plane. Referring to FIG. **7**, first portion **60** and second portion **70** may alternatively contain a plurality of ports **30** arranged semi-annularly about a plane transverse to the longitudinal axis **y** of body **20** (second part **70** only shown.). A first set **80** and a second set **90** of a plurality of delivery structures **40** are, in turn, extendable, through the respective plurality of ports **30** so that each the first set **80** and the second set **90** extend semi-annularly around body **20**. In such as embodiment, first portion **60** and second portion **70** are capable of being rotated about axis **y** to reposition the first set **80** and second set **90** to a different neural tissue site located on the same annular plane if necessary. Although first portion **60** and second portion **70** may contain any number of ports, each port separated by any number of degrees, in a preferred embodiment, first portion **60** and second portion **70** have four ports each and the ports are situated 45 degrees apart from each other in the same annular plane.

Notwithstanding whether first portion **60** and second portion **70** contain ports **30** arranged annularly or semi-annularly, a control mechanism **100** is associated with first set **80** and second set **90** to independently move the plurality of delivery structures **40** of first set **80** and second set **90**. The present invention contemplates any combination of independent movement to selectively stimulate the desired region of neural tissue. For example, each of the plurality of delivery structures **40** of first set **80** may be independently moveable with respect to each other of the plurality of delivery structures **40** of first set **80** and/or second set **90** and each of the plurality of delivery structures **40** of second set **90** may be independently moveable with respect to each other of the plurality of delivery structures **40** of second set **90** and/or first set **80**. In an alternative embodiment, first set **80** is collectively moveable independent of the movement of second set **90** and second set **90** is collectively moveable independent of the movement of first set **80**. Specifically, first set **80** may be collectively advanced to stimulate neural tissue adjacent to the first annular portion **60** while second set **90** may be collectively retracted within body **20**. If it is desired to redirect stimulation to the area of neural tissue adjacent to the second annular portion **70**, second set **90** may be collectively advanced through the respective plurality of ports **30** and first set **80** may be collectively retracted into body **20**. If it is desired to stimulate both the area of neural tissue adjacent to the first annular portion **60** and the second annular portion **70**, both first set **80** and second set **90** may be advanced through the respective plurality of ports **30**.

Although first and second portions **60** and **70** are not limited to a particular relative arrangement, preferably second portion **70** is between first portion **60** and proximal end **400** of body **20**. Furthermore, although the distance between first portion **60** and second portion **70** may depend on the particular application of device **10**, preferably such distance is between 5 to 10 millimeters. More preferably, such distance is between 4 to 5 millimeters. Moreover, although first portion **60** and second portion **70** may include any number of ports, preferably both portions collectively define eight ports. Additionally, the present invention also contemplates embodiments of device **10** where body **20** only includes a first portion **60** or a second portion **70**, notwithstanding whether first portion **60** or second portion **70** define an annular or semi-annular arrangement of a plurality of ports **30**.

The present invention also contemplates an arrangement of the plurality of ports **30** and therefore a plurality of delivery structures **40** individually moveable through the respective plurality of ports **30** that are tailored for the particular target site desired to be stimulated. In other words, in this embodiment, the number, arrangement, and distance between ports **30** are a function of the target site desired to be stimulated. For example, body **20** may define five ports **30** spaced 20 degrees apart from each other and therefore contain five delivery structures **40**, which when in an extended position, are 20 degrees apart from each other to stimulate a particular target site for which this arrangement of delivery structures is most efficacious. For another target site, body **20** may define 3 ports **30** spaced 5 degrees apart from each other and therefore contain five delivery structures **40**, which when in an extended position, are 5 degrees apart from each other to effectively stimulate the target site.

Referring to FIG. **8**, in another embodiment of the present invention, device **10** comprises a body **20** having a proximal end (not shown) and a distal end **410** and defines a plurality of ports **30** between proximal end and distal end **410**. Although the plurality of ports **30** are illustrated as being annularly arranged on the same plane, the present invention contemplates any other arrangement of the plurality of ports **30** as well as including a semi-annular arrangement on the same plane. Device **10** further includes a plurality of delivery structures **40** that are each independently moveable through a respective one of the plurality of ports **30** with respect to each other of the plurality of delivery structures **40**. In this embodiment, device **10** further includes a delivery element **50**, which can either be a drug port or electrode, disposed on body **20**. Although delivery element **50** may be located anywhere in relation to the plurality of ports **30**, in a preferred embodiment, delivery element **50** is located between the plurality of ports **30** and distal end **410** of body **20**. Referring to FIGS. **9** and **10**, delivery element **50** may extend approximately 360 degrees about body **20**, as illustrated in FIG. **10**, or less than 360 degrees about body **20**, as illustrated in FIG. **9** (showing delivery element **50** extending approximately 180 degrees about body **20**). Furthermore, in the case of electrical stimulation where delivery element **50** is an electrode, delivery element **50** may be uniformly powerable such that the entire delivery element **50** is a continuous delivery element that delivers electrical stimulation of uniform pulse, frequency, voltage and other pulsing parameters. Alternatively, as illustrated in FIG. **11**, delivery element **50** may be divided into two or more segments (four segments **50a-d** illustrated) that are each selectively powerable such that each segment **50a-d** can be powered to initiate, stop, increase, or decrease pulsing parameters independent of each other segment **50a-d**. Segments **50a-d** may extend about body **20** by substantially equal number of degrees or by different number of degrees. In a preferred embodiment, electrode **50** is divided into three segments **50a-c**, each extending approximately 120 degrees about body **20**.

Referring to FIG. **12**, in another embodiment of the present invention, device **10** includes two delivery elements **50e** and **50f**, that are spatially distinct and, in the case of electrical stimulation, are preferably electrically distinct from each other. Although delivery elements **50e** and **50f** are illustrated as residing on the same annular plane, they can be disposed anywhere on body **20**. For example, as seen in FIG. **13**, delivery elements **50f** is located between delivery element **50e** and distal end **410** of body **20**. Referring to FIG. **14**, in another embodiment, delivery element **50e** is located between a proximal end (not shown) of body **20** and the plurality of ports **30** and delivery element **50f** is located between the plurality of ports **30** and distal end **410** of body **20**.

In all the above described embodiments of device **10** including at least one delivery element **50** disposed on body **20**, body **20** may define at least one port, and preferably a plurality of ports at distal end **410** of body **20**, as illustrated in FIG. **14**. Furthermore, body **20** may include three, four, or any number of additional delivery elements **50** disposed on body **20**, any one of which or all of which are selectively powerable. It will be readily appreciated by one skilled in the art that delivery elements **50** can vary circumferentially in height, width, axial spacing and/or shape to provide the desired field of use. In addition, although delivery elements **50** are illustrated as being supported or resting on body **20**, delivery elements **50** may alternatively be embedded into, formed integrally with, or otherwise supported on body **20**. Furthermore, although body **20** may define any arrangement or number of the plurality of ports **30** that are located superiorly or inferiorly to delivery element **50**. In a preferred embodiment, body **20** defines an annular arrangement of ports **30** about a plane transverse to the longitudinal axis **y** of device **20** as seen in FIGS. **8**, **13**, and **14**.

Referring to FIG. **15** and **16**, in an alternative embodiment of the present invention, device **10** includes a body **20** having a proximal end (not shown) and a distal end **410**, and defining a first plurality of ports **30** at distal end **410**. Body **20** further includes a first plurality of delivery structures **40** that are each independently moveable through a respective one of the first plurality of ports **30** with respect to each other of the first plurality of delivery structures **40**. Referring to FIG. **16**, although delivery structures **40** are illustrated as having an arcuate configurations, they may also have a non-arcuate configuration, such as a linear configuration. Furthermore, in an alternative embodiment, device **10** further includes a second plurality of ports **30** located between a proximal end and distal end **410** and a second plurality of delivery structures **40** that are extendable through a respective one of second plurality of ports **30**. The second plurality of delivery structures **40** may also be independently moveable with respect to each other of the second plurality of delivery structures **40** and/or each of the first plurality of delivery structures **40**. Moreover, additional delivery elements **50** may be disposed on body **20** as described in more detail above.

In addition to the above-mentioned embodiments modulating the direction in which delivery structures **40** can extend from body **20**, the present invention contemplates alternative embodiments of device **10** that also permit modulating the distance delivery structures **40** can extend from body **20**. In particular, the plurality of delivery structures **40** may be flush with port **30**, as illustrated in FIG. **3**, or advanced varying distances away from body **20** as illustrated in FIG. **17**. Preferably, delivery structures **40** can each be advanced between about 1 millimeters and about 10 millimeters away from port **30** of body **20** to provide stimulation to up to approximately 2 cm^3 of neural tissue. Therefore, depending on the distance between the desired site of stimulation and body **20**, a delivery structure **40** can be fully advanced through a respective port **30**, as illustrated in FIG. **17A** or only partially advanced as illustrated in FIG. **17B**. Thus, if a practitioner initially stimulates a first neural tissue site and then desires to stimulate a second, different neural tissue site located further away from device **10**, the practitioner simply adjusts the distance the delivery structure is extended through port **30** without having to shift the overall position of device **10**, although device **10** is capable of such a positional readjustment.

In addition to modulating the direction and/or the distance each delivery structure **40** can extend, alternative embodiments of device **10** also permit modulating the degree of stimulation each delivery structure **40** can deliver. In such embodiments, delivery structures **40** have delivery elements **50** disposed thereon, and delivery elements **50** are adjustably powerable electrodes. For example, the pulsing parameters of delivery elements **50** may be adjusted to initiate, stop, increase, or decrease the pole combinations, energy, amplitude, pulse width, waveform shape, frequency, and/or voltage or any other pulsing parameter known to one of skill in the art to adjust the degree of stimulation delivered thereby. In a preferred embodiment, each delivery element **50** of each delivery structure **40** is selectively powerable such that the pulsing parameters of a delivery element **50** can be adjusted independent of the pulsing parameters of another delivery element **50**.

Referring to FIG. **1**, in such an embodiment, the selective powerability over each delivery element **50** may be achieved by employed a system including a programmer **520** coupled via a conductor **530** to a telemetry antenna **540**. The programmer **520** is capable of sending signals via the telemetry antenna **540** to control the electrical signal delivered to delivery elements **50** and, optionally, to control mechanism **100**, in embodiments where control mechanism **100** is remotely operated. Such a system permits the selection of various pulse output options after device **10** is implanted using telemetry communications. The present invention also contemplated radio-frequency systems to selectively power delivery elements **50**.

As will be understood by one of skill in the art, the independent powerability of delivery elements **50** also provides a practitioner with another means of modify or steering the direction of stimulation as the locus of stimulation can be selectively adjusted to precisely target portions of neural tissue to achieve the desired therapy. For example, referring to FIG. **4C**, electrode **50'** may be powered to stimulate an area adjacent thereto while the signal to electrode **50''** may be substantially minimized to reduce or stop stimulation to an area adjacent to electrode **50''**. Because the locus of stimulation can be selectively adjusted and/or steered in this embodiment of device **10**, neural tissue can be precisely targeted to achieve the desired therapy. Other or additional means of selectively steering electrical stimulation may also be utilized in the present invention, such as the methods described in U.S. Patent No. 5,713,922, which is incorporated by reference herein.

With respect to the ability of each delivery structure **40** to be independently moveable through a respective port **30**, such independent moveability is effectuated by a control mechanism **100** that is capable of independently advancing and retracting a delivery structure **40** through a respective port **30** of body **20**. As illustrated in FIGS. **3**, **4**, and **17**, in one embodiment, control mechanism **100** includes a gear and clutch assembly that may be disposed within body **20** and is similar to the gear and clutch assemblies described in U.S. Patent Nos. 5,606,975 and 5,034,004, both of which are incorporated herein by reference. In a preferred embodiment, the gear and clutch assembly is motorized, and the motor may be located at the burr hole via a spool magnetically or electrically activated via a radio-frequency coil or an internal power source linked to the burr hole or the implantable signal generator or radio-frequency receiver. The power for the moving of delivery structure **40** originates from a gear and a clutch system that may be controlled by micro-electrical mechanical systems as part of the implantable signal generator and device **10**, which is moved when the clutch is engaged.

Referring to FIG. **18**, in an alternative embodiment, control mechanism **100** includes a rack and pinion gearing mechanism that is capable of being manually operated. In particular, in this embodiment, control mechanism **100** includes a carrier **120**, a plurality of shafts **190** insertable within carrier **120**, each of the plurality of shafts capable of engaging at a distal end thereof a respective one of a plurality of delivery structures **40**, and a plurality of drivers **250** each associable with a respective shaft **190** such that upon manipulation of a driver **250**, the respective delivery structure **40** will endwise be advanced or retracted through body **20**.

In particular, carrier **120** of control mechanism **100** has a proximal end **135**, a distal end **140** optionally defining a set of securement arms **275**, and a lumen **155** extending therethrough. Carrier **120** further includes a first support portion **130** having an inner surface **310** and an outer surface **150** and/or a second support portion **160** having an inner surface **170** and an outer surface **180**. As illustrated in greater detail in FIGS. **19** and **20**, extending from or extensions of inner surface **310** and inner surface **170** are a plurality of clamping members **340** each configured to securedly engage a respective one of a plurality of shafts **190** insertable in lumen **155**. Although preferably, carrier **120** includes both a first support portion **130** and a second support portion **160** to secure shafts **190** to carrier **120**, carrier **120** may include only a first support portion **130** or a second support portion **160**. Furthermore, other means of securing shafts **190** to carrier **120** will be readily appreciated by one of skill in the art and are therefore within the scope of the present invention. Referring to FIG. **19**, one of first portion **130** and second portion **160** preferably defines an annular arrangement of a plurality of apertures **300** about a plane transverse to axis **y**, each aperture **300** configured to accommodate a driver **250**. Furthermore, referring to FIGS. **18** and **19**, distal end **140** of carrier **120** may define securement arms **275** configured to secure carrier **120** atop a burr hole in which carrier **120** may be placed. Alternatively, carrier **120** may be configured to securely fit in a burr hole without the use of securement arms **270**. Accordingly, other means of securing carrier **120** in a desired region will be readily appreciated by one of skill in the art and are therefore within the scope of the present invention.

Referring to FIG. **21**, each shaft **190** has a channel **230** extending therethrough to accommodate a stylet **270**, such channel **230** having a proximal end **200** and a distal end **210**. Shaft **190** further has an outer surface **240** that defines an engaging portion **260**. Engaging portion **260** may be a substantially planar surface **230** from which a series of axially spaced serrations **240** extend or of which a series of axially spaced serrations **245** are extensions. Alternatively, engaging portion **260** may itself be a series of axially spaced serrations **240** (not shown). A hollow fastener **360** configured to engage a proximal end **260** of a delivery structure **40** may be attached to or be defined by shaft **190** about a distal end **210** of channel **230**. Alternatively, distal end **210** of channel **230** may define an aperture that is configured to engage proximal end **260** of delivery structure **40** (not shown). Fastener **360** or the like can engage proximal end **260** of delivery structure **40** through resistance fitting, a screw-like mechanism, adhesive bonding, or the like. Other means of engaging a delivery structure **40** and other mechanisms by which such engagement is accomplished will be readily appreciated by one of skill in the art and are within the scope of the present invention.

Channel **230** of shaft **190** is also configured to allow a leading end **330** of a stylet **270** to pass therethrough to access and pass through delivery structure **40**. Referring to FIGS. **21** and **22**, preferably, channel **230** has a diameter **d** that is only slightly greater than a diameter **D** of leading end **330** of stylet **270** to prevent lateral displacement of leading end **330** during manipulation of shaft **190**. To prevent axial displacement of stylet **270** during advancing movement of delivery structure **40**, stylet **270** preferably includes a limit stop **310** configured to associate with proximal end **200** of channel **230** through resistance fitting, a screw-like mechanism, adhesive bonding or the like.

Control mechanism **100** further includes a plurality of drivers **250** each associable with a respective shaft **190** such that upon manipulation of a driver **250**, the corresponding delivery structure **40** will endwise be advanced or retracted through body **20**. Referring to FIG. **23**, driver **250** includes a handle **340** at a proximal end thereof and a gear **320** at a distal end thereof. Gear **320** defines external threading **290** that is configured for threadable engagement with serrations **240** of shaft **190** such that manipulation of a driver

250 results in axial movement of the corresponding shaft **190** and therefore axial movement of the corresponding delivery structure **40** attached about the distal end **210** of channel **230** of shaft **190**. Depending on the rotational movement provided to the driver **250** (i.e. whether by turning handle **340** in a clockwise or counter-clockwise direction), respective delivery structure **40** is retracted or advanced through body **20** and through port **30**. Preferably, external threading **290** of driver **250** and serrations **240** of shaft **190** have a cooperative pitch fine enough to allow for precise movement of a delivery structure **40** such that delivery structure **40** can be millimetrically extended and retracted through ports **30**. As seen in FIG. **18**, gear **320** of driver **250** may access serrations **240** of shaft **190** by passing through apertures **300** of first or second portion **130** and **160** of carrier **120**.

Referring to FIG. **24**, with respect to one exemplary use of the above-described control mechanism **100**, device **10** is inserted in the brain **B** and positioned at a neural tissue target site. Proximal ends **260** of each of the plurality of delivery structures **40** are attached to respective fasteners **360** of shafts **190** and carrier **120** is mounted atop a burr hole **365**. Preferably, control mechanism **100** is designed to engage a burr hole ring and communicate with a compass mechanism that provides a frame of reference and that is associated with the burr hole ring or associated with control mechanism **100** itself to align control mechanism **100** in the proper reference frame of the stereotactic coordinates setting to actuate independent movement of delivery structures **40** to a desired target site.

The above-mentioned embodiment of control mechanism **100** is only exemplary and several modifications of such mechanism **100** may be made without detracting or departing from the spirit or scope of the present invention. For example, stylet **270** can be designed to engage distal end **210** of channel **230** similar to the engagement of delivery structure **40** with distal end **210** of channel **230** such that shaft **190** need not define channel **230** to accommodate stylet **270**. In addition, each delivery structure **40** can superiorly pass through channel **230** and exit proximal end **200** of shaft **190**. Furthermore, several (or all) components of carrier **120** can be designed to releasably associate or affixedly associate with their cooperative components. For example, delivery structures **40** can be affixedly associate with distal end **210** of channel **230** or releasably associated with distal end **210** of channel **230**. Furthermore, drivers **250** can be releasably insertable through apertures **300** or affixedly insertable through apertures **300**. In addition, the shapes of various components of the above-described embodiment of control mechanism **100** are not limited to the illustrated embodiments. For example, although carrier **120** and shaft **190** are illustrated as being cylindrical in shape, carrier **120** and shaft **190** can take on any shape. Also, although the above-described control mechanism **100** may be manually operated, the present invention also contemplates embodiments that are automated.

Furthermore, the above-described control mechanism **100** is by no means the only control mechanism that can by used in the present invention and the present invention contemplates various other forms of control mechanism **100** to actuate movement of delivery structures **40** including plunger or piston assemblies; springs; guide wires; ceramic motors; other linear motion devices, such as linear actuators and linear guides; rotary motion devices that convert rotary motion to linear motion; external remotely operated means such as electromagnetic signals, radio-frequency signals, or telemetry including the methods described in U.S. Patent No. 6,192,279, which is incorporated by reference herein; or any other means known to one of skill in the art to actuate linear movement of delivery structures **40**. Any control mechanism **100** for use with device **10** may be detachably or attachably mounted atop a burr hole **365**, secured within a burr hole **365**, or placed between the scalp and skull.

With respect to particular details of the present invention, body **20** may be configured in any shape although a preferred shape is tubular. Furthermore, body **20** may be constructed of stainless steel, iridium, titanium, biocompatible plastic or the like. In a preferred embodiment, body **20** is constructed of polyurethane or polypropylene. In order for body **20** to remain associated with delivery structures **40**, body **20** may be secured to delivery structures **40** or to control mechanism **100**. Body **20** may be secured to delivery structures **40** by a slidable engagement mechanism, such as tracks that have a first side affixed to body **20** and a second opposite side slidably engaged with delivery structures to allow delivery structures to move thereon. Such tracks may also allow each delivery structure **40** to remain physically separated from each other. Body **20** may also include C-shaped troughs, posts, or other guiding mechanisms to allow each delivery structure **40** to remain physically separated from each other and to prevent each delivery structures **40** from forming a twisted configuration as each delivery structure is advanced or retracted through body **20**.

Device **10** may also define any number or arrangement of ports **30**. In embodiments where body **20** defines a plurality of ports **30** along the longitudinal axis thereof between distal end **410** and proximal end **400**, and each of a plurality of delivery structures **40** are independently moveable through a respective one of the plurality of ports

30, body **20** may preferably also define at least one port **30**, and more preferably a plurality of ports **30** at the distal end **410** of body **20** as illustrated in FIGS. **4D**, **5**, and **14**. A plurality of delivery structures **40** are, in turn, extendable through the plurality of ports at distal end **410**. Although not required to stay within the scope and spirit of the present invention, the plurality of delivery structures **40** extendable through the plurality of ports **30** at distal end **410** may be independently moveable with respect to each other of the plurality of delivery structures **40** extendable through the plurality of ports **30** at distal end **410** and/or each of the plurality of delivery structures **40** extendable through the plurality of ports along the longitudinal axis of body **20** between proximal end **400** and distal end **410**.

Ports **30** may also be configured to allow each delivery structure **40** to exit body **20** at varying angles with respect to axis **y** of body **20**. Preferably, the angle of exit is less than 90 degrees with respect to axis **y**. For example, referring to FIG. **2D**, delivery structures **40** may exit ports **30** at an angle **A** in the range of about 10 to about 60 degrees with respect to axis **y**. The angle of exit of delivery structure **40** may be predetermined by providing a flexible guide near port **30** in body **20** to provide for the desired angle. Alternatively, delivery structures **40** themselves may be configured to exit body **20** at varying angles. For example, delivery structures **40** may be manufactured of a material that provides delivery structures **40** with a convex tensile bend or memory bend allowing angled exit through port **30** or allow delivery structures **40** to be preformed so that the distal ends curl out at a predetermined curvature when unconstrained by body **20**. With respect to delivery structures **40** manufactured of a material to provide tensile bend, such material may include a string of silicone, resorbable biocomposite or any other suitable inert plastic polymer denser on either the concave or convex side of the bend. With respect to a material that provides delivery structures **40** with memory bend, such material may include shape memory alloy. Alternatively, body **20** may include tracks that are configured to operably engage delivery structures **40** and to guide delivery structures **40** to exit ports **30** along an angled trajectory. One skilled in the art would understand that other means may be used to provide for a desired exit angle and such means are encompassed by the present invention.

The present invention also contemplates any number of delivery structures **40** independently moveable through a respective port **30** with any number of delivery elements **50** disposed thereon. Furthermore, delivery elements **50** can be arranged in any manner on delivery structures **40**. For example, a delivery element **50** may be disposed on a distal section, medial section, and proximal section of delivery structure **40** (all such designs are in reference to embodiments of device **10** where delivery structures have delivery elements **50** disposed thereon). Although in preferred embodiment there are five delivery structures, and each delivery structure **40** is independently moveable through a single port **30**, it is possible to have additional delivery structures **40** extend from any one port **30**. Furthermore, body **20** may be designed such that a single delivery structure **40** can be capable of exiting two different ports **30**. Such a configuration is particularly advantageous if a relatively fewer number, such a five or less, delivery structures **40** are desired to be employed. Referring to FIG. **25** and **26**, one embodiment that achieves this function includes a guide **560** located within body **20** and positioned proximal to ports **30**. Guide **560** defines a plurality of angled through-holes **570** that angle from longitudinal axis **y** of body **20** toward ports **30**. Therefore, through-holes **570** allow a delivery structure **40** to be advanced through a through-hole **570a-c** and exit such throughhole along a predetermined trajectory determined by the angle of throughhole **570a-c**. Device **10** further includes a disc **580** positioned proximal to guide **560** and that defines a single opening **590** through which a delivery structure **40** can pass and that is capable of rotating within body **20** about the longitudinal axis **y** of body **20** indicated by the arrow **a**. In this regard, a delivery structure **40** which passes through opening **590**, can rotate about the longitudinal axis **y** and can be brought in registration above a selected throughhole **570** for deployment of the delivery structure **40** through the respective port **30e-g**. Referring to FIG. **26**, disc **580** allows a delivery structure **40** to be advanced through any of the througholes **570a-c** and through any of the corresponding ports **30e-g**. In one embodiment, to rotate disc **580**, a stalk **600** connects the center of disc **580** to a rotary motor **610** positioned towards proximal end **400** of body **20**. Stalk **590** would transfer rotational motion from rotary motor **610** to disc **580**.

A neural stimulation delivery system including device **10** to stimulate neural tissue to affect a neurological condition may include other components useful in identifying, monitoring, or affecting a specific neural tissue site or a particular neurological condition associated with the specific neural tissue site. For example, such a system could include a component for lesioning and temperature monitoring, and/or a component that has a fiberoptic monitor which allows telemetric intracranial monitoring capabilities, and/or a microelectrode recording component, and/or a sensing component to incorporate a feedback mechanism to assist in determining whether the delivery structures should be adjusted. With respect to a sensing component, referring to FIG. **1**, a sensor **550** can be incorporated with a system of stimulating neural tissue according to the present invention. Sensor **550** can be used with a closed-loop feedback system in order to automatically determine the level of stimulation necessary to provide the desired therapy. Sensor **550** may be implanted into a portion of a patient **P**'s body suitable for detecting characteristics, symptoms or attributes of the condition or disorder being treated such as electrical brain activity, cerebral blood flow, and/or vital signs or other chemical and electrical activity of the body. Sensors suitable for use in a system according to the present invention include, for example, those disclosed in U.S. Patent No. 5,711,316, which is incorporated by reference herein.

Furthermore, such a neural stimulation delivery system may also include a navigation system that provides the exact position/orientation of device **10** within the brain after delivery structures **40** are deployed. For example, if device **10** has a circular cross-section, the navigation system would provide the compass direction (i.e. degree) device **10** is positioned relative to a reference point in the brain, therefore assisting in the determination of which delivery structures **40** to deploy. Preferably the navigation system would incorporate some type of marker that is integral with device **10** or delivery structure **40** that would show up under computer tomography (CT) or magnetic resonance imaging (MRI) scanning techniques. According, the brain scans could be printed and fed into a computer having navigational software and a three-dimensional atlas of the patient's brain to model approximately where all the delivery structures **40** are positioned. The software may then be capable of providing instructions on where best to deploy delivery structures **40** or which delivery elements **40** to activate.

In use, delivery structures **40** of device **10** may be adjusted intra-operatively during an initial surgery when device **10** is implanted, during a minor surgery after device **10** is implanted in which only control mechanism **100** is accessed, or completely remotely in which case no surgery of any kind is required. With respect to intra-operative adjustment of delivery structures **40**, a practitioner may initially place device **10** in the general region of a desired neural tissue site and then more precisely adjust the stimulation to the desired neural tissue site *in situ* by advancing or retracting a delivery structure **40** or specific combination of delivery structures **40**. In such a circumstance, control mechanism **100** may rest atop the burr hole, within the burr hole, or above the burr hole under the scalp.

With respect to adjusting delivery structures **40** after the initial surgery, a practitioner may initially place device **10** in the general region of a desired neural tissue site and then close the incision in the cranium. The practitioner may then more precisely adjust the stimulation to the desired neural tissue site on an out-patient basis, by making a relatively small incision in the scalp to access the area control mechanism **100** is placed or to couple control mechanism **100** to the proximal ends **260** of delivery structures **40**. The practitioner then adjusts the position of a delivery structure **40** or a specific combination of delivery structures **40**. With respect to adjusting delivery structures **40** remotely, the practitioner may initially place device **10** in the general region of a desired neural tissue site and then close the incision in the cranium. The patient may then be transferred to a Neuromodulation Unit (NMU) where device **10** is non-invasively tested to achieve a desired effect. The position of delivery structures **40** may then be adjusted to a desired position to achieve a particular effect. This external adjustment of delivery structure **40** or a combination of delivery structures **40**, allows the stimulation to be adjusted without having to perform a second surgery. The practitioner (or patient) may perform these adjustments of delivery structures **40** any time and as many times as necessary after device **10** is implanted as well. Such adjustments can be made under the visualization of computed tomography, magnetic resonance imaging, fluoroscopy, or the like and can be in response to a chemical, electrical, or any other physiological parameter including nerve action potentials, movement, blood flow, electroencephalograph signals, normal vitals.

Although the invention has been described with reference to the preferred embodiments, it will be apparent to one skilled in the art that variations and modifications are contemplated within the spirit and scope of the invention. The drawings and description of the preferred embodiments are made by way of example rather than to limit the scope of the invention, and it is intended to cover within the spirit and scope of the invention all such changes and modifications.

We claim:

1. A stimulation delivery device for stimulating neural tissue comprising: a body having a proximal end and a distal end and defining a plurality of ports along the longitudinal axis thereof between the proximal end and the distal end of the body; and

a plurality of delivery structures insertable within the body, each of the plurality of delivery structures independently moveable through a respective one of the plurality of ports.

2. The device of claim 1, wherein the plurality of delivery structures is electrodes.

3. The device of claim 1, wherein the plurality of delivery structures is a plurality of leads, each of the plurality of leads having at least one delivery element thereon, the at least one delivery element being an at least one electrode.

4. The device of claim 3, wherein the at least on electrode of each of the plurality of leads is selectively powerable.

5. The device of claim 1, wherein the plurality of delivery structures is catheters, the catheters having at least one delivery element thereon, the at least one delivery element being an at least one drug port.

6. The device of claim 1, further comprising a first delivery element disposed on the body, the first delivery element being either an electrode or drug port.

7. The device of claim 6, further including a second delivery element disposed on the body, the second delivery element being either an electrode or drug port.

8. The device of claim 7, wherein the first delivery element and the second delivery element are electrodes, the electrodes being selectively powerable.

9. The device of claim 1, further comprising a control mechanism in communication with the plurality of delivery structures to independently move each of the plurality of

delivery structures through a respective one of the plurality of ports with respect to each other of the plurality of delivery structures.

10. The device of claim 1, wherein the plurality of delivery structures is exitable through respective ones of the plurality of ports at an angle of less than 90 degrees with respect to the longitudinal axis of the body.

11. The device of claim 1, wherein the body further defines at least one port at the distal end thereof.

12. The device of claim, wherein at least one delivery structure is extendable through the at least one port.

13. The device of claim 1, wherein the plurality of delivery structures is extendable between about 1 to about 10 millimeters from respective ones of the plurality of ports.

14. The device of claim 1, wherein the plurality of delivery structures is capable of non-destructively stimulating neural tissue.

15. A stimulation delivery device for stimulating neural tissue comprising:

a body having a proximal end and a distal end, the body defining an annular arrangement of a first plurality of ports between the proximal end and the distal end about a plane transverse to the longitudinal axis of the body; and

a first plurality of delivery structures insertable in the body, each of the first plurality of delivery structures independently moveable through a respective one of the first plurality of ports.

16. The device of claim 15, wherein each of the first plurality of ports is situated 90 degrees apart from each other in the same annular plane.

17. The device of claim 15, wherein the body further defines an annular arrangement of a second plurality of ports between the first plurality of ports and the proximal end of the body about a plane transverse to the longitudinal axis of the body.

18. The device of claim 17, wherein each of the second plurality of ports is situated 90 degrees apart from each other in the same annular plane.

19. The device of claim 18, further comprising a second plurality of delivery structures insertable in the body.

20. The device of claim 19, wherein the each of the second plurality of delivery structures are independently moveable through a respective one of the second plurality of ports.

21. The device of claim 15, further comprising a first delivery element disposed on the body.

22. The device of claim 21, wherein the first delivery element extends approximately 360 degrees about the body.

23. The device of claim 21, wherein the first delivery element is an electrode divided into segments, each segment being selectively powerable.

24. The device of claim 15, wherein the body further defines at least one port at the distal end thereof.

25. The device of claim 24, wherein at least one delivery structure is extendable through the at least one port.

26. A stimulation delivery device for stimulating neural tissue comprising:

a body having a proximal end and a distal end, the body defining an semi-annular arrangement of a first plurality of ports between the proximal end and the distal end about a plane transverse to the longitudinal axis of the body; and

a first plurality of delivery structures insertable in the body, each of the first plurality of delivery structures independently moveable through a respective one of the first plurality of ports.

27. The device of claim 26, wherein each of the first plurality of ports is situated 45 degrees apart from each other in the same annular plane.

28. The device of claim 26, wherein the body further defines a semi-annular arrangement of a second plurality of ports between the first plurality of ports and the proximal end of the body.

29. The device of claim 28, wherein each of the second plurality of ports is situated 45 degrees apart from each other in the same annular plane.

30. The device of claim 28, further comprising a second plurality of delivery structures insertable in the body.

31. The device of claim 30, wherein each of the second plurality of delivery structures is independently moveable through a respective one of the second plurality of ports.

32. The device of claim 26, further comprising a first delivery element disposed on the body.

33. The device of claim 32, wherein the first delivery element extends approximately 360 degrees about the body.

34. The device of claim 33, wherein the first delivery element is an electrode divided into segments, each segment being selectively powerable.

35. The device of claim 26, wherein the body further defines at least one port at the distal end thereof.

36. The device of claim 35, wherein at least one delivery structure is extendable through the at least one port.

37. A stimulation delivery device for stimulating neural tissue comprising: a body having a proximal end and a distal end and defining a plurality of ports at the distal end thereof; and

a plurality of delivery structures insertable within the body, each of the plurality of delivery structures independently moveable through a respective one of the plurality of ports.

38. A stimulation delivery system for stimulating neural tissue of the brain to affect a neurological condition comprising:

a stimulation delivery device comprising

a body having a proximal end and a distal end and defining a plurality of ports along the longitudinal axis thereof between the proximal end and the distal end of the body; and

a plurality of delivery structures insertable within the body; and

a control mechanism in communication with the stimulation delivery device to independently move each of the plurality of delivery structures through a respective one of the plurality of ports.

39. The system of claim 38, wherein the control mechanism comprises a gear and clutch assembly.

40. The system of claim 39, wherein the gear and clutch assembly is motorized.

41. The system of claim 38, wherein the control mechanism comprises a rack and pinion gearing assembly.

42. The system of claim 41, wherein the rack and pinion gearing assembly comprises:

a carrier;

a plurality of shafts insertable within the carrier, each of the plurality of shafts having a proximal end and a distal end, each of the plurality of shafts engagable with a corresponding one of the plurality of delivery structures at the distal end of each of the plurality of shafts; and

a plurality of drivers each engagable with a corresponding one of the plurality of shafts, such that upon manipulation of each of the plurality of drivers, the corresponding one of the plurality of delivery structures advances or retracts through the respective one of the plurality of ports.

43. The system of claim 42, wherein each of the plurality of drivers are threadably engagable with a corresponding one of the plurality of shafts.

44. The system of claim 38, further comprising a microelectrode recording device in communication with the stimulation delivery device.

45. The system of claim 38, further comprising at least one sensor in communication with the stimulation delivery device to detect a characteristic of the neurological condition being affecting.

46. The system of claim 38, further comprising a navigation system to detect the position of the stimulation delivery device within the brain.

FIG.1

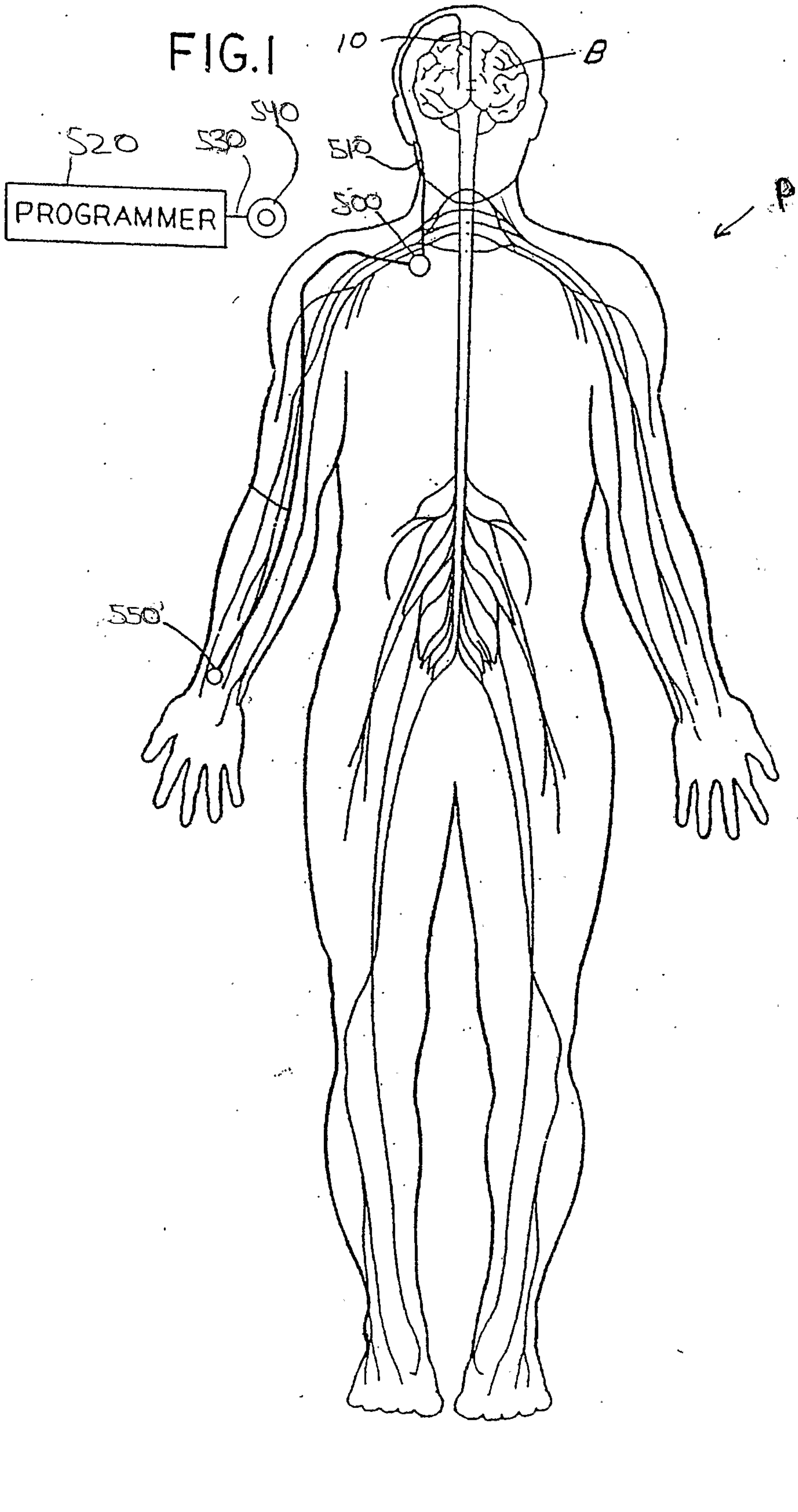
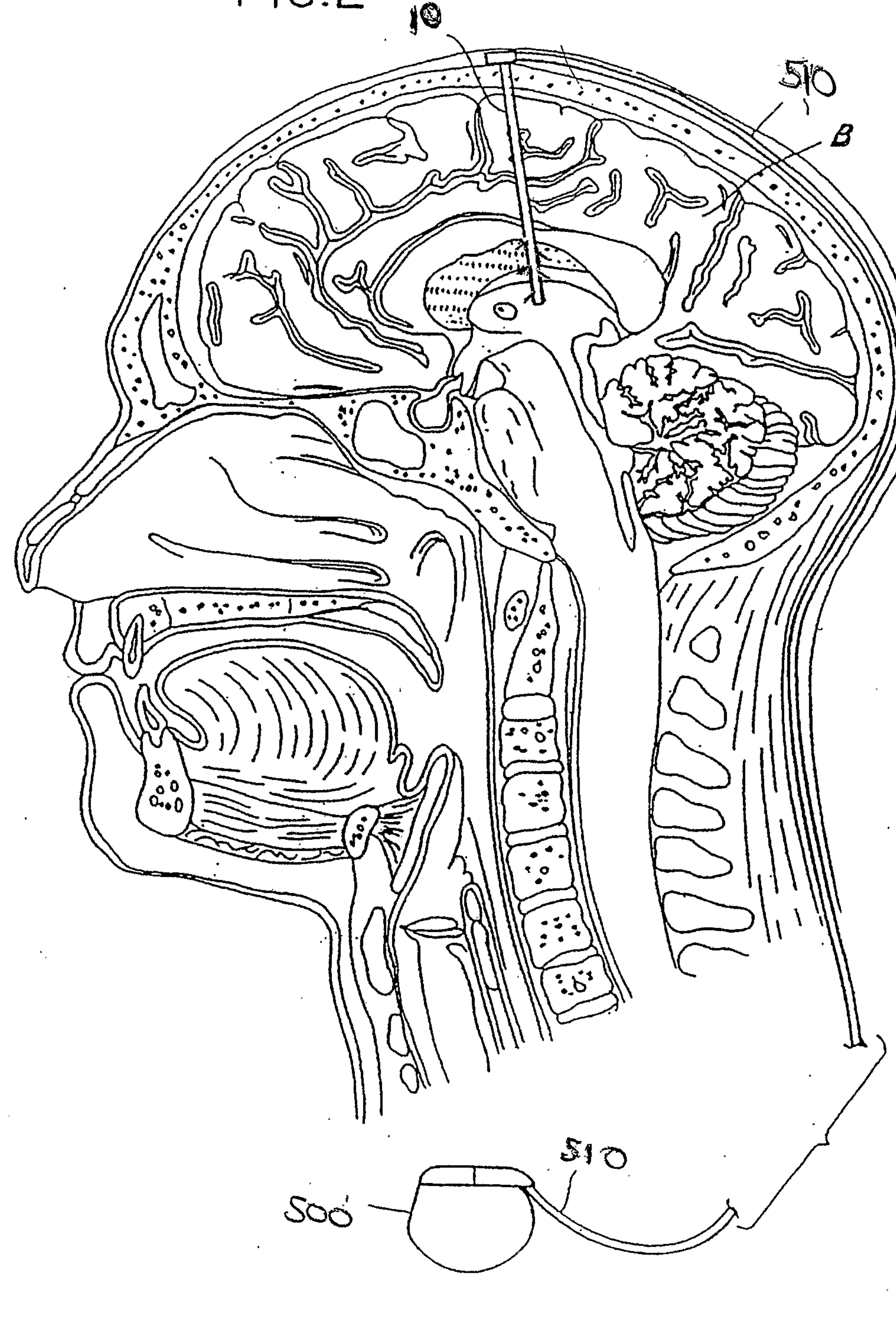


FIG.2



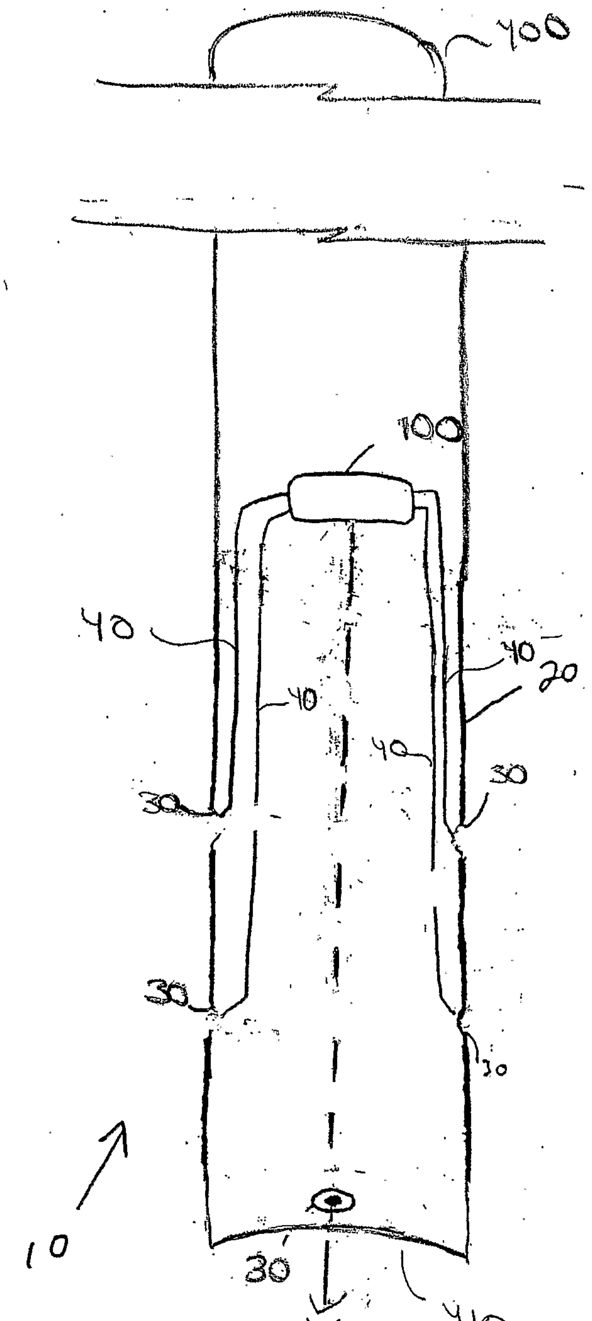


FIG.3

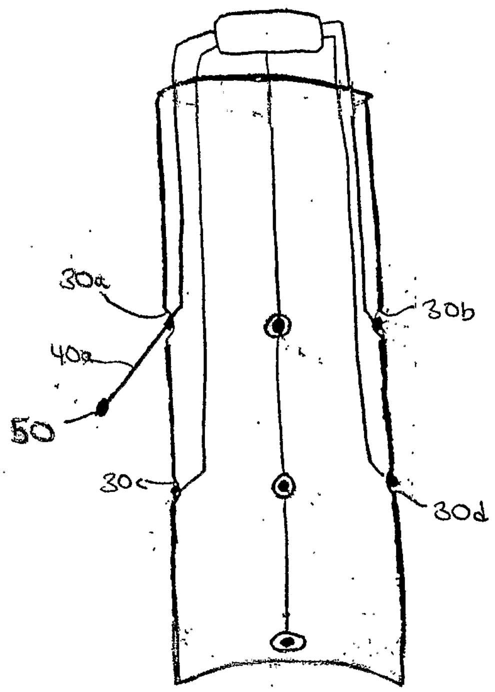


FIG. 4A

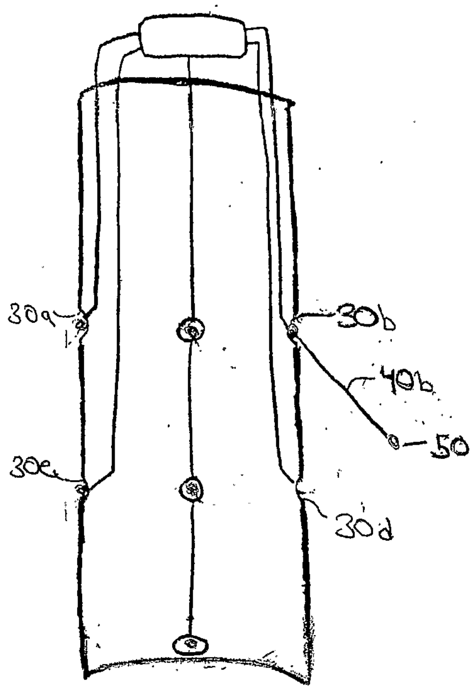


FIG. 4B

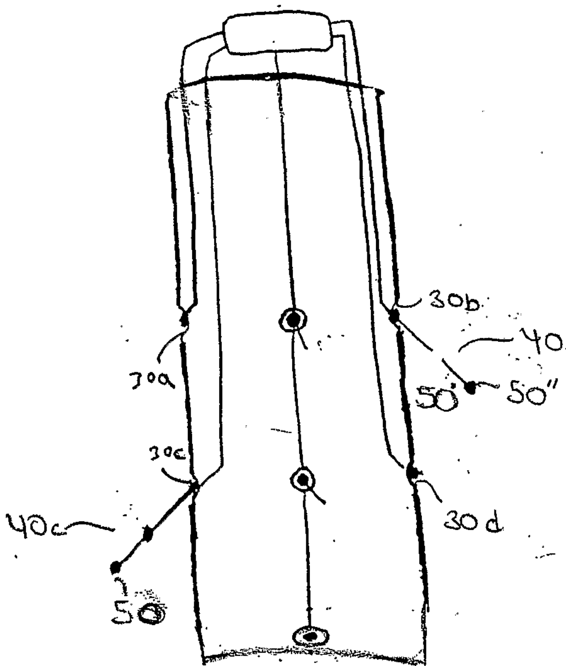


FIG. 4C

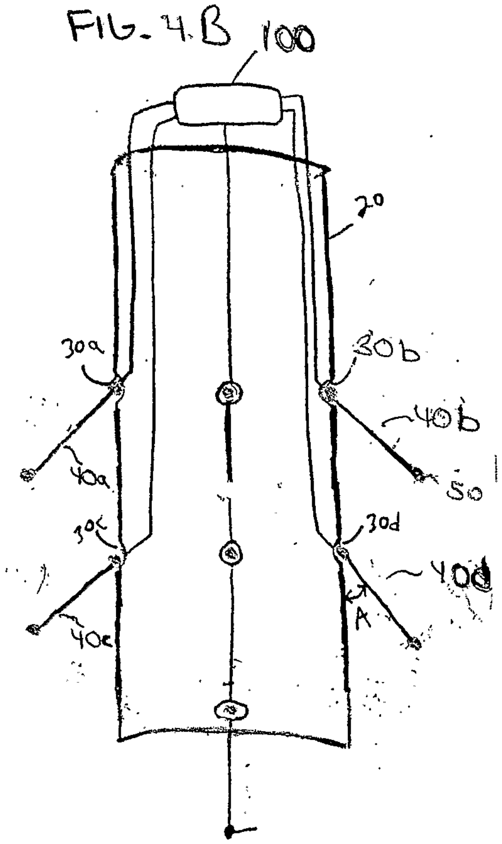


FIG. 4D

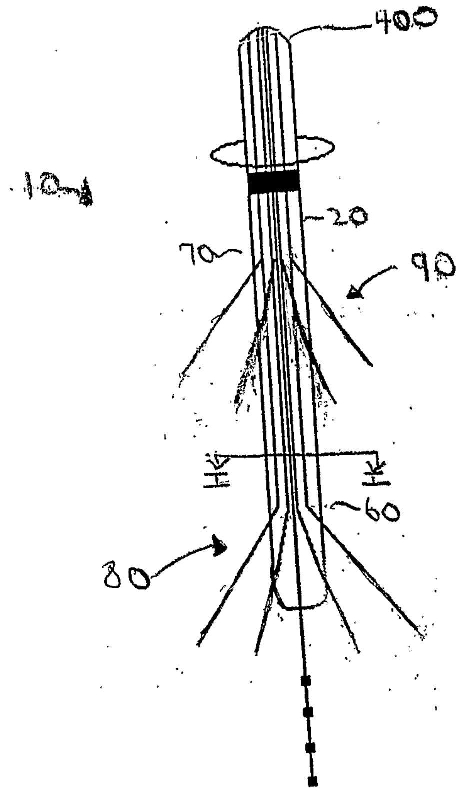


FIG. 5

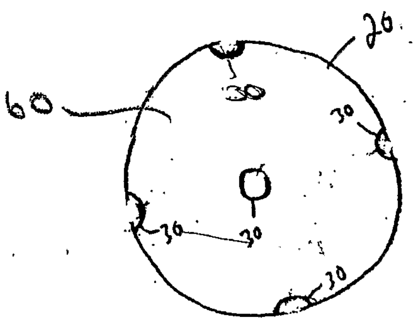


FIG. 6

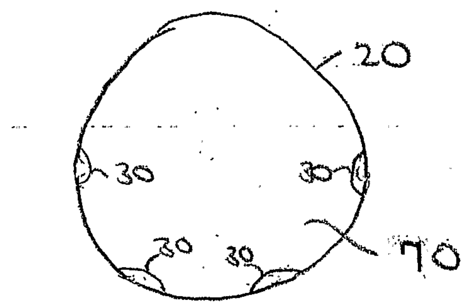


FIG. 7

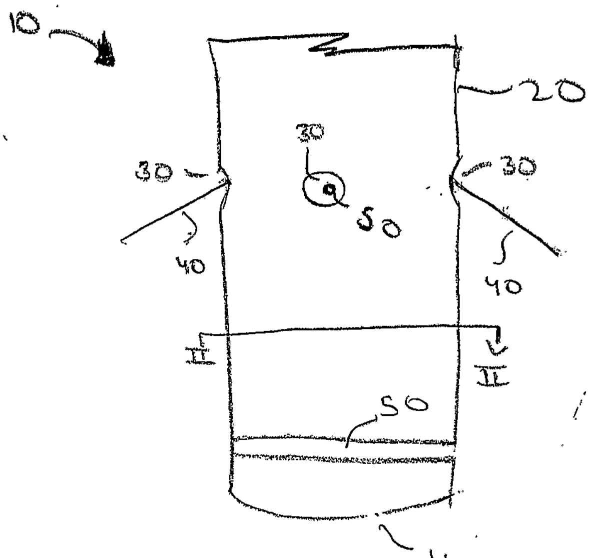


FIG. 8

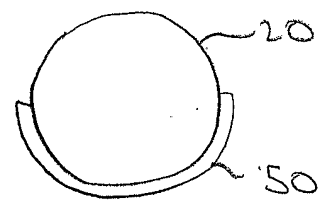


FIG. 9

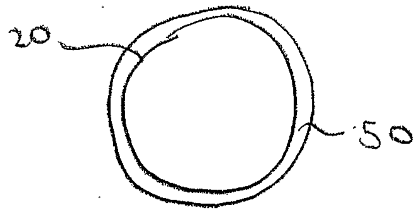


FIG. 10

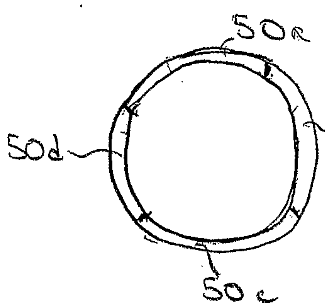


FIG. 11

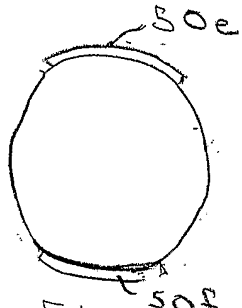


FIG. 12

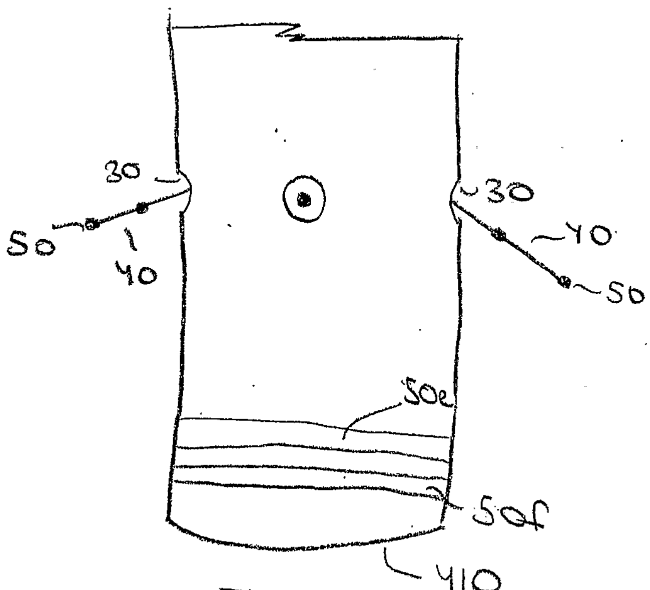


FIG. 13

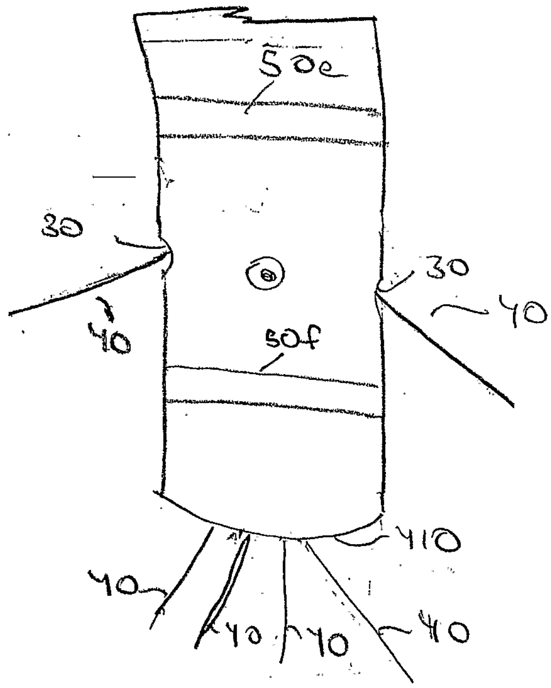


FIG. 14

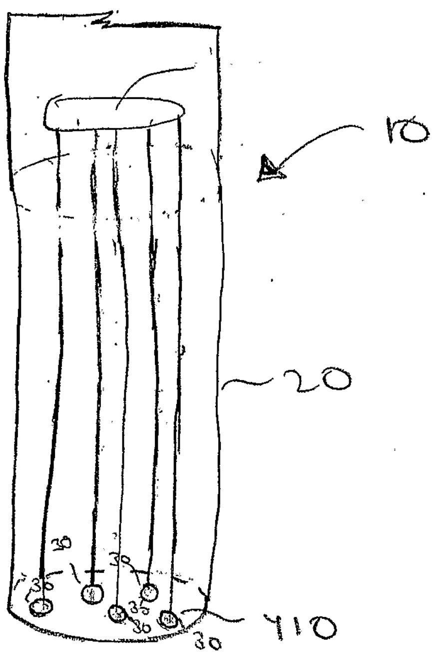


FIG. 15

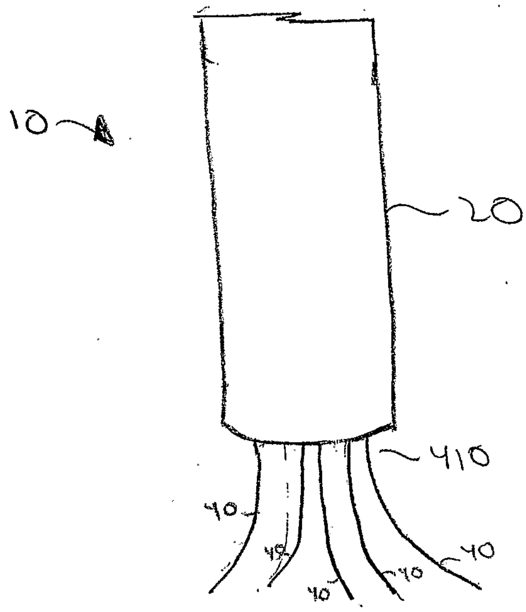


FIG. 16

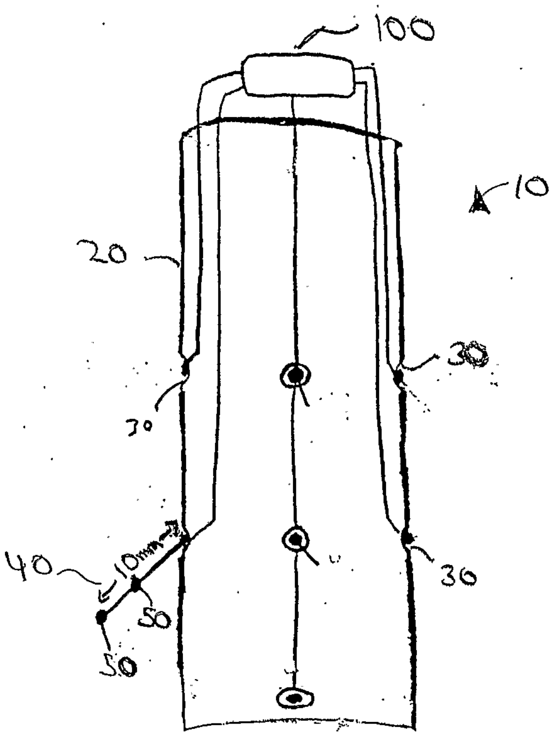


FIG. 17A

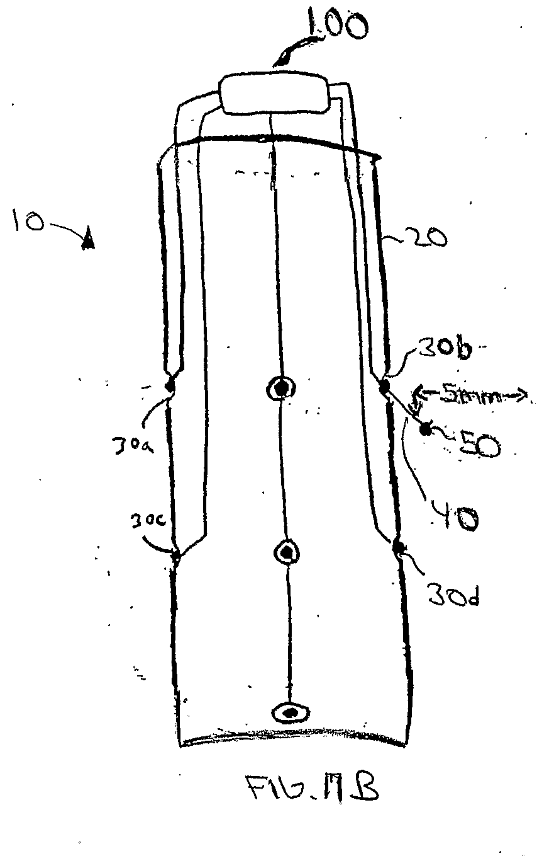
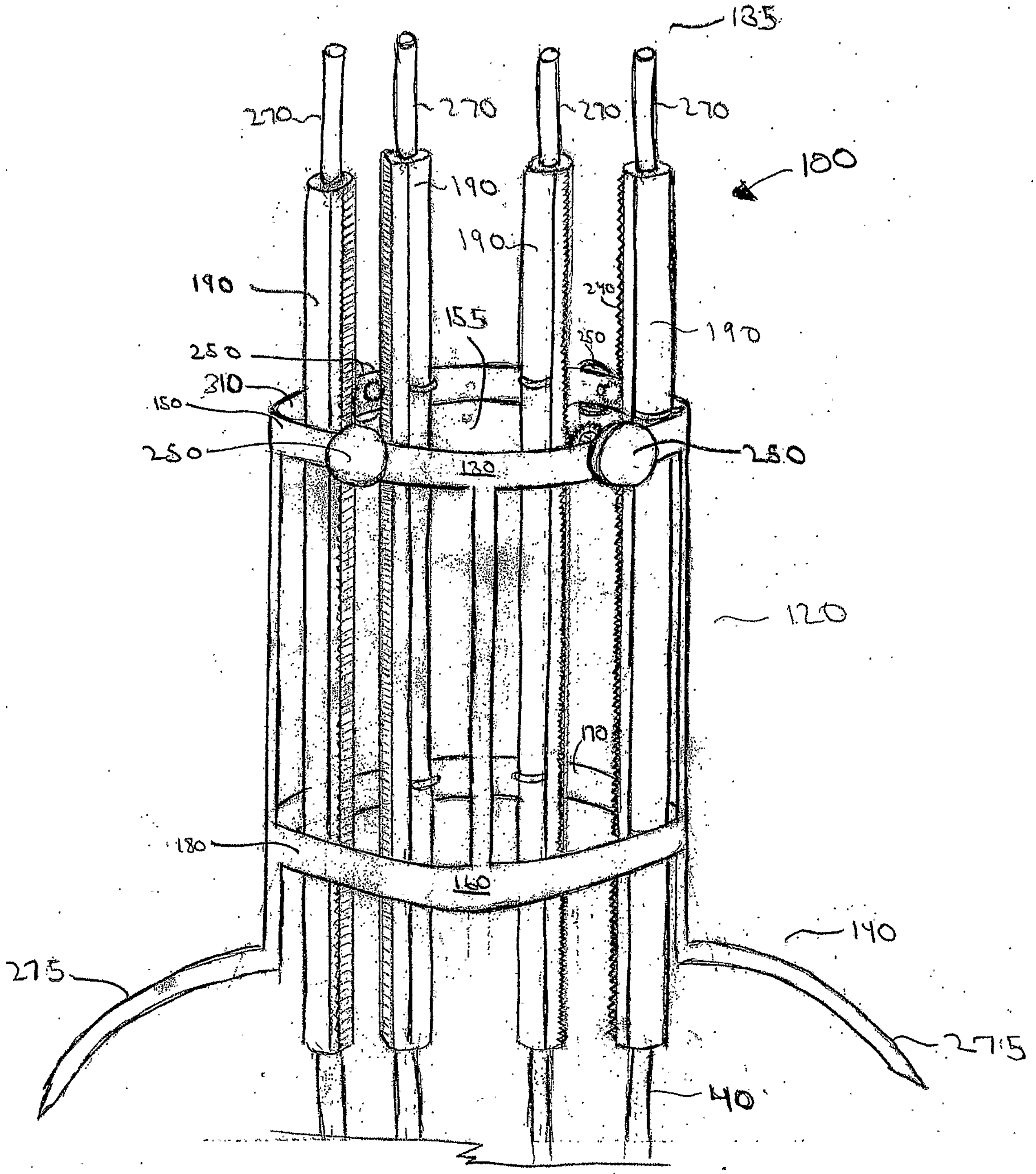


FIG. 17B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170
180
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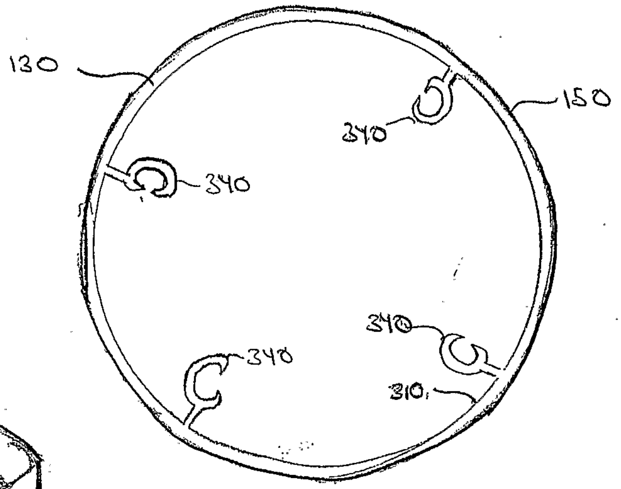
140
275
275
40

FIG. 18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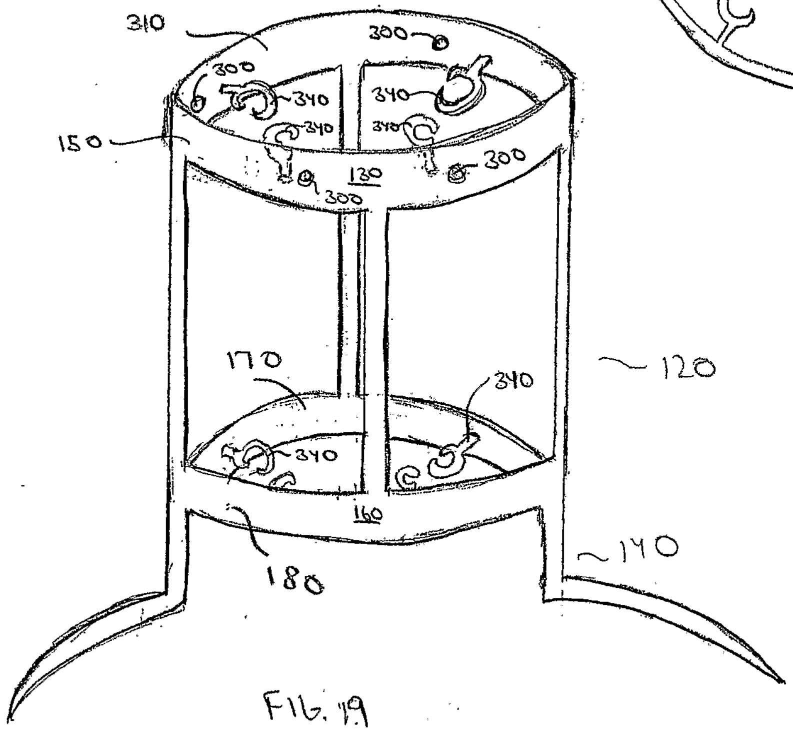
340
340
310

FIG. 20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140

FIG. 19

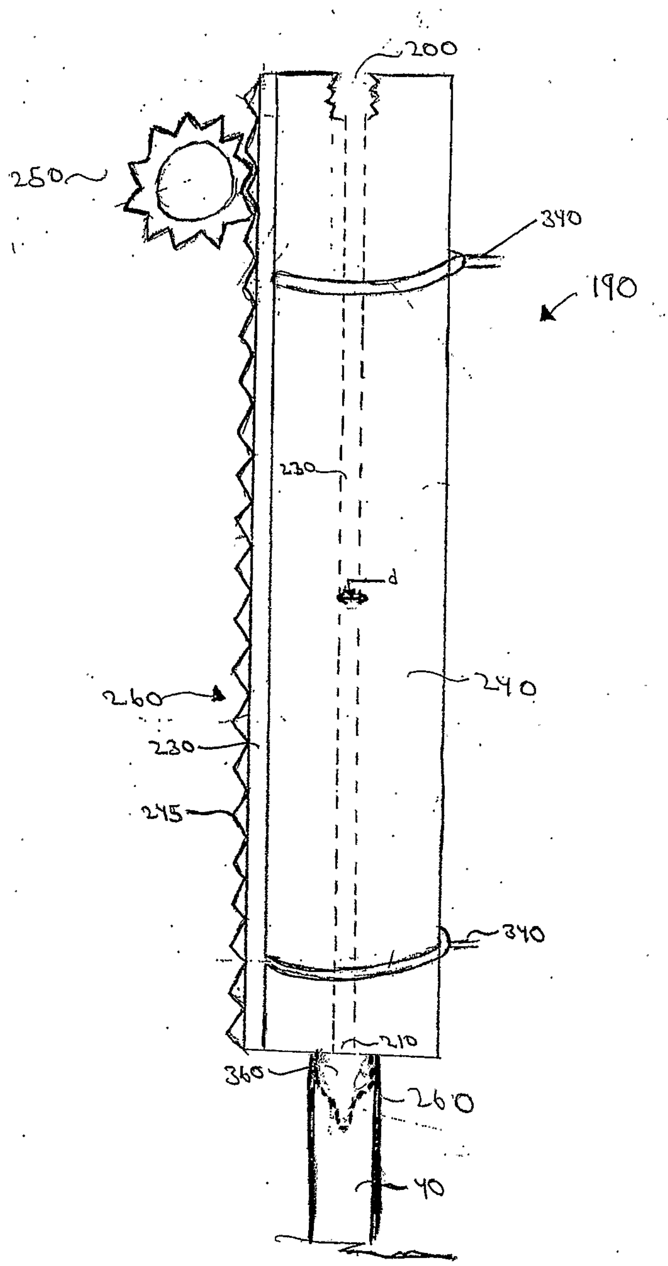


FIG. 21

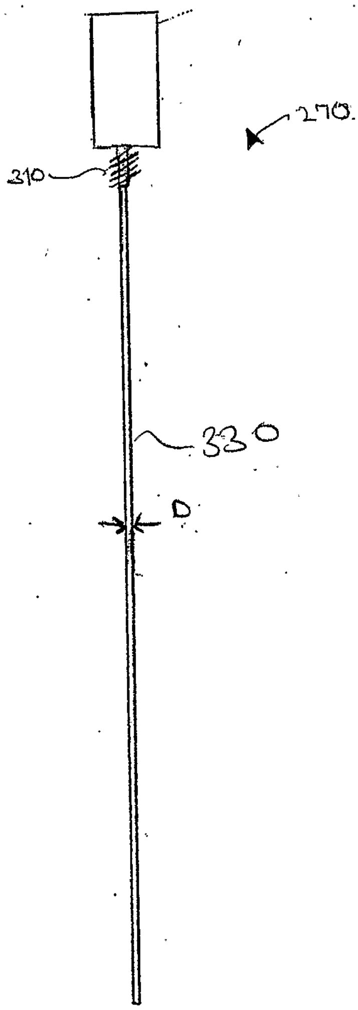


FIG. 22

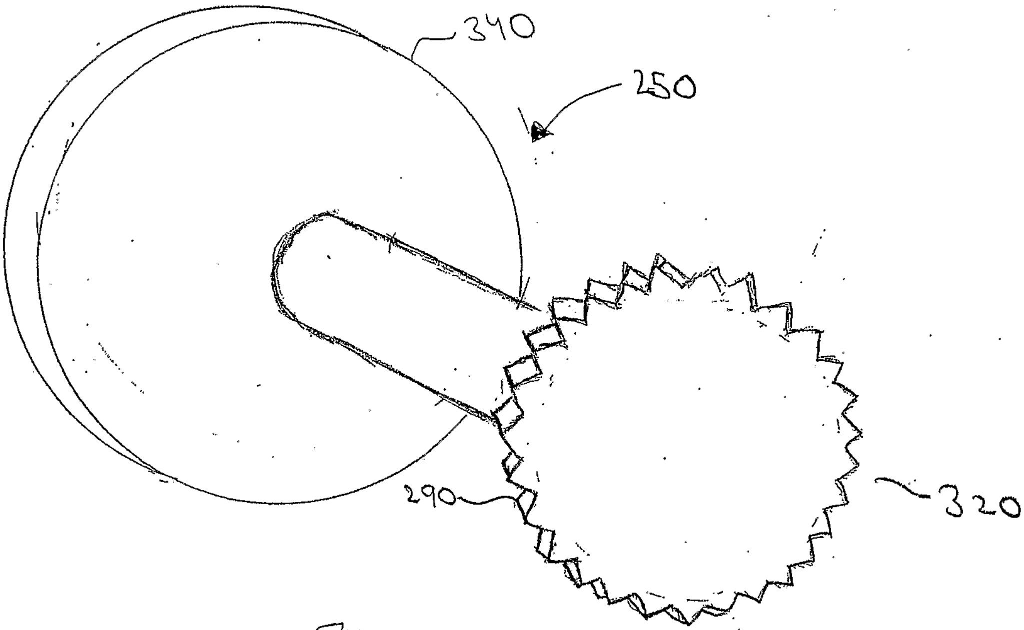
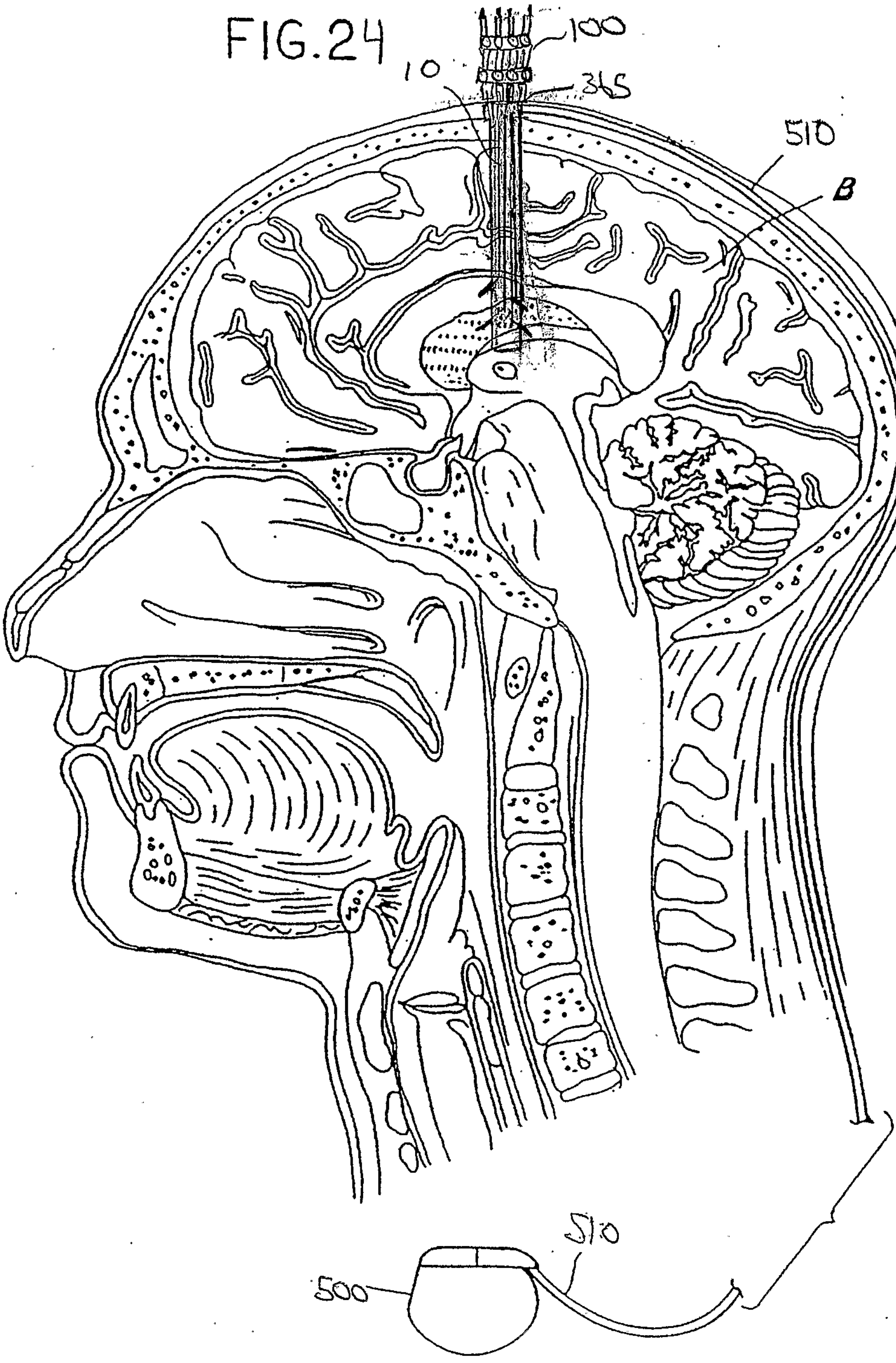


FIG.23

FIG.24



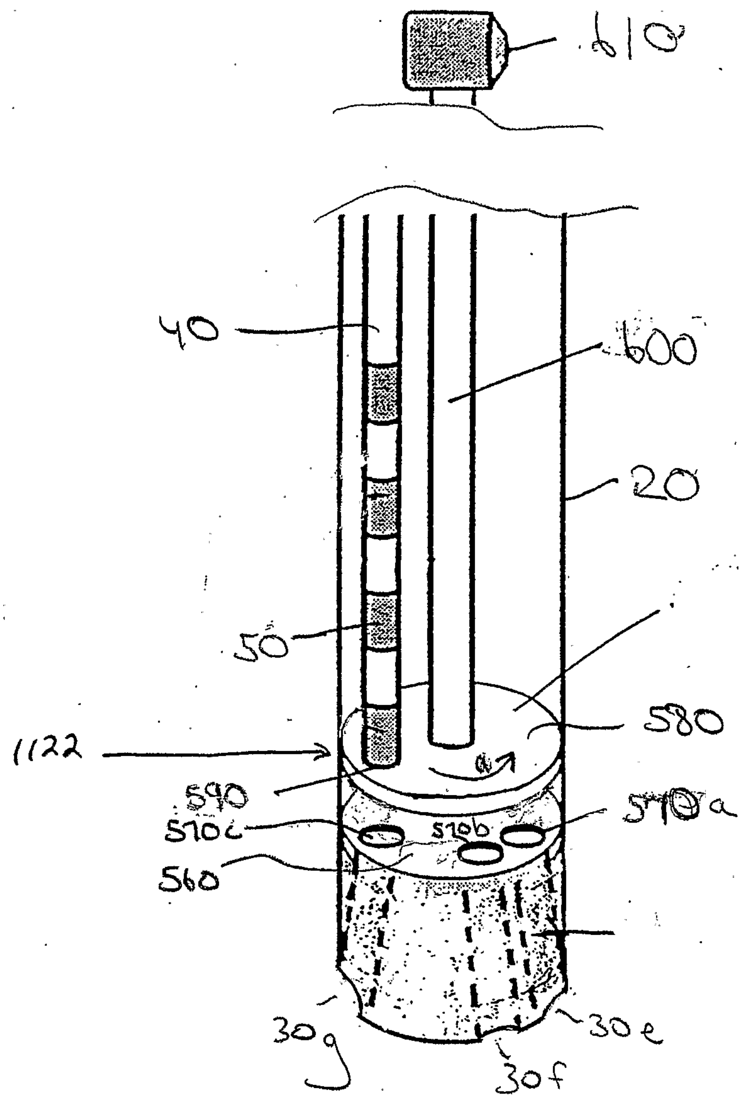


FIG 25

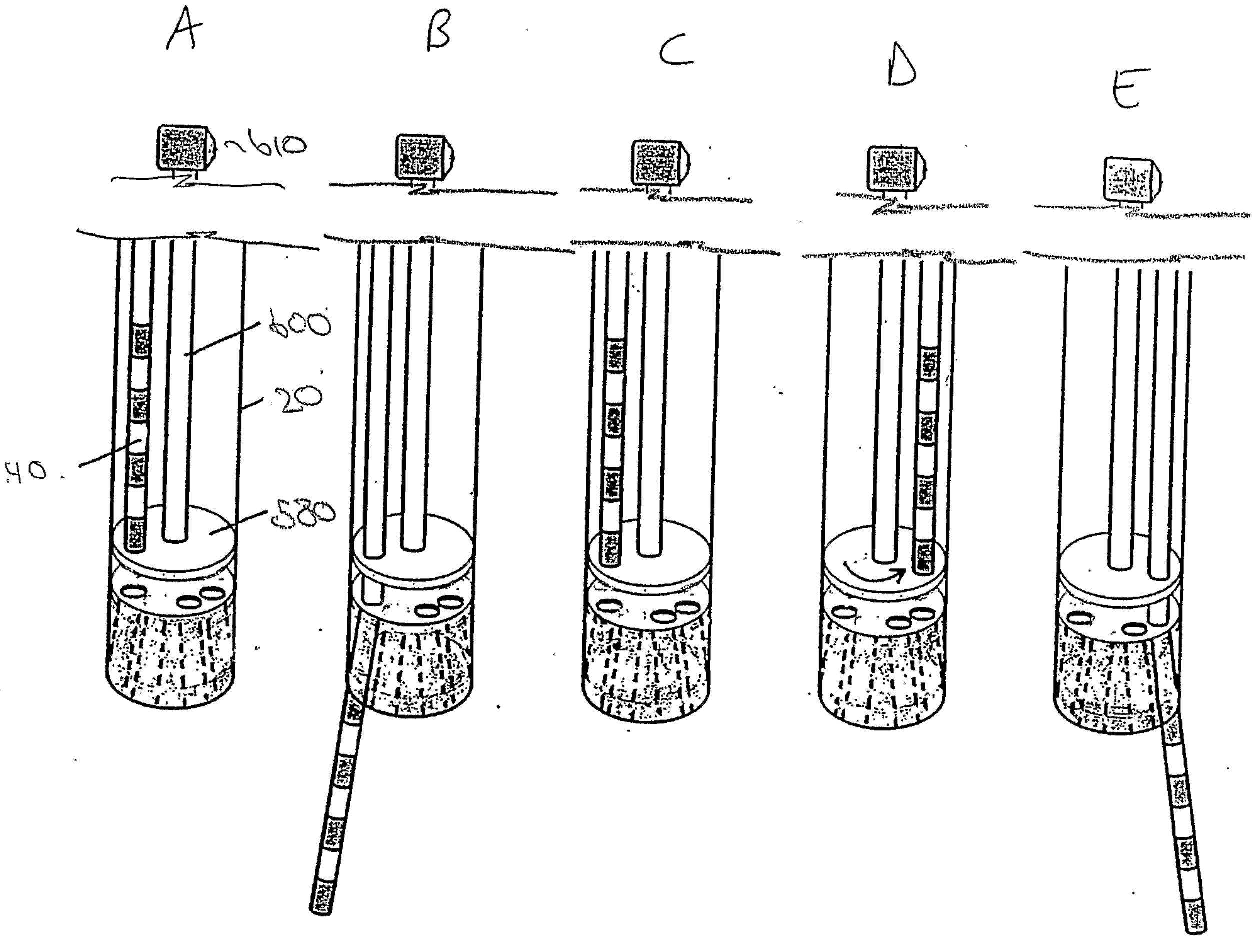


FIG. 26