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(54) Title: DEVICES, SYSTEMS AND METHODS FOR THE TARGETED TREATMENT OF MOVEMENT DISORDERS

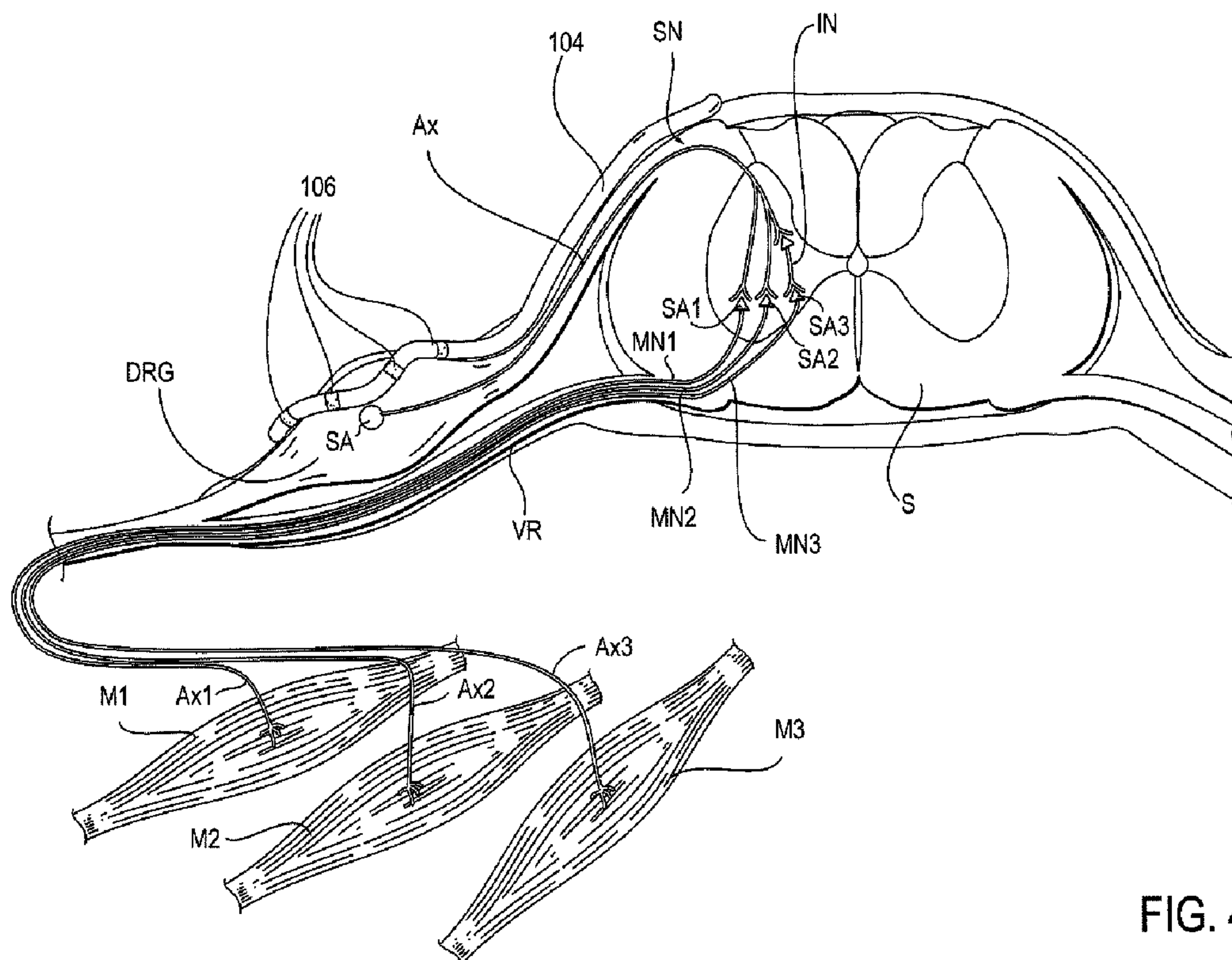


FIG. 4

(57) Abrégé/Abstract:

Devices, systems and methods are provided for the targeted treatment of movement disorders. Typically, the systems and devices are used to stimulate one or more dorsal root ganglia while minimizing or excluding undesired stimulation of other tissues, such as



(57) **Abrégé(suite)/Abstract(continued):**

surrounding or nearby tissues, ventral root and portions of the anatomy associated with body regions which are not targeted for treatment. The dorsal root ganglia are utilized in particular due to their specialized role in movement. It is in these areas that sensory fibers are isolated from motor fibers. Sensory fibers are involved in a variety of reflexes that are involved in movement control, and these reflexes can be utilized in the treatment of various movement disorders. Thus, by stimulating sensory fibers in these areas, fundamental reflexes can be affected to lessen the symptoms of movement disorders.

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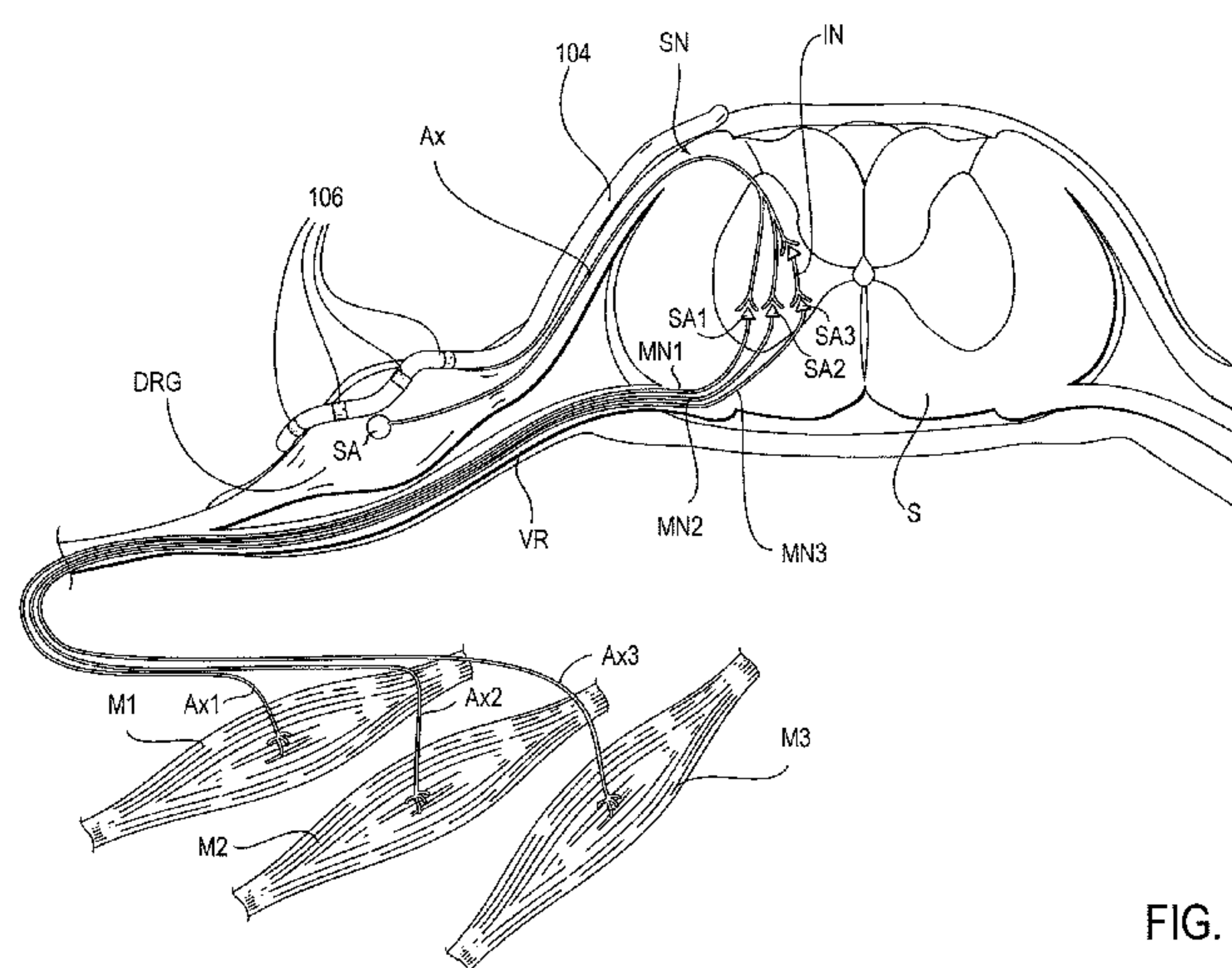


FIG. 4

(57) **Abstract:** Devices, systems and methods are provided for the targeted treatment of movement disorders. Typically, the systems and devices are used to stimulate one or more dorsal root ganglia while minimizing or excluding undesired stimulation of other tissues, such as surrounding or nearby tissues, ventral root and portions of the anatomy associated with body regions which are not targeted for treatment. The dorsal root ganglia are utilized in particular due to their specialized role in movement. It is in these areas that sensory fibers are isolated from motor fibers. Sensory fibers are involved in a variety of reflexes that are involved in movement control, and these reflexes can be utilized in the treatment of various movement disorders. Thus, by stimulating sensory fibers in these areas, fundamental reflexes can be affected to lessen the symptoms of movement disorders.



## DEVICES, SYSTEMS AND METHODS FOR THE TARGETED TREATMENT OF MOVEMENT DISORDERS

### CROSS-REFERENCES TO RELATED APPLICATIONS

5 [0001] This application claims priority under 35 U.S.C. 119(e) to U.S. Provisional Patent Application Serial No: 61/438,895 filed on February 2, 2011, incorporated herein by reference in its entirety.

### STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER 10 FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT

[0002] NOT APPLICABLE

### REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

15 [0003] NOT APPLICABLE

### BACKGROUND OF THE INVENTION

[0004] Movement disorders are neurological conditions that affect the ability to produce and control body movement. In particular, such disorders interfere with the speed, fluency, quality,  
20 and ease of movement. And, in some cases, cognitive and autonomic functions can be affected. Currently it is estimated that over 40 million individuals suffer from some sort of movement disorders. They can occur in all age groups from infancy to the elderly.

[0005] Treatment for movement disorders depends on the underlying cause. In most cases, the goal of treatment is to relieve symptoms. Treatment may include medication, botulinum toxin  
25 injection therapy, and surgery. Medications that are typically used include the following: antiepileptics, antiseizure medications, beta-blockers, dopamine agonists, and tranquilizers. However, these medications have a variety of side effects. Side effects of antiepileptics include dizziness, drowsiness, nausea, and vomiting. Antiseizure medications may cause a lack of coordination and balance (ataxia), dizziness, nausea, and fatigue. Side effects caused by beta-  
30 blockers include slowed heart rate (bradycardia), depression, light-headedness, and nausea. Dopamine agonists may cause nausea, headache, dizziness, and fatigue. Tranquilizers such as benzodiazepines may cause blood clots (thrombosis), drowsiness, and fatigue.



[0006] Botulinum toxin injection therapy is used to treat some types of movement disorders (e.g., spasmodic torticollis, blepharospasm, myoclonus, tremor). In this treatment, a potent neurotoxin (produced by the bacterium *Clostridium botulinum*) is injected into a muscle to inhibit the release of neurotransmitters that cause muscle contraction. In some cases, treatment is repeated every 3 to 4 months. However, patients may develop antibodies to the toxin over time, causing treatment to become ineffective. Side effects include temporary weakness in the group of muscles being treated, unintentional paralysis of muscles other than those being treated and rarely, flu-like symptoms.

[0007] When medication is ineffective, severe movement disorders may require surgery. In such instances, deep brain stimulation may be performed wherein a surgically implanted neurostimulator is used to deliver electrical stimulation to areas of the brain that control movement. The electrical charge blocks nerve signals that trigger abnormal movement. In deep brain stimulation, a lead is inserted through a small incision in the skull and is implanted in the targeted area of the brain. An insulated wire is then passed under the skin in the head, neck, and shoulder, connecting the lead to the neurostimulator, which is surgically implanted in the chest or upper abdomen. However, negative side effects of deep brain stimulation can occur, including: bleeding at the implantation site, depression, impaired muscle tone, infection, loss of balance, slight paralysis (paresis), slurred speech (dysarthria), and tingling (paresthesia) in the head or the hands.

[0008] Another type of surgical treatment for motion disorders is ablative surgery. Ablative surgery locates, targets, and then destroys (ablates) a defined area of the brain that produces chemical or electrical impulses that cause abnormal movements. In this surgery, a heated probe or electrode is inserted into the targeted area. The patient remains awake during the procedure to determine if the problem has been eliminated. A local anesthetic is used to dull the outer part of the brain and skull. The brain is insensitive to pain, so the patient does not feel the actual procedure. However, in some cases, it may be difficult to estimate how much tissue to destroy and the amount of heat to use. This type of surgery involves either ablation in the part of the brain called the globus pallidus (called pallidotomy) or ablation of brain tissue in the thalamus (called thalamotomy). Pallidotomy may be used to eliminate uncontrolled dyskinesia (e.g., jerky, involuntary movements) and thalamotomy may be performed to eliminate tremor. A related procedure, cryothalamotomy, uses a supercooled probe that is inserted into the thalamus to freeze and destroy areas that produce tremors.

[0009] Aside from the risks and side effects associated with the above described therapies, such treatments are not always effective in treating the movement disorder. Therefore, improved



therapies with higher effectiveness and lower side effects are desired. At least some of these objectives will be met by the following invention.

#### SUMMARY OF THE INVENTION

[0010] In a first aspect of the invention, a stimulation system is provided for treating a patient  
5 having a movement disorder. In some embodiments, the stimulation system comprises a lead having at least one electrode, wherein the lead is configured for implantation so as to position at least one of the at least one electrode adjacent a dorsal root ganglion associated with a reflex arc utilizable to affect a symptom the movement disorder, and a pulse generator electrically connected to lead, wherein the pulse generator provides a signal to the at least one of the at least  
10 one electrode which stimulates at least a portion of the dorsal root ganglion so as to activates the reflex arc in a manner that reduces the symptom of the movement disorder.

[0011] In some embodiments, activation of the reflex arc comprises stimulation of at least one sensory neuron so as to activate at least one soma of an alpha motor neuron. In some instances, the at least one sensory neuron comprises an Ia sensory fiber. In other instances, the at least one  
15 sensory neuron comprises an Ib sensory fiber. In some embodiments, the at least of the at least one electrode has a size that selectively stimulates the at least one sensory neuron. In some embodiments, the at least of the at least one electrode has a shape that selectively stimulates the at least one sensory neuron.

[0012] In some embodiments, the signal has at least one parameter that is programmable to  
20 selectively stimulate the at least one sensory neuron. In some embodiments, the at least one parameter comprises frequency. In some instances, the frequency is programmable with a value up to approximately 100 Hz. In some instances, the frequency is programmable with a value up to approximately 50 Hz.

[0013] In some embodiments, the stimulation system further comprises at least one sensor  
25 configured to sense an indicator of the movement disorder. In some embodiments, the at least one sensor comprises an accelerometer, a strain gauge, or an electrical device which measures electrical activity in a muscle or nerve. In some embodiments, the indicator indicates an onset of the symptom of the movement disorder, and wherein the stimulation signal is provided to reduce or avoid the onset of the symptom. In some embodiments, the indicator indicates a status of the  
30 symptom of the movement disorder, and wherein the stimulation signal is provided to treat the symptom in real time. In some embodiments, the indicator indicates a position of at least a portion of a body of the patient.



[0014] In some embodiments, the system further comprises at least one sensor configured to sense an activity or an activity level of the patient.

5 [0015] In a second aspect of the invention, a system is provided for treating a patient having a movement disorder, the system comprising a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrodes is able to stimulate at least a portion of a target dorsal root associated with the movement disorder, at least one sensor configured to sense a symptom of the movement disorder, and an implantable pulse generator connectable with the lead, wherein the generator includes electronic circuitry configured to receive information from the at least one sensor and provide a stimulation signal to  
10 the lead in response to the sensed symptom of the movement disorder, wherein the stimulation signal has an energy below an energy threshold for directly stimulating a ventral root associated with the target dorsal root while the lead is so positioned.

[0016] In some embodiments, the at least one sensor senses an onset of the symptom of the movement disorder, and the stimulation signal is provided to reduce or avoid the onset of the  
15 symptom. In some embodiments, the at least one sensor senses a status of the symptom of the movement disorder, and the stimulation signal is provided to treat the symptom in real time. In some embodiments, the at least one sensor senses an activity or an activity level of the patient. In some embodiments, the at least one sensor detects position of the patient. In some instances, the at least one sensor comprises an accelerometer, a strain gauge, or an electrical device which  
20 measures electrical activity in a muscle or nerve.

[0017] In a third aspect of the present invention, a method is provided of treating a patient having a movement disorder. In some embodiments, the method comprises presenting the patient having the movement disorder, positioning a lead having at least one electrode within the patient so that the at least one electrode is disposed near a target dorsal root ganglion associated  
25 with a reflex arc utilizable to affect a symptom of the movement disorder, and providing stimulation energy to the at least one electrode so as to selectively stimulate at least a portion of the target dorsal root ganglion so as to activate the reflex arc in a manner which reduces the symptom of the movement disorder while providing no or imperceptible amounts of stimulation energy directly to a ventral root. In some embodiments, the movement disorder includes  
30 Parkinson's Disease, Multiple Sclerosis, a Demyelinating Movement Disorder, Cerebral Palsy, Chorea, Dystonia, Spasm, Tic disorder or Tremor. It may be appreciated that other movement disorders may also be treated with the methods, devices and systems of the present invention.



[0018] In some embodiments, activating the reflex arc comprises stimulating at least one sensory neuron so as to activate at least one soma of an alpha motor neuron. In some instances, the at least one sensory neuron comprises an Ia sensory fiber. In some instances, the at least one sensory neuron comprises an Ib sensory fiber.

5 [0019] In some embodiments, stimulating the at least one sensory neuron comprises selectively stimulating the at least one sensory neuron by choice of stimulation signal parameters of the stimulation energy. In some instances, stimulating the at least one sensory neuron comprises selectively stimulating the at least one sensory neuron by choice of frequency of the stimulation energy. In some instances, stimulating the at least one sensory neuron comprises selectively  
10 stimulating the at least one sensory neuron by choice of size of the at least one electrode, shape of the at least one electrode, and/or position of the at least one electrode.

[0020] In some embodiments, providing stimulation energy comprises providing stimulation energy in response to at least one sensor configured to sense an indicator of the movement disorder. In some embodiments, the indicator comprises an onset of the symptom of the  
15 movement disorder, and wherein the stimulation signal is provided to reduce or avoid the onset of the symptom. In some embodiments, the indicator comprises a status of the symptom of the movement disorder, and wherein the stimulation signal is provided to treat the symptom in real time.

[0021] In some embodiments, providing stimulation energy comprises providing stimulation  
20 energy in response to at least one sensor configured to sense an activity or an activity level of the patient.

[0022] In some embodiments, providing stimulation energy comprises providing stimulation energy in response to at least one sensor configured to detect a position of at least a portion of a body of the patient.

25 [0023] In a fourth aspect of the invention, a method is provided of treating a movement disorder of a patient, the method comprising advancing a sheath having a curved distal end along an epidural space of the patient, positioning the curved distal end so as to direct a lead advanced therethrough toward a spinal nerve associated with the movement disorder, advancing the lead having at least one electrode through the sheath so that the at least one electrode is disposed near  
30 the spinal nerve, and providing stimulation energy to the at least one electrode so as to stimulate at least a portion of the spinal nerve in a manner which reduces a symptom of the movement disorder. In some embodiments, the movement disorder includes Parkinson's Disease, Multiple Sclerosis or a Demyelinating Movement Disorder, Cerebral Palsy, Chorea, Dystonia, Spasm, Tic



disorder or Tremor. It may be appreciated that other movement disorders may also be treated with the methods, devices and systems of the present invention.

[0024] In some embodiments, the at least a portion of the spinal nerve comprises at least a portion of a dorsal root ganglion associated with the movement disorder. In some embodiments, providing stimulation energy comprises adjusting at least one signal parameter to reduce the symptom of the movement disorder. In some embodiments, adjusting the at least one signal parameter comprises adjusting a frequency of the stimulation energy. In some instances, adjusting a frequency of the stimulation energy comprises selecting a frequency less than or equal to approximately 100 Hz. In some instances, adjusting a frequency of the stimulation energy comprises selecting a frequency less than or equal to approximately 50 Hz.

[0025] Other objects and advantages of the present invention will become apparent from the detailed description to follow, together with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0026] Fig. 1 illustrates an embodiment of an implantable stimulation system.

[0027] Fig. 2 illustrates example placement of the leads of the embodiment of Fig. 1 within a patient anatomy.

[0028] Fig. 3 illustrates an example cross-sectional view of an individual spinal level showing a lead positioned on, near or about a target dorsal root ganglion.

[0029] Figs. 4-5 illustrates example activation of reflex arc in the treatment of movement disorders.

#### DETAILED DESCRIPTION OF THE INVENTION

[0030] The present invention provides devices, systems and methods for the targeted treatment of movement disorders. Such movement disorders include, among others,

1) Akathisia

2) Akinesia (lack of movement)

3) Associated Movements (Mirror Movements or Homolateral Synkinesis)

4) Athetosis (contorted torsion or twisting)

5) Ataxia

- 6) Ballismus (violent involuntary rapid and irregular movements) and Hemiballismus (affecting only one side of the body)
- 7) Bradykinesia (slow movement)
- 8) Cerebral palsy
- 5 9) Chorea (rapid, involuntary movement), including Sydenham's chorea, Rheumatic chorea and Huntington's disease
- 10 10) Dystonia (sustained torsion), including Dystonia muscularum, Blepharospasm, Writer's cramp, Spasmodic torticollis (twisting of head and neck), and Dopamine-responsive dystonia (hereditary progressive dystonia with diurnal fluctuation or Segawa's disease)
- 11) Geniospasm (episodic involuntary up and down movements of the chin and lower lip)
- 12) Myoclonus (brief, involuntary twitching of a muscle or a group of muscles)
- 13) Metabolic General Unwellness Movement Syndrome (MGUMS)
- 14) Multiple Sclerosis
- 15) Parkinson's disease
- 15 16) Restless Legs Syndrome RLS (WittMaack-Ekboms disease)
- 17) Spasms (contractions)
- 18) Stereotypic movement disorder
- 19) Stereotypy (repetition)
- 20) Tardive dyskinesia
- 20 21) Tic disorders (involuntary, compulsive, repetitive, stereotyped), including Tourette's syndrome
- 22) Tremor (oscillations)
- 23) Rest tremor (approximately 4-8 Hz)
- 24) Postural tremor
- 25 25) Kinetic tremor
- 26) Essential tremor (approximately 6-8 Hz variable amplitude)
- 27) Cerebellar tremor (approximately 6-8 Hz variable amplitude)



28) Parkinsonian tremors (approximately 4-8 Hz variable amplitude)

29) Physiological tremor (approximately 10-12 Hz low amplitude)

30) Wilson's disease

[0031] The present invention provides for targeted treatment of such conditions with minimal deleterious side effects, such as undesired motor responses or undesired stimulation of unaffected body regions. This is achieved by directly neuromodulating a target anatomy associated with the condition while minimizing or excluding undesired neuromodulation of other anatomies. In most embodiments, neuromodulation comprises stimulation, however it may be appreciated that neuromodulation may include a variety of forms of altering or modulating nerve activity by delivering electrical and/or pharmaceutical agents directly to a target area. For illustrative purposes, descriptions herein will be provided in terms of stimulation and stimulation parameters, however, it may be appreciated that such descriptions are not so limited and may include any form of neuromodulation and neuromodulation parameters.

[0032] Typically, the systems and devices are used to stimulate portions of neural tissue of the central nervous system, wherein the central nervous system includes the spinal cord and the pairs of nerves along the spinal cord which are known as spinal nerves. The spinal nerves include both dorsal and ventral roots which fuse to create a mixed nerve which is part of the peripheral nervous system. At least one dorsal root ganglion (DRG) is disposed along each dorsal root prior to the point of mixing. Thus, the neural tissue of the central nervous system is considered to include the dorsal root ganglia and exclude the portion of the nervous system beyond the dorsal root ganglia, such as the mixed nerves of the peripheral nervous system. Typically, the systems and devices of the present invention are used to stimulate one or more dorsal root ganglia, dorsal roots, dorsal root entry zones, or portions thereof, while minimizing or excluding undesired stimulation of other tissues, such as surrounding or nearby tissues, ventral root and portions of the anatomy associated with body regions which are not targeted for treatment. However, it may be appreciated that stimulation of other tissues are contemplated.

[0033] The target stimulation areas of the present invention, particularly the dorsal root ganglia, are utilized due to their specialized role in movement. It is in these areas that sensory fibers are isolated from motor fibers. Sensory fibers are involved in a variety of reflexes that are involved in movement control, and these reflexes can be utilized in the treatment of various movement disorders. Thus, by stimulating sensory fibers in these areas, fundamental reflexes can be affected to lessen the symptoms of movement disorders. In addition, such targeted



stimulation reduces undesired side effects, such as painful tingling or unwanted movements caused by direct stimulation of motor nerves, such as within the ventral root.

[0034] A variety of motor reflexes are involved in movement control. A reflex or reflex arc is the neural pathway that mediates a reflex action. A motor reflex action occurs relatively quickly by activating motor neurons in the spinal cord without the delay of routing signals through the brain. Normally, messages from nerve cells in the brain (upper motor neurons) are transmitted to nerve cells in the brain stem and spinal cord (lower motor neurons) and from there to particular muscles. Thus, upper motor neurons direct the lower motor neurons to produce movements such as walking or chewing. Lower motor neurons control movement in the arms, legs, chest, face, throat, and tongue. However, lower motor neurons can be accessed via a reflex arc to circumvent the involvement of upper neurons. This is beneficial when responding to a harmful stimulus, such as a hot surface, wherein speed is critical. And, this is beneficial when there is damage or disease affecting upper neurons resulting in a movement disorder.

[0035] The present invention utilizes such reflex arcs to treat patients presenting with one or more movement disorders. Fig. 1 illustrates an embodiment of an implantable stimulation system 100 for treatment of such patients. The system 100 includes an implantable pulse generator (IPG) 102 and at least one lead 104 connectable thereto. In preferred embodiments, the system 100 includes four leads 104, as shown, however any number of leads 104 may be used including one, two, three, four, five, six, seven, eight, up to 58 or more. Each lead 104 includes at least one electrode 106. In preferred embodiments, each lead 104 includes four electrodes 106, as shown, however any number of electrodes 106 may be used including one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen or more. Each electrode can be configured as off, anode or cathode. In some embodiments, even though each lead and electrode are independently configurable, at any given time the software ensures only one lead is stimulating at any time. In other embodiments, more than one lead is stimulating at any time, or stimulation by the leads is staggered or overlapping.

[0036] Referring again to Fig. 1, the IPG 102 includes electronic circuitry 107 as well as a power supply 110, e.g., a battery, such as a rechargeable or non-rechargeable battery, so that once programmed and turned on, the IPG 102 can operate independently of external hardware. In some embodiments, the electronic circuitry 107 includes a processor 109 and programmable stimulation information in memory 108.

[0037] The implantable stimulation system 100 can be used to stimulate a variety of anatomical locations within a patient's body. In preferred embodiments, the system 100 is used



to stimulate one or more dorsal roots, particularly one or more dorsal root ganglions. Fig. 2 illustrates example placement of the leads 104 of the embodiment of Fig. 1 within the patient anatomy. In this example, each lead 104 is individually advanced within the spinal column S in an antegrade direction. Each lead 104 has a distal end which is guidable toward a target DRG and positionable so that its electrodes 106 are in proximity to the target DRG. Specifically, each lead 104 is positionable so that its electrodes 106 are able to selectively stimulate the DRG, either due to position, electrode configuration, electrode shape, electric field shape, stimulation signal parameters or a combination of these. Fig. 17 illustrates the stimulation of four DRGs, each DRG stimulated by one lead 104. These four DRGs are located on three levels, wherein two DRGs are stimulated on the same level. It may be appreciated that any number of DRGs and any combination of DRGs may be stimulated with the stimulation system 100 of the present invention. It may also be appreciated that more than one lead 104 may be positioned so as to stimulate an individual DRG and one lead 104 may be positioned so as to stimulate more than one DRG.

[0038] Fig. 3 illustrates an example cross-sectional view of an individual spinal level showing a lead 104 of the stimulation system 100 positioned on, near or about a target DRG. The lead 104 is advanced along the spinal cord S to the appropriate spinal level wherein the lead 104 is advanced laterally toward the target DRG. In some instances, the lead 104 is advanced through or partially through a foramen. At least one, some or all of the electrodes 106 are positioned on, about or in proximity to the DRG. In preferred embodiments, the lead 104 is positioned so that the electrodes 106 are disposed along a surface of the DRG opposite to the ventral root VR, as illustrated in Fig. 3. It may be appreciated that the surface of the DRG opposite the ventral root VR may be diametrically opposed to portions of the ventral root VR but is not so limited. Such a surface may reside along a variety of areas of the DRG which are separated from the ventral root VR by a distance.

[0039] In some instances, such electrodes 106 may provide a stimulation region indicated by dashed line 110, wherein the DRG receives stimulation energy within the stimulation region and the ventral root VR does not as it is outside of the stimulation region. Thus, such placement of the lead 104 may assist in reducing any possible stimulation of the ventral root VR due to distance. However, it may be appreciated that the electrodes 106 may be positioned in a variety of locations in relation to the DRG and may selectively stimulate the DRG due to factors other than or in addition to distance, such as due to stimulation profile shape and stimulation signal parameters, to name a few. It may also be appreciated that the target DRG may be approached by other methods, such as a retrograde epidural approach. Likewise, the DRG may be



approached from outside of the spinal column wherein the lead 104 is advanced from a peripheral direction toward the spinal column, optionally passes through or partially through a foramen and is implanted so that at least some of the electrodes 106 are positioned on, about or in proximity to the DRG.

- 5 [0040] In order to position the lead 104 in such close proximity to the DRG, the lead 104 is appropriately sized and configured to maneuver through the anatomy. In some embodiments, such maneuvering includes atraumatic epidural advancement along the spinal cord S, through a sharp curve toward a DRG, and optionally through a foramen wherein the distal end of the lead 104 is configured to then reside in close proximity to a small target such as the DRG.
- 10 Consequently, the lead 104 is significantly smaller and more easily maneuverable than conventional spinal cord stimulator leads. Example leads and delivery systems for delivering the leads to a target such as the DRG are provided in US Patent Application No. 12/687,737, entitled "Stimulation Leads, Delivery Systems and Methods of Use", incorporated herein by reference for all purposes.
- 15 [0041] Fig. 4 illustrates the lead 104 positioned near a DRG so as to activate an example reflex arc in the treatment of a movement disorder. In this example, the reflex arc includes a sensory neuron SN, which includes a soma SA disposed within the DRG and an axon AX which extends through the dorsal root DR to the dorsal horn of the spinal cord S. The sensory neuron SN connects with a variety of motor neurons MN and interconnector neurons IN within the spinal
- 20 cord S. In this example, the sensory neuron SN connects with two motor neurons MN1, MN2 and an interconnector neuron IN which connects with motor neuron MN3. Motor neuron MN1 (an alpha motor neuron) includes a soma SA1 disposed within the ventral horn of the spinal cord S and an axon AX1 which extends through the ventral root VR and innervates a skeletal muscle M1, such as a flexor muscle. Motor neuron MN2 (a second alpha motor neuron) includes a soma
- 25 SA2 disposed within the ventral horn of the spinal cord S and an axon AX2 which extends through the ventral root VR and innervates a skeletal muscle M2 which is synergistic with muscle M1. Motor neuron MN3 (a third alpha motor neuron) includes a soma SA3 disposed within the ventral horn of the spinal cord S and an axon AX3 which extends through the ventral root VR and innervates a skeletal muscle M3 which is antagonistic to muscle M1 and muscle
- 30 M2.

[0042] In many movement disorders, improper action potentials are generated, either from damage to the upper motor neurons or from other causes. In some instances, such improper action potentials cause muscles (such as muscle M1) and synergistic muscles (such as M2) to undesirably contract while causing antagonistic muscles (such as muscle M3) to undesirably



relax. In some embodiments, treatment of such a condition is achieved by providing selective stimulation to the dorsal root and/or DRG associated with the muscles M1, M2, M3, with the use of an appropriately positioned lead 104, as illustrated in Fig. 4. As mentioned previously, at least one, some or all of the electrodes 106 are positioned on, about or in proximity to the target DRG. In some embodiments, the involved sensory neuron SN, particularly its soma SA within the target DRG, is selectively stimulated so as to inhibit the improper action potentials causing muscles M1, M2 to contract and muscle M3 to relax. This is particularly the case when the involved sensory neuron SN is an Ia sensory fiber. Such stimulation reduces the symptoms of the movement disorder in treatment of the condition.

[0043] In some embodiments, selective stimulation of the involved sensory neuron SN is achieved with the choice of the size of the electrode(s), the shape of the electrode(s), the position of the electrode(s), the stimulation signal, pattern or algorithm, or any combination of these. Such selective stimulation stimulates the targeted neural tissue while excluding untargeted tissue, such as surrounding or nearby tissue. In some embodiments, the stimulation energy is delivered to the targeted neural tissue so that the energy dissipates or attenuates beyond the targeted tissue or region to a level insufficient to stimulate modulate or influence such untargeted tissue. In particular, selective stimulation of tissues, such as the dorsal root, DRG, or portions thereof, exclude stimulation of the ventral root wherein the stimulation signal has an energy below an energy threshold for stimulating a ventral root associated with the target dorsal root while the lead is so positioned. Examples of methods and devices to achieve such selective stimulation of the dorsal root and/or DRG are provided in US Patent Application No. 12/607,009, entitled "Selective Stimulation Systems and Signal Parameters for Medical Conditions", incorporated herein by reference for all purposes. It may be appreciated that indiscriminant stimulation of the ventral root, such as from an electrode which emits stimulation energy which directly stimulates the ventral root, typically causes unpleasant sensations for the patient, such as tingling, buzzing or undesired motions or movements. Therefore, it is desired to stimulate motor neurons M1, M2 and/or M3 via synapses in the spinal cord rather than directly via the ventral root.

[0044] It may be appreciated that even though the motor neurons are stimulated via synapses in the spinal cord, such stimulation is differentiated from stimulating the spinal cord directly to affect motor neurons. The spinal cord is a highly innervated portion of the anatomy; sensory information from receptors throughout most of the body is relayed to the brain by means of ascending tracts of fibers that conduct impulses up the spinal cord, and, the brain directs motor activities in the form of nerve impulses that travel down the spinal cord in descending tracts of fibers. The white matter of the spinal cord is composed of ascending and descending fiber tracts.



These are arranged into six columns of white matter called funiculi. The ascending fiber tracts convey sensory information from cutaneous receptors, proprioceptors (muscle and joint senses), and visceral receptors. The descending fiber tracts convey motor information, and there are two major groups of descending tracts from the brain: the corticospinal, or pyramidal tracts, and the  
5 extrapyramidal tracts.

[0045] From 80%-90% of the corticospinal fibers decussate in the pyramids of the medulla oblongata (hence the name "pyramidal tracts") and descend in the lateral corticospinal tracts, which decussate in the spinal cord. Because of the crossing of fibers, the right cerebral hemisphere controls the musculature on the left side of the body, where the left hemisphere  
10 controls the right musculature. The corticospinal tracts are primarily concerned with the control of fine movement that requires dexterity.

[0046] Given the high number of fiber tracts within the spinal cord and the extensive crossing of fibers, direct stimulation of the spinal cord typically yields highly variable and/or non-specific generalized results. Slight changes in position of the stimulation electrodes on the spinal cord  
15 causes stimulation of different tracts which can easily lead to undesired side effects. For example, given that both sensory and motor information is conveyed within the spinal cord, attempts at stimulating the motor fiber tract often causes inadvertent stimulation of the sensory fiber tract. Likewise, given the interconnectivity of pathways across various spinal levels within the spinal cord, targeting of a particular spinal level or a particular pair of opposing muscle  
20 groups is very difficult when applying stimulation to the spinal cord. Further, a higher frequency signal and a higher level of power is also typically required in attempts to reach specific nerve types with stimulation when directly stimulating the spinal cord.

[0047] By stimulating the motor neurons in the spinal cord via the dorsal root ganglion, the drawbacks associated with direct stimulation of the spinal cord are avoided. In particular, since  
25 the dorsal root ganglion houses primarily sensory neurons, rather than mixed neurons such as in the spinal cord or peripheral nerves, inadvertent stimulation of unrelated or undesired anatomies is obviated. In addition, stimulation of a single dorsal root ganglion only affects muscles that are innervated with motor nerves that synapse with that dorsal root ganglion. Consequently, a single muscle, a single muscle group, pair of opposing muscles or muscle groups or a particular  
30 localized area may be precisely targeted by stimulating a corresponding dorsal root ganglion. Such specificity and targeting is beneficial for treating localized spasticity or other such movement disorders, among other conditions. Further, stimulation of a dorsal root ganglion requires less power than comparative stimulation on the spinal cord. And, stimulation of the dorsal root ganglion involves a lower frequency than comparative stimulation of the spinal cord.



In some embodiments, a low frequency signal is used, particularly a frequency less than or equal to approximately 100 Hz, more particularly less than or equal to approximately 80 Hz, and more particularly 4-80 Hz. In some embodiments, the signal has a frequency of approximately less than or equal to 70 Hz, 60 Hz, 50Hz, 40 Hz, 30 Hz, 20 Hz, 10 Hz, or 5 Hz. It may be

5 appreciated that typically the desired frequency used to treat a movement disorder varies from patient to patient. For example, in one patient a symptom of a movement disorder is reduced with the use of a stimulation signal having a given frequency, such as 100 Hz, by stimulating a particular dorsal root ganglion. And, in another patient having the same or similar movement disorder, a symptom of the movement disorder is reduced with the use of a stimulation signal  
10 having a different frequency, such as 50 Hz, by stimulating a corresponding particular dorsal root ganglion. Such variations may be due to slight differences in anatomy between the patients and differences in disease pathology, to name a few. However, it may be appreciated that the frequency is typically in the low frequency range.

[0048] In other instances, improper action potentials due to movement disorders cause muscles  
15 (such as muscle M1) and synergistic muscles (such as M2) to undesirably relax while causing antagonistic muscles (such as muscle M3) to undesirably contract. In some embodiments, treatment of such a condition is achieved by providing selective stimulation to the dorsal root and/or DRG associated with the muscles M1, M2, M3, with the use of an appropriately positioned lead 104, as illustrated in Fig. 5. In this example, the reflex arc again includes a  
20 sensory neuron SN, which includes a soma SA disposed within the DRG and an axon AX which extends through the dorsal root DR to the dorsal horn of the spinal cord S. The sensory neuron SN connects with a variety of interconnector neurons IN1, IN2, IN3 within the spinal cord S. Interconnector neuron IN1 connects with motor neuron MN1 (an alpha motor neuron) which innervates a skeletal muscle M1, such as a flexor muscle. Interconnector neuron IN2 connects  
25 with motor neuron MN2 (a second alpha motor neuron) which innervates a skeletal muscle M2 which is synergistic with muscle M1. Interconnector neuron IN3 connects with motor neuron MN3 (a third alpha motor neuron) which innervates a skeletal muscle M3 which is antagonistic to muscle M1 and muscle M2. As mentioned previously, at least one, some or all of the electrodes 106 are positioned on, about or in proximity to the target DRG. In some  
30 embodiments, the involved sensory neuron SN, particularly its soma SA within the target DRG, is selectively stimulated so as to inhibit the improper action potentials causing muscles M1, M2 to relax and muscle M3 to contract. This is particularly the case when the involved sensory neuron SN is an Ib sensory fiber. Such stimulation reduces the symptoms of the movement disorder in treatment of the condition.



[0049] In some embodiments, the implantable pulse generator (IPG) 102 comprises circuitry which initiates or modifies the electrical stimulation in response to one or more sensors.

Example sensors include, among others, accelerometers, strain gauges, electrical devices which measure electrical activity in muscles and/or nerves, or other devices capable of measuring

5 physiological parameters indicative of symptoms of the movement disorder under treatment. In some embodiments, the one or more sensors sense the onset of symptoms of the movement disorder, transmitting such information to the electronic circuitry 107 of the IPG 102 so that electrical stimulation is provided to the patient to counteract, reduce and/or avoid the onset of symptoms of the movement disorder. For example, in patients suffering from tremors, such

10 tremors may be sudden in onset and remission. Some have increased incidence with stress or decreased incidence when the patient is distracted. This is particularly the case with psychogenic tremors. In such patients, the tremor activity may be sensed with a sensor, such as on a bracelet or anklet worn on the affected limb or limbs. The sensor may sense a change in acceleration of

the limb, frequency of movement of the limb, position of the limb, or a combination of these, to

15 name a few. It may be appreciated that such sensors may also be used on other affected areas of the body, such as the head, neck, shoulder, torso, etc. When the tremor activity is sensed as increased, such as an onset or increase in activity, the electrical stimulation is changed to inhibit or diminish the increase in tremor activity. This may be achieved by increasing or decreasing

one or more signal parameters, such as amplitude, frequency, pulse width or a combination of

20 these. Likewise, it may be appreciated that when the tremor activity is sensed as decreased, such as a remission or decrease in activity, the electrical stimulation may be changed, such as to more appropriately match the stimulation to the tremor activity. In other instances, stimulation may be changed during remission or decrease in tremor activity to conserve power, prolong battery life, or reduce any side effects or symptoms related to unnecessary or undesired stimulation, to name

25 a few. It may be appreciated that tremor has been used merely as an example and other movement disorders or symptoms related to movement disorders may be similarly sensed. For example, some patients with movement disorders experience jerks or twitches in some part of the body. These jerky movements may be triggered by pain, certain lighting, or even loud noises.

The occurrence of these symptoms may be sensed and counteracted in a manner as described

30 above.

[0050] In some embodiments, the one or more sensors sense the status of the symptoms of the movement disorder, such as the extent of contraction or limb movement. Such status information is utilized to modify the electrical stimulation to a level which is appropriate to counteract or treat the symptoms of the movement disorder in real time. For example, patients

35 suffering from spasticity have altered skeletal muscle performance in muscle tone involving



hypertonia. It is often referred to as an unusual tightness, stiffness, and/or pull of muscles. Spasticity is found in conditions where the brain and/or spinal cord are damaged or fail to develop normally; these include cerebral palsy, multiple sclerosis, spinal cord injury and acquired brain injury including stroke. In some instances, the level of spasticity may increase or decrease, such as over time or with stimulation. In some embodiments, the status of the symptom, such as spasticity, is sensed to determine if a change has occurred. When the symptom is sensed as changed, the electrical stimulation is changed to inhibit or diminish the change in symptom. This may be achieved by increasing or decreasing one or more signal parameters, such as amplitude, frequency, pulse width or a combination of these. Again, it may be appreciated that spasticity has been used merely as an example and other movement disorders or symptoms related to movement disorders may be similarly sensed.

[0051] In other embodiments, the one or more sensors sense a specific activity or an activity level of the patient. Some movement disorders are correlated to certain activities, such as walking. For example, functional movement disorders often cause problems in coordinated locomotion or walking. These problems could involve dragging one foot or difficulty balancing while walking. An activity or activity level sensor may be used to detect the type of activity (such as walking) and/or amount or degree of activity (such as slow walk or fast walk). The sensed information could be an input to dynamically modify the stimulation program to determine the appropriate level of stimulation. Alternatively or additionally, different pre-programmed stimulation algorithms may be designed for an individual patient based on that specific patient's pattern of activity. Pre-programmed stimulation algorithms may be stored in an appropriate medium for use by a stimulation system described herein. Conventional transcutaneous programming techniques may also be used to update, modify or remove stimulation algorithms.

[0052] In other embodiments, the one or more sensors comprise a position sensor which may be used to detect position of the patient. The position of the patient could be an input to the stimulation control system to dynamically modify the stimulation program to determine the appropriate level of stimulation. One example of such a sensor is a multi-axis accelerometer. A conventional 3 or 4 axis accelerometer could be implanted into a patient or maintained on the patient to provide position, activity, activity level, activity duration or other indications of patient status. The detected indications of patient status could in turn be used in determining stimulation level and pattern. The position sensor can be set up or calibrated once positioned or implanted on or in a person. The calibration aids the sensor in correctly recognizing the persons orientation and activity levels.



[0053] In some embodiments, the sensor senses when a patient has lowered to laying or sleeping position. Since most movement disorders rarely occur during sleep, stimulation may be reduced or ceased during sleep to reduce power consumption and extend battery life.

[0054] In some embodiments, the sensor senses when a patient has risen to a standing position and stimulation is provided to counteract a symptom of a movement disorder related to standing. For example, orthostatic tremor is characterized by fast ( $>12$  Hz) rhythmic muscle contractions that occur in the legs and trunk immediately after standing. Cramps are felt in the thighs and legs and the patient may shake uncontrollably when asked to stand in one spot. No other clinical signs or symptoms are present and the shaking ceases when the patient sits or is lifted off the ground.

The high frequency of the tremor often makes the tremor look like rippling of leg muscles while standing. In such patients, stimulation is provided upon sensing of standing wherein the patient immediately feels relief of such symptoms. When the patient moves to a different position, such as sitting, the stimulation is ceased or reduced to a desired level.

[0055] In some embodiments, the sensor senses a particular movement pattern and stimulation is provided to counteract a symptom of a movement disorder related to that particular movement pattern. For example, cerebellar tremor is a slow, broad tremor of the extremities that occurs at the end of a purposeful movement, such as trying to press a button or touching a finger to the tip of one's nose. When such a movement patterns is sensed, stimulation is then provided to counteract the symptom of the movement disorder that follows. Cerebellar tremor is caused by lesions in or damage to the cerebellum resulting from stroke, tumor, or disease such as multiple sclerosis or some inherited degenerative disorder. It can also result from chronic alcoholism or overuse of some medicines. In classic cerebellar tremor, a lesion on one side of the brain produces a tremor in that same side of the body that worsens with directed movement. Cerebellar damage can also produce a "wing-beating" type of tremor called rubral or Holmes' tremor — a combination of rest, action, and postural tremors. The tremor is often most prominent when the affected person is active or is maintaining a particular posture. Thus, a variety of sensors may be used in a complex array of decision making processes as to when and how stimulation is provided or changed for a particular patient.

[0056] Optionally, a position sensor is located within the same physical housing as the IPG 102. If desired, the position sensor may be located elsewhere on the body in an implanted location or may be worn externally by the person. Position information from the position and/or activity sensor is provided to the IPG 102 using suitable means including direct connections or percutaneous transmission. Although a number of embodiments are suitable, the preferred mode employs, by way of example and not to be construed as limiting of the present invention, one or



more accelerometers to determine patient state including, at least, the ability to sense whether the person is erect or recumbent. Additionally, the position sensor could be adapted to provide an indication of activity or level of activity such as the difference between walking and running. In another embodiment, a position sensor may be positioned to sense specific motion such as  
5 activity of a particular part of the body to detect specific movement of a body part or limb that, for example, is being treated for a movement disorder. Using this position sensor embodiment, when the person started activity related to a movement disorder, the sensor would detect such activity and provide the appropriate stimulation. In additional alternatives, the position and/or activity sensor includes one or more multi-axis accelerometers.

10 [0057] In some embodiments, the implantable pulse generator (IPG) 102 comprises circuitry which initiates or modifies the electrical stimulation in response to a timer or clock. Thus, stimulation may be reduced or eliminated during times in which the patient is sleeping or times in which it is determined that the patient desires reduced or no treatment of the movement disorder. Such periods of reduced usage may extend the life of the power supply 110.

15 [0058] As mentioned previously, it may be appreciated that neuromodulation may include a variety of forms of altering or modulating nerve activity by delivering electrical and/or pharmaceutical agents directly to a target area. For illustrative purposes, descriptions herein were provided in terms of stimulation and stimulation parameters, however, it may be appreciated that such descriptions are not so limited and may include any form of  
20 neuromodulation and neuromodulation parameters, particularly delivery of agents to the dorsal root ganglion. Methods, devices and agents for such delivery are further described in U.S. Patent Application No. 13/309,429 entitled, "Directed Delivery of Agents to Neural Anatomy", incorporated herein by reference.

[0059] Although the foregoing invention has been described in some detail by way of  
25 illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications, and equivalents may be used and the above description should not be taken as limiting in scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A stimulation system for treating a patient having a movement disorder comprising:

a lead having at least one electrode, wherein the lead is configured for implantation so as to position at least one of the at least one electrode adjacent a dorsal root ganglion associated with a reflex arc utilizable to affect a symptom the movement disorder; and  
5 a pulse generator electrically connected to lead, wherein the pulse generator provides a signal to the at least one of the at least one electrode which stimulates at least a portion of the dorsal root ganglion so as to activates the reflex arc in a manner that reduces the symptom of the movement disorder.

10 2. A stimulation system as in claim 1, wherein activation of the reflex arc comprises stimulation of at least one sensory neuron so as to activate at least one soma of an alpha motor neuron.

3. A stimulation system as in claim 2, wherein the at least one sensory neuron comprises an Ia sensory fiber.

15 4. A stimulation system as in claim 2, wherein the at least one sensory neuron comprises an Ib sensory fiber.

5. A stimulation system as in claims 2, 3 or 4, wherein the at least one of the at least one electrode has a size that selectively stimulates the at least one sensory neuron.

20 6. A stimulation system as in claims 2, 3, 4 or 5, wherein the at least one of the at least one electrode has a shape that selectively stimulates the at least one sensory neuron.

7. A stimulation system as in claim 2, 3, 4, 5 or 6, wherein the signal has at least one parameter that is programmable to selectively stimulate the at least one sensory neuron.

8. A stimulation system as in claim 7, wherein the at least one parameter comprises frequency.

25 9. A stimulation system as in claim 8, wherein the frequency is programmable with a value up to approximately 100 Hz.

10. A stimulation system as in claim 8, wherein the frequency is programmable with a value up to approximately 50 Hz.



11. A stimulation system as in any of the above claims, further comprising at least one sensor configured to sense an indicator of the movement disorder.

12. A system as in claim 11, wherein the at least one sensor comprises an accelerometer, a strain gauge, or an electrical device which measures electrical activity in a muscle or nerve.

13. A system as in claim 11 or 12, wherein the indicator indicates an onset of the symptom of the movement disorder, and wherein the stimulation signal is provided to reduce or avoid the onset of the symptom.

14. A system as in claim 11, 12 or 13, wherein the indicator indicates a status of the symptom of the movement disorder, and wherein the stimulation signal is provided to treat the symptom in real time.

15. A system as in claim 11, 12, 13 or 14, wherein the indicator indicates a position of at least a portion of a body of the patient.

16. A system as in any of the above claims, further comprising at least one sensor configured to sense an activity or an activity level of the patient.

17. A system for treating a patient having a movement disorder, the system comprising:

a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrodes is able to stimulate at least a portion of a target dorsal root associated with the movement disorder;

at least one sensor configured to sense a symptom of the movement disorder; and

an implantable pulse generator connectable with the lead, wherein the generator includes electronic circuitry configured to receive information from the at least one sensor and provide a stimulation signal to the lead in response to the sensed symptom of the movement disorder, wherein the stimulation signal has an energy below an energy threshold for directly stimulating a ventral root associated with the target dorsal root while the lead is so positioned.

18. A system as in claim 17, wherein the at least one sensor senses an onset of the symptom of the movement disorder, and wherein the stimulation signal is provided to reduce or avoid the onset of the symptom.



19. A system as in claim 17 or 18, wherein the at least one sensor senses a status of the symptom of the movement disorder, and wherein the stimulation signal is provided to treat the symptom in real time.

20. A system as in claim 17, 18 or 19, wherein the at least one sensor senses  
5 an activity or an activity level of the patient.

21. A system as in claim 17, wherein the at least one sensor detects position of the patient.

22. A system as in claim 17, 18, 19, 20 or 21, wherein the at least one sensor comprises an accelerometer, a strain gauge, or an electrical device which measures electrical  
10 activity in a muscle or nerve.

23. A method of treating a patient having a movement disorder comprising:  
presenting the patient having the movement disorder;

positioning a lead having at least one electrode within the patient so that the at least one electrode is disposed near a target dorsal root ganglion associated with a reflex arc  
15 utilizable to affect a symptom of the movement disorder; and

providing stimulation energy to the at least one electrode so as to selectively stimulate at least a portion of the target dorsal root ganglion so as to activate the reflex arc in a manner which reduces the symptom of the movement disorder while providing no or imperceptible amounts of stimulation energy directly to a ventral root.

24. A method as in claim 23, wherein the movement disorder includes  
20 Parkinson's Disease, Multiple Sclerosis, a Demylenating Movement Disorder, Cerebral Palsy, Chorea, Dystonia, Spasm, Tic disorder or Tremor.

25. A method as in claim 23 or 24, wherein activating the reflex arc comprises stimulating at least one sensory neuron so as to activate at least one soma of an alpha motor  
25 neuron.

26. A method as in claim 25, wherein the at least one sensory neuron comprises an Ia sensory fiber.

27. A method as in claim 25 or 26, wherein the at least one sensory neuron comprises an Ib sensory fiber.



28. A method as in claim 25, 26, or 27, wherein stimulating the at least one sensory neuron comprises selectively stimulating the at least one sensory neuron by choice of stimulation signal parameters of the stimulation energy.

29. A method as in claim 25, 26, 27 or 28, wherein stimulating the at least one sensory neuron comprises selectively stimulating the at least one sensory neuron by choice of frequency of the stimulation energy.

30. A method as in claim 25, 26, 27, 28 or 29, wherein stimulating the at least one sensory neuron comprises selectively stimulating the at least one sensory neuron by choice of size of the at least one electrode, shape of the at least one electrode, and/or position of the at least one electrode.

31. A method as in any of claims 23-30, wherein providing stimulation energy comprises providing stimulation energy in response to at least one sensor configured to sense an indicator of the movement disorder.

32. A method as in claim 31, wherein the indicator comprises an onset of the symptom of the movement disorder, and wherein the stimulation signal is provided to reduce or avoid the onset of the symptom.

33. A method as in claim 31 or 32, wherein the indicator comprises a status of the symptom of the movement disorder, and wherein the stimulation signal is provided to treat the symptom in real time.

34. A method as in any of claims 23-33, wherein providing stimulation energy comprises providing stimulation energy in response to at least one sensor configured to sense an activity or an activity level of the patient.

35. A method as in any of claims 23-34, wherein providing stimulation energy comprises providing stimulation energy in response to at least one sensor configured to detect a position of at least a portion of a body of the patient.

36. A method of treating a movement disorder of a patient comprising:  
advancing a sheath having a curved distal end along an epidural space of the patient;

positioning the curved distal end so as to direct a lead advanced therethrough toward a spinal nerve associated with the movement disorder;



advancing the lead having at least one electrode through the sheath so that the at least one electrode is disposed near the spinal nerve; and

providing stimulation energy to the at least one electrode so as to stimulate at least a portion of the spinal nerve in a manner which reduces a symptom of the movement disorder.

5                   37.     A method as in claim 36, wherein the movement disorder includes Parkinson's Disease, Multiple Sclerosis or a Demyelinating Movement Disorder, Cerebral Palsy, Chorea, Dystonia, Spasm, Tic disorder or Tremor.

                  38.     A method as in claim 36 or 37, wherein the at least a portion of the spinal nerve comprises at least a portion of a dorsal root ganglion associated with the movement  
10   disorder.

                  39.     A method as in claim 36, 37 or 38, wherein providing stimulation energy comprises adjusting at least one signal parameter to reduce the symptom of the movement disorder.

                  40.     A method as in claim 39, wherein adjusting the at least one signal  
15   parameter comprises adjusting a frequency of the stimulation energy.

                  41.     A method as in claim 40, wherein adjusting a frequency of the stimulation energy comprises selecting a frequency less than or equal to approximately 100 Hz.

                  42.     A method as in claim 41, wherein adjusting a frequency of the stimulation energy comprises selecting a frequency less than or equal to approximately 50 Hz.  
20



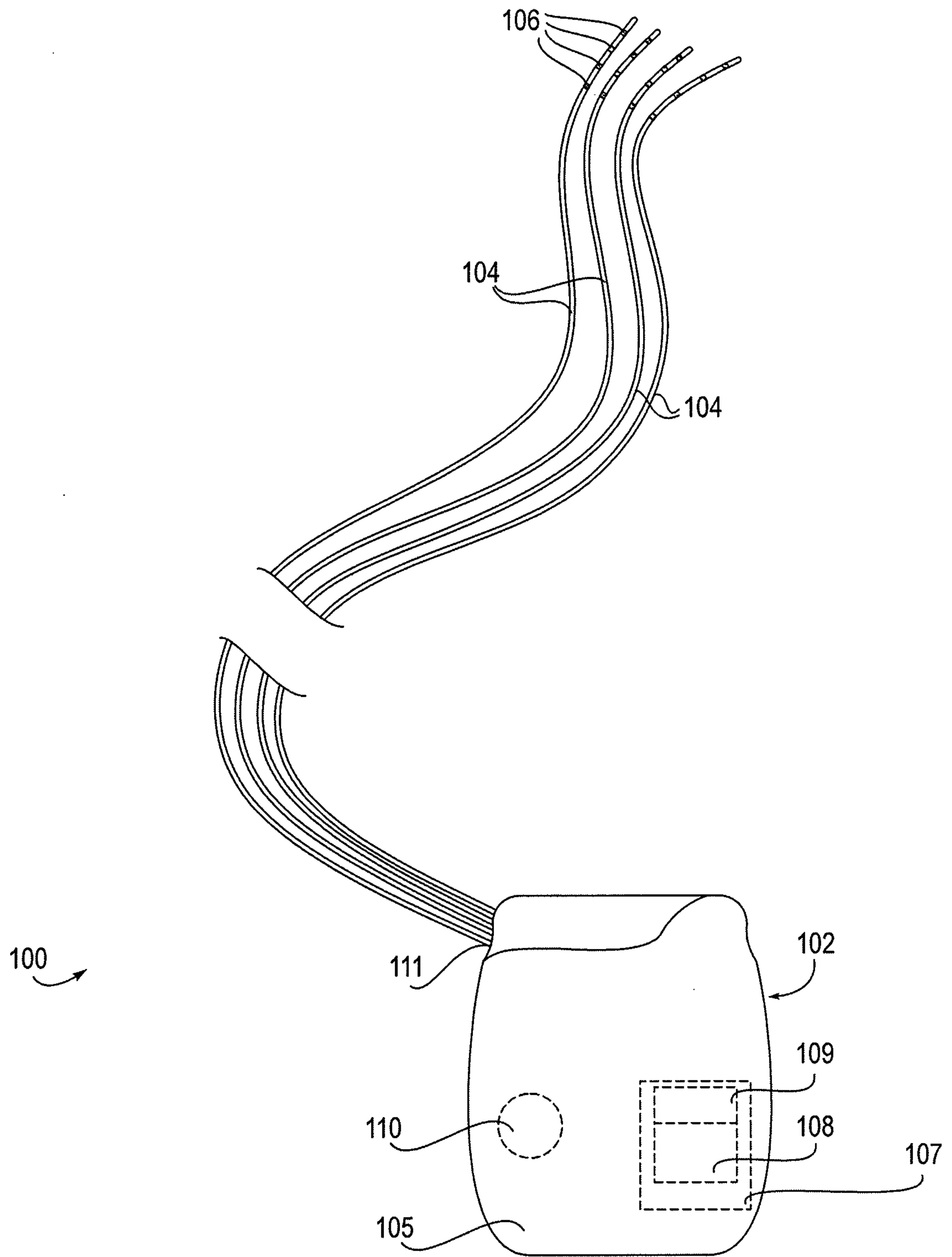


FIG. 1



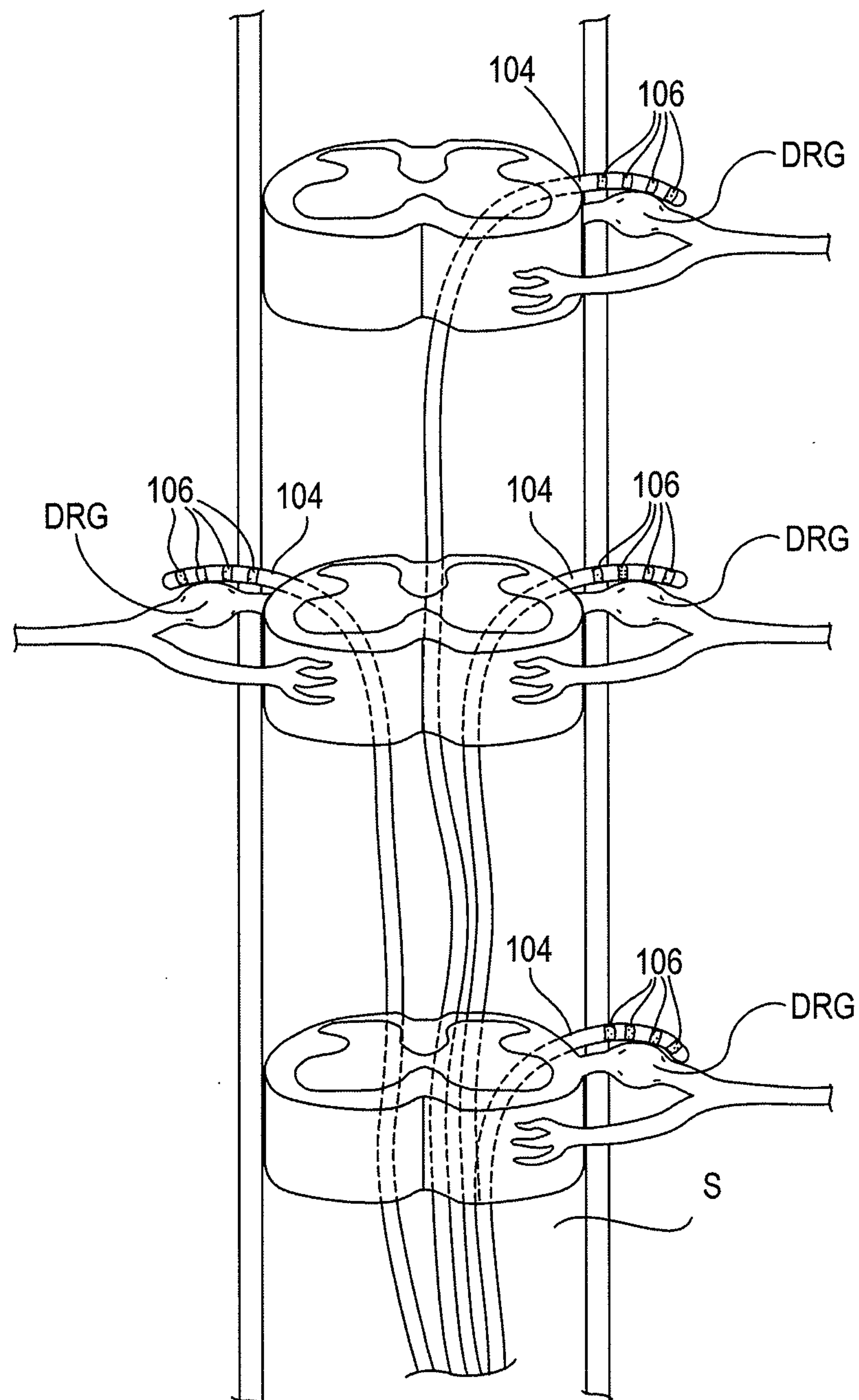


FIG. 2



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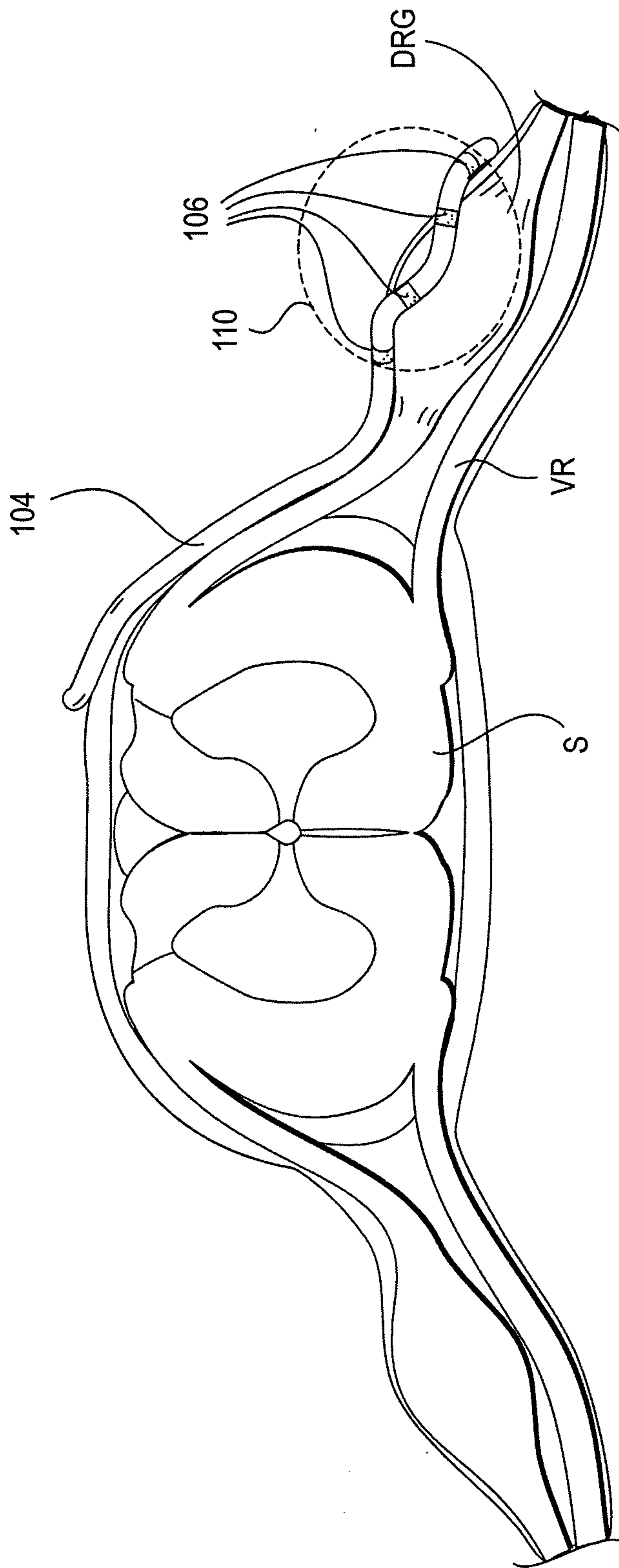


FIG. 3

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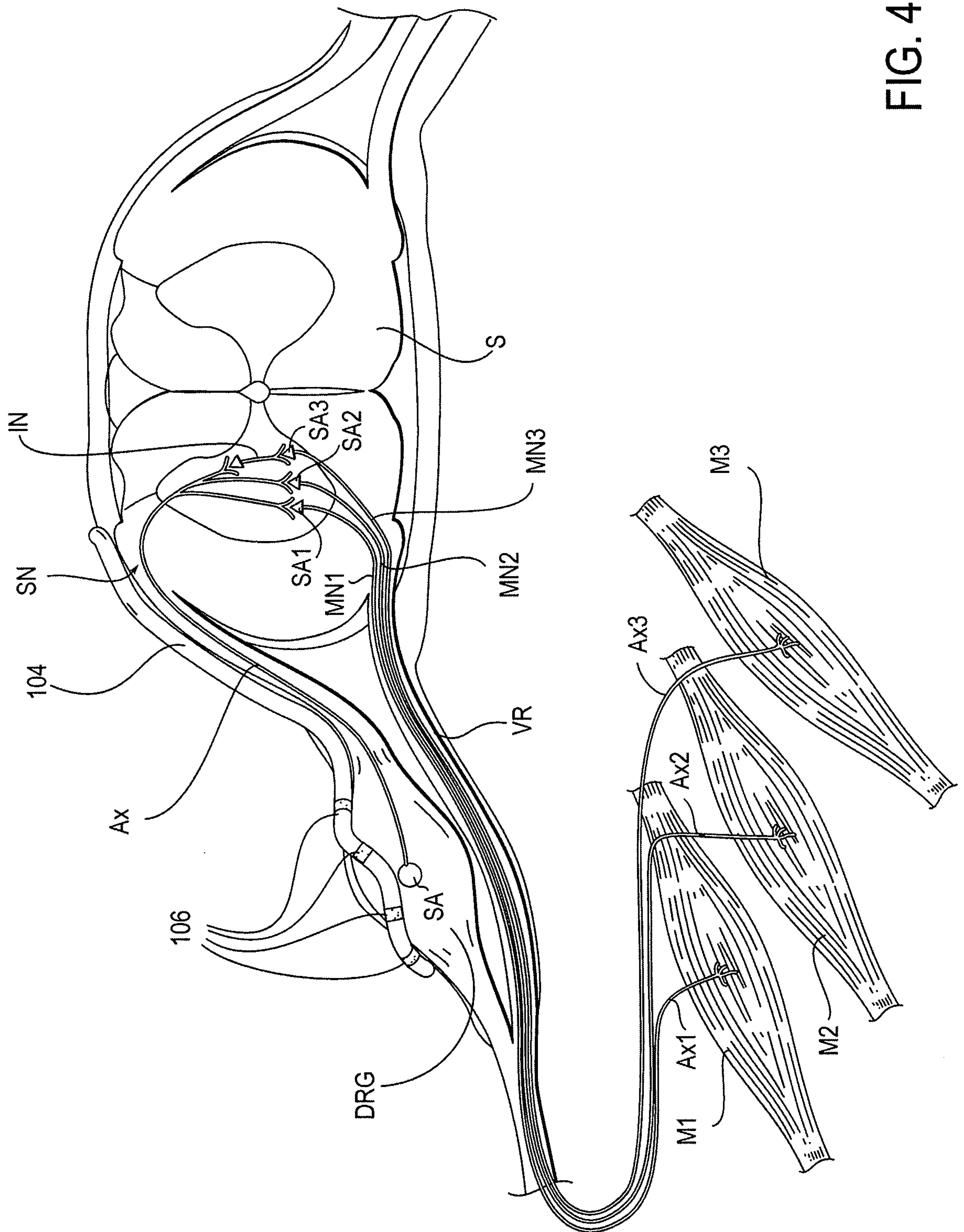


FIG. 4



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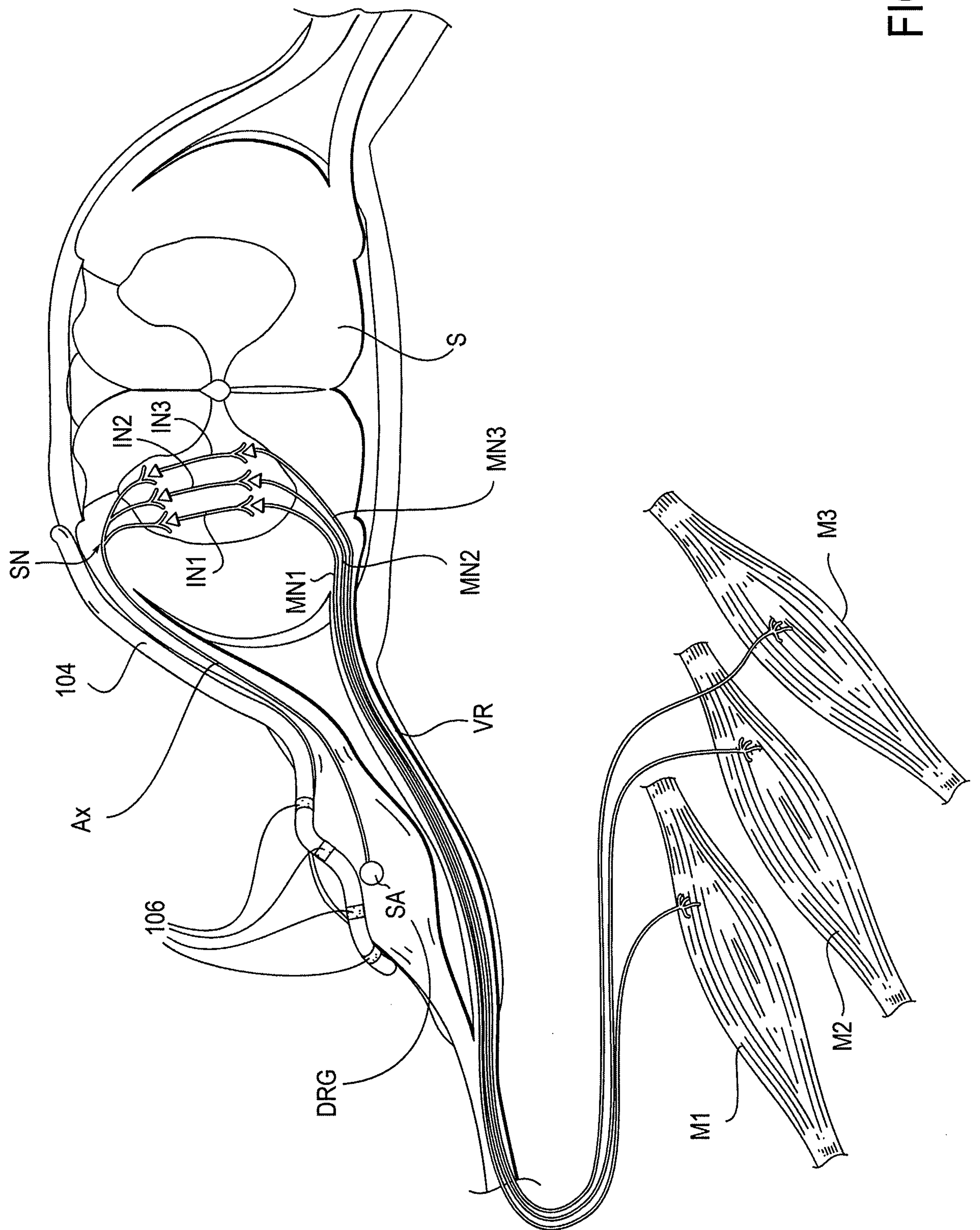


FIG. 5

