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(54) **Title**: NERVE INTERFACE ELECTRODE WITH FIBERS FOR INSERTION BETWEEN NERVE FASCICLES

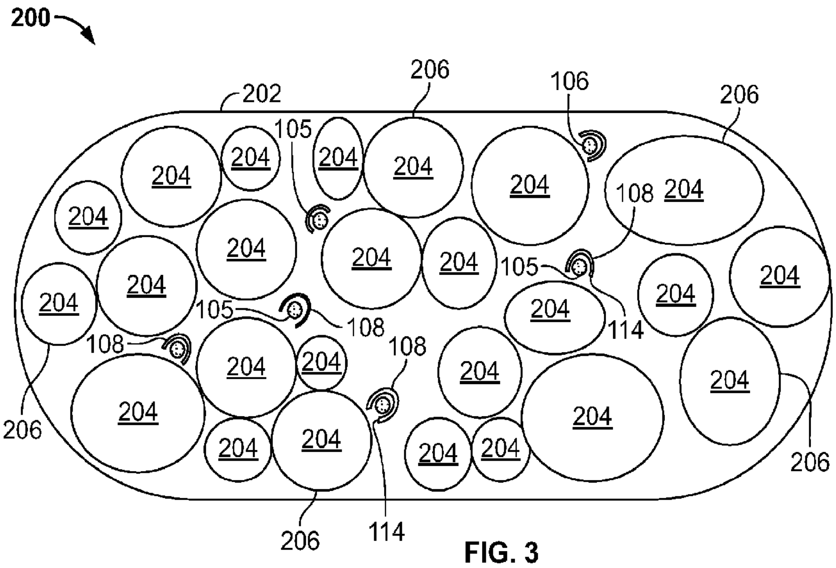

FIG. 3

(57) **Abstract**: A nerve interface electrode has a plurality of conductive fibers. The fibers have a nonconductive sheath (108) surrounding a conducting wire. A conducting region (105) of the wire is exposed to the interior of the nerve (200). The fibers are configured for insertion between fascicles (204) of the nerve. In other teachings, a layer of polymer material configured to switch from a high strength/tensile modulus state to a low strength/tensile modulus state upon introduction of the fibers into the nerve is disposed on the fibers.

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NERVE INTERFACE ELECTRODE WITH FIBERS FOR INSERTION BETWEEN NERVE FASCICLES

PRIORITY

[0001] This application claims priority to U.S. Provisional Application No. 61/478,664, filed on April 25, 2011, which is incorporated by reference as if fully set forth herein.

FIELD OF THE INVENTION

[0002] This disclosure is directed to nerve interfaces, such as peripheral nerve electrodes.

BACKGROUND

[0003] Nerve interfaces such as peripheral nerve electrodes allow recording and stimulation of nerve activity. For example, electrodes may be used to activate nerves connected to a particular muscle. One of the most important aspects of nerve interfaces is their ability to selectively activate or record nerve signals. For example, selective activation of single or small groups of fascicles can assist in "pure" activation of certain muscle groups, such as knee extensor muscles, with minimal activation of other non-synergistic muscle groups, for example hip flexors. In some instances, selective activation or recording of smaller groups or individual fascicles is desirable.

SUMMARY

[0004] In one embodiment, a nerve interface electrode comprising a plurality of conductive fibers is disclosed. The fibers comprise a nonconductive sheath surrounding a conducting wire. A conducting region of the wire is exposed to the interior of the nerve. The fibers are configured for insertion between fascicles of the nerve. In other embodiments, a layer of polymer material configured to switch from a high strength/tensile modulus state to a low strength/tensile modulus state upon introduction of the fibers into the nerve is disposed on the fibers. This configuration allows the fibers to be rigid prior to insertion but become flexible after insertion into the nerve.

[0005] In another embodiment of the present disclosure, a method of implanting a nerve interface electrode is disclosed. An electrode having multiple conductive fibers configured to flexibly disperse in a nerve in the region between the fascicles is selected. The fibers are inserted through the epineurium and into the nerve. The fibers then electrically stimulate the fascicles or record electrical activity within the nerve.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] It will be appreciated that the illustrated boundaries of elements in the drawings represent only one example of the boundaries. One of ordinary skill in the art will appreciate that a single element may be designed as multiple elements or that multiple elements may be designed as a single element. An element shown as an internal feature may be implemented as an external feature and vice versa.

[0007] Further, in the accompanying drawings and description that follow, like parts are indicated throughout the drawings and description with the same reference numerals. The figures may not be drawn to scale and the proportions of certain parts have been exaggerated for convenience of illustration.

[0008] **Figure 1** illustrates an exemplary nerve interface 100.

[0009] **Figure 2** illustrates a nerve interface **100** inserted through the epineurium **202** of nerve **200**.

[0010] **Figure 3** illustrates a cross-sectional view along the nerve **200** after insertion of fibers **104**.

[0011] **Figure 4** illustrates a cross-sectional side view along the nerve **200** after insertion of fibers **104**.

[0012] **Figure 5** illustrates exemplary method of implanting nerve interface 100.

[0013] **Figure 6** illustrates a nerve interface 100 inserted through the epineurium **202** of nerve **200** with the aid of guide **600**.

[0014] **Figure 7** illustrates a graph of a computer simulation for a single contact placed within the nerve at various distances from the target fascicle.

[0015] **Figure 8** illustrates cross sections of a simulated nerve under various contact placements and various activation levels.

[0016] **Figure 9** illustrates a graph of subfascicular selectivity at certain percent levels of selectivity amplitude.

[0017] **Figure 10** illustrates locations of activations for contacts **1000**, **1002**.

[0018] **Figures 11-13** illustrate a graph of the results of stimulations having multiple contact points in single sciatic nerve of a rabbit.

DETAILED DESCRIPTION

[0019] Certain terminology will be used in the following description for convenience in describing the figures will not be limiting. The terms "upward," "downward," and other directional terms used herein will be understood to have their normal meanings and will refer to those directions as the drawing figures are normally viewed.

[0020] **Figure 1** illustrates a nerve interface 100 according to the present disclosure. The illustrated interface **100** has a housing **102** from which fibers **104** extend. In the illustrated embodiment, the fibers **104** have a nonconductive sheath **108** that covers a core of conductive wire **106** that is coupled to the control unit **112**. Nonconductive sheath **108** covers a substantial portion of the surface of the wire **106**, exposing only a portion of wire **106**, corresponding to the conducting region **105**, through sheath opening **114**. The opening **114** may take a variety of shapes and sizes, but preferably exposes a conducting region **105** that faces a subset of the interior of the nerve **200**, making the fiber **104** able, for example, to emit current in the direction the conducting region **105** faces while minimizing current emitted in other directions. As illustrated in **Figure 1**, the sheath opening **114** exposes only a small portion of wire **106**, allowing the fibers **104** to be directionally sensitive to received electrical signals and directionally selective in transmitting electrical signals. Throughout this disclosure, reference may be made to fibers **104** as stimulating nerves, while in other instances, fibers **104** may be described as recording nerve signals. It should be noted that, while the preferred embodiment stimulates and records electrically, the nerve interface need not be so limited according to the present disclosure. The fibers may be configured to detect, for example, different forms of energy transfer reflecting neuronal activity and communication, such as detection of the concentration particular chemicals. It should also be noted that the placement of the nerve interface 100 described in the present disclosure with regard to nerve stimulation will also be applicable in recording nerve signals.

[0021] Interface **100** is connected to control unit **112** by lead **110**. Fibers **104** are each connected to the control unit **112**, which may include monitoring circuitry, electrical signal generating circuitry, and a user interface. Several alternative implementations of control unit **112** and leads **110** are well known in the art and will not be discussed further herein. Fibers **104** have a longitudinal length much larger than the thickness of the generally cylindrical fibers **104** illustrated in the present disclosure. It should be noted that the fibers **104** illustrated in the current disclosure are not drawn to scale, and will preferably have a much thinner size relative to, for example, the nerve **200** shown in **Figure 2**. Fibers **104** may have different cross-sectional shapes, such as elliptical, polygonal, or a combination of multiple shapes. In such cases, the length of fibers **104** will be much larger than a characteristic thickness of fibers **104** having such cross-sectional shapes.

[0022] As shown in **Figure 2**, the fibers **104** are inserted into the nerve **200** through the epineurium membrane **202**. As will be discussed further below in connection with **Figure 3**, insertion of the fibers **104** through the epineurium **202** exposes the portion of the fibers **104** that has penetrated the epineurium **202**, which includes the conducting region **105** of the fibers **104**, to the interior of the nerve **200**. Fibers **104** may be used to pierce the epineurium **202**. In such cases, the fibers **104** may be configured with sharp tips in order to more easily pierce the epineurium **202**. The thinness of fibers **104** will aid in the insertion of the fibers **104** and minimize the disturbance to the nerve **200**. Alternatively, separate incisions through which the fibers **104** are inserted may be made prior to insertion of fibers **104**. Endoscopic and minimally invasive implantation are exemplary methods of implantation of fibers 104.

[0023] **Figure 3** illustrates a cross-section of a peripheral nerve **200** after insertion of fibers **104**. While a peripheral nerve **200** is used for purposes of illustration, the interface **100** according to the present invention will also be applicable to other types of nerve tissue, such as nerve tissue found in the central nervous system. The nerve **200** is surrounded by the epineurium membrane **202**, or simply "epineurium." The nerve **200** contains several fascicles **204**, which comprise bundles of axons. Each fascicle **204** is surrounded by a perineurium membrane **206**, or simply "perineurium." **Figure 3** also illustrates the placement of fibers **104** throughout the interior of the nerve **200**. Fibers **104** in the nerve **200** are flexible and so spread out, distributing themselves throughout the interior of the nerve **200** in the area between the fascicles **204**. The fibers **104** do not penetrate the perineurium membrane **206**, which minimizes trauma to the nerve **200**. The distribution of fibers **104** between the fascicles **204** allows for improved selectivity in the control and measurement of individual fascicles **204** and their electrical activity.

[0024] As shown in **Figure 3**, several conducting regions **105** of fibers **104** come into contact with perineurium membranes **206** of fascicles **204**, while other conducting regions **105** are disposed adjacent but not in contact with a fascicles **206**. In such an arrangement, fibers **104** can conduct electrical current in a directed manner, in the direction the conducting regions **105** face. This allows for relatively increased current density in the direction the conducting region **105** faces. This arrangement also allows for fibers **104** to be directionally sensitive when recording electrical activity. Fibers **104** will be most sensitive to electrical activity received from the direction the conducting region **105** faces. Further, in the illustrated configuration, fibers **104** may be placed nearby fascicles **204** located centrally within the nerve **200**. Activation of an individual fiber **104** may stimulate a single fascicle **204** or multiple fascicles **204**. This may in turn result in recruitment of additional fascicles **204** depending on the distribution of fascicles **204** in the nerve. Likewise, multiple fibers **104** may be activated, which may result in stimulation of multiple fascicles **204**.

[0025] In addition to directed stimulation of individual fascicles **204**, the fibers **204** may generate a desired electrical field ("field shaping") within the nerve **200** by selectively applying the appropriate level of electrical current to each of the fibers **104**, the fibers **104** may create an electrical field that may selectively activate one or more fascicles **204**, including fascicles **204** that are not adjacent to or in direct contact with a fiber **104**.

[0026] In order to disperse among the spaces between the fascicles **204**, the fibers **104** are preferably flexible. Flexibility allows the fibers **104** to disperse within the nerve **200**, which allows for broader distribution of fibers **104,** and therefore more selective control or recording of fascicles **204**. However, flexibility can make insertion of the fibers **104** through the epineurium **202** more difficult. In one embodiment, the fiber **104** is coated with a layer of polymer nanocomposite material that switches from a high tensile modulus and strength to a low modulus and strength in response to introduction to the interior of the nerve **200**. This layer may be part of the nonconductive sheath **108** or may be a separate layer. In the high tensile modulus/strength state, the polymer nanocomposite renders the fibers **104** rigid enough to puncture the epineurium **202**. Such materials and the manner in which they may be manufactured are disclosed in U.S. Published Patent Application Nos. 2009/0318590 and 2008/0242765, incorporated herein by reference. For example, nanocomposite such as ethylene oxide-epichlorohydrin ("EO-EPI") combined with a cellulose matrix can exhibit high tensile strength in the absence of solvent. When an appropriate solvent, preferably a hydrogen-bond forming solvent, is introduced to the nanocomposite, the interactions giving the nanocomposite its strength are "switched off" by the competitive binding of the solvent. Other host polymers or coploymers may include, but are not limited to, various alkylene oxide polymers and copolymers such as ethylene oxide, propylene oxide, copolymers of ethylene oxide and epichlorohydrin and/or other monomers; a vinyl aromatic (co)polymer such as polystyrene and styrene copolymers; polyolefin polymers or copolymers such as polyethylene and polypropylene; diene polymers and copolymers, such as cis-polybutadiene; polyacrylates and acrylate copolymers, such as methyl methacrylate; polyamides; and polyester polymers or copolymers such as poly(vinyl acetate) or polycaprolactone.

[0027] **Figure 4** illustrates a cross-sectional side view of a single fiber **104** inserted through the epineurium **202** and disposed adjacent a fascicle **204**. In the illustrated embodiment, the fiber **104** is inserted through the epineurium **202** at an acute angle relative to the direction of the nerve **200**. This configuration allows the fibers **104** to orient themselves parallel with the fascicles **204**. As shown in **Figure 4**, the conducting region **105** is disposed adjacent the perineurium membrane **206** of fascicle **204**.

[0028] As shown in **Figure 5**, in one method of stimulation and/or recording of peripheral nerve electrical activity, an interface **100** having multiple conductive fibers **104** configured to flexibly disperse in the nerve **200** in the region between the fascicles **204** is selected in step **500**. In another embodiment, an interface **100** having additional qualities such as fibers **104** each having a sheath **108** configured to switch from a high tensile modulus and strength to a relatively low tensile modulus and strength upon insertion into the nerve **200**, thereby permitting the fibers **104** to flexibly disperse in the region in the nerve **200** between the fascicles **204**, is selected. In yet another alternative embodiment, an interface 100 configured for insertion into a peripheral nerve is selected. In the illustrated embodiment, the electrode is then inserted through the epineurium **202** and into the nerve in step **510**. Step **510** may be accomplished by a variety of approaches, such as an open surgical procedure, or alternatively a minimally invasive approach. In step **520**, upon dispersal of the fibers **104** in the nerve **200** and between the fascicles **204**, the fibers **104** record and/or stimulate nerve **200** activity.

[0029] **Figure 6** illustrates an alternative embodiment of nerve interface 100 having a guide **600** that assists in insertion of fibers **104**. The guide provides additional rigidity to the fibers **104** as they are inserted, for example when using the fibers **104** to penetrate the epineurium **202**. The guide **600** reduces the length of fibers **104** that must kept rigid for insertion into nerve **200**. The guide **600** may be placed adjacent the epineurium membrane **202** prior to insertion of fibers **104**.

[0030] **Figures 7** and **8** show the results of a computer simulation demonstrating the selectivity of a single contact placed within the nerve and at various distances from the target fascicle. The plot shown in **Figure 7**, illustrates the selectivity for contacts directly next to the fascicle shown as line **702**, 10 um from the target fascicle shown as line **704**, 50 um from the target fascicle shown as line **706**, and 100 um from the target fascicle shown as line **708** as compared to a contact on the surface of the nerve shown as line **710**. A selectivity value of 100 reflects perfect selectivity for the target fascicle and can be achieved if the contact is in direct contact with the fascicle. The selectivity drops, but is still desirable as the distance between the fascicle and contact is increased. **Figure 8** illustrates the areas of activation at the point indicated by the grayscale **800** for two contact-fascicle separations. The two columns correspond to contact placement adjacent to the target fascicle and 100 um from the target fascicle, which in all of the simulations in **Figure 8** is the upper right fascicle **802**. The three rows correspond to higher 20%, 60% and 100% of target activation.

[0031] **Figure 9** and **10** illustrate results of a simulation for sub-fascicular selectivity. **Figure 9** shows a graph of subfascicular selectivity at certain percent levels of selectivity amplitude. The line **900** represents interfascicular placement while line **902** represents intrafascicular placement. . **Figures 9** and **10** show that each of the contacts **1000**, **1002** outside the nerve **1001** excite about 80% of the fibers in the closest half of the fascicle without activation of any fibers on the other side. **Figure 10** illustrates the locations of activations, with activated fibers shown with an x, while non-activated fibers are shown with an oval shape. For example, fibers **1004** activated by contact **1000** are on the right side of the nerve **1001**, while fibers **1006** activated by contact **1002** are isolated on the left side of the nerve

1001. The simulations also show that two electrodes outside of the fascicle are as selective as two contacts placed directly within the fascicle.

[0032] **Figures 11** through **13** illustrate the results of a stimulation of multiple contact points in single sciatic nerve of a rabbit. The effected muscles are the Tibialis Anterior muscle, abbreviated "TA," the Lateral Gastrocnemius muscle, abbreviated "LG," the Medial Gastrocnemius muscle, abbreviated "MG" and the "Soleus" muscle. As shown in **Figures 11** through **13**, three completely different recruitments are possible. Thus, multiple point sources within the nerve may produce multiple different outputs.

[0033] For the purposes of this disclosure and unless otherwise specified, "a" or "an" means "one or more." To the extent that the term "includes" or "including" is used in the specification or the claims, it is intended to be inclusive in a manner similar to the term "comprising" as that term is interpreted when employed as a transitional word in a claim. Furthermore, to the extent that the term "or" is employed (e.g., A or B) it is intended to mean "A or B or both." When the applicants intend to indicate "only A or B but not both" then the term "only A or B but not both" will be employed. Thus, use of the term "or" herein is the inclusive, and not the exclusive use. See, Bryan A. Garner, A Dictionary of Modern Legal Usage 624 (2d. Ed. 1995). Also, to the extent that the terms "in" or "into" are used in the specification or the claims, it is intended to additionally mean "on" or "onto." Furthermore, to the extent the term "connect" is used in the specification or claims, it is intended to mean not only "directly connected to," but also "indirectly connected to" such as connected through another component or multiple components. As used herein, "about" will be understood by persons of ordinary skill in the art and will vary to some extent depending upon the context in which it is used. If there are uses of the term which are not clear to persons of ordinary skill in the art, given the context in which it is used, "about" will mean up to plus or minus 10% of the particular term. From about X to Y is intended to mean from about X to about Y, where X and Y are the specified values.

[0034] While the present disclosure illustrates various embodiments, and while these embodiments have been described in some detail, it is not the intention of the applicant to restrict or in any way limit the scope of the claimed invention to such detail. Additional advantages and modifications will readily appear to those skilled in the art. Therefore, the invention, in its broader aspects, is not limited to the specific details and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the applicant's claimed invention. Moreover, the foregoing embodiments are illustrative, and no single feature or element is essential to all possible combinations that may be claimed in this or a later application.

CLAIMS

1. A nerve interface electrode comprising:

A plurality of conductive fibers having a nonconductive sheath surrounding a conducting wire:

a conducting region configured to be exposed to an interior of a nerve, the plurality of fibers configured for insertion between fascicles of the nerve.

2. The nerve interface electrode of claim 1 wherein the conducting region is configured to be exposed to an interior of a peripheral nerve, the plurality of fibers configured for insertion between fascicles of the peripheral nerve.

3. The nerve interface electrode of claim 1 further comprising:

a layer of polymer material disposed the fibers and configured to switch from a high strength or tensile modulus state to a low strength or tensile modulus state upon introduction of the fibers into the peripheral nerve.

4. The nerve interface electrode of claim 3 wherein the layer of polymer material includes oxide-epichlorohydrin and a cellulose matrix.

5. The nerve interface electrode of claim 3 wherein the layer of polymer material includes an alkylene oxide polymer or copolymer.

6. The nerve interface electrode of claim 5 wherein the layer of polymer material includes at least one of ethylene oxide, propylene oxide, ethylene oxide copolymer and epichlorohydrin.

7. The nerve interface electrode of claim 3 wherein the layer of polymer material includes a vinyl aromatic polymer or copolymer.

8. The nerve interface electrode of claim 7 wherein the layer of polymer material includes at least one of polystyrene and styrene copolymer.

9. The nerve interface electrode of claim 3 wherein the layer of polymer material includes a polyolefin polymer or copolymer.

10. The nerve interface electrode of claim 3 wherein the layer of polymer material includes a diene polymer or copolymer.

11. The nerve interface electrode of claim 1 wherein the sheath defines a sheath opening, the conducting region disposed at the sheath opening.

12. A nerve interface electrode comprising:

A plurality of conductive fibers having a nonconductive sheath surrounding a conducting wire:

a conducting region configured to be exposed to an interior of a nerve, the plurality of fibers configured for insertion between fascicles of the nerve; and,

a layer of polymer material disposed the fibers and configured to switch from a high strength or tensile modulus state to a low strength or tensile modulus state upon introduction of the fibers into the nerve

13. A method of implanting a nerve interface electrode comprising:

selecting an electrode having multiple conductive fibers configured to flexibly disperse in a nerve in the region between fascicles of the nerve;

inserting the fibers through the epineurium and into the nerve; and,

electrically stimulating or recording one or more fascicles.

14. The method of claim 13, wherein the selecting step comprises selecting an electrode having fibers having an outer layer configured to switch from a high tensile modulus and strength to a low tensile modulus and strength upon insertion into the nerve.

15. The method of claim 13, wherein the selecting step further comprises:

selecting an electrode configured to flexibly disperse in a peripheral nerve.

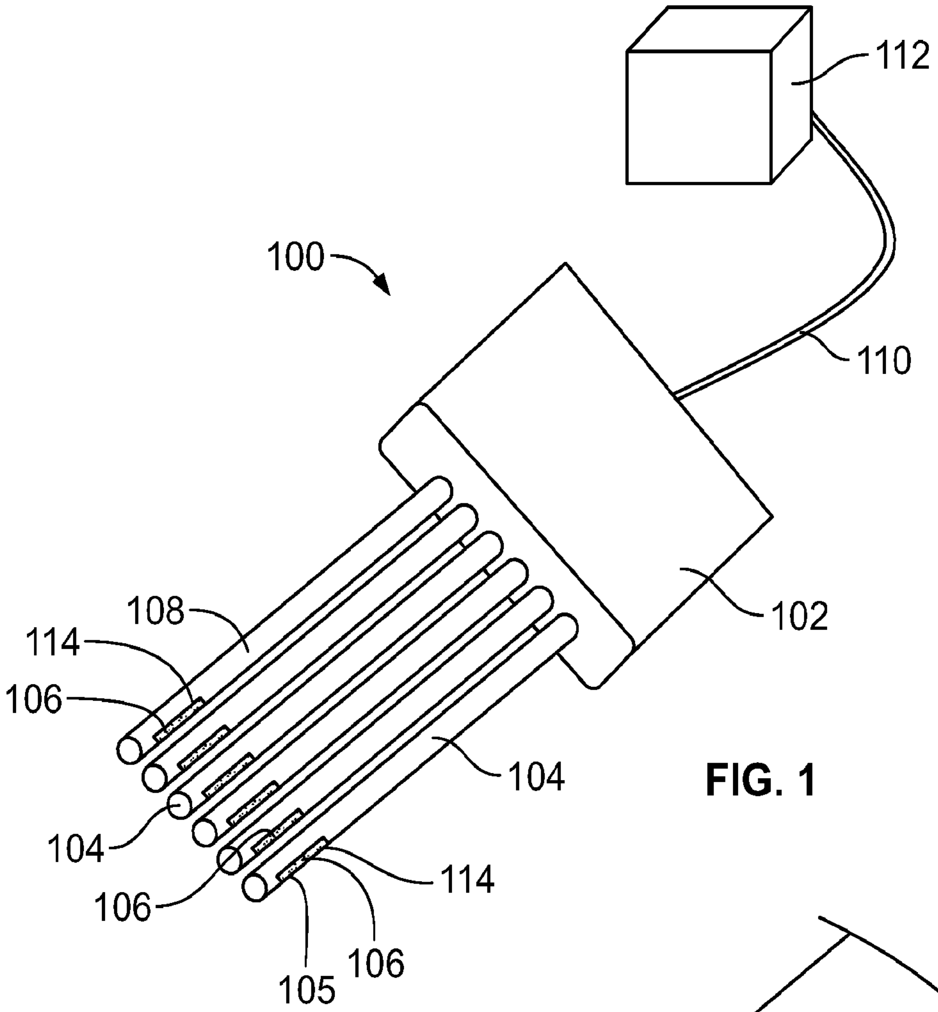

112
100
110
108
102
114
106
104
104
106
114
105
106

FIG. 1

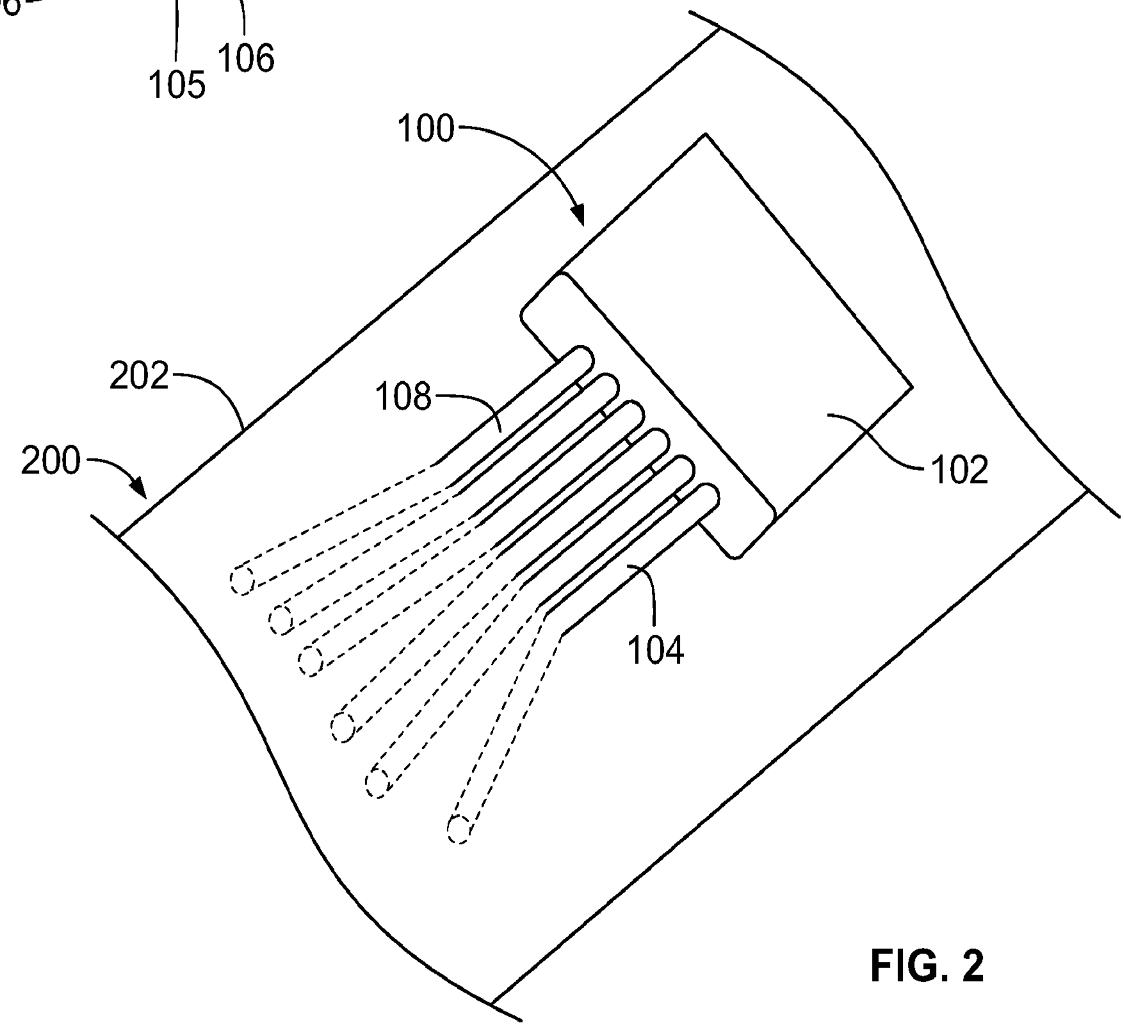

100
202
108
200
102
104

FIG. 2

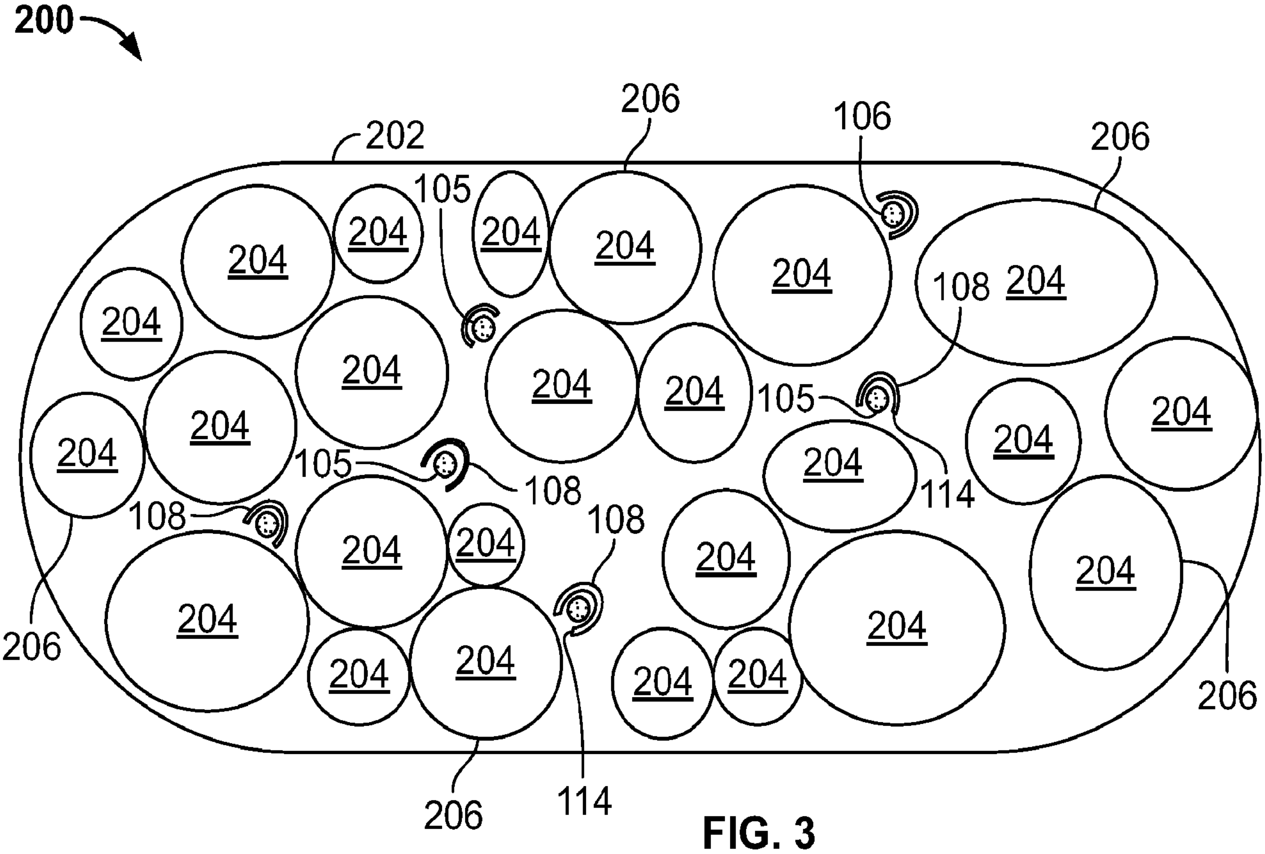

200
202
206
106
206
105
204
108
105
114
108
105
108
206
206
206
114

FIG. 3

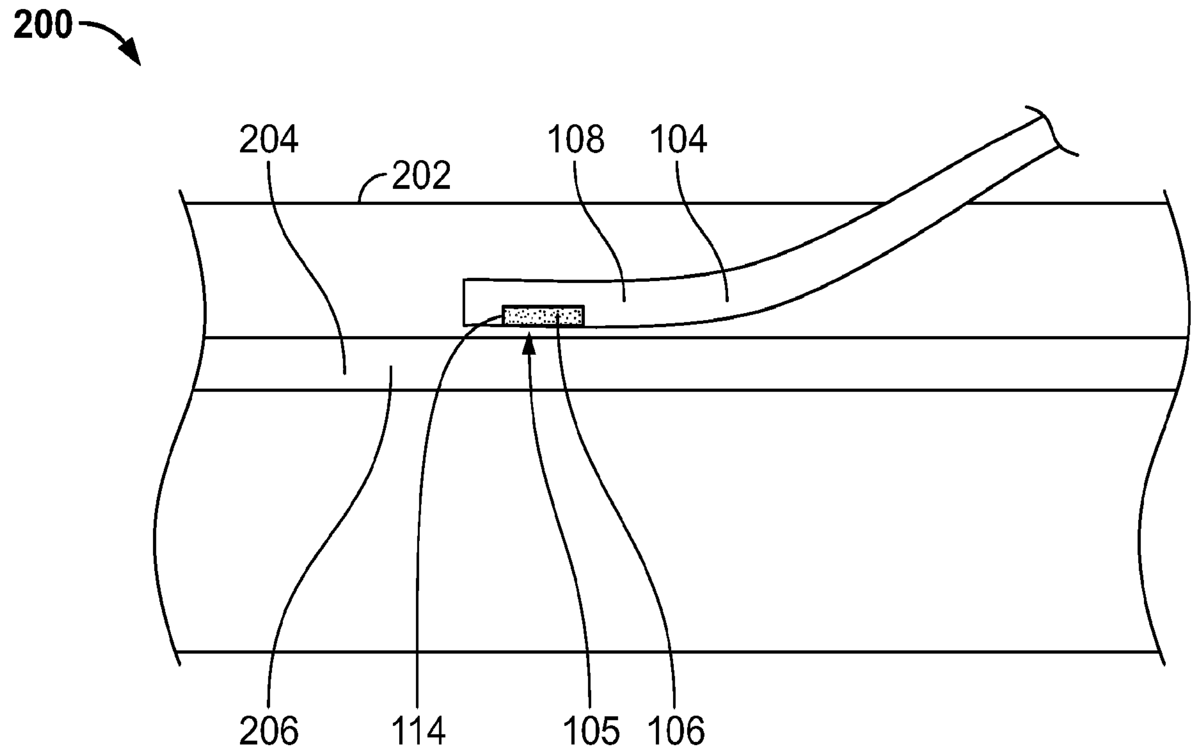

200
204
108
104
202
206
114
105
106

FIG. 4

500

Select a Nerve Electrode Having Multiple Conductive Fibers Configured to Flexibly Disperse Throughout the Interior of a Nerve and Between the Fascicles of the Nerve

↓

510

Insert the Electrode Fibers Through the Epineurium and into the Nerve

↓

520

Upon Dispersal of the Fibers in the Nerve and Between the Fascicles, Stimulating and/or Recording Nerve Activity

FIG. 5

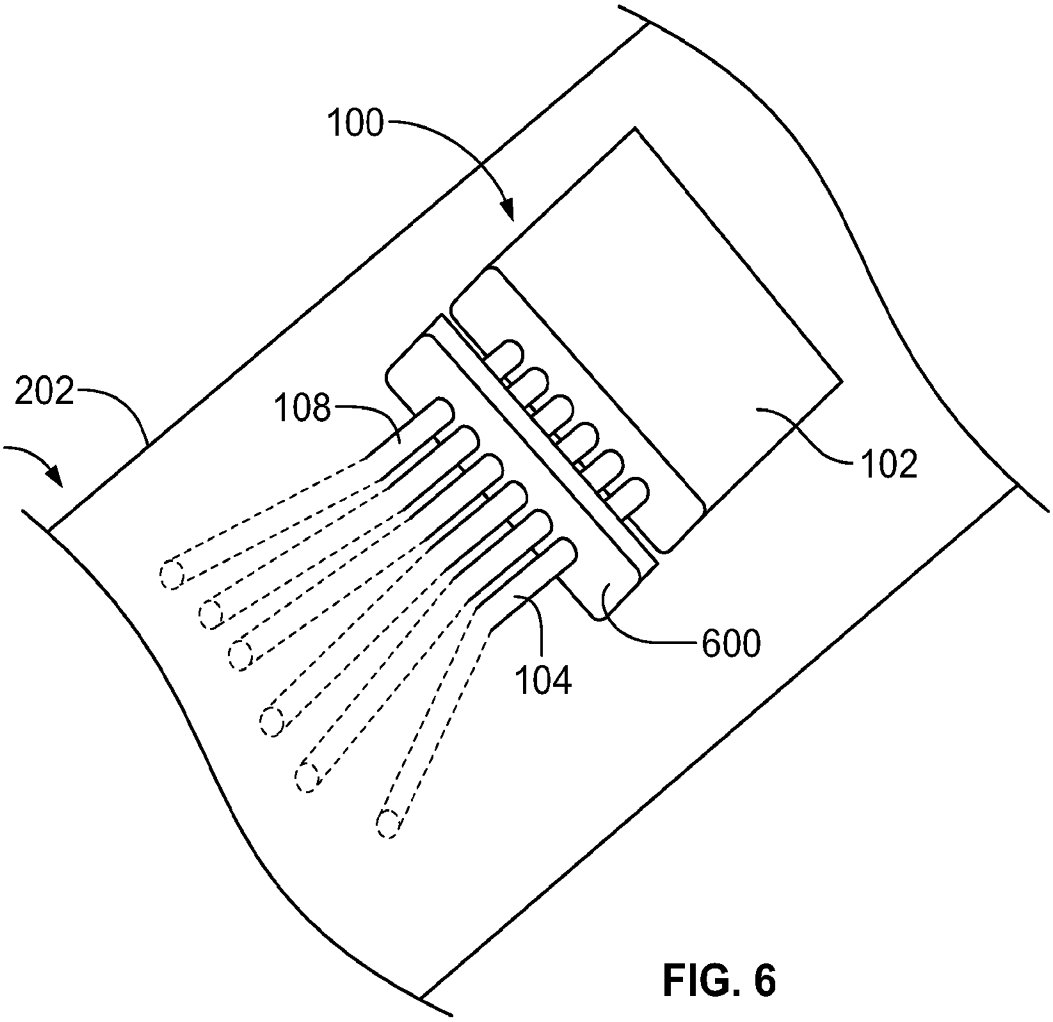


FIG. 6

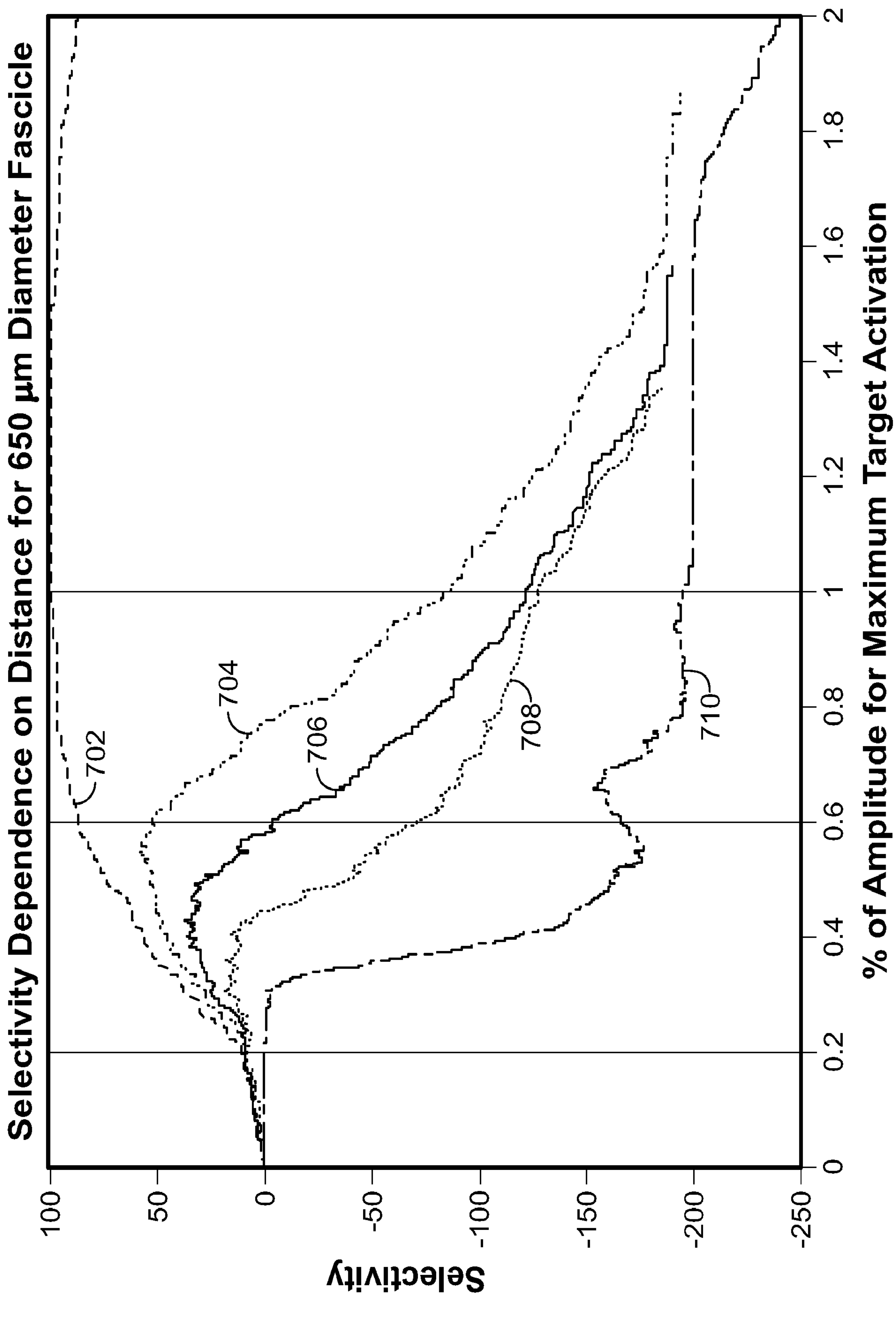

Selectivity Dependence on Distance for 650 µm Diameter Fascicle
Selectivity
% of Amplitude for Maximum Target Activation
100
50
0
-50
-100
-150
-200
-250
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
702
704
706
708
710

FIG. 7

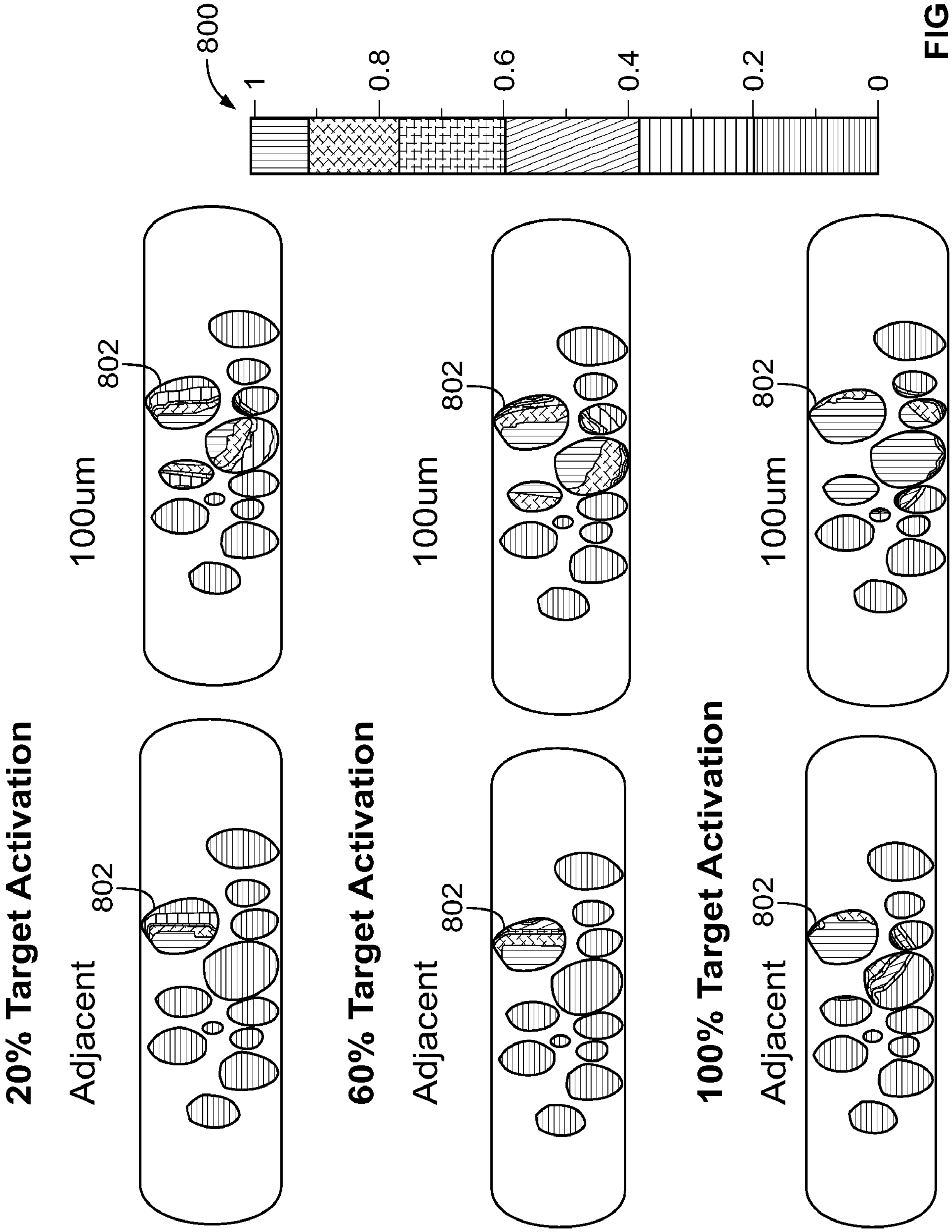

800
1
0.8
0.6
0.4
0.2
0
20% Target Activation
Adjacent
802
100um
802
60% Target Activation
Adjacent
802
100um
802
100% Target Activation
Adjacent
802
100um
802

FIG. 8

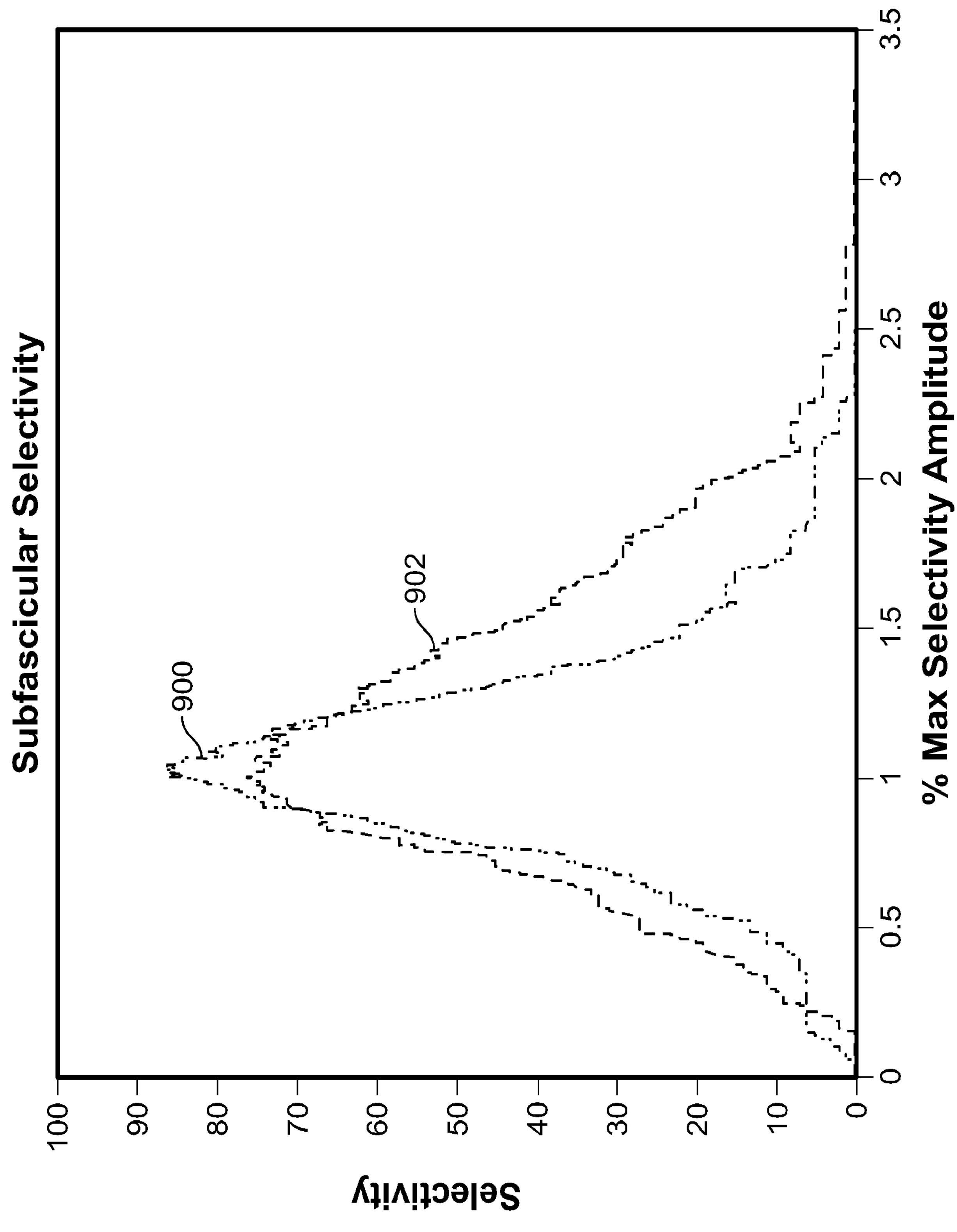
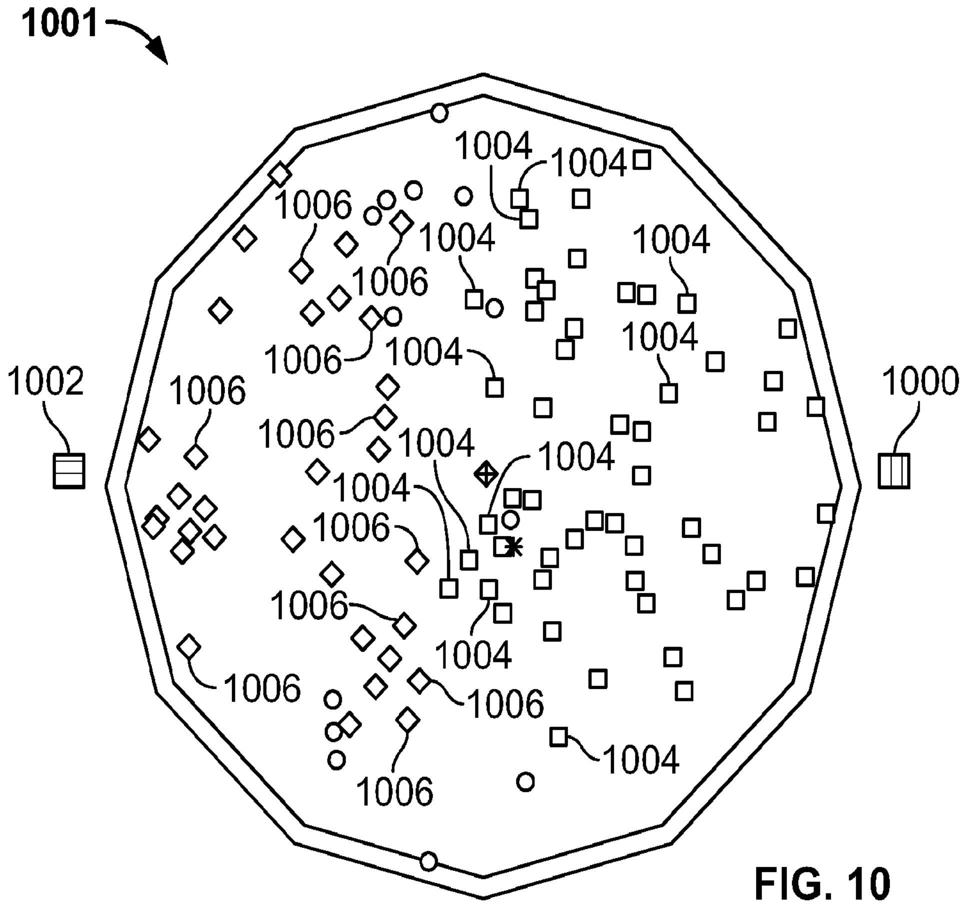

Subfascicular Selectivity
Selectivity
100
90
80
70
60
50
40
30
20
10
0
0
0.5
1
1.5
2
2.5
3
3.5
900
902
% Max Selectivity Amplitude

FIG. 9


1001
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1006

FIG. 10

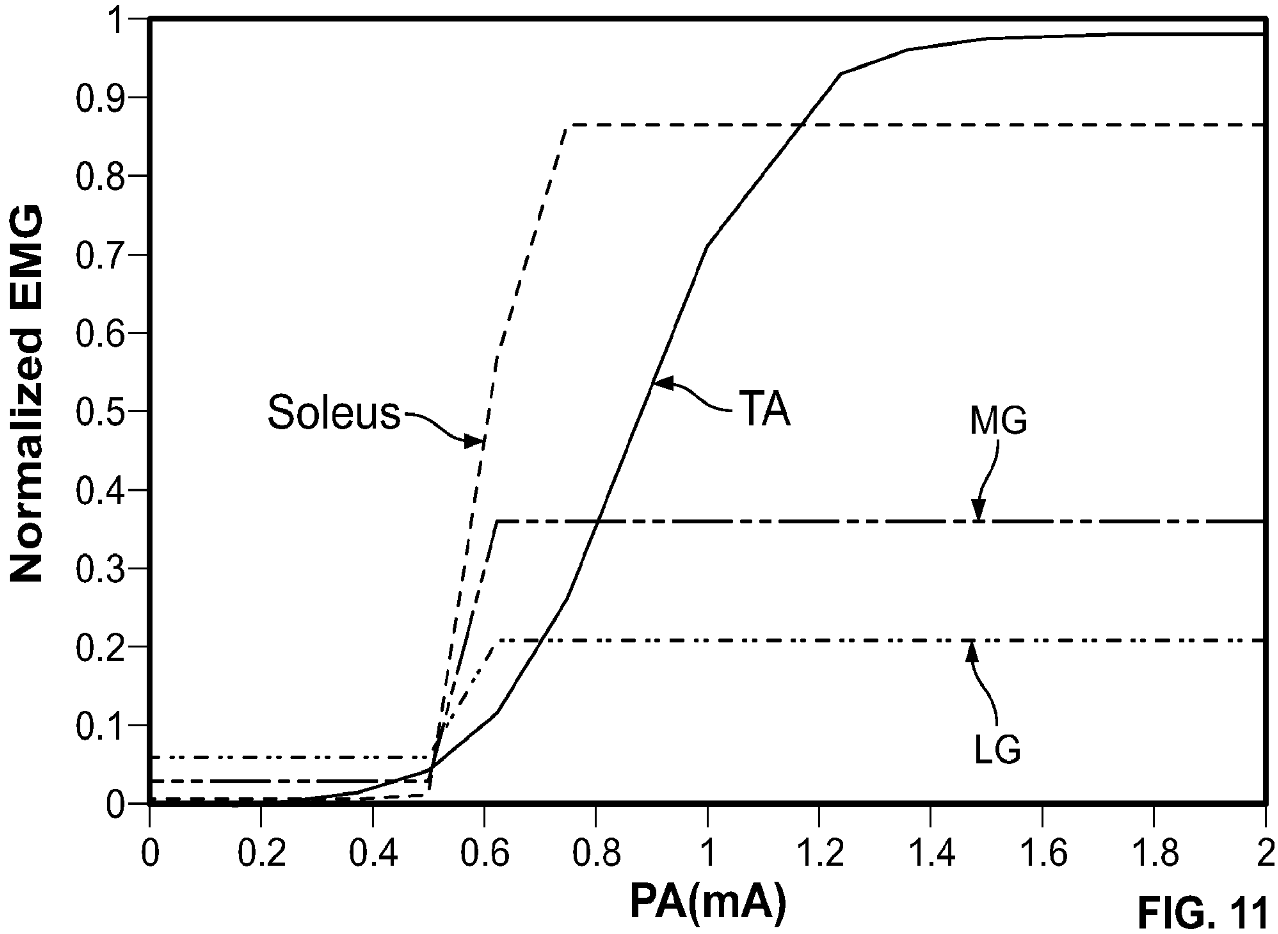
Normalized EMG
PA(mA)
Soleus
TA
MG
LG
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2

FIG. 11

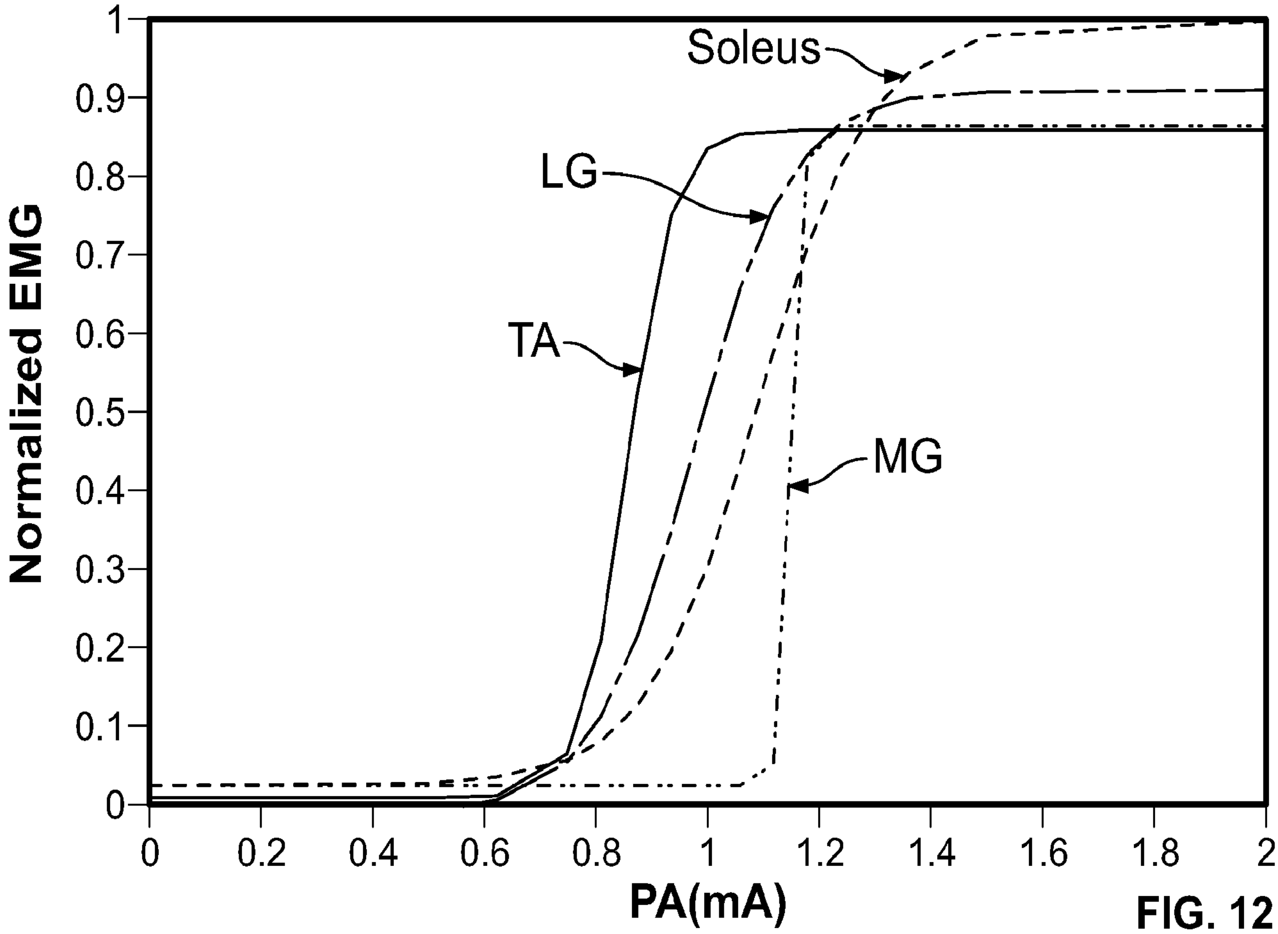
Normalized EMG
PA(mA)
Soleus
LG
TA
MG
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2

FIG. 12

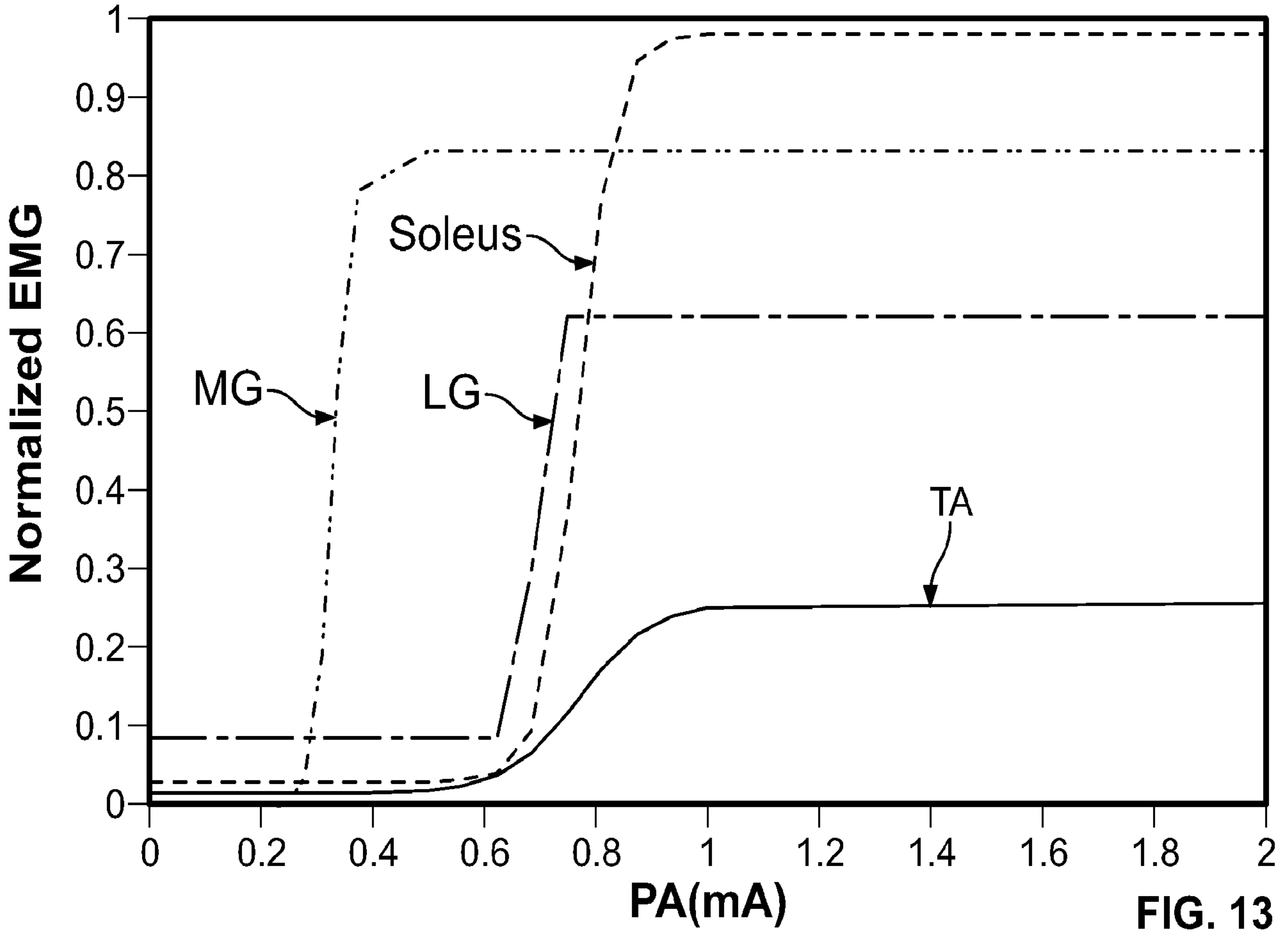
Normalized EMG
PA(mA)
Soleus
MG
LG
TA
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/035027

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/04 A61N1/05 B81B3/00 B82B3/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N A61B B81B B82B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/176905 A1 (NICOLELIS MIGUEL A L [US] ET AL) 18 September 2003 (2003-09-18) paragraph [0061] - paragraph [0069] paragraph [0096] - paragraph [0098] paragraph [0106] - paragraph [0107]; figures 1A, 1B -----	1,2,11
X	WO 2008/091197 A1 (NEURONANO AB [SE]; SCHOUENBORG JENS [SE]) 31 July 2008 (2008-07-31) page 3, line 5 - line 14 page 4, line 8 - page 5, line 7 page 8, line 14 - page 9, line 19; figure 1 -----	1,2,11
	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 July 2012	31/07/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Sigurd, Karin

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/318590 A1 (WEDER CHRISTOPH [US] ET AL) 24 December 2009 (2009-12-24) paragraph [0002] - paragraph [0007] paragraph [0030] - paragraph [0038] paragraph [0042]	1-12
A	US 2008/228240 A1 (EDELL DAVID J [US] ET AL) 18 September 2008 (2008-09-18) paragraph [0017] - paragraph [0020] paragraph [0026] - paragraph [0034]; figures 2, 4	1-12

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/035027

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
US 2003176905	A1	18-09-2003	AU	2003214176	A1	29-09-2003
			US	2003176905	A1	18-09-2003
			US	2006206161	A1	14-09-2006
			WO	03077988	A1	25-09-2003
WO 2008091197	A1	31-07-2008	AT	507773	T	15-05-2011
			AU	2008208093	A1	31-07-2008
			CA	2676021	A1	31-07-2008
			DK	2117426	T3	22-08-2011
			EA	200901026	A1	26-02-2010
			EP	2117426	A1	18-11-2009
			JP	2010516327	A	20-05-2010
			WO	2008091197	A1	31-07-2008
US 2009318590	A1	24-12-2009	NONE			
US 2008228240	A1	18-09-2008	US	2008228240	A1	18-09-2008
			WO	2006009722	A2	26-01-2006

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/035027

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-15
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 13-15

Claims 13-15 relate to methods for implanting an electrode and, as one alternative, also for electrically stimulating one or more fascicles of a nerve. As these are methods for treatment of the human or animal body by surgery or by surgery and therapy, the International Searching Authority is not required to search the subject-matter of claims 13-15 according to Rule 39.1(iv) PCT.