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(54) IMPLANTABLE HEAD MOUNTED NEUROS HMULATION SASTEM FOR HEAD PAIN

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(51) Int. CL A64N L/36 (2006.01) A64N L/85 (2008.01)

See application tile, or complete search history

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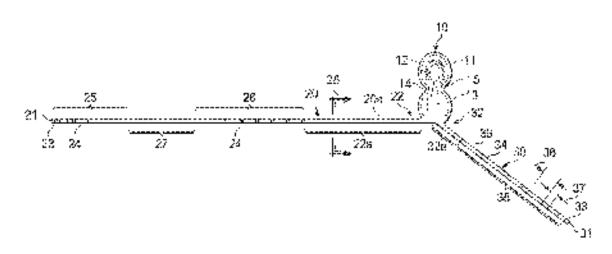
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(57) ABSTRACT

An amplituble head industed infloory peripheral neurostimulation system is provided for implantation in the bend for the purpose of treating chronic head pain, metading migraine. The system may include an implemable rules genexter (IPO) from which multiple stimulating leads may extend sufficient to allow for adequate stimulation over maltiple regions of the head, preferably including the frental. paraetal and eccipital regions. A anadmicy include an extended hody, along which may be disposed a plurality of earliest motal electrodes, which may be sub-divided into a phyrality of electricle arrays. A plumity of interrul metal wires may runuportform of its long hand compositive IPG's internal circuit to the surface metal electrones. The LPG may include a rechargeinhle hattery, im an entra and imagentical fen specific integral of circuit. The IPG may be expable of functional connection. with an external cathofrequency unit for purposes that may include exchanging, diagnos to evaluation, and mogramming

23 Claims, 6 Drawing Shoers



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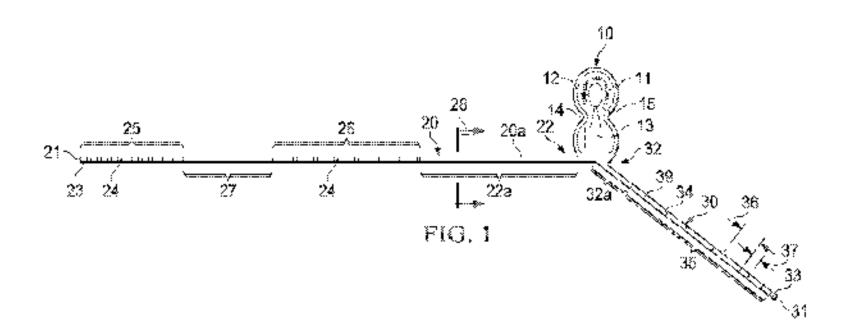
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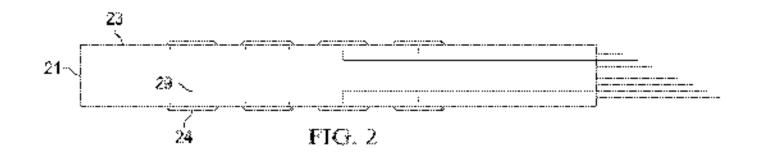
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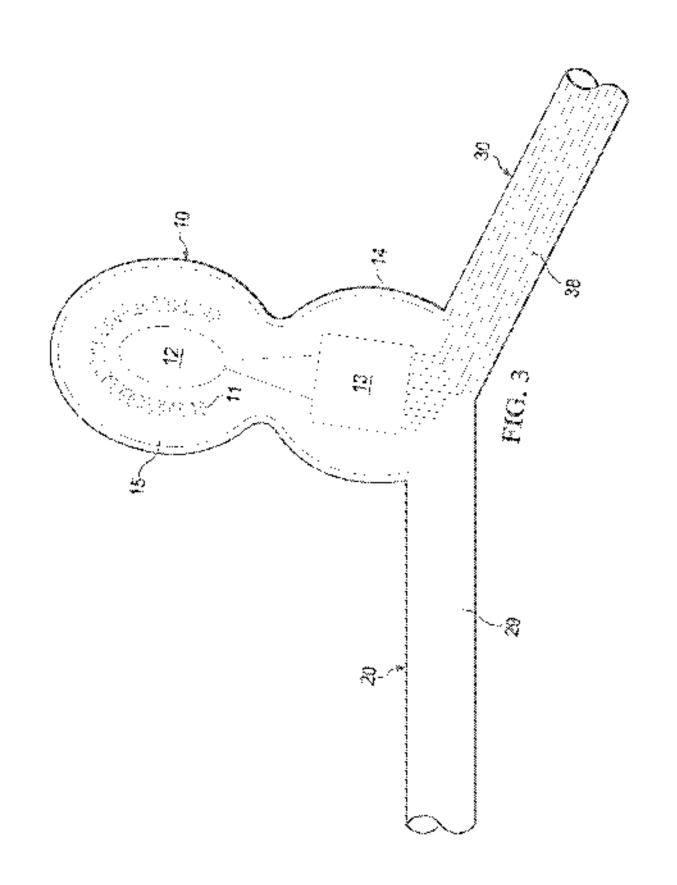
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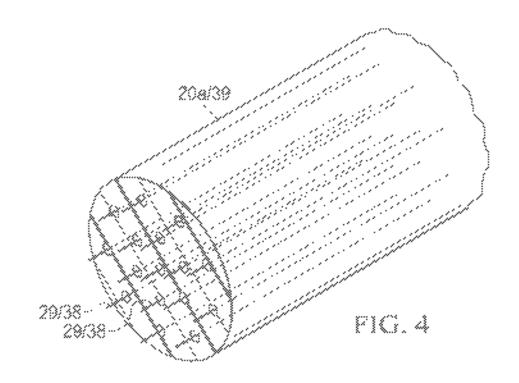
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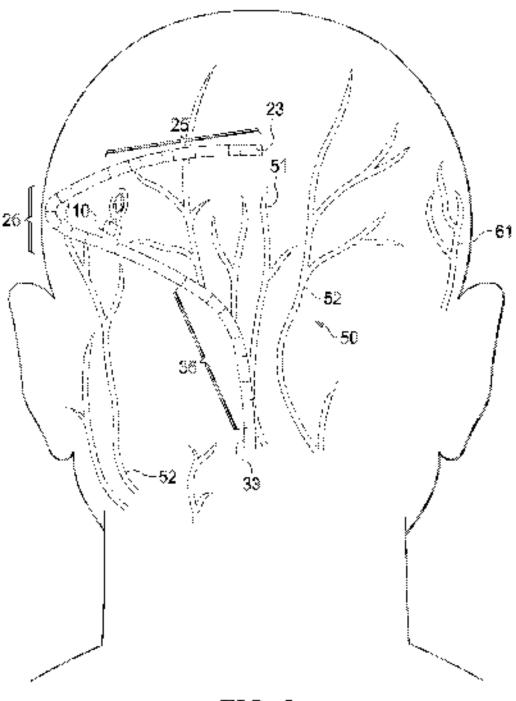
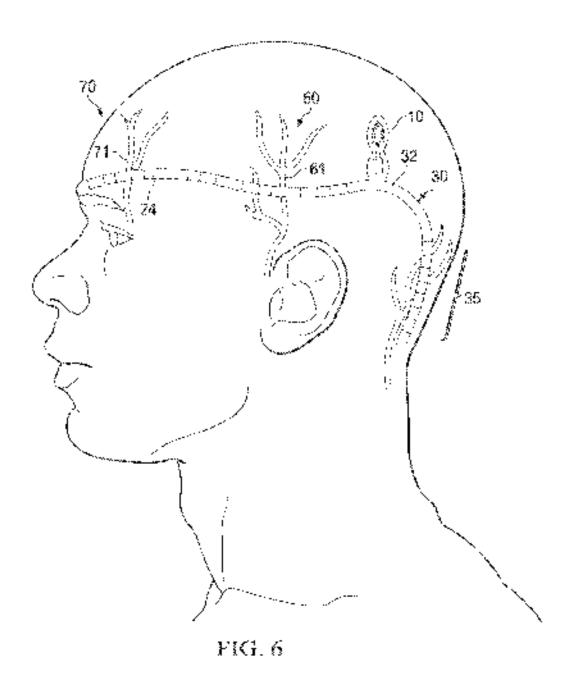
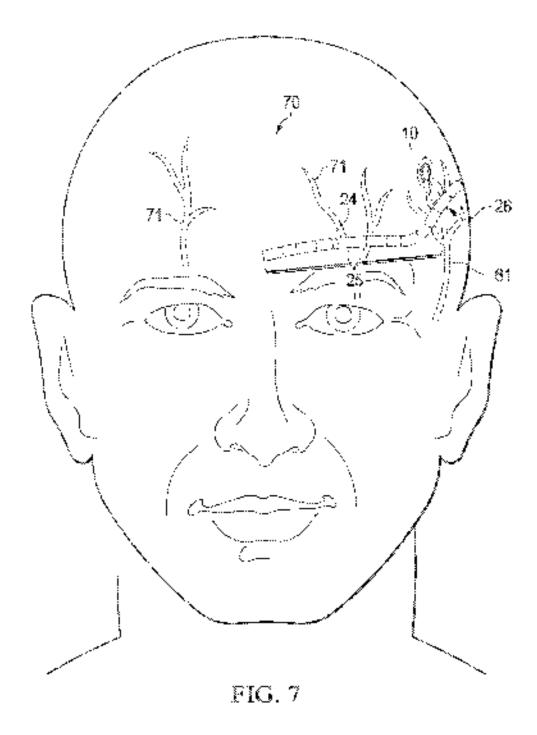


FIG. 5





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IMPLANTABLY HEAD MOUNTED NEUROS HMULATION SYSTEM FOR HEAD PAIN

GROSS-RIPERRING, TO RELATED APPLICATIONS

This amphication claims benefit of U.S. Provisional Apa is cation. No. 61/804,795. filed Oct. 23, 2013. catioled EMPLAN IABLE, ILCAD MOUNTED INDUROSHM. II A-10 HON SYSTEM DOCK HEND PAIN, the specification of which is incorporated by reference per uninits cuttiety. This application is related to U.S. putent amphication Ser. No. 14/460. TH. filed of even date berowich, catioled IMPLANT-ABLE NEOROSHM. I AHON LEAD FOR HEAD PAIN. 15 which claims benefit of U.S. Provisional Amplication No. 61/865.896. filed Aug. 14, 2013. The specification of which is incorporated by reference never notice entirety.

TECHNICAL CELD

The present disclosure relates generally to a fully head muotites implantable riet restinuation system and methods of treating migraine headaches and lo ber forms of chronic less, pain.

BACKGROUND

Neutronismulation systems comprising immigratifule neutrostimulation leads are used to treat obtaining pain. Conventional 197 implantable pempheral net restinutiation leads are designed for placement in the spinal conducts pain of a spinal cord stimulation system, and for the therapeutic purpose of treating various, orms of chronic back and extremity main.

SUMMARY

In carcus, implementations, an implementable headmounced, unfloody periphenal nerve stimulation system may be configured for implementation of substantially all electronics, including an original nattery, at or near the immunited electrodes on the skull. The system may include an implemable pulse generated (LPG) from which two nonastimulating leads may extend to a length sufficient to movide the appearing reatostimulation unflatorally over the frontal, parietal and occinital repriors of the hermomium. The system may be operable to provide medically acceptable therapear in nearestimulation to multiple regions of the head, including the moral, parietal and occipient egyptics of the hemicranium, substantially simultaneously.

Factor of the leads may include an extended lead body; a plurally of sorbice model electrodes disposed along the lead leady, which may be divided into two or made electrade arrays; and a plurally of internally estimately conducting model wires coming along at least a portion of the length of settle lead body and individually connecting an internal circuit of the IPC to individual surface metal electrodes. The extended lead body may comprise a moderal goade plastic. The IPC introduced a recipility and an application specific integrated circuit (ASIC). The IPC is may be configured for functionally connecting with an external hadiotheoremy unit in the external hadiotheoremy unit may be operable to perform various functions including reciping the rechargeable natteny, diagnostically evaluating the IPC, and programming the IPC.

Implementations may include one demore of the following on cross. The IPC may be of impermispect ratio with respect 2

to the specific site of intended implumation in the head, such as an area posterior to unellog a menor to the exit. The emay be a mexternal portane programming unit that is capane of achieving a code-frequency couple to the implanted IPG. The IPG may have a rechargeable pattery as a power source. The rechargeable bettery may be inductively recharged through the skin.

Implementations may include one or more of the following features. A neurostimulating lend may not include a control cosmic from a stylet. A neurostimulating lead may have a smaller districter than conventional leads.

Implementations may include one or more of the following liestures. The system may include the disposition of a stiff cient plotality of surface electrodes over a soliticient linear distance along the nonrost mulating leads to enable medically indequate. For specific stimulation across multiple regions of the bend, including the frontal, parietal, and occipital region of the hemicrarium is a balantially simultaneously. The extended array of publice electrodes may be divided in a two or more discrete terminal surface electrode arrays. The linear layout of the run tiple of those electrode arrays may include at least one array positioned over the parietal region, and at least one array positioned over the parietal region, and at least one array positioned over the positional region.

Specific intravairay design features may include sociations in the specific number of electrodes all offectioles along the slispol of the electrodes, e.g., whether the electrodes are cylindrical on feature at the width of each electrode within each intray, and the linear distance in ervals of senantion of the electrodes within each array.

Various implementations may include a plurality of connection parts that can be connected with a plurality of leads and thus allow for attaching additional leads.

In readons implementations, the body of freating chronic paint may include methods of treating caronic head and/ar lace paint to that fine et olophes, including any trial bead policy; and other primary hasdoches, including aluster head-acros, hermorianic continua meadacros, tension type head-acros, chronic daily herduches; orthor including secondary headaches, such as cervicogenic heads chos and other secondary musculoskeletal headaches.

In various implementations, methods of treating obsents pain may method methods of treating mead and/or face pain of multiple of obegins, including neuropathic head and/or lines pain, nad/or sympathetic related beam and/or line pain.

In various implementations, the beds of heating obtained pain may metade methods of treating mediand/or face pain of multiple eriologies, including greater conflicts neutralyia, as well as the other various conjutal neutralgies, supposibilitation ruly a carried to temporal neutralgie, infraredital neutralgies, and other head and line neutralgas.

The betans to the or more implementations are set for than the accompanying drawing sand the description below. Other lieutures, objects, and advantages of the implementations will be expaned from the description and drawings.

BRIDE DESCRIPTION OF THE DRAWINGS.

For a more complete understanding of this disclosure and its features, to come is now made in the inflowing description, taken in conjunction with the second snying durwings, in which:

FIG. 1 depicts a side view of a head-menuted, uniloody memostimulator system for magazine and other head pain. The system fectures are implantable pulse generator (IPG) from

which two reamstimulating lends as and in a limito-Purioual Lead (TPL) and in Occapital Lead (OL). Each lead includes a plurarity of electrodes in a costabilition and over a length to allow full unilateral coverage of the feetfal, periotal, and accipital portions of the mad.

FIG. 2 depicts a side view of a firm of Electrode Array (FEA) with Internal Wires. The FEA is disposed over the cital portion (such as 8,10 cm) of the PH, which a rate of cally places it over the frontal region and specifically over the supraorbitat nervo and other adjacent nerves of the region. In 10 general the beyont, disposition and connections of the Internal Wires and Surface Electrodes disposed eventic Parliers Electrode Array (PFA) and the Occional Flectrode Array (OFA) are the same as that denicted for the FFA.

FR4. 3 depicts a sade view of the Internal Wices exiting 13 mm the IPG's Internal Circuit eximple to the Sortice Pleasuredes disposed over the FPL and the CL.

FIG. 4 depicts a cross sectional view of a Lead Central Body commising a Cylindrical Lead Body (with Internal Wires) between the IPP Internal Circuit and the Lead Surface. 20 Dectropes.

FIG. 5 depicts a rear view of a Head with a full Head-Monnted Neurostanulator System In Sign. Promoter, here is the CT depicted possing from the IPG condully undimedicity seross the occupital region, whereby the OLA is disposed in a 23 astrongle consequence of the major associated rerives primarily the greater eccipital nerve, but replicably including the lesses analog third occupital nerve as well. Also depicted are the PTA and the TEA of the PT as they cross and cover the primary nerves of the Paretal Region, including the P2 aurients temporal nerve, and the Libertal Region, including the approachital nerve.

FR4. 6 depicts a size view of a Head with a full Head-Monned Neumaticulator System In-Silic. Prominer there is the PRA, as it eswers a portion of the Partetal Region and the 35 major is speciated increes, including the annual often popul nervo, as well as adjacent extaneous nerves. Also depleted are the estates of the distal portion of the PR and the OL, as they pass over and deven the associated herees of the Prenial (Sugracebiral) and Occipital Regions.

FIG. 7 depicts a front view of a Head with a firl Head Mounte? Neurostimulator System In-Sitt. Prominent here is the L.D. as if covers a partial of the Frental (Suprarabilal) Region and the major assectional nerves, primarily the suprachital nerve, but also commonly the greater trachless nerve, as well as adjacent nerves. Also depicted is the course of the partial portion of the PI.

NDDX O OF IMAN S

HI: I oplantanie Palse Generator

11: Viterio

12. daltary

13: Auphration Specific Integrated Chorit

14 Medical Plastic Cever

20. okonto-l'Abiotaccoad

200: Play to Body Member

21 Distal Ltd.

32: Post rul bud

226: Proximal Load Scament

23. Distal Non-Stimulating Tip-

24: Sturlinge Me ni Pleetrede

25. Essaral Blocussic Array.

36: Nation Identage Array

Later-Array Informal.

28 Paint of Cross Section LIC: 4

29 Level Internal Winter

30 Coximital Leaf.

31 Distal From

32 Proximal Fra-

320 Proximal Land Segment

33 Distal Non-Stimulating Tip.

34 Sim and Moral Edge inde-

35 Ossipital Electrode Aцру

36 interelectricae Distunce

37 Surface Blecuedo Width

384 car, internal Wire

39 Play io Body Member -

50 Occipital Region of Head

51 Greater Occipital Nerve

52 Lesson Occipi ni Nerve

53 Third Occipital Nurve

60 Parfet/1 Region of Head

61 Auriculatemporal Nerve

70 I norsa Region of Head

71 Suppoprietal Nerve

AODS ROSOLICE HEAL

Referring now to the decivings, wherein like reference numbers are used bettern in designate like elements brought-out, the various views and embediments of implantable test mounted neurostamulator system, or head pain are a histoared and described, and other possible embediments are described. The figures are not necessarily drawn to scale, and in some insumpes the drawings have been evaporated and/or simplified in places for illustrative purposes only. One of ordinary skill in the art will uppreciate the many possible applications and variations based on the following examples of possible embediments.

A. In exhibition

The present disclosure provides a fully load mounted implantable perponent remonstratish to reystem deep next or the protoneat of chronic bend pain. It incorporates are triple claiments and features that take into account the unique anatomic, physiologic, and other robued challenges or proming head pain with implantable nearostimulation, thereby greatly improving on thempende response, patient safety, medical fix and medical costs, which combine to improve event patient satisfaction.

Prior implant to encripheral necrostimulation systems and comparents, including leads and pulse generators, have been designed a midevelopen specifically us spiral our distinulator systems and for the specific therapeutic parmose of treating enround back and extendily pain. Over the years, these spiral coulds include sweet it indely accorded a altadapted for use as implantable peripheral nerve stimulators for the treatment of migraine headaches, and other to this other no the adopting however, they were so utilized with full necessariation of the underent risks and firm tations given that they were developed only to address, and accommodate to, the number anatomic and physiologic features of the back and chemic back pain

U.S. Pecvisional Patent Application Sun No. 61,865,893 describes the minifold problems a social edwith the application of spinal cora stimulators for head pain as fundamentally the to be significant sensition with fundinherent to, then selof 67 on implemented the appearing device in an area of the body that they also designed for.

Indeed, the initiarry of the head, and the multiphysiology of beadaches, and other forms of head pain, are so significantly different from the anatomy of the spirul canal, and pathophysiology of chronic back pain, that when spiral confistingulators are utilized for granical implants, the climeat problems associated with those differences manifest their selves.

Importantly, these well-shourmented problems are clinically very significant and include issues of parion safety and satisfactor; the risk of unit categories, or subaptimal, the apeutic response; and issues with parion conflort and observations, as well as a recognized increases; risk of surgical complications of and technical problems.

These modified issues stem from the design of conventional leads and the 180. Conventional lead deep no methods a relatively large diameter in cylindrical shape, to ten's inudequate length and broncessally of impainting the IPO in the torse and to distant from the distal leads, and a number and disposition of the surface electrodes and active lead masys that de not match the requirements. A cylindrical lead of relatively large drain over reads in increased measure on, and numities that in the contract of the overlying skin, particularly of the forefreed. Because constructional leads are of monocurate length to extend from the lead to the IPO implicatisite, commonly in the lower book abdomen, for ightest region, lead extensions are refered association, and there are attentian trisks of infaction, local discountert, and cosnette conceans.

With respect to prior tested 1/1 here is only along a array of electrodes, with common lead options including 4, 8, etc. 3 electrodes disposed even that single array, 21 the array is relatively short with most leads broking in unity of limit 5,12 em intength; 3; Within this single array, the individual closes trades are disposed in pointly with constant, equal times electrode (istances. This results in the need to implain multiple toften four as more) of the constant leads to adequately cover the paintful resisms on the best.

There are several practical clinical concernes that result to non the use of and flexis for the treatment of climinic head. paid. First, since they comprise a single, relatively shert active. array. The contently available reads provide the apendic stimulation to only a single region of the head; that is, they can provide stimulation to only the frontal region, on a portion of list the panetal region, one portion of the occiontal region. Therefore, if a patient has pain that extends over amitiple regions. then multiple separate lead impends are required. Basically one keel implicit is required for each units and region. A great majority of patients with chronic headaches experience holecephuha pana that is they experience puint over the frontal and parietal and occipital regions bilaterally. Therefore, commonly those patients will need 1 to 7 leads implanted to achieve adequate. Ferapec to results (2 or 3 leads on each sider

Second, the need for an Itiale leads includes considerable added expense, and more importantly, added medical hisk associated with adverse events attendent to the multiple surpical procedures. Such adverse events include a micreased distributional blooding, and technical issues with the leads. (5) e.g., lead fracture, lead migration, and local protation.

Third, as the clinical durabase discloses, the interselve mole spacing may occidental thoropositic significance. That is, for example, whereas commonly parrower the occident reprior is consistently effectively treated by quadripolar leads (leads so with four exemply spaced open (approximately open or more spart), clinically it is often found, that electrodes configurations that are not enanowely spaced may be more effective eventhe supracribial nerve and regions. Thus, a quadripolar to lead, that has the decreased only 1-2 min apart may be more effective in this region, as in Toxas formore precise control of the delivered electrical pulse wave (elivery).

Inter electrode spacing is a so of therapeutic significance. For example, whereas pain over the coalgital region is come or mody feeded offectively by systems more positing relatively widely-spaced quadripolar leads (non-electrodes at approxi-

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mutely if one or more intervals), more narrowly spaced contacts are often more officerive even the supervisited region.

When an IPC median, besigned for sample core still indation. systems is employed as a peripheral nerve stimulator for bendpain, soveral outcomes result. First, the IPG is implicited at a considerable and omic distance for the practial lead implants. Indeed, the leads most pass from their distal cranial implant. positions across the cervical region and appear accurate the IPG implent location, which are most correctly in the lower back, lower abdorner, or gluteat region. The leads must oress multiple anatomic motion segments, including the reak and upper back audior obest at a minimum, and commonly miclade the infid had splower back and waist separents, as well. The simple are ions of rearral duity life produce adverse. tension and torque forces on the leads across those motion sepinents, winch in turn incresses the risk of various outcomes, including lead migration and/or lead fracture. In addifrom the relatively large size of a spiral condistinuation IPG. contributes to Josef discorriforal cosmo id concerns, and Indicases risk of infection that may become larger and lander. to treat in amportion to the size of the IIX i pocket.

The present disclosure is directed to an implantable headmounted analody peripheral neurostinulation system. That includes on IPG from which two metrostinulations plants extend to a length sufficient to allow for increpentic neurostroutations, plate alsy over the norm, parietal and occipital regions of the lead.

The present disclosure addresses and offcollycy solves problems a tendinal to mublically available leads. The most imperious of these is the fact that encent leads can only adequately stimulate a single region of the head one to design. element flaws associated with terminal surface electrode member and disposition. The disclosure additionally addresses and solves other problems inherent with the ourcontly available leads, including problems with assuratios and patient coin ort, particularly over the manal regions, due the undenfertable prossure placed on the skin of the ferchead. due the cycleanical shape and relatively large diameter of the distal portion of the lead. Finally, the lead of the present disclosure solves the currently available leads' problem of madequate lead length to reach a plateal location to the implemable pulse generator, which therefore necessitates the additional risk and expense of further surgery to impeaut lead. extensions

In each spect, the implicatable, bend-movated, actuostimeution system for read paint's cheering elform plantation in the head, and to provide neurostimulation thermy for chemic head pain, including coronic head pain caused by migranic and other headsches, as well as dimondifield pain due other miologies. The peripheral neurostimulator system disclosed. herein takes hito account unique anatomic features of the homan head, as well as the unique, prisingular, features of the various pathologies that give rise to head pain, including rimpraine and other headaches, as well as other forms of chronic head pain. To date, all commercially available systerns that have been clinically utilized for implantation as a peripheral neuros implient system were actually originally. designed specifically for placement in the epitarial space, as: part of a sornal cord stimu attor system, for the therapentic. purpose of treating chronic back and/or extremity pain. Thus, there are currently no conunercially available teads or a concplete system that have designs in the multifoldomain, that have been designed and developed for use in the head and for head pain.

In another sepect, the implantable, head-mounted, netwostructulation system for head pain comprises multiple design fectures, including discosition of a sofficient plurality of ser-

ace electrodes over a willicitant linear distance along the cistal lead such as will result in lead that as a virigle lead, is capable to providing medically adequate theraper to still in lation over the entire hermora number that is, over the Pointal, parietal, and occupital region substantially simultaneously. Currently cosidable systems, which were designed specifically for epidoral placement for channe back pain, are capable of only providing stimulation over a single region; that is over either the frontal region alone, or the parietal region alone, or the parietal region alone, or the parietal region alone.

In yet and her active, the implimable, handsmorm ed, nonmicrostimulation system, or hend that comprises multiple design
energy, including the physical grouping of the extended
array of surface electivities into three comore discrete termirul annual electivities in more) surface electivities arrays is
designed such that following implantation there would be at
least one array positioned, even the frontal region, at least one
array positioned even the particle region, and at least one array
positioned even the particle region. This feature further
improves upon the openic effectiveness of the extended terminal surface electived acress sufficient for hemicanial
stimulation by allowing for more precise centrel of the frontpentic necrostimulation parameers.

In still unother aspect, the implantable, head incurted, nen vishmulation system für head pain comprises ihn tiple. design features, including incorporating individual design duatines within each of the three or more individual surface. electrode arrays; examples of such intra-array costenifeatures : would include the specific number of electrisdes altotted to each group; whether the electrodes are cylindrical or flatrened, the width of each electrode within each newly, and the linear distance intervals of segmention of the electrodes within [15] ench array 11th a feature further improves onor the operate allied between of the extended terminal purlice electrode array. sufficient, or hemionerial stimulation, and the emoping of these electrodes into three or more separate sur lace electrode. arrays, by providing each specific array location a rangue. intranantay beggin that takes into appoint, and thereby seeks to optimizes, cosign exemunts that are known to be possibly or likely beneficial to the therapeutic end result, given the anticipated nos simplem insuemic locution of that army

In vertice the aspect, the implantable, head-mounted, neunotion lation system for head pain comprises in this encovel design features, including incorporating individual design features into a single lead design and thereby achieving additive benefits.

In still another aspect, an implantable, head-mounted, neu- 50. modinalistical system, or head pain results have marked decrease in the number of serious a lead implement quired to adequately treat a single patient. A single implant will provide the same the apelitical rate indepoverage that it would take the implantation of three or four of the currently available leads: [55] that is instead of the current which often calls for three or more leads to be implemed to provide adequate femicionial. coverage, the same anatomic region may be envered with a single stimulator lead implant. The lead provides extended coverage even the full hemicipalism; that is achieving mediates early acceptable monostimulation unitaterally over the frontal, parietal, and occipital regions simultaneously. In contrast, publically known leads are able to consistently provide medically acceptante ner rosti nu ation the tapy only over a single. region; meaning that it would exquire these separate snegi- or early pureed lead implants to achieve the same therapeution coverage of a single implant of a lead of the mesent disple8

sore. This will decrease the relation minutes of surperior equired, as well as the extent of each individual suggery, for many patients.

In another aspect, the present disclosure is directed to a system that is fully accalled to the need, which obvious the requirement of currently available system; of having leng leads and extensions extending across the neck and back to PG heatings or more yin the low back and plateat region, and thereby decreases the risk of moblems abordon to such be applicated and extensions including discontinut, infection, technical extension issues such as meture, and other morbidities. This ultimately results in a decreased number of an genea required by a patient.

In other aspects the system only include one or more of the following features. A neurostimulating lead may not ecquire a central charmel five a cyle. A neurostimulating lead may have a smaller diameter than ecureurly available leads.

In other aspects the system may include one or more of the following purpose. The system may include the disposition of a sufficient purality of surface electrodes over a sufficient inear distance along the system's leads to enable mediculty adequate the appear is simulated horross multiple regions of the head, and preferably the entire homogenium, that is, over the fremal, porion', and occipital region simultaneously. The extended analy of surface electrodes may be district into two or more discrete terminal or three electrode arrays. The preferred linear layout of these multiple surface electrode arrays includes at least one array positioned over the fractal region, in less one array moditional over the parietal region, and an least one array positioned over the parietal region, and an least one array positioned over the coaloital region.

In other espects intra array design (features may include variations in the specific number of electrodes allotted to each group, the stage of the electrodes, e.g., whether the electrodes are cylindrical on to tened; the width of each electrode or surface electrode width 37 within each stray, and the linear distance intervals to separation of the electrodes or interferenced distance 36 within each array.

In other aspects, the system may a purishty of elemention ports that can be connected with a number lity of leads and thus a allow for attaching additional leads should they later be required.

In another especia on implicately, head-mounted, neurostimulation system for lose, pain comprisos multiple designlectures; including on cresulmed at improving ration sailely. by improving the incidence of adverse events, including the nisk of infection, as well as the risk and indicence of known rechnical amblems as actiated with implemed leads, includang load migration and load fracture, amongst others. The teatmay comprise two or more (i.e. three or indire) at face electrade active, coch uniquely designed, that are disposed over a ar IT die it lead lengt i to a low for medically acceptable the tapeofic remostimulator coverage of at least regions within the supraorbital, partetal, and occupital cranial regions. To achieve the same of rical coverage form a single implant, it would require three or more separately surgically implanted acads. Therefore, by reducing the number of surgical incisions, as well as the number of purgically implicated leads, the associated risks of adverse exerts are proportionally dimin-

In yet mether aspect, an implantable, head-mounted, neurostimulation system for mod pair, may thest chrome bead und/or line pair of multiple aniologies, including emigrains headaches; and other primary headaches, including chaster headaches, her normal continual headaches, tension type headaches; chronic daily headaches, tensionad migraine headaches; further including scoondary headaches, such as convicegent cheadaches, and other secondary mescaleskele at headaches; including reimpathic head undoor lace pain. nonceptive residund/or lace parh, und/or sympathetic related head a room face paint melaching preater decipital means graas well as the other various occupitation reliadgies, supratorbital romalgia, amiomator pora nouralgia, mfraorbitat nouralgia. P and other trigorimal neuralgias, and other head and face neuralgias.

In other aspects, an implemable, head-mounted, neurostimulation system for bond pain may not cognice a contral. channel for stylet placement ever its (isral (frental) corrions. The lead may improve minimum from ort and cosmeries by vinue of its relatively small diame enover the distal pontions. of the lend, partially due the luck of a central style, channel, as well us one to a propressive becrease in the number of internal $_{13}$ wires continuing after each terminal elect side. The lead may urther minimize cosmetic appearance and patient conflict, by incorporating a flattenes, load design for that portion of the teas, expected to be over the frontal portion of the head.

Thus the present disclosure provides for a peripheral neu- [55] restinutation lead that is uniquely designed for implantation. in the bend as a thereby for chronic hord pain, and is designed. to solve the known design issues associated with content leads, as the lead of the present disclosure seeks to emirrize cos netical reduce the number of surplical leads required, reduce method in signard reduce method larks.

Overcrew

Furning they to the drawings, which depict the system and several of its components in various aspects and news, and its which similar reference numerals denote similar elements. The drawings illustrate an IPO from which two neurostimulating leads may extend to a length sufficient to allow fee thers positio neurostimulation unilaterally even the frontal. parietal and popinital regions. The leads include an extended plustic lead body, a plurality of sorthor metal electroics disposed along the lead, which may be divided in a two or more. electrode arrayo: a plurality of internal electrically could of ing metal wires running along at least a portion of its length. and and would by connecting the LXCPs internal circuit to individual surface metal electrodes. The impantance pulse generator includes a rechargeable lattery, an enternal cont. and ASTI. The system may be operable to introvide medically. acceptable therapeutic noncostimulation to multiple regions. of the read, including the frontal, pametal and occipital. region saimpliance (sby, and three tigues) demons in a writous views of this feature as the lead is appreted in-situ. C. Full Fead Mounted Neurosti milator System

FIG. 1 deplets a side view of a full neurostimulater system. (5): which consists of an implantable pulse generator (IPC). Dialong with two unlinely also to lead open dons in Prome-Particial Lead, (CPL) 20 and an Occipital Lead (OL) 30 of adequate length to extend to roughly the and fine of the fore-Lead and to the midline at the service-tranial junction of rospectively.

PIGS, S. 6 and 7 depict not enforch encland, romal views. of the system in-xitu. The unit is demonstrated at an implant position where the IPG/IBCs proternor and cep at an to the piana of the car. The drawings demonstrate the FPL 20 pass- (6). ing over the periods, 60 and frantal 70 regions of the head in a marner from places the FEA even the sommorbing nerve 71. and the PEA over the anticuloromy-extineeve 61. The OL 30 is slown bassing caucally alic methally over the occipital region of the head 50 such that the OEA 35 cross ever the legreater occipital nerve 51, Incitesser eccipital nerve 52, and the third eccinital nerve 53.

D. Fromo-Parietal Lead.

Continuing with FIG. 1, the FPL as part of the unilecty construction, extends from the IPC. The IPI, comprises a plastic body member 20% and a set of internal conducting wises 29.

The plantic body member 20x is an elongated, cylindrical, flexible member, which may be formed of a medical grade. plastic polyment. It has a proximal end 22, a distalle al 21, a mi may be conceptually divided into tive segments along its tinear dimension. Progressing from the proximal end 32, these segments sequentially include a moximal lead segment (PLS) 22a. a parietal electro/clarray (PEA) 26, an inter-array. niterial 27, a mina electivile array (L.DA) 25, and a distanon-stimulating tip 23

The lead internal wards 29 pass along the interior of the plastic body meinbehasidepicted in F.C. 4. E. Freatal Electro/e Array

Continuing with PKi, I, the PFA 35 consists of a plurality a military metal electrodes (SML) 24 uniformly disposed. over a position of the distal aspect of the PPU 20. I collection at wires 29 connect to the SM 124 as depicted in FIG. 2, which represents the distal four SME 24 of the load. Acida: fleetrode Array

Returning to FIG. 1, the PFA 26 consists of a plurality of the therapeuric response, immove nutien, comport, immove 23, SMI-24 anticomly disposed along a linear portion of the PFL. The PLOA 3ft is separated along the PPL from the PPA by an inter-preaving easily 27. It is supposed only the lead from the 1.20 by the PLS 22a. The lead internal wires 29 connect to the individual SMB 24 or the PMA in the same, ashion as the dowith the SME of the FBA as shown in F10. 2

C. Occipital nead

Continuing with FDS, 1, the coclettal lead SOL: 50 as part. of the unibady construction, extends from the IPG 10, it comprises a plastic body member 39 and a set of lead in email wires 38 that pass through the central evilinder of the lead toconnect to a series of SMD 34 that are uniformly disposed plong a pertion of the length of the lend. These lend internal wises 38 pass and connect in the same manner as acsoribed. above, or FoSMIv24 or the FIVA 2S as dericted in FIG. 2 and 7 FIG 4.

The plastic body member 39 is an elongated, cy i idrical, lexible member, which may be formed of a medical grade. plastic polymer. It has a proximal one 32 and a distal end 31. Progressing along the lead from the proximal and 32, base. segments sequentially include a proximal load segment (PLS). 32), un decipitar e estrede array (OPA) 35, a m a distul non stimulating Ep 33.

Cooipital Lead Array.

As demoted in LIC, 1. the OPA 35 consists of unit rubity of suctave metal electrodes (SME) 34 uniformly dispessed over a portro (OL 30). Lead in ternal wires 38 domined to the SMI, 24 in the come tachion as depicted for the FEA as shown in PRG.

malamable Pulse Generator

Referring to FIG. 1 and FIG. 5, the three primary physical and functional components of the IPtr 10 included reclargeable but any 12, ao antenna 11, and an amplication specific. integrated electric (ASIC) 13, along with the necessary interhall were connected is amongst these related on opponents, as well as to the incoming lead internal wires 29, 39. These individual components may be eneased in a can make of a medical guide me al and plasfic cover 14, which itself mansitions over the exiting FPL 20 and OL 50.

C. Connections of Main Ide nerts and Sub-Diements

The system may include a unibody constitution to provide physical and functional continuity of the relates components. und sub-components

·····,···-,···-

The overall mechanistic primese of an implantial chemical standards and conduct a prescribed electrical pulse wave from an 1.% Ill boson a set of lead internal wires 29, 38 running a portion of the length of the lead to specified programmed set of SMIs 24, 34, whereby the 3 current is then conducted by 3 secund/or fluid to an adjucent or nearby, set of one or more SME 24, 34, which in runn passes the signal proximally down the lead wire 29, 38 back to the TVL 10 and its MSIC 13, thus completing the circuit.

1 I

1. First Innbodiaged

The first embediment innerios for a leaf that incomorates one or more of the features outlined above and includes a hear more test, and undy neurostimulating system community an IPG 10 and in less two neurostimulating leads (CPI 20 and OI, 30). The system may be imposted in a manner such 15 that the IPG 10 and of two leads 20, 30 are discussed as this trated in FIG 5. FIG. 6 and FIG. 7. The IPG 10 is appolle of understandly connecting to and communicating with a pertable programmen and an external newer source for his kery recogning.

In this embodyment, the leads are constructed as described above suches (opicted in the deswings. The FPL 20 is approximately 20 centur length from its proximations 22 to its distalland 21. The 19PL 20 has a distalland and 22 to its distalland 21. The 19PL 20 has a distalland the rt.A. which may 23 have ten SMF 24 uniformly disposed over approximately 8 cm. This is followed by an inter-analy interval 27 of approximately 1 cm, then the PLA, which may include eight SMF 24 uniformly disposed over approximately 6 cm, and finally approximately 4 cm terminal lead segment 22c that ends at the proximal cn (22, b) where the lead transitions to the IPK 10 and the leaf interval wires 29, 38 connect to the ASIC 13.

In this embodiment, the occipital lead may compute a plustic body member 39 over which via SMC 34 may be disposed uniformly even approximately a 10 embergth of the or lead, and the lead terminates in approximately a 3 min distulben-stimulating tip 35.

In this embodiment. The IRF 10 comprises the elements described above and devicted in the drawings, including an ASIC 13, a rechargeable battery 12, and an antenna 11, which a timay be baused in a common interior 15 that may include a medical grade me all our with plustic cover 14. In this embodiment the aimensions of the IPtr 10 measured along the orders are colline plustic cover 14 may be approximately 5 cm by 3 cm by 0.5 mm.

The system metades a portain eip signammer and a psinable recharging unit, both of which function. Ty couple to the IPG through a radio frequency mechanism.

In this embodiment, the system is capable of tanching a program from the portable programmer that includes such tall purameters as subsectingly that, frequency and pulse width, M. Alterna of Embodiments.

There are multiper alternate embodiments that preserve the issures of the neurostrouland respective and programmable as LPC, sixed and configured for implantation in the head, and more which librato-parietal and eccipital leads, along with their respect surface metal electrode arrays, extend to cover multiple regions of the need, in various entrodonie its, the specing and dimensions of the electrode arrays) may be so constant, or the electrode arrays may be specifically designed with respect to electrode type, dimensions, and hyport for improving the their pentic effectiveness.

Thus, the disclosure of up uses extended electivite amoly designs five or more regions by a single lead, and/or mol- or tiple arrays and optimized intra-kinay electrode dispositions. The disclosure also comprises lead configurations, which

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include the capability of a modular lead design, hat provides for ports on either the standard FPL and OLs. In another eithoriment, the FRG receive additional separate leads if a mass necessary either at the time of initial implant or in the forms.

For her, the lead lengths, clong with the specific technical anskemp and dimensions of the individual surface metal electrodes and electrode arrays, may be suried to include more or less than three or little of regions on the head good pital, particular, and feorably esitemptated by the first embodiment. For example, a single IPC may energize and control multiple additional leads of varying lengths that ultimately could be disposed over writingly every region of the head and line hillaganity.

At least two electrodes may be included per region, and while the first enumerated calls for a total of 24 electrodes disposed over three arrays obvering three different regions of the head. The occupitatips rietal and frontal regions. The enumerated is white the first endodingent calls for three electrodes arrays, the disc occurs contemplates below a revenime array (so long as the array covers at least two regions). There is also no finiting maximum for the number of arrays. Also, there may be multiple whin ions of design within each separate array, and metal composition of the number, dimensions, shape, and metal composition of the number dual electrodes, as well as the distance and constancy of distance between electrodes, within each array, parther, each analy may have the same or completely different designs.

While the netrostimulation system has been described for implentation as a pempile of heart stimulator in the head and for head pain, it is capable of being implanted and used as a peripheral nerve standator even other reguests of the best and lines than described above and also even other perinteral nerves in the body.

N. Ozieracio i

When functioning, that is when the internal circuit of lead internal rands is evaluated to an IPO: the SMF of the cardius integs are programmed to function as anodes and cathodos. The generated electrical pulse wave then passes from the ASIC of the IPG to the associated internal lead wire, a miof imagely in its assectional terminal purface metal electrode. The current their passes a short distance from the subcutance. ous rissue, our configuration of memby, electrode, whereby in passes back up the lead to its associated preximal metal. contact, and then back to the IPG to complete the circuit. The generated pulse waves pass through the subcuraneous lipsce. Between two turnings electrodes that stinualities the sensory nerves of the area. When active, the IPG may be programmed to produce continuous series of pulse waves of specified frequency, umphante, and purse width, this this series of pulse. waves no ivoly stimulating a prior is locally associated nerves that undergoes the therapeutic effect of the implanted. unit. The electrical prilise wave then pusses from a connected preximal surface metal contact, along the associated internal lead wire, and ultimately to its associated terminal surface

If is to be understood that the implementations disclosed here in a error, hunted to the particular by stems or processes described which might, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing nonlinear implement from only, and its monimented to be limiting. As used in this specification, the singular forms for "ton" fund into the "motion plant reference unless the content closely indicates of herwise. In addition, the term "ecopology" neduces direct and/or indirect coupling of members.

Although the present displeants has been described in detail, it should be understood that various changes, substitations a coalterations may be made be eil (without departmp) from the spirit and scope of the disclosure as defined by the appended claims. Moreover, the scape of the present appoints oution is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, meshal methods and steps described in the specifical tion. As one of ordinary skill in the antwill need by appreciate. from the diseassure, processes, machines, manufacture, com- 10 positions of marter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve at Estantially the same read that the corresponding embediment (described herein may be millized according to the present disclosure. Accordingly, the 18appended claims are intended to include within their scope such processes, anachines, manufacture, compositions of marter, means, methods, or steps.

I will be approximed by those shilled in the art having the benefit of this disclassing that this impositiable less, mounted [25] neurostimulation system for read pain provides a michally construction with implanted lends to cover the frontal, parietal, and occipital regions of the head, it should be understood. that the drawings and detailed description began are to be are not intended to be limiting to the particular corns and examples disclosed. On the conferey, included are now forther. modifications, changes, comangements, substitutions, afternatives, design phoices, and embodiments upparent to those of ordinary skill in the act, without deporting from the spicit (x)and scripe here dijus defined by the following duties. Thus, it is intended that the following claims be interpreted to embrace all suell further modifications, changes, rughangements, substitutions, afternatives, design choices, and ambodiments

What is obtained is:

- A head ascated neurostantilating comprising;
- a main body, the main body comprising:
- a power source, and
- uprices on the an desympaets riet agenerate a first and second selled stimulating signals for empty or usesetated first set and second set of stimulating outputs.
- a first wire hundle having a first set and a second set of stimulating senductors, each connected to associated. dilearn the first set and second set of stimulating outputs, respectively:
- a first exagated lead body extending from the manufedy toa distal end, the tirstle origined lead bridy configured to ocataia at least a portion of the first wire bundle, the first (5)elongated lead body being liabracated from a flexible material:
- a destignery of surface electrones comprising destilelecto desispaced uport by a first interrelectorde spacing and disposed along a first pertian of the length of the first be unaterial la fabricated from a medical grade plastle. clongified lead body, the first array of surface electrones. composed to the final set of stimulating conductors:
- a second array of surface electrodes comprising accordelect vides spaced apart by a second intenel ectrode space ing disposed along a second pertion of the length of the $|6\rangle$ first clongified lead popy, the second array of surface electrodes corrected to the second set of stimulating estaductors, whosein the first portion and account portion are separated by an interior by interval, and wherein the first inter-electride spacing, the second inter electride (c spacing and the infer analy influence are different dislimeest and

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- a covering over the main body fabricated, mrs the flexible material and merged with the flexible material of the first eld quited lead body to form a milbody sealed assembly comprised of the intrinsbody and the first elongated leadbody.
- The neurostinualator of claim 1, wherein the processor. and the power source in the main pody are contained in a metal bassing.
- The networthmulater of elsim 1, wherein the processor. further includes communication capabilities with a wireless. communication link and the main body further includes an unternulassociated with the communication link.
- 4. The means implied of claim 1, wherein the power source comprises a battery.
- The neurosti mulatorio claimi I, wherein the processoria. riperable to generate the first set and second set of still radating. signals with a first and second series of pulse waves of specihed frequency, amplitude, and passe width, respectively.
- The nethestimulator of claim 1, wherein the first areay of suctade electricides includes at least two types of stuface electrades, and for exciting surremoding rissue and the other for completing a circuit back to the processor.
- The neuros implicion of plaint. It wherein the line elecregarded in an illustrative reflier than a restrictive manned and 15% trades of the first array of surface electrodes are arranged in pairs, each pair having an exciting electricle and a returning electrode for completing the circuit
 - 8. The reducation date of claim 7, wherein the first array of surface electricles and the second array of purlice electrodes. are each configured to independently receive the first set of shimulating signary and the second set of shimulating signary, respectively, from the processor.
 - The neurostimulator of claim 8, wherein the first array of surface electrodes is contigued for placement in subcutameor one dispute premiumne to a frontal region containing the si amorbital nerve a la asperiated nerves i aproximity thereto: and the second array of surface electrodes is configured for placement in suboutanceus tissuo proximate to a parietaregion committing the artiful often point herve, as well as adjacent eutaneous neuves.
 - The new visitor allabore fighting by and finisher on opinising. a second elongated lead body that extends from the main body. to a second clongated lead pady distal unal the second clongated lead hody comprising a third set of a implicing conducters, rechisting leting conductor connected to associated ones. or a third set of stimulating putputs associated with a timp set or stimulating signals from the processor, the second clorgated lead body fabricates, from the fluxible material and merged with the flexible material covering the main budy a mithe first elongated lead body; and the second elongated lead body further orman sing a third plurality of similace elect coles. disposed along the length thereof and connected to the third set of stimulating conductors.
 - The neurosticulation of quiling L, wherein the flexible.
 - A umbody implantable neurostimulator, comprising. on enclosing having a first enclosed nortion and a second encloses, portion, the first encloses, portion and the sooold enclosed porton comprising a common mutody interior, the common unibody interior comprising
 - в рожит вологи,
 - ammoessonementhie to generate a first stimulation signal and a second stimulation signal wherein the first and second stimulation signals are different signals; and
 - a philadity of entrins comprising a first output for the liest stimulation signal and a second output for the second stimulation signal; and

- a first a implicion lead having one and integraled with the militions interior, the first stimulation lead having a forgitudinally appeared at least one territories end, the first stitulation ead comprising:
 - a first purcality of stimulation conductors disposed along 📑 the length of the first stinualation lead, cach having first unds and second ends, whereas a first end of a first one of the first plurality of stimulation conductors is interfaced with the first output and a first end of a second one of the first plumlity of stimulation condue ors is interfaced with the second on poly
 - a first minuality or simbles electrodes special a first interelectrode distance upon and discressed along the length of a first portion of the first stimuland i lead where $r_{\rm eff}$ one of the first plurality of surface elect sides is connepted to a second end of the first one of the first plurarity of stimulation conductors; and
 - a second plurality of surface operiodus spaced a secondinter-dectrisdo distanco apart and disposes, along the [25] length of a second portion of the first stimulation lead. wherein the second pertion and the first portion of the first standatum lead are separated by a defined ratearrow interval, wherein the linar intervalentmee distance, the second inter-electrode distance and the notes [25] array interval are different distances, and wherein one of the second placelity of suchool electrodes is conneeted to a sexura, and of the sexual one of the first plumity of stirmlation conductors.
- The networthmulator of claim 12, wherein the enclosure (5). is sharted to the blate an idemial implantation posterior and erphaled to the piona of the eac.
- 14. The neurostanutator of claim 13, wherein the first stimulation lead is dimensioned to limit are subdestral implementarian in a pariour so that the first stimulation load is to: configured to extend from the end on reinfider nully advise. the parieur's parietal bone to extend the terminus and possess a portion of the patient's frontal benu-
- The meanistic relation of claim 14, wherein the tiest plumity of surface electrodes are configured to be positioned. and dispensed over a frontal region proximate to the patient's minut home so that they are a special ed with the supriorbital. nerve bundle and esseciated nerves in proximity thereis.
- Tre neumstimulator of claim 14, wherein the second plumity of surface electrodes are configured to be positioned. and dispersed over a parietal regio appointable to the datie it is parietal hone and the ranjor associated nerves, including the aurioula-temporal nervo, as well as adjacent entaneous remes.
- 17. The networthmulator of claim 12, wherein the enclosure $|s_{ij}|$
 - The negrestim dator of obtimit 2. Letther comprising: the processor operable to guidrate a third stimulation sign nal cillieren, from the first and second stimulation sig-
 - the planality of outputs comprising a finial output for the third air almion signal:
 - a second standation lead having one end of the second stimulation lead integrated with the milbody interior, the at least one terminus once the second, stimulation leadcover prisings:
 - a second plurality of stimulation conductors each having. first ends and second ends, wherein a limit end of a first and of the second plurality of stimulation conductors, ea is interfaced with the third output of the plurality of on puls previding the third stimulation signal:

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- bird plumliny of sorthog elegatedes disposed clorigin first portion of the second stimulation lead wherein one of the tinno plantity or surface electrodes to connected to a sociald end of the first one of the second plurality of standation conductors.
- The neuropir ulater of claim 48, wherein:
- the suction electrodes are managed in at least one first. prouping of surface electrodes and configured to be dispersed even and mostimate to the nurient's limital horie. such that the first grouping of surface electrones are as antiated with the potter is supraorbital nerve hundle and associated herves in proximity thereto:
- wherein the second portion has a second prouping of suraccelectredes disposed, hereon which median lighted to he positioned and dispursed over and proximate to the patient's panetal hore and the inajona specialed nerves, including the attribute-temporal nerve, as well as adjacention briefly silences; and
- wherein the second per ferrhase third grouning of surface. electrodes disposed thereisn which are configured to be positioned and dispersed over and processes to the patient's eccipital bone and the associated nerves. including at least one of the greater decipital to nerve, the lessen obcipital nerve and third possible nerve-
- A neurostimulator device comprising. a mann body, the main body comprising:
 - а ражес воиме, адб
 - a processor, connected to the power source, the process ser configured to generate a first set of airculating signals and a second set of stimulating signals for or tpri, or an associated first set and second set of microlating corpora-
- a dest wise buildle having a first set of conductors conneeded to the first set of a implicing outnots and a second set of conductors connected to the second set of stimulating outputs;
- a first elengated lead body extending from themain body toa distantinal, the first olongated feed hedy configured tocontain a les a a l'exportion of the line wire bondle, the first clongsted lead body being fabricated from flexible. materul:
- Instructory of surface electrodes having a little intervolect-Eade specing and aisposed along a first portion of the length of the first elongated lead body, the first erray of studios electrodes being connected to the first set of conductors:
- a second array of surface electrodes having a second interelectrode specing different from the first inter-clustrate. spacing and disposed along a second polycomol the longth of the first clonested lead body, the second stray of surface electrices being connected to the second set of conductors, the first portion and the second portion of the length of the first exequited lead heavy being separrated by a interumiy interval different from both the first. and scoonal inter-cleatrede spacings; and
- the nearestimulator device being configured for surgical implantation only in subcutments tissue of a horizons.
- The neuroscimi lator decice of claim 20, wherein the second stimulation load having a longitudinal shape and $\langle \phi \rangle$ processor is further configured to generate a faird set of stimulating stenals for outpution a third set of stinualating sutputs, wherein the first wire hundle forther comprises a third set of conductors scanceted to the third set of stimulating outputs. the new saturalistic device but her comprising:
 - a second elengated lead body extending from the main lody to accord clongs, od lead body sistal end, the secand alongsted lead body configured to contain at least at

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second partial of the tirst wire bundle, the second elemgated lead body being fabricated from flexible material; and

- s third array of surface electrodes having a third interelectrode spacing and disposed along a portion of the 3 length of he second-clorys collect body, he third may of surface electrodes being connected to the third set of could clore.
- 22. The neutronismulation device of claim 20, wherein the first portion of the length of the first clongated lead body is 10 configured to be continily positioned over a minimal rerve region and the second portion of the length of the first clonquied lead body is configured to be one nully positioned over a supracribital nerve region of a horizon comfort when the temperaturated device is suggestly implicated only in sub-13 cuts is a strategy of the horizontal in the sub-13 cuts is a strategy of the horizontal in the sub-13 cuts is a strategy of the horizontal in the supracribed supports the sub-13 cuts is a strategy of the horizontal in the sub-13 cuts is a strategy of the horizontal in the sub-13 cuts is a strategy of the sub-14 cuts is a sub-14 cut in the sub-14 cuts in the sub-14 cuts is a sub-14 cut in the sub-14 cuts in the sub-14 cu
- 23. The necrostimulates device of claim 21, wherein the tirst portion of the length of the first chargated lead budy is configured to be comicily positioned over a parie of region proximate the suricular-temporal tense, the second portion of 20 the length of the first energiated lead body is configured to be conially positioned over a frontal region proximate the supracolsist herve, and the portion of the length of the second elengated lead body is configured to be comicily mositioned over an occupital region proximate the occupital tense when 23 the new continuous moscole is surpreally implanted only in subottaneous fissue of a configure.

* * * * *