(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 January 2011 (06.01.2011)

PCT

(10) International Publication Number
WO 2011/000791 Al

(51) International Patent Classification:
A61N 1/05 (2006.01)

(21) International Application Number:
PCT/EP2010/059099

(22) International Filing Date:
25 June 2010 (25.06.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09164015.1 29 June 2009 (29.06.2009) EP

(71) Applicant *(for all designated States except US):* **3WIN** N.V. [BE/BE]; Galileilaan 18, B-2845 Niel (BE).

(72) Inventors; and
(75) Inventors/Applicants *(for US only):* **MCGIVERN, James** [US/BE]; Orteliuskaai 2 bus 7A, B-2000 Antwerpen (BE). **BAKS, Christof** [BE/BE]; Welkomstraat 20, B-2160 Wommelgem (BE). SCHOLIERS, **Hugo** [BE/BE]; Schensbossen 3, B-2840 Reet (BE).

(74) **Agents: DE** CLERCQ, **Ann** et al; De Clercq & Partners, E. Gevaertdreef 10a, B-9830 Sint-Martens-Latem (BE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available):* AE, AG, AL, AM, **AO, AT, AU, AZ, BA,** BB, **BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC,** EE, **EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.**

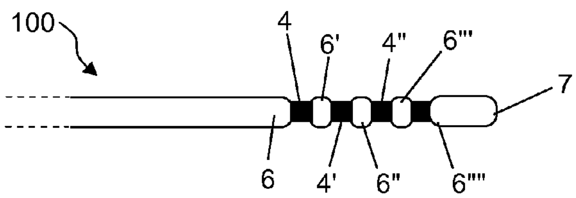
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, **FI,** FR, GB, GR, HR, HU, IE, IS, **IT, LT,** LU, LV, MC, MK, MT, NL, NO, PL, **PT,** RO, SE, SI, SK, SM, TR), OAPI (BF, **BJ,** CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *of inventorship (Rule 4.1 7(iv))*

Published:
— *with international search report (Art. 21(3))*

(54) Title: ATRAUMATIC LEAD FOR DEEP BRAIN STIMULATION

FIG. 1B



(57) Abstract: The present invention relates to an implantable lead (100) for deep brain stimulation comprising: - a longitudinal shaft (2) formed from electrical insulating material having a proximal (12) and distal end (20); - two or more ring-shaped electrical contacts (4, 4', 4", 4'"); - wherein each electrical contact (4, 4', 4", 4'") extends circumferentially around the longitudinal axis (A-A') of the shaft (2), and the electrical contacts (4, 4', 4", 4'") are dispersed longitudinally on the shaft (2) in electrical isolation; - wherein the outer surface of at least one electrical contact (4, 4', 4", 4'") is recessed compared with the outer surfaces of the flanking regions (6, 6', 6", 6'", 6"") of the shaft (2); - wherein at least one of the electrical contacts (4, 4', 4", 4'") is electrically connected to a conductor (10, 10', 10", 10'") that exits the lead at the proximal end (12) of the shaft (2), the connection being via an electrical joint located exclusively on the inner circumferential surface of the electrical contact (4, 4', 4", 4'"). It further relates to a kit and a method of manufacture of the lead.

WO 2011/000791 A1

ATRAUMATIC LEAD FOR DEEP BRAIN STIMULATION

FIELD OF THE INVENTION

The present invention is in the field of electrical leads for deep brain stimulation in the treatment of neurological conditions.

BACKGROUND TO THE INVENTION

Deep brain stimulation (DBS) leads are used to stimulate nerve structures in specific areas of the brain to either excite or inhibit cell activity. A stimulation lead is implanted by a surgeon at an exact location within the brain, often assisted by imaging techniques and stereotactic guidance. Once implanted, the stimulation lead is connected to a pulse generator to deliver electrical stimulation to produce nerve impulses that can inhibit symptom of a brain disorder. Deep brain stimulation can be effective in the management of chronic pain of neuropathic and or nociceptive origin. In addition, deep brain stimulation can be used to treat movement disorders, such as Parkinson's Disease, as well as epilepsy and psychiatric disorders. DBS leads are known in the art, for example, from US 6,529,774.

The depth, position and angle of entry of the lead in the brain are important. In some applications, the lead must be positioned to deliver stimulation exclusively to a region-specific brain target without stimulating adjacent brain tissue. Precision is important, for example, in SubThalamic Nucleus (STN) stimulation and Globus Pallidus internal (Gpi) stimulation. If stimulation is not delivered with precision to a desired brain target, adjoining areas may additionally be stimulated, leading to side effects that are not well tolerated by the patient.

Typically, the desired region of the brain for treatment is found empirically. The surgeon will insert the lead in one position in the brain tissue known to be responsible for the condition, and test for an effect in the patient by stimulating the lead and observing, for example, a reduction in tremors in a Parkinson's patient. If no effect is observed, the lead is withdrawn, and an alternative location is testing for an effect. Because the current applied must not be too high to prevent tissue damage, no effect may be seen, even when the lead is close to the target. Thus, procedure of insertion, testing, removal, adjusting position and re-inserting, needs to be repeated until an effect is observed. Once the region is found, it is often fine-tuned by applying stimulation between different contacts of a multi-contact lead.

A problem arises in the art because there is potential damage to the brain tissue each time the lead is inserted and removed. While most leads are provided with an atraumatic (rounded) tip, the body of the lead is disposed with electrodes raised from the surface. These give rise to abrupt edges against which the brain tissue can snag and disrupt upon insertion and withdrawal. This can damage the tissue, possibly leading to side effects, additional complications and conditions. Polishing the longitudinal electrode to obtain a smooth finish is expensive, and, moreover, technically challenging. Since the metallic and non-metallic electrode materials do not polish down at the same rate, distortions in the lead structure can arise. Moreover, polishing is a time-consuming process.

The prior art known various leads. US 2006/0171587 describes a lead where the electrical contacts are flush with the shaft, and the shaft is provided with an insulative member that masks a portion of the electrode. WO 2008/005142 describes a lead for stimulation therapy aimed at reducing electrical contact between adjacent leads. WO 2009/025816 describes a shielded electrode lead for preventing thrombosis, that is isodiametric along the length of the lead.

The present invention aims to provide a simple, cost-effect atraumatic lead construction that avoids the problems of the art.

SUMMARY OF SOME EMBODIMENTS OF THE INVENTION

The embodiment of the invention relates to an implantable lead (100) for deep brain stimulation comprising:

- a longitudinal shaft (2) formed from electrical insulating material having a proximal (12) and distal end (20);
- two or more ring-shaped electrical contacts (4, 4', 4'', 4''');
- wherein each electrical contact (4, 4', 4'', 4''') extends circumferentially around the longitudinal axis (A-A') of the shaft (2), and the electrical contacts (4, 4', 4'', 4''') are dispersed longitudinally on the shaft (2) in electrical isolation,
- wherein the outer surface of at least one electrical contact (4, 4', 4'', 4''') is recessed compared with the outer surfaces of the flanking regions (6, 6', 6'', 6''', 6'''') of the shaft (2).

According to one embodiment, at least one of the electrical contacts (4, 4', 4'', 4''') is electrically connected to a conductor (10, 10', 10'', 10''') that exits the lead at the proximal end (12) of the shaft (2), the connection being *via* an electrical joint (14, FIG. 6) located exclusively on the inner circumferential surface (18) of the electrical contact (4, 4', 4'', 4''').

Another embodiment of the invention relates to a lead (100) as described above, wherein the size transition between the outer surface of a recessed electrical contact (4') and outer surfaces of the flanking regions (6', 6'') of the shaft (2) is gradual.

Another embodiment of the invention relates to a lead (100) as described above, wherein the transverse profiles of the outer surfaces of the flanking regions (6', 6'') of the shaft (2) transition gradually toward the transverse profile of the outer surface of the flanked recessed electrical contact (4').

Another embodiment of the invention relates to a lead (100) as described above, wherein a flanking region (6, 6', 6'', 6''', 6'''') is rounded at the junction with an electrical contact (4, 4', 4'', 4''').

Another embodiment of the invention relates to a lead (100) as described above, wherein the longitudinal profile of at least one flanking region (6'') adjacent to the electrical contact (4', 4'') has a convex shape where the bulging curve of the convex profile (26, FIG. 4A) directly abuts (8) the profile of the adjacent electrical contact (4', 4'').

Another embodiment of the invention relates to a lead (100) as described above, wherein the longitudinal profile of at least one electrical contact (4', 4'') adjacent to the flanking region (6'') has a convex shape where the bulging curve of the convex profile (26', FIG. 4B) directly abuts (8) the profile of the adjacent flanking region (6'').

Another embodiment of the invention relates to a lead (100) as described above, wherein each of the electrical contacts (4, 4', 4'', 4''') is circumferentially intact.

Another embodiment of the invention relates to a lead (100) as described above, wherein

- the shaft (2) is cylindrical, and
- the ring-shaped electrical contacts (4, 4', 4'', 4''') are cylindrical.

Another embodiment of the invention relates to a lead (100) as described above, wherein the electrical contacts (4, 4', 4'', 4''') are arranged along the distal (20) part of the shaft (2).

Another embodiment of the invention relates to a lead (100) as described above, wherein at least part of the shaft (2) is disposed with a lumen (8).

Another embodiment of the invention relates to a lead (100) as described above, wherein at least part of the shaft (2) is hollow.

Another embodiment of the invention relates to a lead (100) as described above, wherein the distal (20) end of the shaft (2) is moulded and comprises the region along which the electrical contacts (4, 4', 4", 4"') are arranged.

Another embodiment of the invention relates to a lead (100) as described above, wherein the moulded part of the shaft (2) comprises:

- a first sub-region (SCZ, FIG. 3) having longitudinal uniform stiffness and optionally uniform hardness,
- a second sub-region region (TCZ, FIG. 3) abutting the first sub-region having a flexibility and optionally hardness that gradually transitions longitudinally in the proximal (12) direction from the first sub-region (SCZ) towards a shaft (2) body (BZ) that is more flexible and has optionally lower hardness than the first sub-region of the distal moulded end.

Another embodiment of the invention relates to a lead (100) as described above, wherein at least one of the electrical contacts (4, 4', 4", 4"') is connected to an electrical conductor (10, 10', 10", 10"') that exits the lead at the proximal end (12) of the shaft (2).

Another embodiment of the invention relates to a lead (100) as described above, wherein at least one of the electrical contacts (4, 4', 4", 4"') is connected to an electrical conductor (10, 10', 10", 10"') that terminates in an electrical connector at the proximal end (12) of the shaft (2).

Another embodiment of the invention relates to a lead (100) as described above, wherein

- the electrical connector is a slip-ring (24, 24', 24"), and
- the proximal (12) end of the shaft (2) is moulded and comprises the region along which the slip-rings (24, 24', 24") are arranged.

Another embodiment of the invention relates to a lead (100) as described above, wherein the moulded part of the shaft (2) comprises:

- a first sub-region (SSR, FIG. 3) having longitudinal uniform stiffness and optionally hardness,
- a second sub-region region, (TSR, FIG. 3), abutting the first sub-region having a flexibility and optionally hardness that gradually transitions longitudinally in the proximal (12) direction from the first sub-region (SSR) towards a shaft body (BZ) that is more flexible and optionally has lower hardness than the first sub-region of the moulded proximal end.

Another embodiment of the invention relates to a lead (100) as described above, wherein the shaft (2) is made from a biocompatible flexible material configured for pushability for advancement into brain tissue.

Another embodiment of the invention relates to a lead (100) as described above, wherein the shaft (2) is made from polyurethane.

Another embodiment of the invention relates to a lead (100) as described above, wherein at least one electrical contact (4, 4', 4", 4"') is made from platinum, platinum-iridium or MP35.

Another embodiment of the invention relates to a lead (100) as described above, wherein the transverse profile of at least one electrical contact (4, 4', 4", 4"') is between 5 % and 45 % less in area than that of a flanking region (6, 6', 6", 6"', 6"") of the shaft (2).

Another embodiment of the invention relates to a kit comprising a lead (100) as defined above, and an implantable pulse generator.

Another embodiment of the invention relates to a method for preparing a lead (100) as defined above, comprising the step of crimping a ring shaped electrical contact (4, 4', 4", 4"') over the shaft (2) by the application of a radial pressure to the electrical contact determined according to the material, dimension and thickness of the electrical contact.

FIGURE LEGENDS

FIG. 1A Shows a view of the exterior of an atraumatic lead of the invention.

FIG. 1B Shows a magnified view of region 1BC indicated in FIG. 1A where, in one aspect, the electrical contacts are recessed and have flat edges abutting the probe shaft.

FIG. 1C Shows magnified view of region 1BC indicated in FIG. 1A where in one aspect, the electrical contacts are recessed and have rounded edges abutting the probe shaft.

FIG. 2A Shows a magnified view of region 1B indicated in FIG. 1A with transverse-cross section positions (B-B', C-C, D-D') and body zone (BZ) and contact zone (CZ) indicated.

FIG. 2B Shows a transverse-cross section through the plane perpendicular to the longitudinal (A-A') axis at position B-B' in FIG. 2A.

FIG. 2C Shows a transverse-cross section through the plane perpendicular to the longitudinal (A-A') axis at position C-C in FIG. 2A.

FIG. 2D Shows a transverse-cross section through the plane perpendicular to the longitudinal (A-A') axis at position D-D' in FIG. 2A.

FIG. 2E Shows a transverse-profile of the lead at position B-B' in FIG. 2A.

FIG. 2F Shows a transverse-profile of the lead at position C-C in FIG. 2A.

FIG. 2G Shows a transverse-profile of the lead at position D-D' in FIG. 2A.

FIG. 3 Shows a view of the exterior of an atraumatic lead of the invention with proximal slip ring contacts indicated.

FIG. 4 Shows a view of the exterior of an atraumatic lead of the invention with longitudinal **3AB** section indicated that is parallel to the longitudinal (A-A[1]) axis.

FIG. 4A Shows an enlarged view of a longitudinal-profile of the lead at position 3AB in FIG. 4, where the electrical contacts are recessed and have flat edges abutting the probe shaft.

FIG. 4B Shows an enlarged view of a longitudinal-profile of the lead at position 3AB in FIG. 4 where the electrical contacts are recessed and have rounded edges abutting the probe shaft.

FIG. 5 Shows a transverse-profile of the lead of the prior art at the location where the electrical contact joins an electrical conductor, and the joint is formed on the exterior of the contact.

FIG. 6 Shows a transverse-profile of the lead of the prior art at the position of the solder joint on the electrical contact, and the joint is formed on the inner surface of the contact.

FIG. 7 Magnified view of the distal region of an atraumatic lead constructed according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by one of skill in the art. All publications referenced herein are incorporated by reference thereto. All United States patents and patent applications referenced herein are incorporated by reference herein in their entirety including the drawings.

The recitation of numerical ranges by endpoints includes all integer numbers and, where appropriate, fractions subsumed within that range (e.g. 1 to 5 can include 1, 2, 3, 4 when referring to, for example, a number of articles, and can also include 1.5, 2, 2.75 and 3.80, when referring to, for example, measurements). The recitation of end points also includes the end point values themselves (e.g. from 1.0 to 5.0 includes both 1.0 and 5.0)

The terms "distal" and "proximal" are used through the specification, and are terms generally understood in the field to mean towards (proximal) or away (distal) from the surgeon side of the apparatus. Thus, "proximal" means towards the surgeon side denoted by reference sign 12 herein, and, therefore, away from the patient side. Conversely, "distal" means towards the patient side denoted by reference sign 20 herein, and, therefore, away from the surgeon side.

In the following detailed description of the preferred embodiments, reference is made to the accompanying drawings that form a part hereof, and in which are shown by way of illustration only of specific embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilised and structural or logical changes may be made without departing from the scope of the present invention. The following detailed description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

With reference to FIGs. 1A to 1C, the present invention relates to an implantable lead 100 for deep brain stimulation (DBS) comprising:

- a longitudinal shaft 2 formed from an electrically insulating material having a proximal 12 and distal end 20;

- two or more ring-shaped electrical contacts 4, 4^1, 4", 4'";

- wherein each electrical contact 4, 4^1, 4", 4'" extends circumferentially around the outside of the shaft 2, and the electrical contacts 4, 4^1, 4", 4'" are dispersed longitudinally on the shaft 2 in electrical isolation,

- wherein the outer surface of at least one electrical contact 4, 4^1, 4", 4'" is recessed compared with the outer surfaces of the flanking regions 6, 6^1, 6", 6'", 6"" of the shaft 2.

The use of recessed electrical contacts may provide one or more advantages. The edges of the contacts are sealed against the flanking regions of the shaft, meaning they do not present an edge for cutting, scrapping or snagging tissue during insertion and withdrawal. Moreover, a gradual size transition between each electrical contact and flanking region gives the electrical contact zone a rounded finish. The lead driven into the brain is able to advance without or with reduced hindrance; because the flanking regions are rounded in both the insertion and withdrawal directions, withdrawal is equally atraumatic. There may be a significant reduction in damage to the tissue, moreover, the surgeon is able to insert and withdraw the lead more rapidly, thereby establishing the target region quickly. A magnified view of an exemplary lead characterised by the invention is provided in FIG. 7.

The longitudinal shaft 2, has a proximal 12 and distal end 20, and a longitudinal axis (A-A^1) in the straight (unbent) state. The longitudinal shaft 2 is formed from a fluid impermeable, electrically insulating material. Examples of suitable materials include bio-compatible polymeric substances, and other electrically-insulative materials. For example, the longitudinal shaft may be made from a flexible material such as polyurethane, pellethane, Teflon, silicone rubber or the like. It typically, but not necessarily, has a cylindrical shape. For example, in some embodiments, the shaft 2 may have alternative profiles such as square, rectangular, hexagonal, or oval.

The shaft may be solid *i.e.* without a lumen. Alternatively, and reference to FIGs. 2A to 2D, the shaft 2 may be at least partly hollow; in other words it may be disposed at least partly with an inner lumen 8. The lumen preferably extends from the proximal 12 to the distal end 20. Where the part of the shaft 2 over which the electrical contacts (4, 4^1, 4", 4"') are disposed is moulded (contact zone, CZ, see later below), the lumen 8 may also extend through the moulded region. Alternatively, the lumen 8 may extend essentially proximal 12 to the proximal 12 most flanking region (e.g. 6) when the part of the shaft 2 over which the electrical contacts (4, 4^1, 4", 4"') are disposed is moulded (see later below). The lumen 8 is preferably sealed at the distal 20 end to prevent entry of fluid into the lumen 8 *in situ.* The lumen 8 may be adapted to receive a stiffened stylet to provide temporarily the distal end 20 with enhanced column strength to support insertion, which stylet gains entry through a port in the proximal end of the shaft 2. The stylet can preferably be advanced all the way through the lumen 8 to the distal end 20. The lumen 8 may alternatively be sealed at the proximal 12 end to prevent ingress of dust, dirt and fluids. The distal end of the shaft 2 is preferably rounded and or softened *i.e.* it is provided with an atraumatic tip.

Disposed towards the distal end 20 of the shaft are the electrical contacts 4, 4^1, 4", 4"'. Electrical conductors 10, 10', 10", 10"' extending longitudinally along the shaft connect the distal electrical contacts 4, 4^1, 4", 4"' to the proximal end 12 of the shaft 2. A conductor may be attached to a contact by any suitable means including soldering, welding, crimping, wire-bonding or by way of other suitable electrical joint.

According to one embodiment of the invention, the distal 20 end of at least one, preferably all electrical conductors 10, 10', 10", 10"' is electrically connected to an electrical contact 4, 4^1, 4", 4"' *via* an electrical joint located on the inner circumferential surface of the electrical contact 4, 4^1, 4", 4"'. The electrical joint is preferably a solder or weld joint. Preferably, the electrical joint is exclusively located on the inner circumferential surface of the electrical contact 4, 4^1, 4", 4"'. By confining the joint so, the outer circumferential surface of the distal electrical contact 4, 4^1, 4", 4"' is devoid of joint material, which would otherwise traumatize tissue upon lead insertion without the additional step of smoothing. FIG. 5 depicts the state of the art where the joint 14 is located on the exterior surface 16 of the electrical contact 4, while FIG. 6 shows an embodiment of the invention where the joint 14 is exclusively located on the inner circumferential surface 18 of the electrical contact 4.

In FIG. 2B, four electrical conductors 10, 10', 10", 10"' are visible in the shaft 2 lumen 8 in the zone proximal to the electrical contacts, one conductor for each electrical contact 4, 4^1, 4", 4"'. FIG. 2C corresponds to a transverse cross-section (perpendicular to the A-A' axis) through one electrical contact 4" of the shaft 2, whereby one electrical conductor 10 is visible that is connected to the distal-most electrode 4"', and an electrical connection 11 between the outer contact 4" and conductor 10' is seen. FIG. 2D shows a transverse cross-section through one flanking region 6"' of the shaft 2, whereby one electrical conductor 10 is visible that is connected to the distal-most electrode 4"'. The conductors 10, 10', 10", 10"' may be fixed on or in the wall of the lumen 8 as shown in FIGs. 2B to 2D in which case the conductors need not be coated or sheathed with an insulating material, though this is not excluded. Alternatively, the conductors may pass though the lumen 8 as a bundle of conductors, loose or bound, in which case each conductor would need to be coated or sheathed with an insulator such as PVC or other polymeric material.

The conductors 10, 10', 10", 10"' may exit at the proximal end 12 of the shaft 2. Alternatively, the conductors may terminate in an electrical connector attached to the proximal terminal end 12 of the shaft 2. The electrical connector is typically formed from a plurality of conductive slip rings 24, 24', 24" arranged in longitudinal displacement at the proximal end 12 of the shaft 2 in electrical isolation, one slip ring for each electrical contact. Slip ring connectors of this type are well known in the art. The electrical connector is configured for electrical and mechanical connection to an extension lead or into a header unit of an implantable pulse generator (IPG), which devices contain a reciprocating arrangement of electrical contacts. Thereby, each electrical contact 4, 4[1], 4", 4"' can be independently stimulated using an electrical means attached to the proximal end 12 of the shaft 2 via the connector.

At least the distal end shaft 2 is configured for pushability into the neural tissue, meaning it is resistant to kinking and can be inserted with the normal force without undue buckling. It will be appreciated that pushability depends several factors such as the materials used in the shaft, the outer diameter of the shaft and lumen diameter. Generally, the factors are balanced to minimise the outer diameter of the shaft and maximize the lumen space available for the passage of conductors and optional stylet. The dimensions of the shaft, therefore, are typically within the limits of known leads utilised in deep brain stimulation.

The distal end 20 of the shaft 2 may contain a section in the longitudinal direction known herein as a contact zone CZ, depicted in **FIG.** 3 which comprises the region of the shaft onto which the contacts 4 are disposed. The CZ may refer the part of the shaft 2, between the proximal most flanking region 6 and the distal terminal end 20 **(FIG.** 2A). However, it is to be understood that the CZ may not be limited strictly to the region of the shaft onto which the contacts are disposed, but may extend proximal 12 of the proximal most electrode and/or extend distal 20 of the distal most electrode. The proximal end 20 of the shaft 2 may contain a section in the longitudinal direction that known herein as the slip ring zone **(SRZ)** which comprises the region of the shaft onto which the slip rings 24, are disposed. It is to be understood that the **SRZ** may not be limited strictly to the region of the shaft onto which the slip-rings are disposed, but may extend distal 20 of the distal most slip ring and/or extend proximal 12 of the proximal most slip ring. The section of longitudinal shaft 2 joining the distal CZ and proximal **SRZ** is known herein as the body zone (BZ). The BZ is also the region proximal to the contact zone CZ.

As a general guidance, the maximum outer cross-sectional diameter of a cylindrical shaft 2, taken transverse to the longitudinal axis (A-A[1]), may be equal to or no more than 0.5 **mm, 0.6 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1 mm, 1.1 mm, 1.2 mm, 1.3 mm, 1.4 mm, 1.5 mm, 1.6 mm, 1.7 mm, 1.8 mm, 1.9 mm, 2.0 mm, 2.2 mm, 2.4 mm, 2.6 mm, 2.8 mm 3.0** mm, 4.0 mm, 6.0 mm, 8.0 mm, 10.0 mm, 12.0 mm, 14.0 mm or a value in the range between any two of the aforementioned values, preferably between 2.0 and 14.0 mm. According to one aspect of the invention, said diameter is 0.5 mm or greater. The aforementioned values preferably refer to the diameter of the shaft 2 in the contact zone (CZ - FIG. 2A) which is the part of the shaft 2, between the proximal most flanking region 6 and the distal terminal end 20.

In flanking regions sandwiched between contacts e.g. 6^1, 6", 6"', the outer cross-sectional diameter increases from a minimum diameter at the junction with an adjacent electrical contact 4, 4^1, 4", 4"' to a maximum diameter approximately mid-length of the flanking region 6^1, 6", 6"', and, decreases again in diameter toward the other adjacent electrical contact. In this manner, the flanking regions 6^1, 6", 6"' provides rounded surfaces that are smooth and not abrasive when driven into tissue.

The outer cross-sectional diameter of the shaft 2 region in the BZ (may be essentially constant from the proximal end 12 to the distal end 20. Alternatively, the shaft 2 in the body zone BZ may widen out towards the proximal end 12 where it does not enter the body, in order to provide more strength for attachment to other devices such as an extension lead or an IPG. As a general guidance, the maximum outer cross-sectional diameter of the cylindrical shaft 2 in the body zone BZ, taken transverse to the longitudinal axis (A-A^1), may be equal to or no more than 0.5 mm, 0.6 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1 mm, 1.1 mm, 1.2 mm, 1.3 mm, 1.4 mm, 1.5 mm, 1.6 mm, 1.7 mm, 1.8 mm, 1.9 mm, 2.0 mm, 2.2 mm, 2.4 mm, 2.6 mm, 2.8 mm 3.0 mm, 4.0 mm, 6.0 mm, 8.0 mm, 10.0 mm, 12.0 mm, 14.0 mm 15.0 mm, 16.0 mm, 17.0 mm, 18.0 mm or a value in the range between any two of the aforementioned values, preferably between 2.0 and 17.0 mm. According to one aspect of the invention, said diameter is 0.5 mm or greater.

The maximum cross-sectional diameter of a lumen 8, where present, taken transverse to the longitudinal axis (A-A^1), may be equal to or no more than 90 %, 80 %, 70 %, 60 %, 50 %, 40 %, 30 %, 20 %, or 10 % of the maximum outer cross-sectional diameter of a cylindrical shaft 2 in the contact zone CZ, or a value in the range between any two of the aforementioned values, preferably between 10 % and 90 %, more preferably between 20% and 70 %.

As a general guidance, the shaft length from the proximal 12 to distal end 20 may be equal to or no more than 10 cm, 20 cm, 40 cm, 60 cm, 80 cm, 100 cm, 120 cm, 140 cm, 160 cm, or 180 cm or a value in the range between any two of the aforementioned values, preferably between 10 and 70 cm.

The length of the contact zone CZ may be equal to or no more than 0.1 cm, 0.2 cm, 0.3 cm, 0.4 cm, 0.5 cm, 0.7 cm, 1 cm, 2 cm, 4 cm, 6 cm, 8 cm, 10 cm, 12 cm, 14 cm, 16 cm, or 18 cm or a value in the range between any two of the aforementioned values, preferably equal to or less than 1 cm, more preferably between 0.2 cm and 7 cm.

The longitudinal region of the shaft in the contact zone (CZ) may be formed from a hollow tube, that is a continuous extension of the hollow shaft 2 in the shaft body zone (BZ). Alternatively, the CZ may be moulded according to known techniques such as injection moulding. Suitable moulding techniques are performed according to the art, as described, for example, in Douglas M. Bryce. Plastic Injection Moulding: Manufacturing Process Fundamentals. SME, 1996. Suitable materials for the moulded CZ include epoxy and phenolic polymers, nylon, polyethylene, polyurethane or the like. It will be understood that a moulded CZ is formed separately from the shaft body zone (BZ), and they may be later co-joined using an adhesive, heat bonded, or frictional joint or the like. It will be appreciated that the longitudinal axes of the respective parts are co-axially aligned. The lumen 8 of the BZ may extend at least partially through the moulded CZ; a lumen in the moulded region may be achieved using a suitable spacer in the mould.

The distal 20 end of the shaft 2 *i.e.* the CZ, may be moulded and comprise the region along which the electrical contacts 4, 4^1, 4'', 4''' are arranged. A moulded end provides a firmer structure for mounting the electrical contacts, which does not kink or buckle when the contacts are radially compressed over the shaft. Accordingly, the contacts do not translate longitudinally, for example, during insertion or withdrawal, and the spacing between contacts can be reduced.

The CZ may be moulded using a material composition and volume that is constant along the longitudinal length of the CZ. Such moulding generates a CZ that has uniform stiffness and optionally uniform hardness along the longitudinal length. Alternatively, the CZ may comprise a first sub-region (stiffened zone **(SCZ, FIG.** 3)) at the distal 20 end of the CZ having a uniform stiffness and optionally uniform hardness along the longitudinal length, and a second sub-region (region of transitional flexibility **(TCZ))** in which its flexibility and optionally hardness gradually transitions in the proximal 12 direction towards the more flexible and lower hardness body zone BZ. In other words, the flexibility and optionally hardness of the **TCZ** transition gradually from the stiff and optionally harder **SCZ** to the flexible (less stiff) and optionally lower hardness BZ. The **TCZ** abuts the **SCZ** and the BZ. The electrical contacts 4, 4\ 4" may be disposed exclusively in the **SCZ.** The skilled person will understand that hardness may be measured according to the ASTM D2240 type A or type D scales. The longitudinal length of **SCZ** may be 20 %, 30 %, 40 %, 50 %, 60 %, 70 %, 80 % or 90 % of the length of the contact zone CZ. The transition of flexibility and optionally hardness may be achieved by employing materials of different stiffness and optionally hardness in the moulding and/or a thicker or solid wall where stiffness and optionally hardness is required. The **TCZ** provides a gradually changing flexibility and optionally hardness from a stiffer and optionally higher hardness **SCZ** to a less stiff (more flexible) and lower hardness BZ, thereby imparting differential flexibility and optionally hardness on the shaft 2. The transitional flexibility reduces stress forces at the interface between the CZ and the BZ, preventing or reducing the damage to the shaft in the folded or coiled state.

The longitudinal region of the shaft in which the slip rings are disposed, the slip ring zone **(SRZ, FIG.** 3), may be formed from a hollow tube, that is a continuous extension of the hollow shaft 2 in the shaft body zone (BZ). Alternatively, the **SRZ** may be moulded according to known techniques such as injection moulding. Suitable moulding techniques are performed according to the art, as described, above. Suitable materials for the moulded **SRZ** include epoxy and phenolic polymers, nylon, polyethylene, polyurethane or the like. It will be understood that a moulded **SRZ** may be formed separately from the shaft body zone (BZ), and they may be later co-joined using an adhesive, heat bonded, or frictional joint or the like. It will be appreciated that the longitudinal axes of the respective parts are co-axially aligned. The lumen 8 of the BZ may extend at least partially through the moulded **SRZ;** a lumen in the moulded region may be achieved using a suitable spacer in the mould. The stiffened CZ provides the requisite pushability, without kinking, to advance the proximal end into a connector of an extension lead or into a header unit of an implantable pulse generator (IPG), which devices contain a reciprocating arrangement of electrical contacts.

The proximal 12 end of the shaft *i.e.* the **SRZ** may be moulded and comprise the region along which the slip-rings 24, 24', 24" are arranged. A moulded end provides a firmer structure for mounting the slip rings, which does not kink or buckle when the rings are radially compressed over the shaft.

The SRZ may be moulded using a material composition and thickness that is constant along the longitudinal length of the SRZ. Such moulding generates a SRZ that has uniform stiffness and optionally hardness along the longitudinal length.

Alternatively, the SRZ may comprise may comprise a first sub-region (stiff zone (SSR)) at the proximal 12 end of the SRZ having a uniform stiffness and optionally hardness along the longitudinal length, and a second sub-region ((region of transitional flexibility (TSR)) in which its flexibility and optionally hardness gradually transitions in the distal 20 direction towards the more flexible and optionally lower hardness body zone BZ. In other words, the flexibility and optionally hardness of the TSR transitions gradually from the stiff and optionally higher hardness SRZ to the flexible (less stiff) and optionally lower hardness BZ. The TSR abuts the SSR and the BZ. The slip rings 24 may be disposed exclusively in the SCZ. The skilled person will understand that hardness may be measured according to the ASTM D2240 type A or type D scales. The longitudinal length of SSR may be 20 %, 30 %, 40 %, 50 %, 60 %, 70 %, 80 % or 90 % of the length of the slip ring zone SRZ. The transition of flexibility and optionally hardness may be achieved by employing materials of different stiffness and optionally hardness in the moulding and/or a thicker or solid wall where stiffness and optionally hardness is required. The TSR provides a gradually changing flexibility and optionally hardness from a stiffer and optionally higher hardness SSR to a less stiff (more flexible) and optionally lower hardness BZ, thereby imparting differential flexibility and optionally hardness on the shaft 2. The transitional flexibility and optional hardness reduces stress forces at the interface between the SRZ and the BZ, preventing or reducing the damage to the shaft in the folded or coiled state. It also absorbs lateral tension applied to the shaft engaged with an extension lead or header unit of the IPG.

Two or more ring-shaped electrical contacts 4, 4^1, 4", 4''' are disposed towards the distal 20 end of the shaft 2. The electrical contacts are formed from a bio-compatible, electrically conductive material. Examples of suitable materials include platinum, platinum iridium alloy, nickel-cobalt alloy and MP35. The number of electrical contacts 4, 4^1, 4", 4''' on a shaft 2 may vary according to a given stimulation application. In some embodiments, the shaft 2 may include 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36 more contacts 4, 4", 4", 4^{111} or a number in the range between any two of the aforementioned numbers, preferably between 4 and 16, to provide a large number of independently accessible stimulation orientations within a target stimulation site. An electrical contact typically, but not necessarily, has a cylindrical shape. For example, in some embodiments, an electrical contact may have an alternative profile such as square, rectangular, hexagonal, or oval.

At least one, preferably each and every electrical contact 4, 4^1, 4", 4'" extends circumferentially around the outside of the shaft 2, more in particular, around the A-A^1 axis. The contacts are dispersed longitudinally along the shaft 2 in electrical isolation. The result is a plurality of contacts 4, 4^1, 4", 4'" arranged along the shaft 2, where each contact is flanked by an isolating region 6, 6^1, 6", 6'", 6"" of shaft 2. The electrical contacts 4, 4^1, 4", 4'" may be circumferentially intact, meaning there may be no slits or cuts through the ring of the contact, however, this does not exclude the possibility of utilizing C-shaped rings. One or more, preferably all electrical contacts 4, 4^1, 4", 4'" may be arranged essentially co-axially with respect to the shaft 2. One or more, preferably all electrical contacts 4, 4^1, 4", 4'" may be arranged essentially concentrically with respect to the shaft 2.

The dimensions of the contacts are within the limits of known leads used in deep brain stimulation in terms of their length and area. As a general guidance, given a surface area of approximately 30 to 450 square mm, each electrical contact 4, 4^1, 4", 4'" may have a surface area of approximately 0.25 to 25 square mm for eight contacts, approximately 0.25 to 15 square mm for sixteen contacts, and approximately 0.125 to 10 square mm for thirty-two contacts. Electrical contacts 4, 4^1, 4", 4'" of the size and number described above should provide a relatively large number of independently accessible stimulation sites while leaving sufficient spacing between electrodes to avoid excessive redundancy. The maximum outer cross-sectional diameter of an electrical contact 4, 4^1, 4", 4'", taken transverse to the longitudinal axis (A-A^1), is essentially constant along the length of the contact. The above dimensions may vary according to the application envisioned for lead 100.

Electrical contacts 4, 4^1, 4", 4'" may have common or different sizes and be positioned along the longitudinal length of the shaft at regular or irregular intervals. At least one (preferably all) of the electrical contacts 4, 4^1, 4", 4'" is connected to an electrical conductor 10, 10', 10", 10'" that exits the lead at the proximal end 12 of the shaft 2. Alternatively, at least one (preferably all) of the electrical contacts 4, 4^1, 4", 4'" is connected to a separate electrical conductor 10, 10', 10", 10'" that terminates in an electrical connector at the proximal end 12 of the shaft 2.

The outer surface of at least one electrical contact 4, 4', 4", 4"' is recessed compared with the outer surface the shaft 2. The outer surface of at least one electrical contact 4, 4^1, 4", 4"' is recessed compared with the outer surfaces of the flanking regions 6, 6^1, 6", 6"', 6"" of the shaft 2. Preferably, the entire circumference of the electrical contact 4, 4^1, 4", 4"' is recessed. Preferably, the outer surface of all the electrical contacts 4, 4^1, 4", 4"' are recessed. The recessed electrical contacts 4, 4^1, 4", 4"' may further be sheathed with a directional shield as described, for instance, in US 2005/0171587 which is incorporated herein by reference, which sheath is concentrically arranged over the distal end of the shaft 2. According to one aspect of the invention, the shaft is devoid of such directional shield.

The size transition between the outer surface of a recessed electrical contact (e.g. 4") and outer surfaces of the flanking regions (e.g. 6", 6"') of the shaft 2 may be gradual, meaning there is no abrupt size transition.

Preferably, the transition between the outer surface of a recessed electrical contact (e.g. 4") and outer surfaces of the flanking regions (e.g. 6", 6"') of the shaft 2 is met by a change in the transverse profile of the flanking regions (e.g. 6", 6"') as opposed to only a change in the transverse profile of the recessed electrical contact (e.g. 4").

The transverse profile refers to the outer shape of a section through the lead **100** in a plane perpendicular to the longitudinal (A-A^1) axis, as exemplified in **FIG.** 2E (profile across line B-B^1 in **FIG.** 2A), **FIG.** 2F (profile across line C-C in **FIG.** 2A), and **FIG.** 2G (profile across line D-D^1 in **FIG.** 2A). Thus, the diameter of the circular transverse profile of an electrical contact 4" **(FIG.** 2F) as a function of its length may be essentially constant, compared with the diameter of the circular transverse profile of flanking region 6"' **(FIG.** 2G) as a function of its length; the latter exhibits reduced diameter towards the interface with an adjacent electrical contact 4". Thus, the transverse profiles of the outer surfaces of the flanking regions (e.g. 6", 6^{111}) of the shaft 2 may transition gradually toward the transverse profile of the outer surface of the recessed electrical contact (e.g. 4").

According to one aspect of the invention, the diameter of the circular transverse profile of an electrical contact 4" **(FIG.** 2F) as a function of its length may exhibit a reduced diameter towards the interface with an adjacent flanking region (e.g. 6", 6^{111}). This embodiment is depicted in **FIGs. 1C** and **4B** where both the proximal 12 and distal 20 edges of each electrical contact are each disposed with a rounded shoulder, preferably in a convex. Thus, the transverse profiles of the outer surfaces of the electrical contacts (e.g. 4', 4") of the shaft 2 may transition gradually toward the transverse profile of the outer surface of the adjacent flanking region (e.g. 6"). By providing shoulders at the edges of the contact that are convex, each contact adopts a rounded form that is efficient at conductance of stimulatory signals tangential to the surface of the electrode *i.e.* signals propagate closer to spherically compared with a cylindrical propagation when the electrode is not rounded.

The transverse profile of at least one electrical contact 4, 4', 4", 4"' **(FIG.** 2F) may be less in area than that of an adjacent flanking region 6, 6', 6", 6"', 6"" **(FIG.** 2G) of the shaft 2 **(FIG.** 2E). The transverse profile of at least one electrical contact 4, 4', 4", 4"' **(FIG.** 2F) may be equal to or at least 2 %, 5 %, 10 %, 15 %, 20 %, 25 %, 30 %, 35 %, 40 %, 45 %, 50 %, 60 %, 70 %, or 80 % less in area than that of an adjacent flanking region 6, 6', 6", 6"', 6"" **(FIG.** 2G) of the shaft 2 **(FIG.** 2E), or a value in the range between any two of the aforementioned values, preferably between 5 % and 50 %. The measurement preferably compares profiles obtained across maximum diameters.

The gradual size transition may alternatively be realised by any suitable longitudinal profile of the flanking regions (e.g. 6", 6"'). The longitudinal profile refers to the outer shape of a section through the lead **100** in a plane parallel to the longitudinal (A-A') axis, as exemplified in **FIGs. 4A and B.**

Preferably, the longitudinal profile of the size transition of a flanking region (e.g. 6") adjacent to the electrical contact (e.g. 4', 4") has a convex shape. Preferably, the bulging curve of the convex profile 26 abuts 8 the essentially oblong profile of the adjacent electrical contact (e.g. 4). This embodiment is depicted in **FIG.** 4A. According to another embodiment of the invention, the longitudinal profile of a flanking region (e.g. 6) adjacent to the electrical contact (e.g. 4) has an arc shape, the arc being a section of a circle; preferably, the outward curve of the arc profile abuts 8 the essentially oblong profile of the adjacent electrical contact (e.g. 4). By presenting a plurality of convex surfaces, tissue is directed away from the electrical contacts upon insertion or withdrawal of the lead. This contributes to an ease of passage through the tissue, without surface tension drawing the tissue onto the contacts which other e.g. gradually sloping profiles can cause.

Preferably, the longitudinal profile of the size transition of an electrical contact (e.g. 4', 4", **FIG.** 4B) adjacent to the flanking region (e.g. 6) has a convex shape. Preferably, the bulging curve of the convex profile 26' of the electrical contact 4^1, 4" abuts 8 the profile of the adjacent electrical contact (e.g. 6"). According to another embodiment of the invention, the longitudinal profile of the electrical contact (e.g. 4^1, 4") adjacent to the flanking region (e.g. 6") has an arc shape, the arc being a section of a circle; preferably, the outward curve of the arc profile abuts 8 the profile of the adjacent flanking region (e.g. 6"). By presenting a plurality of convex surfaces, tissue is directed away from the electrical contacts upon insertion or withdrawal of the lead. This contributes to an ease of passage through the tissue, without surface tension drawing the tissue which other e.g. gradually sloping profile can cause. It further provides each contact with a rounded form that is efficient at radial conductance of stimulatory signals.

Another embodiment of the invention concerns a method for the manufacture of an atraumatic lead of the invention.

According to one aspect of the invention, the method of manufacture comprises the step of crimping a ring shaped electrical contact 4, 4^1, 4", 4"' over the shaft 2 by the application of a radial pressure to the electrical contact. The radial pressure is that which reduces the diameter of the electrical contact such that electrical contact is recessed. The radial pressure is determined according to the material, dimension and thickness of the electrical contact as understood by the skilled artisan.

Typically, a length of shaft is provided, having two longitudinally displaced holes at the distal end that join the lumen to the surface, which holes serve as outlets for electrical conductors that connect the electrical contacts to the proximal end of the shaft. The position of the holes is coincident with the positions of the electrical contacts. A ring-shaped electrical contact is placed over each hole through which an electrical conductor protrudes. Each contact is pressed using a radial press that compresses the ring radially towards its central axis, thereby reducing its diameter. The radial press is set to reduce the diameter until is in the recessed condition. The radial compression force may be sufficient also to conductively crimp the electrical conductor to the corresponding contact without the need for soldering. The radial compression may be greater at the edges of the contact so as to provide each contact with a rounded shoulder at the proximal and distal edges of the contact.

As mentioned above, at least one (preferably all) electrical conductors 10, 10', 10", 10"' may be connected to an electrical contact 4, 4^1, 4", 4"' *via* an electrical joint located exclusively on the inner circumferential surface of the electrical contact 4, 4', 4", 4'". This avoids forming a contact on the exterior surface of the electrical conductors 10, 10', 10", 10'" which would otherwise traumatize tissue upon lead insertion without the additional step of smoothing.

The electrical contacts 4, 4', 4", 4'" carried by a lead 100 as described herein may be used to deliver a variety of electrical stimulations to a desired target in the brain, and thereby deliver a variety of therapies, for example as described in US 5,843,148, US 6,01 1,996, US 6,253,109, and US 6,319,241 . The stimulation may take the form of a pulse pattern generated by a pulse generator, typically an IPG that is emitted by one or more contacts 4, 4', 4", 4'" in a synchronised or unsynchronised manner. For example, the pulse pattern of electrical stimuli can include pairs of two or more electrical stimuli delivered from different contact pairs 4, 4', 4", 4'" to the brain structure. Alternatively, the pulse pattern of electrical stimuli can be a short train, or burst, of a predetermined number of stimuli. The exact pattern and number of electrical stimuli in the pulse pattern may be selected based in part on the brain structure to which the stimuli are delivered, and the particular brain disorder to be treated. In one embodiment, the pulse pattern may be repeated such that the electrical stimuli are continuously delivered to the patient.

The pulse pattern may be a pair of stimuli delivered to the brain structure. In this example, the pair of stimuli includes a first and a second stimulus, where the stimuli are delivered by different contact 4, 4', 4", 4'" pairs and separated by a predetermined time interval. The predetermined time interval may be a value in the range of approximately 5 to 2000 milliseconds. The specific time interval used depends upon the brain structure being treated, and may be a programmable value.

Additional electrical stimulus parameters are also programmable. Exact parameter values are specific for the brain structure involved. For example, the duration of each stimulus can be selected to fall in a range of approximately 30 microseconds to 10 milliseconds. Additionally, the waveform shape of the stimuli can also be programmed. Waveform shapes can include, but are not limited to, rectangular, sinusoidal and/or ramped shapes Other known waveform shapes can also be useful.

The magnitude of each stimulus of the pulse pattern may also be a selectable value in a range of approximately 10 microamperes to 10 milliamperes. Also, the pulse pattern of electrical stimuli may be delivered two or more times. In one embodiment, the pulse pattern may be repeatedly delivered to the patient in order to continuously treat the patient. The repeated delivery of the pulse pattern may include a repetition frequency, where the repetition frequency is programmed in the range of approximately 1 second to 30 minutes. Other values are also possible.

Deep brain stimulation can be effective in the management of chronic pain of neuropathic and or nociceptive origin. In addition, deep brain stimulation can be used to treat movement disorders, such as Parkinsons Disease, as well as epilepsy and psychiatric disorders.

The lead 100 of the invention may be used alone or in combination. For example, unilateral stimulation of the brain is typically accomplished using a single lead 100 implanted in one side of the brain, while bi-lateral stimulation of the brain is typically accomplished using two leads 100 implanted in opposite sides of the brain.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, therefore, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the invention or the scope of the appended claims. For example, the present invention is not limited to lead configurations with cylindrical ring electrodes. In some embodiments, machined C-shaped ring electrodes could be embedded in a lead body to form selected electrode surfaces without windowing techniques. The present invention includes within its scope methods of implanting, using and making the leads described hereinabove.

*

CLAIMS

1. An implantable lead (100) for deep brain stimulation comprising:

- a longitudinal shaft (2) formed from electrical insulating material having a proximal (12) and distal end (20);

- two or more ring-shaped electrical contacts (4, 4', 4", 4"');

- wherein each electrical contact (4, 4', 4", 4"') extends circumferentially around the longitudinal axis (A-A') of the shaft (2), and the electrical contacts (4, 4', 4", 4"') are dispersed longitudinally on the shaft (2) in electrical isolation;

- wherein the outer surface of at least one electrical contact (4, 4', 4", 4"') is recessed compared with the outer surfaces of the flanking regions (6, 6', 6", 6"', 6"") of the shaft (2); and

- wherein at least one of the electrical contacts (4, 4', 4", 4"') is electrically connected to a conductor (10, 10', 10", 10"') that exits the lead at the proximal end (12) of the shaft (2), the connection being *via* an electrical joint (14, FIG. 6) located exclusively on the inner circumferential surface (18) of the electrical contact (4, 4', 4", 4"').

2. Lead (100) according to claim 1, wherein a flanking region (6, 6', 6", 6"', 6"") is rounded at the junction with an electrical contact (4, 4', 4", 4"').

3. Lead (100) according to claim 2, wherein the longitudinal profile of at least one flanking region (6") adjacent to the electrical contact (4', 4") has a convex shape where the bulging curve of the convex profile (26, FIG. 4A) directly abuts (8) the profile of the adjacent electrical contact (4', 4").

4. Lead (100) according to any of claims 1 to 3, wherein the longitudinal profile of at least one electrical contact (4', 4") adjacent to the flanking region (6") has a convex shape where the bulging curve of the convex profile (26', FIG. 4B) directly abuts (8) the profile of the adjacent flanking region (6").

5. Lead (100) according to any of claims 1 to 4, wherein each of the electrical contacts (4, 4', 4", 4"') is circumferentially intact.

6. Lead (100) according to any of claims 1 to 5, wherein:

- the shaft (2) is cylindrical, and

- the ring-shaped electrical contacts (4, 4', 4", 4"') are cylindrical.

7. Lead (100) according to any of claims 1 to 6, wherein the electrical contacts (4, 4', 4", 4"') are arranged along the distal (20) part of the shaft (2).

8. Lead (100) according to any of claims 1 to 7, wherein at least part of the shaft (2) is disposed with a lumen (8).

9. Lead (100) according to any of claims 1 to 8, wherein the distal (20) end of the shaft (2) is moulded and comprises the region along which the electrical contacts (4, 4', 4", 4"') are arranged.

10. Lead (100) according to claim 9, wherein the moulded part of the shaft (2) comprises:
- a first sub-region (SCZ, FIG. 3) having longitudinal uniform stiffness and optionally uniform hardness; and
- a second sub-region region (TCZ, FIG. 3) abutting the first sub-region having a flexibility and optionally hardness that gradually transitions longitudinally in the proximal (12) direction from the first sub-region (SCZ) towards a shaft (2) body (BZ) that is more flexible and has optionally lower hardness than the first sub-region of the distal moulded end.

11. Lead (100) according to any of claims 1 to 10, wherein the at least one electrical contact (4, 4', 4", 4"') terminates in an electrical connector at the proximal end (12) of the shaft (2).

12. Lead (100) according to claim 11, wherein
- the electrical connector is a slip-ring (24, 24', 24"); and
- the proximal (12) end of the shaft (2) is moulded and comprises the region along which the slip-rings (24, 24', 24") are arranged.

13. Lead (100) according to claim 12, wherein the moulded part of the shaft (2) comprises:
- a first sub-region (SSR, FIG. 3) having longitudinal uniform stiffness and optionally hardness; and
- a second sub-region region, (TSR, FIG. 3), abutting the first sub-region having a flexibility and optionally hardness that gradually transitions longitudinally in the proximal (12) direction from the first sub-region (SSR) towards a shaft body (BZ) that is more flexible and optionally has lower hardness than the first sub-region of the moulded proximal end.

14. Lead (100) according to any of claims 1 to 13, wherein the shaft (2) is made from a biocompatible flexible material configured for pushability for advancement into brain tissue.

15. Lead (100) according to any of claims 1 to 14, wherein the body of the shaft (2) is made from polyurethane.

16. Lead (100) according to any of claims 1 to 15, wherein at least one electrical contact (4, 4', 4", 4"') is made from platinum, platinum-iridium or MP35.

17. Lead (100) according to any of claims 1 to 16, wherein the transverse profile of at least one electrical contact (4, 4', 4", 4"') is between 5 % and 45 % less in area than that of a flanking region (6, 6', 6", 6"', 6"") of the shaft (2).

18. Kit comprising a lead (100) as defined in any of claims 1 to 17, and an implantable pulse generator.

19. Method for preparing a lead (100) as defined in any of claims 1 to 17, comprising the step of crimping a ring shaped electrical contact (4, 4', 4", 4"') over the shaft (2) by the application of a radial pressure to the electrical contact determined according to the material, dimension and thickness of the electrical contact.

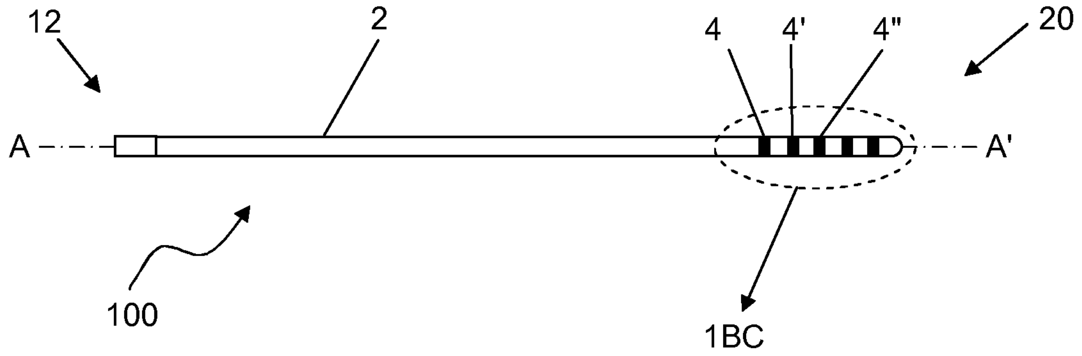


FIG. 1A

FIG. 1B

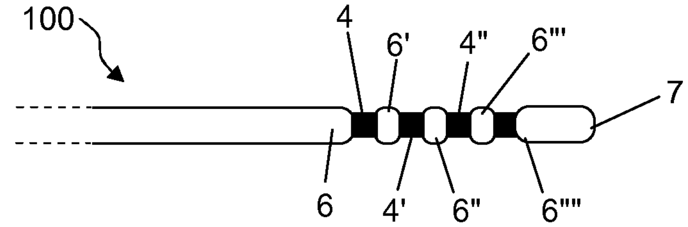
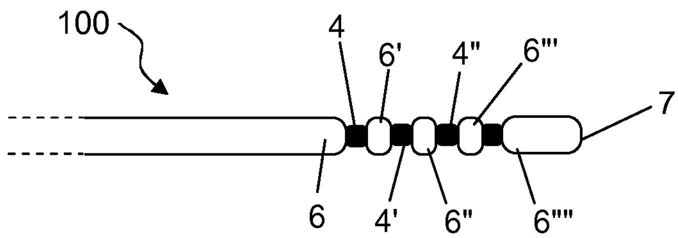


FIG. 1C



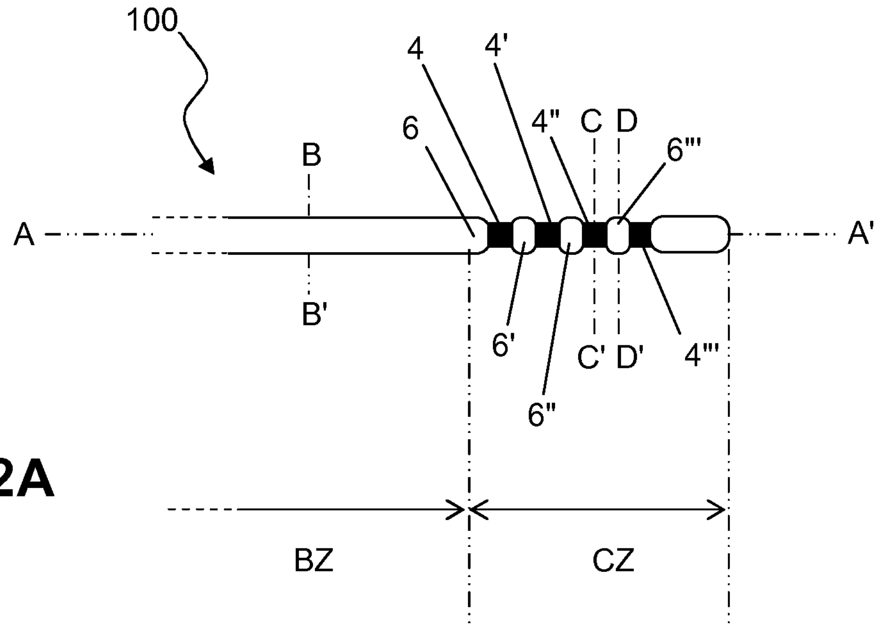
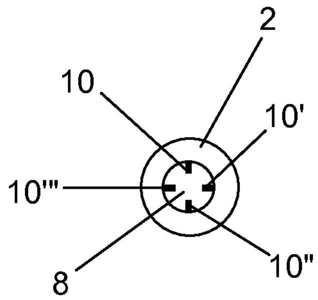
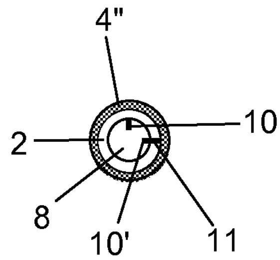


FIG. 2A



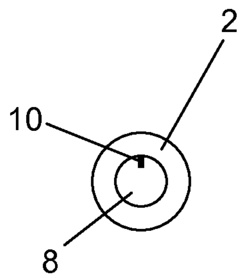
B-B'

FIG. 2B



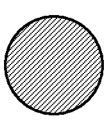
C-C'

FIG. 2C



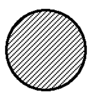
D-D'

FIG. 2D



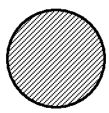
B-B'

FIG. 2E



C-C'

FIG. 2F



D-D'

FIG. 2G

FIG. 3

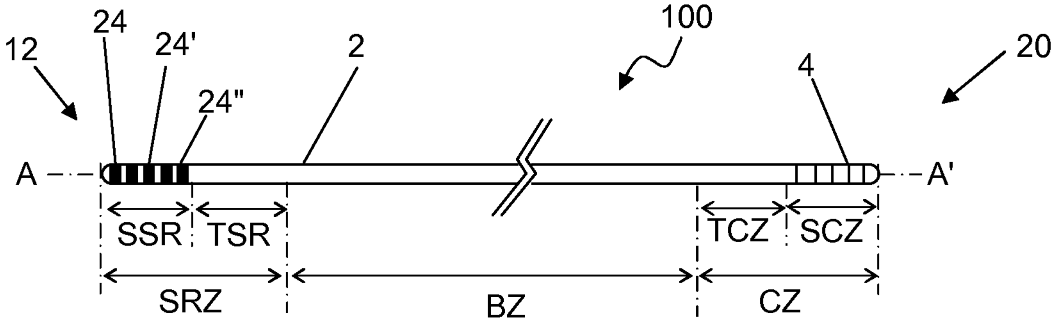


FIG. 4

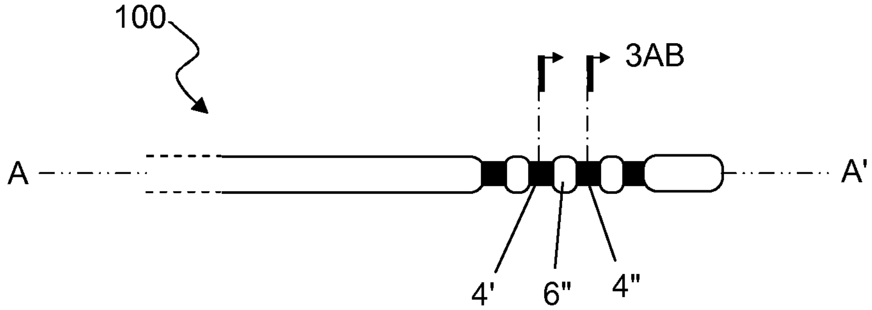


FIG. 4A

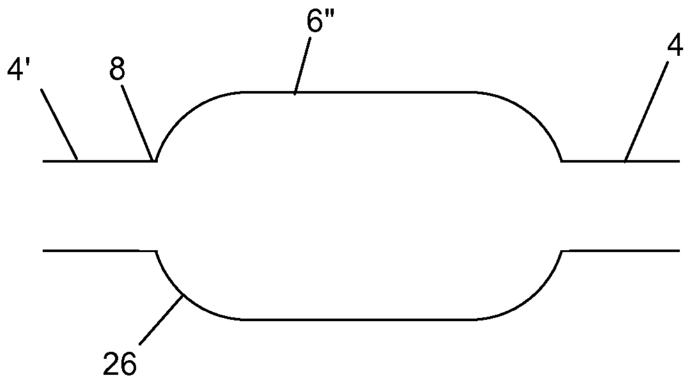
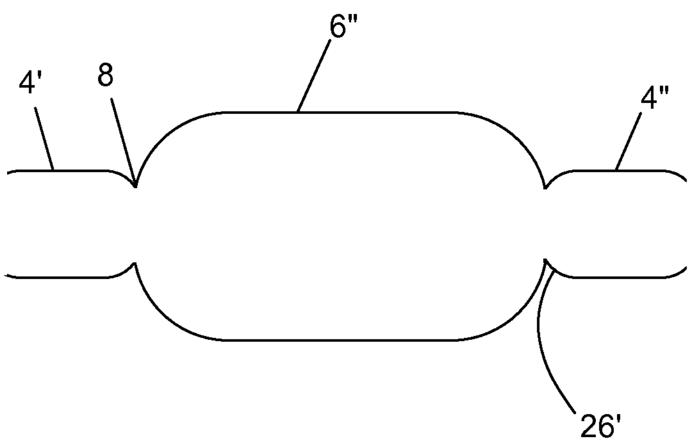
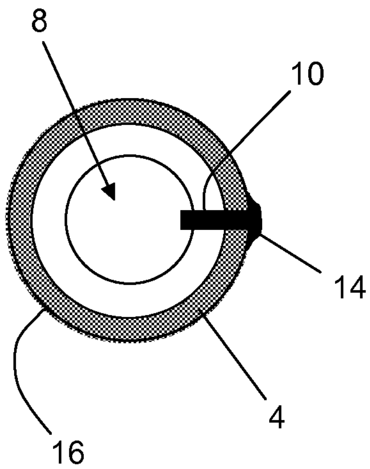


FIG. 4B





PRIOR ART
FIG. 5

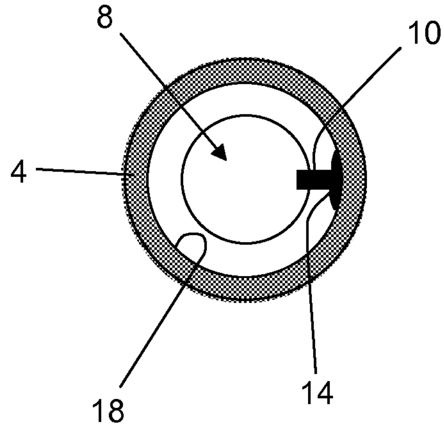


FIG. 6

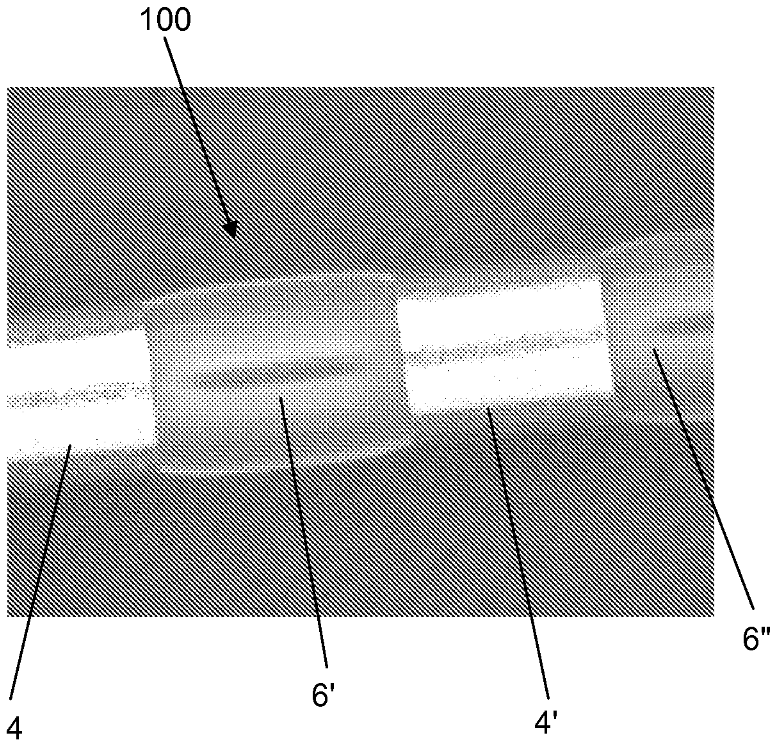


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/059099

A. CLASSIFICATION OF SUBJECT MATTER
INV . A61N1/05
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

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

Electronic data base consulted dunng the international search (name of data base and where practical search terms used)

EPO-Internal

C DOCUMENTS CONSIDERED TO BE RELEVANT

Category'	Citation of document with indication where appropnate, of the relevant passages	Relevant to claim No
X	WO 2009/025816 Al (MEDTRONIC INC [US]; BOURN DAVID WAYNE [US]; SOMMER JOHN L [US]; MARSHA) 26 February 2009 (2009-02-26) paragraph [0035] paragraphs [0060] - [0067]; figures 4a, 4b, 5a, 5b paragraph [0077] paragraph [0089] - paragraph [0092]; figure 6	1-19
Y	WO 2008/005142 Al (MEDTRONIC INC [US]; KING GARY W [US]; TIDEMAND KEVIN K [US]; WESSELINK) 10 January 2008 (2008-01-10) paragraph [0096] paragraphs [0108] - [0116]; figures 2a-2b	1-19
	-/--	

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

[X] See patent family annex

* Special categoпes of cited documents

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

"E' earlier document but published on or after the international filing date

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

O ' document refernng to an oral disclosure, use, exhibition or other means

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

[1]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
6 October 2010	14/10/2010

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	Loveniers, Kris

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation ot document, with indication, where appropnate, of the relevant passages	Relevant to claim No
Y	US 2005/228469 Al (ZAREMBO PAUL E [US] ET AL) 13 October 2005 (2005-10-13) paragraphs [0030] - [0038] ; figures 2-5 -----	1-19
A	EP 0 647 435 Al (ARROW INT INC [US] ARROW INT INVESTMENT [US]) 12 April 1995 (1995-04-12) column 8, line 40 - column 9, line 30 -----	16
A	US 5 014 720 A (BARCEL JAMES E [US] ET AL) 14 May 1991 (1991-05-14) column 2, line 42 - column 3, line 8; figures 2-3 column 3, line 18 - column 4, line 19; figures 4-7 -----	1-19
A	US 4 214 804 A (LITTLE RICHARD L [US]) 29 July 1980 (1980-07-29) column 2, lines 1-46; figures 1-3 -----	1-19
A	US 2005/171587 Al (DAGLOW TERRY [US] ET AL) 4 August 2005 (2005-08-04) paragraphs [0006] - [0007] paragraphs [0023] - [0024] paragraphs [0048] - [0052] paragraphs [0057] - [0061] ; figures 2-3 -----	1,5-15
A	US 2002/183817 Al (VAN VENROOIJ PAUL [NL] ET AL VAN VENROOIJ PAUL [NL] ET AL) 5 December 2002 (2002-12-05) paragraphs [0054] , [0059]; figures 3-4 -----	2-4
A	US 2003/195602 Al (BOLING C LANCE [US]) 16 October 2003 (2003-10-16) paragraph [0108] - paragraph [0120] -----	7-13
A	US 2003/236562 Al (KUZMA JANUSZ A [US]) 25 December 2003 (2003-12-25) paragraphs [0041] , [0043] , [0053] ; figure 2 -----	16

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2010/059099

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
WO 2009025816	A1	26-02-2009	EP	2195081	A1	16-06-2010
			US	2009054947	A1	26-02-2009
WO 2008005142	A1	10-01-2008	EP	2043735	A1	08-04-2009
			EP	2043729	A2	08-04-2009
			US	2008004674	A1	03-01-2008
			US	2008046036	A1	21-02-2008
			US	2008004675	A1	03-01-2008
			WO	2008005144	A2	10-01-2008
			WO	2008005153	A2	10-01-2008
US 2005228469	A1	13-10-2005	NONE			
EP 0647435	A1	12-04-1995	AT	147958	T	15-02-1997
			DE	69401562	D1	06-03-1997
			DE	69401562	T2	15-05-1997
			DK	647435	T3	14-07-1997
			ES	2098872	T3	01-05-1997
			GR	3022910	T3	30-06-1997
			JP	3654671	B2	02-06-2005
			JP	7222808	A	22-08-1995
			US	5417208	A	23-05-1995
			US	5555618	A	17-09-1996
US 5014720	A	14-05-1991	NONE			
US 4214804	A	29-07-1980	NONE			
US 2005171587	A1	04-08-2005	NONE			
US 2002183817	A1	05-12-2002	NONE			
US 2003195602	A1	16-10-2003	US	2007043410	A1	22-02-2007
			US	2010107408	A1	06-05-2010
US 2003236562	A1	25-12-2003	US	2004015221	A1	22-01-2004