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DENNIS T T PLACHTA / OSCAR COTA / THOMAS STIEGLITZ / MORTIMER GIERTHMUEHLEN: "Selektive Ableitung und Stimulation fuer ein blutdrucksenkendes Implantat unter Verwendung von Vielkanal-Cuff-Elektroden", TECHNISCHES MESSEN TM, R.OLDENBOURG VERLAG. MUNCHEN, DE, Bd. 80, Nr. 5, 1. Januar 2013 (2013-01-01) , Seiten 163-172, XP009187692, ISSN: 0171-8096 in der Anmeldung erwähnt

TECHNICAL FIELD

The invention relates to an implantable electrode arrangement for spatially-selective detection of neuronal electrical signals, which propagate along at least one nerve fibre contained in a nerve fascicle, and for selective electrical stimulation of the at least one selected nerve fibre, comprising a biocompatible carrier substrate, which has at least one carrier substrate region that can be placed around the nerve fascicle in a cuff-like manner and has a straight cylinder-shaped carrier substrate surface oriented facing the nerve fascicle in the implanted state, said carrier substrate surface having an axial extent and an extent oriented in the circumferential direction and a first electrode arrangement being attached thereto. The first electrode arrangement comprises, in an axial sequence and spaced apart from one another, at least three first electrode structures with in each case at least two first electrode surfaces arranged in a manner distributed in the circumferential direction, and at least two first electrode strips, which are spaced apart from one another in the axial direction, extend in the circumferential direction and in each case assume a ring shape, said first electrode strips enclosing the at least three electrode structures on both sides in the axial direction. The first electrode arrangement is connectable to a signal detector and generator, i.e. the electrode arrangement is connected to the signal detector and generator by means of a separable electrical interface, for example in the form of a plug unit, or is directly, i.e. non-separably, connected.

PRIOR ART

Arterial hypertension is a globally widespread, typical lifestyle disease, which threatens the life of millions of patients and at the same time places the health systems under great strain. Previously known therapeutic measures are based on the administration of blood-pressure-lowering drugs, such as ACE inhibitors, beta-blockers, etc., however these have considerable side effects in addition to the desired blood-pressure-lowering effect, for example bradycardia, cardiac insufficiency, asthma attacks, etc. In addition, in spite of the development of new blood-pressure-lowering drugs, it is not possible to achieve adequate target blood pressure in up to 30% of all patients with corresponding medication; see the article by H. R. Black, et al., Principal results of the

controlled onset Verapamil investigation of cardiovascular end points (Convince), TRIAL. Jama, 289 (16), pages 2073 - 2082), 2003.

Another therapeutic approach for combating high blood pressure is pursued in a study by the applicant published in the article by Dennis T. T. Plachta, Oscar Cota, Thomas Stieglitz, Mortimer Gierthmuehlen, "Selektive Ableitung und Stimulation für ein blutdrucksenkendes Implantat unter Verwendung von Vielkanal- Cuff-Elektroden" (Selective Discharge and Stimulation for a Blood Pressure-Lowering Implant with Use of Multi-Channel Cuff Electrodes", tm - Technisches Messen (Technical Measurement), 2013, vol. 80 (5), pages 163-172. The findings obtained on the basis of animal tests performed on rats establish the possibility of detecting neuronal electrical signals in a spatially resolved manner from a nerve fascicle portion of the vagus nerve by means of an electrode arrangement implanted at said nerve fascicle portion, and of applying electrical signals to selected nerve fibres for stimulation thereof for the purposes of a technically initiated blood pressure reduction. A vagus nerve stimulation of this type thus in principle has the potential to become established as an alternative for the treatment of therapy-resistant blood pressure.

The concept of selective vagus nerve stimulation is supported on experience gained in the case of neuromodulation therapy of severe forms of epilepsy, which therapy has been applied and established for many years and in which the vagus nerve is electrically stimulated as a whole with the aid of an implanted electrode arrangement so as to at least reduce the extent of imminent epileptic seizures in respect of their strength and duration; see F. Sidiqui, et al., "Cumulative effect of Vagus nerve stimulators on intractable seizures observed over a period of 3 years", Epilepsy and Behavior, 18(3), pages 299 - 302, 2010 and also T. Stieglitz, "Neuroprothetik und Neuromodulation - Forschungsansätze und klinische Praxis bei Therapie und Rehabilitation" (Neuroprosthetics and Neuromodulation - Research Approaches and Clinical Practice in Therapy and Rehabilitation), Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz (public health journal), 53(8), pages 783 - 790, 2010.

By contrast, for the chronic treatment of hypertension it is necessary to firstly localise the blood pressure-relevant fibres by way of measurement in order to then selectively electrically stimulate them suitably. In order to treat the vagus

nerve as gently as possible by means of the implantation for application of an electrode arrangement and so as to cause minimal irritation to the epineurium of the vagus nerve, it is proposed in the cited article by Dennis T. T. Plachta et al. to use what is known as a cuff electrode, which can be attached to the vagus nerve extraneurally. This has the advantage of a relatively easy positioning of the cuff electrode along the vagus nerve and in addition enables a surgical intervention on the patient that is only slightly invasive and therefore can be performed in a gentle and quick manner.

For the natural blood pressure regulation, the baroreflex is used, which constitutes a homeostatic, self-regulating mechanism and in the case of increased blood pressure activates different effectors by way of reflex. Among other things, the heart rate is reduced, but the arterial vessels are also expanded so as to thus lower the blood pressure. In the case of a low blood pressure, the baroreflex is suppressed, whereby the heart rate rises and blood vessels are constricted so that the blood pressure rises again. The sensory inputs for the baroreflex constitute what are known as baroreceptors, which are disposed, *inter alia*, in the walls of the aortic arch. From there, the blood pressure information travels monosynaptically along the nerve fibres relevant for blood pressure, referred to hereinafter as baroreceptive fibres, into the brainstem. When a threshold value for the blood pressure is exceeded, the baroreflex triggers an inhibition of sympathetic nerve fibres, which leads to an immediate lowering of the blood pressure. With the aid of the sleeve electrode illustrated with reference to Figures 2a and b, which is often referred to in the English-language literature as a cuff electrode, it is possible to use this baroreflex mechanism by selectively detecting the pressure information supplied to the brainstem and also selectively "overwriting" this information in order to thus suggest a significantly increased blood pressure situation to the brainstem, whereby a natural significant blood pressure lowering is initiated.

Figure 2a shows the known cuff electrode CE in a two-dimensional plan view in a planar unfolded state. Figure 2b shows the cuff electrode CE in the implanted state, in which regions B1, B2 of the cuff electrode CE have been folded together for the purpose of providing a space-saving form, and in addition a carrier substrate region 1B of the cuff electrode CE provided with an electrode arrangement 2 surrounds a region of a nerve fascicle NFB in a sleeve-like manner.

The cuff electrode CE consists of a flexible, biocompatible carrier substrate 1, which in the provided embodiment is a polyimide film approximately 11 µm thick, there being an electrode arrangement 2, composed of a multiplicity of individual electrodes, applied to the carrier substrate upper side of said carrier substrate, facing towards the drawing plane in Figure 2a, for the purpose of spatially resolved detection of neuronal electrical signals and also for selective electrical stimulation of individual nerve fibres NF running in the nerve fascicle NFB. The individual electrodes of the electrode arrangement 2 are in direct surface contact with the epineurium E of the nerve fascicle NFB, since the carrier substrate 1 in the carrier substrate region 1B rolls up automatically as a result of appropriate impression of a mechanical film bias, so as to form an oriented straight cylinder-shaped carrier substrate surface 1' facing the nerve fascicle NFB, as can be seen in Figure 2b. The individual electrodes of the electrode arrangement 2 thus assume an annular three-dimensional form curved around the nerve fascicle NFB in the circumferential direction U.

Three first electrode structures 3, which are spaced apart from one another equally in the axial direction and which in the circumferential direction U in each case comprise at least two, and in the illustrated exemplary embodiment according to Figures 2a and b eight, first electrode surfaces 4 are used both for spatially-selective detection of neuronal electrical signals and for selective electrical stimulation of at least one nerve fibre NF. The eight first electrode surfaces 4 belonging in each case to a first electrode structure 3 are arranged equally distributed in the circumferential direction U, i.e. at angular intervals of 45°. This enables a spatial selectivity divided eightfold in the circumferential direction for spatially-selective detection of neuronal electrical signals from the nerve fascicle NFB to be examined. The first electrode strips 5 arranged axially on both sides next to the three first electrode structures 3, which strips surround the nerve fascicle NFB fully in an annular manner, serve in the case of the spatially-selective detection of neuronal electrical signals as ground potential; if, by contrast, it is necessary to selectively electrically stimulate selected nerve fibres NF within the nerve fascicle NFB, these first electrode strips 5 each serve as anode or as opposite polarity.

The triple or tripole arrangement of the first electrode structures 3, via the first electrode surfaces 4 of which neuronal electrical signals can be detected or

electrical signals can be delivered for the purpose of spatially-selective stimulation, makes it possible to determine impedance changes on account of tissue growth at the metal electrode surfaces 4 and to eliminate these by way of analysis, and on the other hand blood pressure-relevant neuronal signals which run through the tripole arrangement axially along a corresponding nerve fibre NF with a slight time offset can be detected by means of suitable tripolar amplification. Besides the above-mentioned first electrode structures 3 and also first electrode strips 5 each assuming a ring shape, which are all applied to the carrier substrate surface 1' facing the drawing plane in Figure 2a and which end on the proximal side at connection structures V via corresponding electrical conductive tracks L, reference electrodes 12 are disposed on the rear side of the carrier substrate 1 and serve to detect the intracorporeal electrical background ground signal or noise level, which forms the basis of the signal evaluation, and on the other hand provide the possibility of detecting ECG signals with the aid of the cuff electrode CE. The electrode arrangement implantable as a cuff electrode CE is connectable via the electrical connection structures V to a hermetically encapsulated signal detector and generator 6, which is also formed as an implant.

With the known implantable electrode arrangement, it was possible to show, within the scope of animal tests on rats, that with the aid of the total of 24 first electrode surfaces arranged in a tripolar manner equally distributed about the fascicle NFB, neuronal electrical time signals (referred to hereinafter as baroreceptive signals) can be detected, which additionally serve to locate the barorecpetive nerve fibres on the basis of their circumferential direction-dependent signal level. The stimulation was performed in a tripolar manner in each case with the electrode surface 4 or the electrode surfaces 4 of the centrally arranged first electrode structure 3 of the tripole arrangement via which the greatest signal level from the baroreceptive signals was detected in each case during the detection. It was possible to show that, by means of selective stimulation of baroreceptive nerve fibres, the blood pressure can be significantly reduced, wherein merely a very slight bradycardia (pulse reduction below 60 beats per minute) and only an insignificant bradypnoea (reduction in breathing less than 20 breaths per minute) are experienced.

For selective electrical stimulation of the baroreceptive nerve fibres, electrical stimulation signals having a stimulation frequency in each case between 30 and

50 Hz, a stimulation period of from 0.1 to 0.5 msec, and also a stimulation amplitude of from 0.4 to 1.5 mA were applied to the selected electrode surfaces 4 of the centrally arranged electrode structure. Here, the electrical stimulation along the baroreceptive nerve fibres was isotropic, i.e. with no specification of a fixed signal propagation direction, and therefore the electrical stimulation signals could propagate along both afferent and efferent nerve fibres. The latter can exert a direct, uncontrolled influence on the heart activity, which can lead to undesirable side-effects, in particular in the case of living beings larger than rats.

DISCLOSURE OF THE INVENTION

The object of the invention is to further develop an implantable electrode arrangement of the above-mentioned type for spatially-selective detection of neuronal electrical signals, which propagate along at least one nerve fibre contained in a nerve fascicle, and for selective electrical stimulation of the at least one nerve fibre having the features of the preamble of claim 1, in such a way that measures are taken to rule out (as completely as possible) any possible side effects caused by uncontrolled signal propagation effects of the electrical stimulation signals selectively coupled-in along baroreceptive nerve fibres. In particular, measures should be taken to suppress a propagation of electrical stimulation signals along efferent nerve fibres without, in so doing, exerting a significantly lasting influence on non-baroreceptive afferent and also efferent nerve fibres within the nerve fascicle.

The solution to the problem forming the basis of the invention is specified in claim 1. Features that advantageously further develop the concept of the solution are the subject of the dependent claims and also can be inferred from the further description with reference to the exemplary embodiments.

The implantable electrode arrangement according to the solution according to the features of the preamble of claim 1 is characterised in that at least one second electrode arrangement is arranged next to the first electrode arrangement in the axial sequence on the straight cylinder-shaped carrier substrate surface facing the nerve fascicle, said second electrode arrangement comprising at least two second electrode strips, which are axially spaced apart from one another, extend in the circumferential direction and in each case

assume a ring shape, and at least one second electrode structure, extending axially between the at least two second electrode strips, in each case comprising at least two second electrode surfaces arranged equally distributed in the circumferential direction, wherein the second electrode arrangement is connected at least with the signal generator or a further signal generator

The implantable electrode arrangement explained in the introduction formed as a cuff electrode, as has been explained with reference to Figures 2a and b, has been supplemented in accordance with the solution by at least one second electrode arrangement designed for inhibition of a unidirectional electrical signal transfer along at least one selected nerve fibre within a nerve fascicle.

The second electrode arrangement also applied to the same carrier substrate formed continuously in one piece on the same carrier substrate surface as the first electrode arrangement is in a spatially fixed arrangement relative to the first electrode arrangement, in particular relative to the first electrode surfaces of the at least three first electrode structures, with the aid of which baroreceptive nerve fibres within the nerve fascicle are detected in a spatially-selective manner and additionally can be electrically stimulated selectively. In the knowledge of the localised baroreceptive nerve fibres, the second electrode arrangement can be used for the purpose of a selective inhibition of the baroreceptive nerve fibres in order to suppress a forwarding of electrical stimulation signals along efferent nerve fibres, that is to say nerve fibres leading to the heart. For this purpose, at least two, preferably four or more second electrode surfaces of at least one second electrode structure are used, which, similarly to the first electrode surfaces of one of the at least three first electrode structures, are arranged equally distributed in the circumferential direction of the straight cylinder-shaped carrier substrate surface oriented facing the nerve fascicle. For the purpose of inhibition of localised efferent baroreceptive nerve fibres, at least one of the second electrode surfaces of the second electrode structure is electrically activated, thus resulting in a targeted, temporally limited, selective inhibition of the efferent nerve fibres in question. Here, an electrical polarisation field passes from the at least one activated, second electrode surface into the nerve fascicle and interacts primarily with the nerve fibres to be inhibited. In order to axially delimit the electrical polarisation field propagating into the nerve fascicle during the inhibition, second electrode strips are used, which in each case are attached to the second electrode

structure axially on either side and in the implanted state of the cuff electrode constitute ring electrodes completely surrounding the nerve fascicles.

For the purpose of the inhibition of selective efferent nerve fibres, the implantable electrode arrangement formed in accordance with the solution is to be applied to the nerve fascicle in such a way that the second electrode arrangement provided in accordance with the solution is oriented facing the heart, or facing the baroreceptive receptors, i.e. caudally, and the first electrode arrangement, with which the selective detection of neuronal electrical signals and also the electrical stimulation of localised nerve fibres is performed, is oriented facing the brain, i.e. rostrally, along the nerve fascicle.

With the aid of the second electrode arrangement, the inhibition can be provided either by way of what is known as an anodal block or by application of sinusoidal signals having frequencies in the kilohertz range. In the case of the anodal block, at least one of the second electrode surfaces is anodically polarised, whereby a voltage potential prevailing at the location of the efferent nerve fibres is produced, by means of which an activating stimulation of the corresponding nerve fibres is suppressed. An inhibition by way of a high-frequency signal application can also be attained, in which case a high-frequency electrical inhibition signal is applied to at least one selected second electrode surface, whereby the electrical signal transfer mechanisms along the efferent nerve fibres come to a stop temporarily.

In both cases, on account of its spatially limited extent axially, which is caused by the axial spacing of both second electrode strips, and in spite of its spatial vicinity to the first electrode structure (the implantable electrode arrangement should nevertheless not exceed an axial length of 4 cm), the second electrode arrangement provided in accordance with the solution acts axially in a spatially limited manner along the efferent nerve fibres to be inhibited, such that the electrode arrangement arranged first along the nerve fascicle on the brain side can couple electrical stimulation signals leading to the brain into the localised afferent nerve fibres in a manner uninfluenced by the inhibition mechanism. In this way, any side effects caused by possible direct stimulation in the direction of the nerve fibres leading to the heart, i.e. efferent nerve fibres, can be excluded.

The second electrode surfaces of the second electrode structure are advantageously arranged equally distributed along a virtual circular line in the implanted state of the cuff electrode so as to thus selectively and effectively inhibit localised efferent nerve fibres relative to the circumferential edge of a nerve fibre fascicle.

The second electrode surfaces, however, advantageously are not necessarily formed identically to one another in terms of shape and size, wherein their axial extents are in each case selected identically, that is to say identically to the axial extents of the first electrode surfaces of the first three electrode structures. The extent of the second electrode surfaces oriented in the circumferential direction is selected to be greater than the extent of the first electrode surfaces oriented in the circumferential direction. The second electrode surfaces thus preferably have a greater area dimension compared to the first electrode surfaces, whereby the location selectivity with which the second electrode surfaces can electrically polarise specific efferent nerve fibres is lower than the location selectivity with which the first electrode surfaces can electrically stimulate localised nerve fibres. Alternatively, the second electrode surfaces can also be formed as circular areas instead of having a rectangular shape. This has the advantage that no local electrical potential field peaks caused by edges or corners can form.

The second electrode arrangement is preferably formed as a tripolar electrode arrangement, i.e. the second electrode structure is delimited axially on either side in each case by an annular second electrode strip, wherein the axial distance between both second electrode strips along the carrier substrate is selected preferably to be between 0.5 cm and 3 cm, in particular between 0.75 cm and 1.25 cm. The annular second electrode strips preferably have an axial extent between 1 µm and 5 mm, preferably between 100 µm and 4,000 µm.

The second electrode surfaces of the second electrode structure are arranged axially centrally between both second electrode strips and have an axial extent such that the axial distance between the second electrode strips is in each case greater than their own axial extent.

In particular in view of the possibility of carrying out depolarising measures, it is conceivable, instead of one second electrode structure, to arrange three

axially distanced second electrode structures between the second electrode strips, so as to form the first electrode structure within the first electrode arrangement so to speak. It should be mentioned here, only for the sake of completeness, that it would also be conceivable to arrange more than three first and second electrode structures between the respective first and second electrode strips. Three, five, seven, or a greater odd number of first and/or second electrode structures could thus be provided.

In a preferred exemplary embodiment illustrated hereinafter, a second electrode structure comprises four second electrode surfaces, the electrode area dimension of which is in each case smaller than a quarter of the area of a second electrode strip. Since the first and second electrode strips provided in the first and second electrode arrangement serve in each case as ground or opposite pole for polarisation of the first and second electrode structure respectively, the areas of the first and second electrode strips must be selected identically for reasons relating to charge-symmetrical conditions. However, it is also conceivable to provide an individual, independent area selection when forming the first and second electrode strips.

It has also proven to be advantageous to manufacture all electrodes of the second electrode arrangement, i.e. the second electrode surfaces and second electrode strips, from an electrically conductive material which has a lower charge transfer capacity than the electrode material from which the first electrode surfaces of the first electrode arrangement are made. Iridium oxide is used as a particularly suitable material having a particularly high charge transfer capacity in order to form the first electrode surfaces of the first electrode arrangement, whereas the material of the second electrode surfaces and second electrode strips consists of platinum or of an electrically conductive polymer.

All electrode surfaces both of the first and second electrode arrangement are preferably formed flush with the carrier substrate surface of the carrier substrate or are lower by comparison therewith, such that they do not protrude beyond the carrier substrate surface, so as to produce the most gentle surface contact possible to the epineurium of the nerve fascicle. Due to the non-invasive surface contact, the implantable electrode arrangement can be easily

applied and positioned along the nerve fascicle by means of a surgical operation, wherein the epineurium is irritated only minimally, or not at all.

In order to also counteract tissue irritation and sensitivity reactions caused by implantation, it is possible to provide the carrier substrate consisting of a biocompatible polymer with an active substance inhibiting inflammatory reactions, at least in those regions which come into direct surface contact with the nerve fascicle. A further measure for reducing mechanical irritation of the nerve fascicle, which can be caused as a result of the surface contact with the sleeve-like cuff electrode, concerns a rounding of axial delimitation edges of the carrier substrate surrounding the nerve fascicle, such that the biocompatible carrier substrate, in the region of the straight cylinder-shaped carrier substrate surface oriented facing the nerve fascicle, has edge regions in each case disposed opposite one another axially, at which the carrier substrate has a greater substrate thickness than in the other carrier substrate region, wherein the edge regions have rounded edges.

In the region of the second electrode arrangement, which serves for the electrical inhibition of localised nerve fibres, a further preferred embodiment provides at least one, and preferably a plurality of light wave conductor openings or apertures, via which light can be applied or coupled in through the epineurium of the nerve fascicle. The light wave conductor openings are preferably arranged axially adjacently to both second electrode strips and in terms of shape, size and distribution are emulated in a manner corresponding to the second electrode surfaces of the second electrode structure. By providing a plurality of spatially separated light wave conductors, which open out on the carrier substrate surface in a manner facing the nerve fascicle, uniform or different optical signals with different wavelengths can be applied to the nerve fascicle for the purpose of optically activating neuronal optogenetic reactions within the nerve fascicle. Neuronal activation or inhibition reactions can thus be triggered in a spatially-selective manner by a multiplicity of suitably arranged light wave exit openings or apertures within the nerve fascicle, which reactions can be performed alternatively or in addition to the neuronal processes caused via the electrode surfaces.

As already mentioned, the implantable electrode arrangement formed in accordance with the solution must be applied along the nerve fascicle in such a

way that the second electrode arrangement comes to lie along the nerve fascicle in the direction facing the heart. It is ensured in this way that efferent nerve fibres can be inhibited, whereas the first electrode arrangement oriented facing the brain along the nerve fascicle can be used for the purpose of selective stimulation of localised afferent nerve fibres, i.e. nerve fibres leading to the brain. Should it be necessary to selectively inhibit afferent nerve fibres, the implantable electrode arrangement formed in accordance with the solution can be implanted with reverse orientation along the nerve fascicle. A further possible embodiment provides a second inhibiting second electrode arrangement, which is attached axially beside the first electrode arrangement, opposite the second electrode arrangement.

For actuation and electrical signal and power supply of all electrode surfaces and electrode strips applied to the carrier substrate, at least one signal detector and generator is provided, which together with an electrical power supply unit is hermetically closed separately from the carrier substrate within a capsule-like housing or is provided as an integral part of the carrier substrate. In the case that the signal detector and generator is formed separately, this is connectable via a corresponding electrical and possibly optical interface to the implantable electrode arrangement formed in accordance with the solution.

The intracorporeal implantation of the electrode arrangement surrounding the nerve fascicle in a cuff-like manner is additionally confronted by the fundamental problem that the electrode strips and electrode surfaces applied to the polyimide carrier substrate are exposed to a permanently moist environment, whereby signs of degradation can occur in particular at the planar connections between the electrode surfaces and the polyimide carrier substrate, which lead to local separations and to contact degradations associated at least therewith, as a result of which the electrical efficiency of the electrode arrangement ultimately is impaired. In order to confront the signs of separation between metal electrode surfaces and the polyimide carrier substrate caused by this environment, at least the first and second electrode strips in a preferred embodiment in each case have at least one local opening, wherein the first and second electrode strips are connected in a planar manner to the carrier substrate or the carrier substrate surface in such a way that the polymer or polyimide, from which the carrier substrate is formed, at least partially

penetrates through an opening. An improved mechanical anchoring of the respective electrode strips to the carrier substrate is thus created.

A further possibility for a durable and stable connection between the electrode surfaces or electrode strips and the biocompatible polyimide or polymer material of the carrier substrate is reflected in a specific embodiment of the electrode surfaces or electrode strips, and also in a resultant possible special integration of the electrodes in the carrier substrate. For this purpose, the first and second electrode strips in particular in each case have a metal base plate with a flat upper side and lower side, with at least one, preferably a plurality of structural elements protruding orthogonally and locally beyond the upper side of the base plate, which elements are preferably pillar-like, rib-like, sleeve-like or web-like. The metal base plate is completely encased by the biocompatible polymer of the carrier substrate, with the exception of a first surface region of the at least one structural element, which is oriented facing the carrier substrate surface and does not protrude therebeyond. The electrode contact surface freely accessible at the carrier substrate surface thus reduces, but is completely encased by the biocompatible polymer of the carrier substrate on account of the hermetic encapsulation of the base plate and also the structural elements integrally connected thereto, with the exception of the surface regions oriented facing the carrier substrate surface. An infiltration of environment-induced liquid or moisture between the electrode strips and the biocompatible polymer of the carrier substrate is significantly hindered, such that signs of degradation can be largely ruled out. In a further preferred embodiment, an adhesion promoter layer or an adhesion promoter layer arrangement is preferably introduced between the lower side of the metal base plate and the biocompatible polymer of the carrier substrate and counteracts potential moisture-induced signs of separation.

Further preferred embodiments in relation to the possible design of the electrode strips will be explained in conjunction with the following figures.

BRIEF DESCRIPTION OF THE INVENTION

The invention will be described hereinafter by way of example, without limitation of the general inventive concept, on the basis of exemplary embodiments with reference to the drawings, in which:

Fig. 1 shows a plan view of a schematic implantable electrode arrangement with a second electrode arrangement for the inhibition of selective nerve fibres,

Figs. 2a, b show illustrations of an implantable electrode arrangement, known *per se*, for the spatially-selective detection of neuronal electrical signals and also selective electrical stimulation of individual nerve fibres,

Fig. 3a shows an illustration of an electrode strip with opening,

Fig. 3b shows a detailed illustration of an electrode strip integrated in the carrier substrate,

Fig. 3c shows an alternative design of a structural element,

Figs. 4a-f show illustrations of a cuff additionally strengthening the implantable electrode arrangement, and

Fig. 5 shows hydraulic application structures of the implantable electrode arrangement.

WAYS OF CARRYING OUT THE INVENTION, INDUSTRIAL APPLICABILITY

Figure 1 shows a schematic plan view of an implantable cuff electrode CE formed in accordance with the solution, with a second electrode arrangement 7 for the inhibition of at least one selective nerve fibre being applied to the carrier substrate 1 of said cuff electrode, which carrier substrate is preferably made of polyimide, in addition to the first electrode arrangement 2 provided for the spatially-selective detection of neuronal electrical signals and also for selective electrical stimulation of individual nerve fibres. In order to avoid repetitions, reference is made to the above description of Figures 2a and b with regard to the explanation of the individual electrodes of the first electrode arrangement 2.

The second electrode arrangement 7, for inhibiting the signal propagation along efferent nerve fibres, here nerve fibres leading to the heart H, comprises two axially spaced-apart second electrode strips 8, between which there is provided, centrally, a second electrode structure 13, which consists of four second electrode surfaces 9 arranged separately from one another. All electrodes 8, 13 of the second electrode arrangement 2 are connected or connectable via electrical conductive tracks L applied to the carrier substrate 1 or integrated therein to a signal generator 6', which together with the signal detector and generator 6 and also with a power source is integrated in a separately encapsulated, implantable unit. The electrical conductive tracks L can optionally comprise a separable connection structure V.

The second electrode arrangement 2 optionally comprises light wave conductor arrangements 10, which in each case comprise four separate light wave conductor openings 11 arranged distributed in the circumferential direction U. The light wave conductors LI run within the carrier substrate 1 to the individual light wave conductor openings or apertures 11 and can be combined proximally with a uniform light source LQ or with separate light sources LQ of different wavelengths so as to bring about optogenetically selectively activated stimulations and/or optically activated and selective inhibition along specific nerve fibres.

The geometric selection of the shape and size of the individual electrodes, i.e. of the first and second electrode strips 5, 8 and also of the first and second electrode surfaces 4, 9 can be made in principle in a manner coordinated individually with one another and is based in particular on the diameter of the nerve fascicle so as to be able to place the implantable cuff electrode FE in position. The extent of the first and second electrode structures and electrode strips oriented in the circumferential direction U and also possibly of the optical light wave conductor arrangements 10 thus preferably corresponds to the circumferential edge of the nerve fascicle around which the cuff electrode CE is to be wound. The axial spacing of the tripolar electrode arrangement should preferably be adapted to the diameter and the resultant spacing of what are known as the nodes of Ranvier in myelinated nerve fibres of the nerve fibres to be excited. In the exemplary embodiment illustrated in Figure 1, the electrodes are illustrated as rectangular electrode surfaces. It is advantageous to form the

electrode surfaces at least with rounded corners, in particular for the purpose of avoiding field line densifications occurring at electrode rectangle corners.

In humans, it is necessary to inhibit or to activate specific, large and myelinated fibres. This is possible only at points along the nerve fibres at which these fibres are not myelinated, i.e. at what are known as nodes of Ranvier. With increasing diameter of the nerve fibres, the intervals, i.e. the axial distances between the nodes of Ranvier, become larger, and accordingly it is necessary to select the axial spacing between two axially distanced first electrode strips 5 to be approximately the same length as the axial spacing of the rings or slightly greater so as to also reach the nodes of Ranvier of very large fibres with sufficiently high statistical probability. The same is preferably also true for the axial spacing of the second electrode strips 8.

The axial total extent of the entire cuff electrode CE should be adapted to the intracorporeal proportions of the particular nerve fascicle and typically should not exceed 4 cm.

The additional reference electrode surfaces 12 attached to the carrier substrate 1 on the rear side serve to detect the noise level detectable intracorporeally, and thus ECG signals as necessary.

The carrier substrate 1 additionally has at least one, preferably two or three openings 14 strengthened by metal ring structures, which openings serve to fasten the implanted electrode arrangement CF to the nerve fascicle. The fastening is provided with the aid of a surgical thread, which is threaded at least once through each of the openings 14 and is sewn in the tissue surrounding the nerve fascicle. In contrast to the region 1B of the carrier substrate rolled into a straight cylinder, to which the first and second electrode arrangements 2 and 7 are applied, such that they contact the surface of the epineurium of the nerve fascicle in the implanted state, the carrier substrate 1 adjoining the carrier substrate region 1B protrudes laterally from the nerve fascicle in the manner of a flat lug and projects into the surrounding tissue. The metal ring structures 14 are intended to help mechanically reliably absorb the fastening forces acting along the surgical thread and to prevent damage to the carrier substrate caused by the thread cutting in.

The second electrode arrangement 7 should be arranged along the nerve fascicle on the side H leading to the heart in order to wind the implantable electrode arrangement CF in a cuff-like manner around a nerve fascicle (not illustrated in greater detail). The second electrode arrangement 2 serving for selective detection and also for selective stimulation of localised nerve fibres is attached along the nerve fascicle on the brain side G.

The first and second electrode strips 5, 8 and also the first and second electrode surfaces 4, 9 are preferably applied to the carrier substrate by vapour deposition or sputtering; a galvanic reinforcement is conceivable. Laser structuring of thin metal foil is also a possible technique. For a permanent joining in particular of the first and second electrode strips 5, 8, to the carrier substrate 1, the electrode strips have local openings 15, see Figure 3a, through which the polymer material of the carrier substrate 1 passes or projects at least in part. The electrode surface 16 of the first and second electrode strips 5, 8 are in each case for the rest arranged flush with the carrier substrate upper side 1' and directly contact the surface of the nerve fascicle.

In order to permanently improve the joining of the electrode strips 5, 8, it is proposed in a preferred exemplary embodiment to integrate the electrode strips largely into the carrier substrate in the following way (see Figure 3b):

The electrode strips 5, 8 in each case have a metal base plate 17, which provides an upper side 18 and a lower side 19. Orthogonally raised structural elements 20 are provided integrally with the upper side 18 of the base plate 17, distributed in a planar manner over the surface of the upper side 18, preferably over the entire surface of the upper side, preferably in the form of pillar-like, rib-like, web-like or sleeve-like extensions, which have a surface region 21 facing the carrier substrate surface 1', which surface region can be in direct contact with the epineurium of the nerve fascicle. In addition, an adhesion promoter layer 22 is advantageously provided at least between the lower side 19 and the polymer material of the carrier substrate 1 surrounding the base plate 17. The adhesion promoter layer 22 can additionally also be applied to the upper side 18. Particularly suitable adhesion promoter layers consist of silicon carbide (SiC) and also diamond-like carbon (DLC). The electrode strips 5, 8 are preferably manufactured from iridium oxide, which is a material having one of the highest charge transfer capacities.

A further improved variant for forming the structural elements 20, which are applied in a distributed manner to the upper side of the base plate 17, is illustrated in Figure 3c. Figure 3c shows the longitudinal section through a structural element 20 which has a longitudinal extent LA oriented orthogonally to the upper side 18 of the metal base plate 17, along which the structural element 20 provides at least one second surface region 23, which is oriented parallel to the upper side 18 of the metal base plate 17 and to which the adhesion promoter layer 22 or an adhesion promoter layer arrangement 22' is applied. The second surface region 23 is fully surrounded by the biocompatible polymer in a manner arranged distanced and separated from the first surface region 18 by the first adhesion promoter layer (22) or the adhesion promoter layer arrangement (22'). As can be inferred from Figure 3c, the second surface region is oriented facing the upper side 18 of the base plate 17 and it is additionally possible and advantageous to provide the adhesion promoter layer 22 or the adhesion promoter layer arrangement 22' both on a third surface region 24, which is opposite the second surface region 23, and/or on the upper side and/or lower side 18, 19 of the base plate 17.

The number and also arrangement of the individual structural elements 20 can be selected arbitrarily, but geometrically ordered constellations KO, such as square, pentagonal, hexagonal or higher-value arrangement patterns, are preferably suitable, as can be inferred from Figure 3b.

In a preferred arrangement of the base plate 3 within the carrier substrate 1, the base plate 17 is disposed centrally within the carrier substrate 1, i.e. the thickness of the biocompatible polymer layer bordering the lower side 19 of the base plate 17 should correspond approximately to the thickness of the polymer layer bordering the upper side 18 of the base plate 17. With an arrangement of this type of the base plate 17, there is provided the advantage, which can be demonstrated by way of experiments, that the metal-inherent stresses acting on the base plate 17 and which form during a tempering process are compensated. The tempering process is necessary in order to impress a material bias into the carrier substrate, by means of which the implantable cuff electrode can wind autonomously around the nerve fascicle.

Figures 4a to f illustrate a cuff M which partially surrounds the carrier substrate 1 of the implantable cuff electrode CE and which surrounds the region of the carrier substrate 1, both on the lower side and also upper side thereof, that directly adjoins the carrier substrate region 1B and, in contrast to the carrier substrate region 1B, does not deform independently in a straight cylinder-shaped manner by way of a material-inherent mechanical bias and in this way is made to bear flush against the epineurium of the nerve fascicle in the implanted state.

The cuff M primarily serves to provide improved handling of the implantable cuff electrode CE, which on account of its very small carrier substrate thickness and also the filigree electrode arrangements applied to the carrier substrate surface, requires particularly careful handling on the part of the surgeon. The cuff M is preferably formed in one part and has a cuff lower part Mu and a cuff upper part Mo, which are both connected in a hinged manner via a living hinge joint 25; see Figures 4b and 4c. The cuff lower part Mu has an indentation 26 in which the carrier substrate 1 is embedded and into which the carrier substrate 1 can be inserted. In the inserted state, the cuff lower part Mu comprises the carrier substrate 1 in the framing manner deducible from Figure 4b, i.e. the cuff lower part Mu protrudes laterally beneath the carrier substrate 1.

The cuff upper part Mo connected integrally to the cuff lower part Mu via the hinge joint 25 is adapted in terms of shape and size to the cuff lower part Mu and, similarly to the cuff lower part Mu, has an indentation 27 in which the carrier substrate 1 is embedded, so that in the closed state the cuff M encases the carrier substrate 1 hermetically in the manner illustrated in Figure 4a, wherein merely the carrier substrate region 1B protrudes from the cuff M.

Besides an improved handling, the cuff M in particular also serves to provide an improved fixing of the cuff electrode CE relative to the nerve fascicle. For this purpose, the cuff upper and lower sides Mo, Mu in each case provide fastening openings 14', see Figs. 4a, b and d, which, when the cuff M is folded together, are aligned with the fastening openings 14 formed within the carrier substrate 1. In this way, it is possible to guide a surgical thread 28 through the openings 14, 14' in the cuff electrode CE surrounded by the cuff M. The fastening opening 14 of the cuff electrode CE surrounded by a metal ring can thus be relieved by the fastening opening 14’ formed within the cuff M. The cuff M is

preferably manufactured from a stable plastics material, for example from parylene. In order to further increase the strength, the Mo and Mu can also consist of a polymer hybrid (for example parylene (internally) and silicone rubber (externally)). This hybrid has the advantage that the stability of the parylene is combined with the tear resistance of the silicone. In a preferred embodiment the fastening openings 14' within the cuff M are reinforced by an appropriate material thickening.

Opening windows 29, which ensure free access to the reference electrode surfaces 12, are formed in the cuff upper part Mo. In Figure 4e a cross-section in this respect through the carrier substrate 1 comprised by the cuff M is illustrated, on the upper side of which reference electrode surfaces 12 are formed, which remain freely accessible through the opening windows 29 formed within the cuff upper part Mo. The opening windows 29 preferably comprise the reference electrode surfaces 12 with a delimiting flank 29' falling away in a sloped manner, such that it is ensured that the reference electrode surfaces 29 can come into body contact with surrounding tissue over the entire surface.

In order to ensure that the cuff M remains in a closed state, locking structures V are arranged between the cuff upper part and lower part Mo, Mu and for example consist of a pin 30 and indentation 31 arranged oppositely; see Figures 4c and f. When the cuff upper part and lower part are folded together, the pins 30 engage in the corresponding indentation 31 in a manner acted on by a force, in that the pins 31 are held in place permanently in each case in a frictionally engaged manner. The closed state of a locking structure V is illustrated in Figure 4f. Here, the pin 30 attached to the cuff upper part Mo protrudes through a corresponding opening formed in the carrier substrate 1 and leads at the end into the indentation 31 of the cuff lower part Mu. Of course, alternative embodiments for the locking structures are conceivable, for example in the form of suitably embodied latching mechanisms.

Figure 5 illustrates a further embodiment which enables a facilitated implantation of the cuff electrode CE formed in accordance with the solution. A fluid channel system 32 is formed within the carrier substrate 1 and is comprised fully by the carrier substrate 1. The fluid channel system 32 extends substantially in the region of the carrier substrate region 1B, which, on account of a material-inherent bias, assumes the form of a straight cylinder by way of

an autonomous self-rolling, without the application of external force. If, by contrast, the fluid channel system 32 is filled with a fluid, preferably water, the water pressure forming along the fluid channel system 32 can thus cause the carrier substrate region 1b to spread out in a planar manner, against the material-inherent rolling forces. For this purpose, the fluid channel system 32 has fluid channel branches 33, which run in the circumferential direction of the lateral surface of the autonomously-forming straight cylinder and which, in the filled state, force the necessary extension of the carrier substrate region 1B.

In order to fill the fluid channel system 32, at least two channel openings 34 are provided within the carrier substrate 1, the size and arrangement of said openings being such that they open out in a fluid-tight manner at entry and exit openings of fluid feed and discharge lines 35, 36 running within the cuff M. The feed and discharge lines 35, 36 running within the cuff M are fluidically connected to a fluid control system 37, which can be actuated by a surgeon.

In the case of an implantation, the fluid channel system 32 is filled with a fluid, whereby the carrier substrate region 1B is stretched out. In this state, the surgeon places the cuff electrode CE in a precise manner at a predefined point along the nerve fascicle. The fluid channel system 32 is then emptied by the surgeon, whereby the carrier substrate region 1B autonomously winds around the nerve fascicle. As a last step, the cuff electrode CE is fixed using a surgical thread to the surrounding tissue by the fastening openings 14' provided in the cuff.

In an advantageous embodiment of the above fluid channel system 32, it is conceivable to fill this with a shape-memory metal and shape-memory polymer. For the purpose of activation, the channel openings 34 are provided with metallised contacts, via which an electrical voltage can be applied along the feed lines 35, 36 in order to unfold the implantable electrode arrangement CE via an accordingly modified control apparatus 37, until the electrode is ultimately placed in position.

REFERENCE LIST

1	carrier substrate
1'	carrier substrate surface
1B	carrier substrate region
2	first electrode arrangement
3	first electrode structures
4	first electrode surfaces
4a	axial extent of the first electrode surfaces
4U	extent of the first electrode surfaces oriented in the circumferential direction
5	first electrode strips
6, 6'	signal detector and generator
7	second electrode arrangement
8	second electrode strips
9	second electrode surfaces
9a	axial extent of the second electrode surfaces
9U	extent of the second electrode surfaces oriented in the circumferential direction
10	light wave conductor arrangement
11	light wave conductor openings
12	reference electrode surfaces, ECG electrode surfaces
13	second electrode structure
14	fastening openings
14'	fastening opening
15	opening
16	electrode strip surface
17	base plate
18	upper side
19	lower side
20	structural element
21	surface region
22	adhesion promoter layer
22'	adhesion promoter layer arrangement
23	second surface region
24	third surface region

24	third surface region
25	living hinge joint
26	indentation
27	indentation
28	surgical thread
29	opening window
29’	delimitation flank
30	pin
31	indentation
32	fluid channel system
33	fluid channel branches
34	channel opening
35	feed line, within the cuff
36	discharge line, within the cuff
37	fluid control system
CE	cuff electrode
L	conductive track
V	connection structure
U	circumferential direction
A	axial direction
M	cuff
Mo	cuff upper part
Mu	cuff lower part
NF	nerve fibre
NFB	nerve fascicle
G	brain
H	heart
LI	light wave conductor
LQ	light source(s)
LA	longitudinal axis of the structural element
KO	geometric constellations
V	locking structure

Patentkrav

1. Implanterbar elektrodeindretning til optagelse ved valgte positioner af neuronale elektriske signaler der udspredes langs mindst en nervefiber indeholdt i et bundt af nervefibre, såvel som til den selektive elektriske stimulation af den mindst ene nervefiber, med et biokompatibelt bærersubstrat (1) der omfatter mindst ét bærersubstratområde der kan påføres på en manchetagtig måde rundt om nervefiberbundtet og en lige cylindrisk bærersubstratoverflade (1'), som er orienteret vendende mod nervefiberbundtet når implanteret og som har en aksial (a) forlængelse såvel som en forlængelse orienteret i omfangsretningen (U) og på hvilken en første elektrodeindretning (2), er påført, der

- aksialt omfatter mindst tre første elektrodestrukturer (3) hver med mindst to første elektrodeflader (4) indrettet i omfangsretningen og

- mindst to aksialt adskilte første elektrodestriber (5) der strækker sig i omfangsretningen og hver antager en ringformet form, der på begge sider aksialt omgiver de mindst tre elektrodestrukturer og som kan forbindes til en signaldetektor og generator (6),

kendetegnet ved at i aksialsekvens på den lige cylindriske bærersubstratoverflade (1') der vender mod nervefiberbundtet, indrettet aksialt ves siden af den første elektrodeindretning (2) er mindst en anden elektrodeindretning (7), der omfatter

- mindst to aksialt adskilte anden elektrodestriber (8) der strækker sig i omfangsretningen (U) og hver antager en ringformet form såvel som

- aksialt mellem de to anden elektrodestriber (8) mindst en anden elektrodestruktur (13) omfattende mindst to anden elektrodeflader (9) indrettet ligeligt fordelt i omfangsretningen (U) og

den anden elektrodeindretning (7) kan forbindes mindst med signalgeneratoren (6) eller en yderligere signalgenerator (6').

2. Elektrodeindretning ifølge krav 1
kendetegnet ved at i implanteret tilstand er de første og anden elektrodeflader

(4, 9) hver indrettet ligeligt fordelt langs en virtuel krydslinje i omfangsretningen (U).

3. Elektrodeindretning ifølge krav 1 eller 2
kendetegnet ved at de første og anden elektrodeflader (4, 9) hver har en aksial (4a, 9a) forlængelse og en forlængelse orienteret i omfangsretningen (4U, 9U) **ved at** forlængelsen (4a, 4U) af de første elektrodeflader (4) hver er identiske, **ved at** forlængelserne (9a, 9U) af de anden elektrodeflader (9) hver er identiske og ved at forlængelsen (9U) orienteret i omfangsretningen af de anden elektrodeflader (9) er større end forlængelsen (4U) orienteret i omfangsretningen af de første elektrodeflader (4).

4. Elektrodeindretning ifølge krav 3
kendetegnet ved at den aksiale forlængelse (4a, 4U) af de første og anden elektrodeflader (4, 9) er den samme.

5. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 4
kendetegnet ved at bærersubstratoverfladen (1'), er påført de første og anden elektrodeindretninger (2, 7) er udformet i ét stykke, sammenhængende, dvs. uden afbrydelser.

6. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 5
kendetegnet ved at den aksiale afstand mellem de første elektrodestriber (5) er valgt til at være større end eller lig med den aksiale afstand mellem de anden elektrodestriber (8), og ved at den aksiale afstand mellem de anden elektrodestriber måler mellem 0,5 cm og 3 cm, fortrinsvis mellem 0,75 cm og 1,25 cm.

7. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 6
kendetegnet ved at formen og størrelsen af de første og anden elektrodestriber (5, 8) er identiske og
ved at overfladearealet af de første og anden elektrodeflader (4, 9) er mindre end overfladearealet af respektivt de første eller anden elektrodestriber (5, 8),

fortrinsvis mindre end en fjerdedel af overfladearealet af de første eller anden elektrodestriber (5, 8).

8. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 7 **kendetegnet ved at** de første elektrodeflader (4) består af et metallisk materiale der har en større ladningsoverførselskapacitet end et materiale af hvilket de anden elektrodeflader (9) består af.

9. Elektrodeindretning ifølge krav 8, **kendetegnet ved at** det metalliske materiale af de første elektrodeflader (4) er iridiumoxid og/eller materialet af de anden elektrodeflader (9) er et metallisk materiale, fortrinsvis platin, eller en elektrisk ledende polymer.

10. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 9 **kendetegnet ved at** både de første og anden elektrodeindretning (2, 7) kan drives som en tripolær elektrodeindretning, dvs. de første og anden elektrodestriber (5, 8) hver kan polariseres til den modsatte pol af den første og anden elektrodestruktur (3, 13).

11. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 10 **kendetegnet ved at** i området at den anden elektrodeindretning (7) er mindst en optisk lysbølgelederindretning (10) tilvejebragt, der omfatter mindst to separate optiske lysbølgelederåbninger (11) indrettet i omfangsretningen (U).

12. Elektrodeindretning ifølge krav 11 **kendetegnet ved at** de mindst to separate optiske lysbølgelederåbninger (11) er indrettet ligeligt fordelt langs en virtuel krydslinje og **ved at** de optiske lysbølgelederåbninger (11) hver har en aksial (11a) forlængelse og en forlængelse orienteret i omfangsretningen (11U), der svarer til forlængelsen (9a, 9U) af de anden elektrodeflader (9).

13. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 12 **kendetegnet ved at** de første elektrodeflader (4) såvel som de første elektrodestriber (5) af den første elektrodeindretning (2) såvel som de anden elektrodeflader (9) såvel som de anden elektrodestriber (8) af den anden

elektrodeindretning (7) er påført til bærersubstratoverfladen (1') på en sådan måde at de ikke rager over bærersubstratoverfladen (1').

14. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 13 **kendetegnet ved at** bærersubstratet (1) er fremstillet af mindst én biokompatibel polymer og mindst delvist på den lige cylindriske bærersubstratoverflade (1') der vender mod nervefiberbundtet omfatter et aktivstof der inhiberer inflammatoriske reaktioner.

15. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 14 **kendetegnet ved at** mindst signaldetektoren og generator (6), den eventuelt tilvejebragte anden signaldetektor (6') og/eller en elektrisk energiforsyningsenhed er hermetisk omgivet adskilt fra bærersubstratet (1) inde i et kapsel-lignende hus eller form af en integreret del af bærersubstratet (1).

16. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 15 **kendetegnet ved at** bærersubstratet (1) indeholder biokompatibel polymer.

17. Elektrodeindretning ifølge krav 16 **kendetegnet ved at** de første og/eller de anden elektrodestriber (5, 8) hver har mindst en lokal åbning og **ved at** de første og/eller anden elektrodestriber (5, 8) er fladt forbundet til bærersubstratoverfladen (1') på en sådan måde at polymeren mindst delvist gennemtrænger den mindst ene åbning.

18. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 17 **kendetegnet ved at** på bagsiden af bærersubstratoverfladen (1') er anbragt mindst to reference-elektrodeflader (12) på bærersubstratet (1).

19. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 18 **kendetegnet ved at** det biokompatible bærersubstrat (1) i området af den lige cylindriske bærersubstratoverflade (1') der vender mod nervefiberbundtet har aksialt modstående marginalområder på hvilke bærersubstratet (1) har en større substrattykkelse end i det resterende bærersubstratområde og **ved at** marginalområdet har afrundede randkanter.

20. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 19 **kendetegnet ved at** det biokompatible bærersubstrat (1), i et område af bærersubstratet der ikke kan påføres rundt om nervefiberbundtet på en manchetagtig måde, omfatter mindst en fastgørelsesåbning (14) der fuldstændigt gennemtrænger bærersubstratet.

21. Elektrodeindretning ifølge krav 20 **kendetegnet ved at** den mindst ene fastgørelsesåbning (14) mindst delvist er omgivet af et metallisk materiale.

22. Elektrodeindretning ifølge krav 16 **kendetegnet ved at** de første og/eller de anden elektrodestriber (5, 8) hver omfatter et metalbasisplade (17) med en flad over- (18) og underside (19), med mindst ét strukturelement (20) lokalt ortogonalt udragende under oversiden (18), **ved at** den flade overflade (18) af den metalliske basisplade (17) er orienteret parallelt med bærersubstratoverfladen (1') og **ved at** den metalliske basisplade (17) er fuldstændigt direkte og/eller indirekte omgivet af den biokompatible polymer med undtagelse af et første overfladeområde (21) af det mindst ene strukturelement (20), som er orienteret vendende mod bærersubstratoverfladen (1') og ikke rager over det.

23. Elektrodeindretning ifølge krav 22 **kendetegnet ved at** et lag af bindemiddel (22) eller en bindingsmiddel-laganordning (22') er indført mindst mellem undersiden (19) af den metalliske basisplade (17) og den biokompatible polymer af bærersubstratet (1).

24. Elektrodeindretning ifølge krav 22 eller 23 **kendetegnet ved at** det første overfladeareal (21) af det mindst ene strukturelement (20) eller et plan (E) tildelt til det første overfladeareal (21) er orienteret parallelt med bærersubstratoverfladen (1'), i det første overfladeområde (21) er indrettet til at være frit tilgængeligt fra bærersubstratoverfladen (1') og at det mindst ene strukturelement (20) er forbundet i ét stykke til den metalliske basisplade (17).

25. Elektrodeindretning ifølge et hvilket som helst af kravene 22 til 24 **kendetegnet ved at** en flerhed af tilvejebragte strukturelementet (20) er indrettet i et geometrisk mønster (KO) på oversiden (18) af den metalliske basisplade (17) og er identiske i design.

26. Elektrodeindretning ifølge et hvilket som helst af kravene 22 til 25 **kendetegnet ved at** det mindst ene strukturelement (20) er udformet i en søjle, ribbe, bøsning eller web-lignende måde.

27. Elektrodeindretning ifølge et hvilket som helst af kravene 23 til 25 **kendetegnet ved at** det mindst ene strukturelement (20) har en langsgående forlængelse (LA), orienteret ortogonalt til oversiden af den metalliske basisplade (17), langs hvilken strukturelementet (20) forventer mindst ét overfladeområde (23) der er orienteret parallelt med oversiden (18) af basispladen (17) og på hvilken bindingsmiddellaget (22) eller bindingsmiddellaganordningen (22') er påført og
ved at det andet overfladeområde (23) er indrettet i en afstand fra det første overfladeområde (18) og er fuldstændigt omgivet af den biokompatible polymer.

28. Elektrodeindretning ifølge et hvilket som helst af kravene 1 til 27 **kendetegnet ved at** mindst i et delområde af bærersubstratet (1) ikke indeholdende bærersubstratoverfladen (1') omfatter bærersubstratet (1) en manchet (M).

29. Elektrodeindretning ifølge krav 28 og 20 eller 21,
kendetegnet ved at manchetten (1) har en manchetoverside (Mo) og -underside (Mu) der er forbundet til hinanden i ét stykke på en hængslet måde
og
ved at manchetoversiden (Mo) og -undersiden (Mu) hver har fastgørelsesåbninger (14') der er indrettet kongruent med fastgørelsesåbningerne (14) af bærersubstratet (1) i tilstanden i hvilken manchetten (M) omfatter bærersubstratet (1).

30. Elektrodeindretning ifølge et hvilket som helst af kravene 16 til 29 **kendetegnet ved at** bærersubstratet (1) har en substrattykkelse orienteret

ortogonalt til bærersubstratoverfladen (1') og **ved at** basispladen (17) er indrettet centreret på substrattykkelsen.

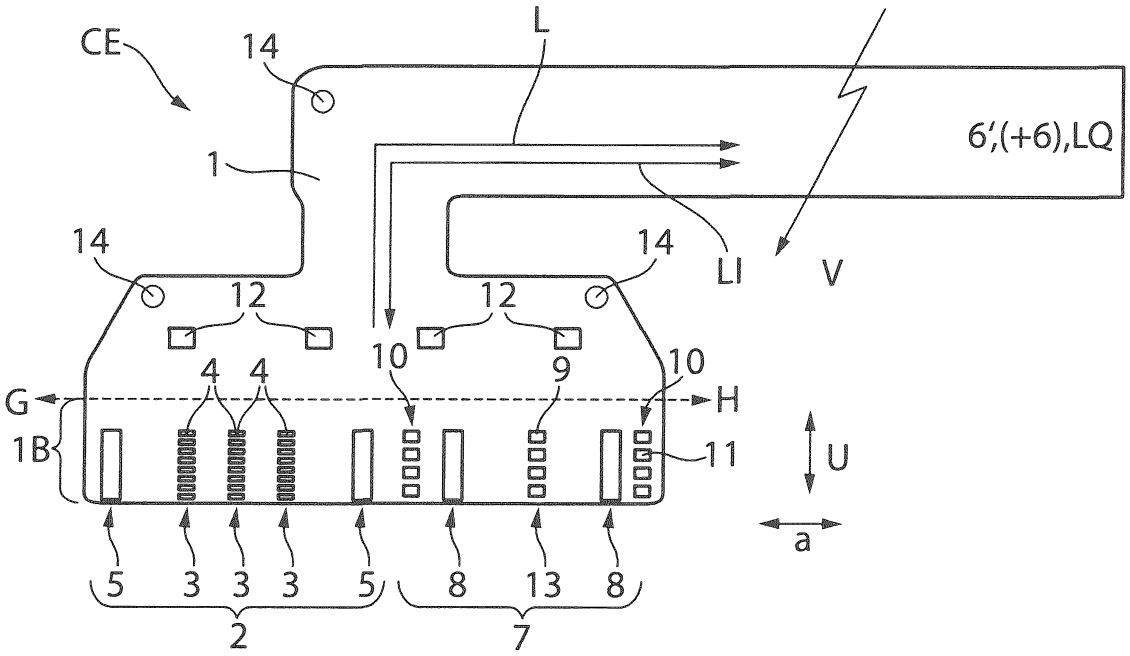

Fig. 1

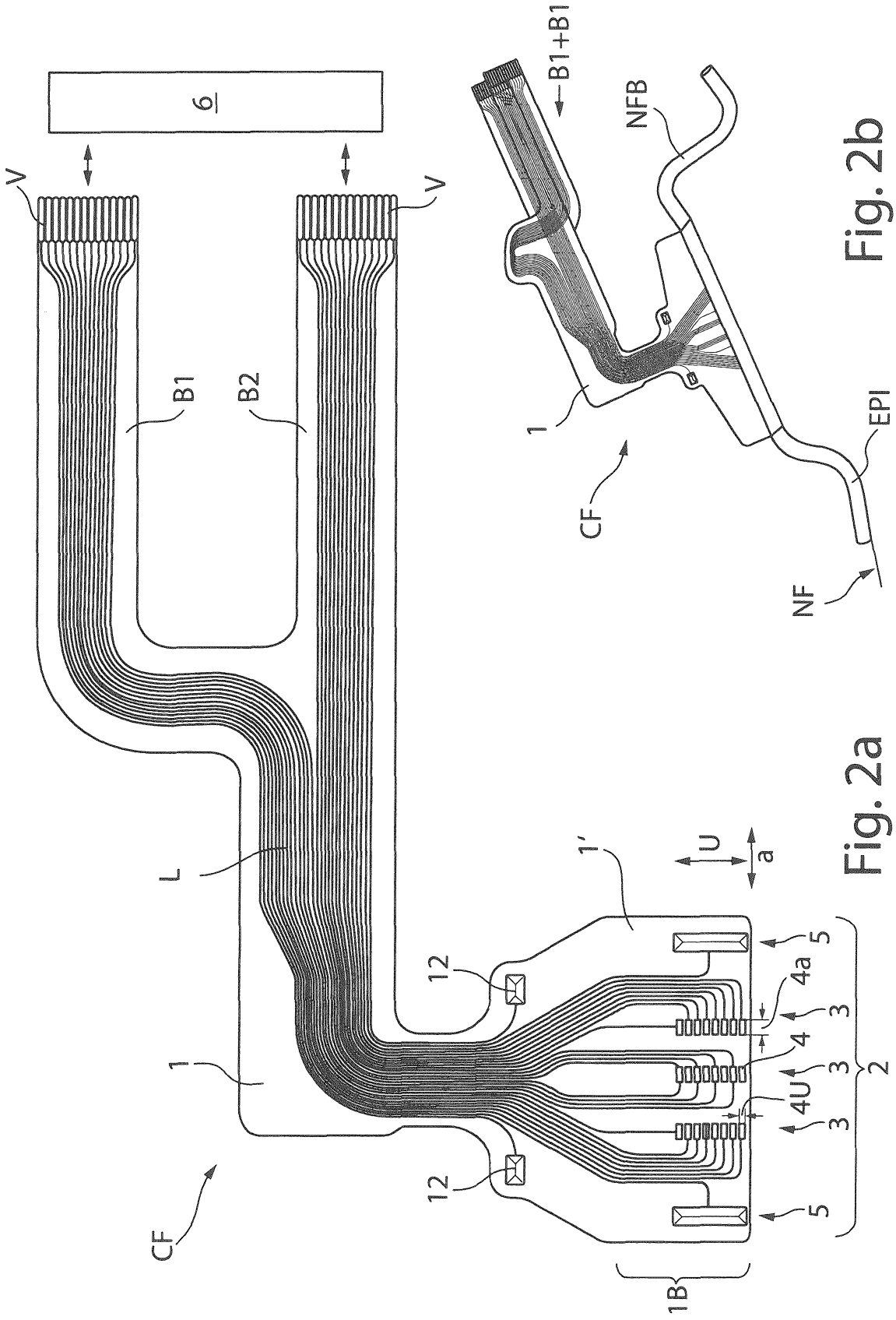

Fig. 2a

Fig. 2b

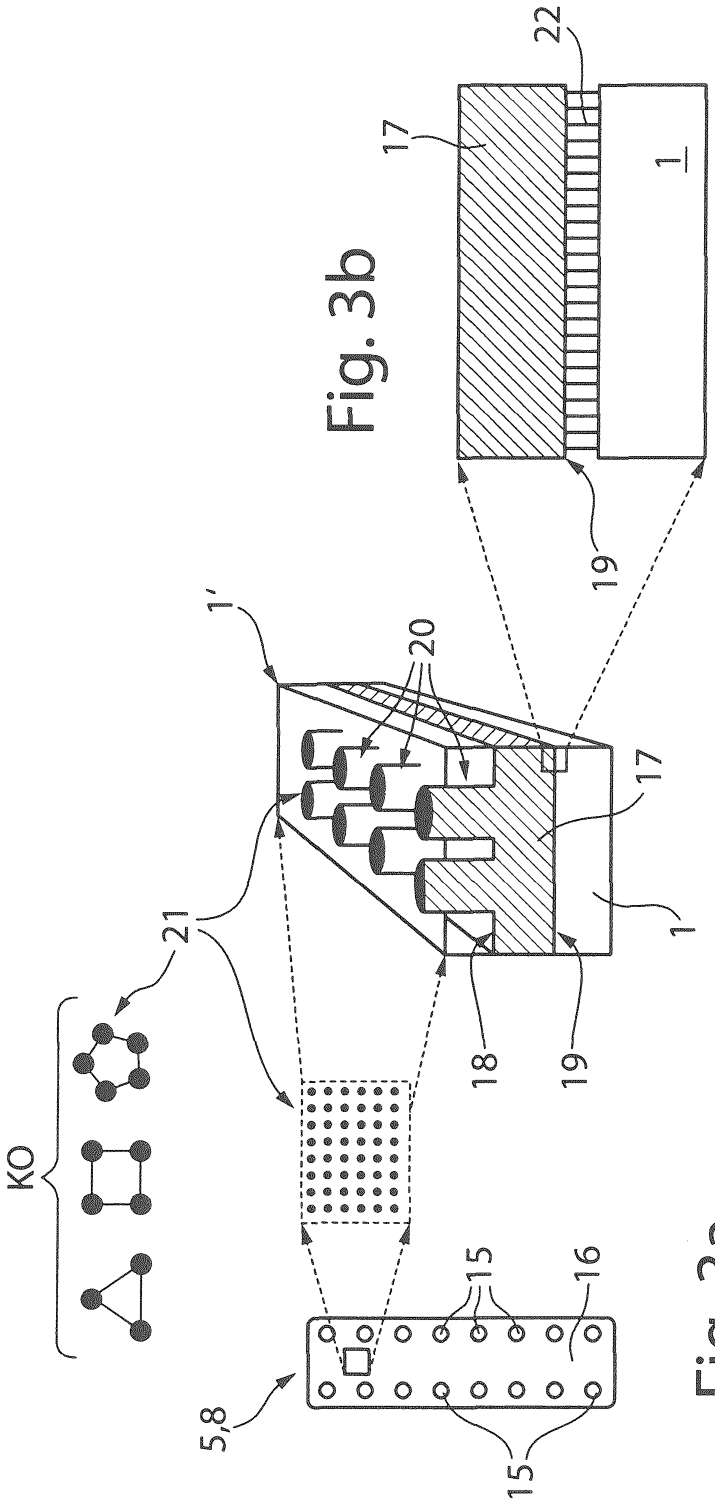

Fig. 3a

Fig. 3b

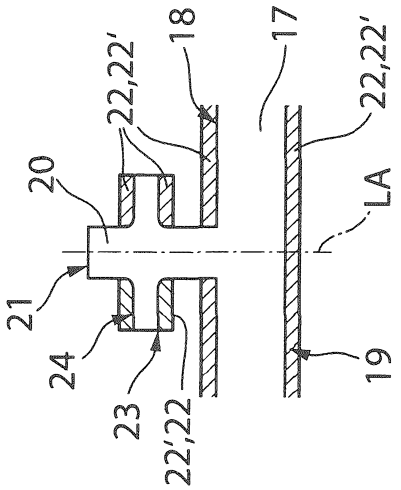

Fig. 3c

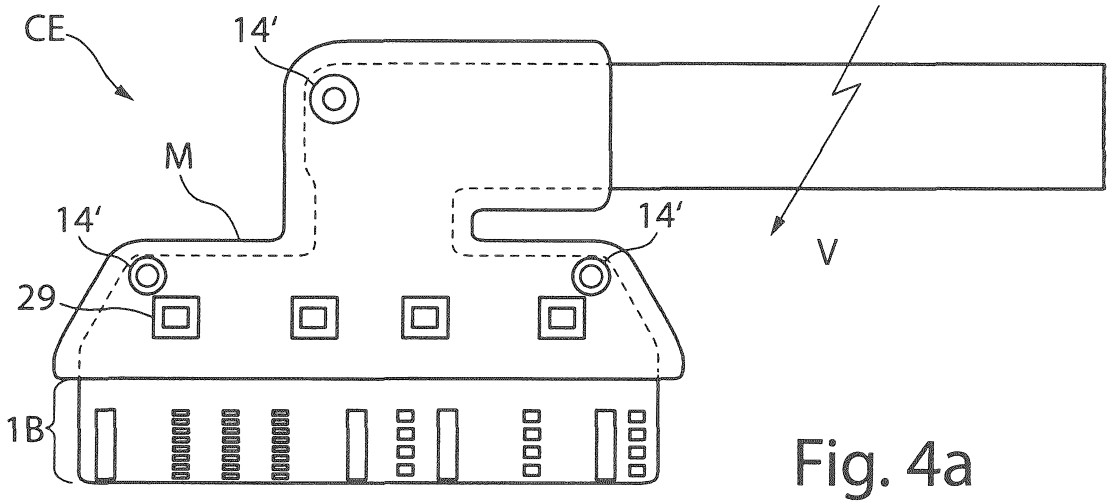

Fig. 4a

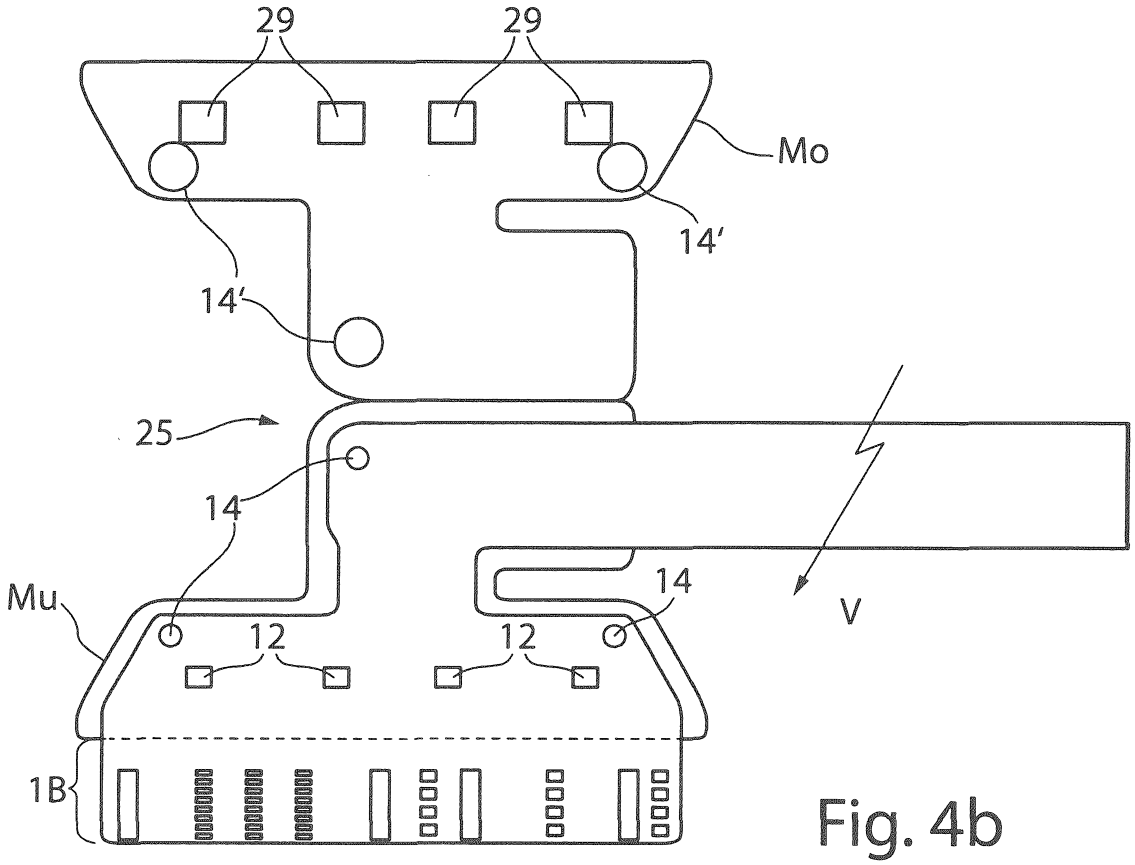

Fig. 4b

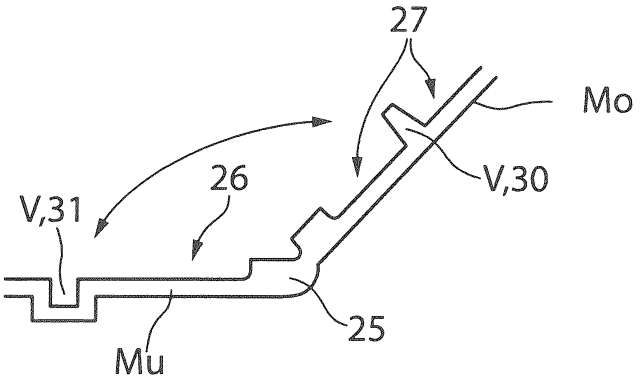

Fig. 4c

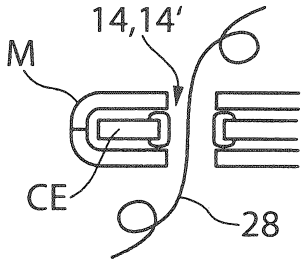

Fig. 4d

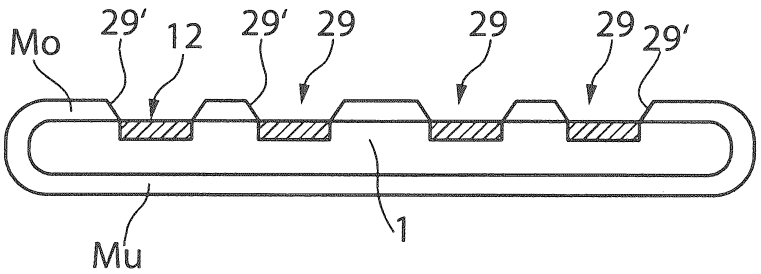

Fig. 4e

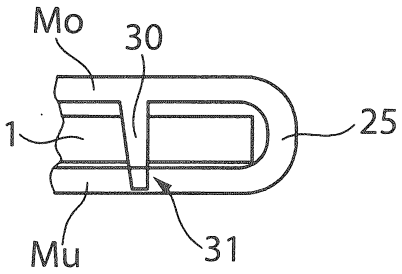

Fig. 4f

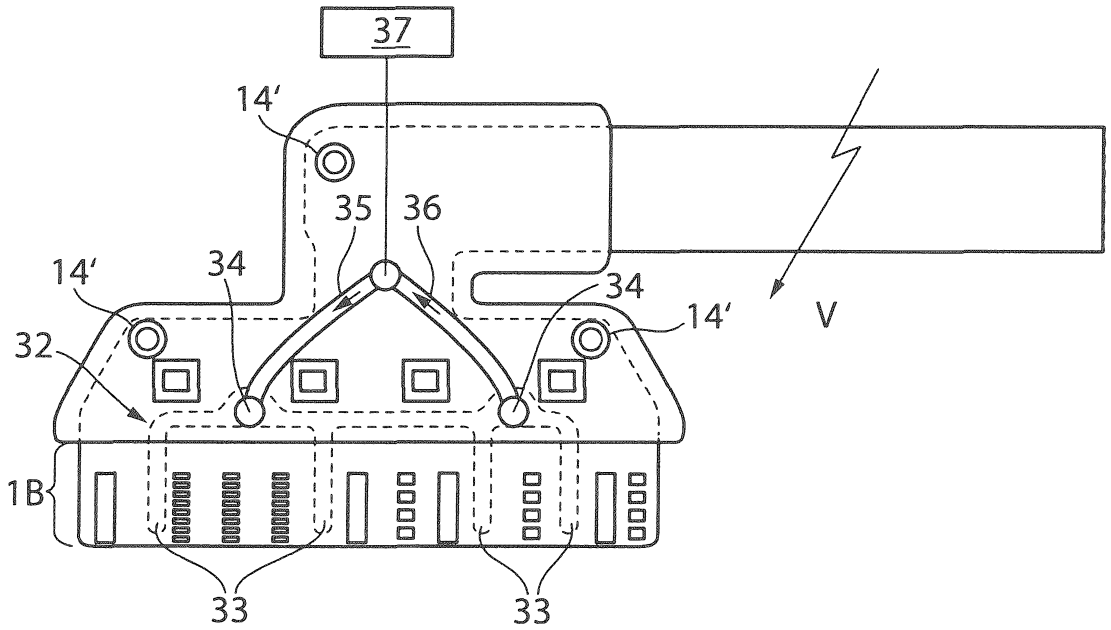

Fig. 5