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(54) INTRACRANIAL SENSING & MONITORING DEVICE WITH MACRO AND MICRO ELECTRODES

INTRAKRANIELLE MESS- UND ÜBERWACHUNGSVORRICHTUNG MIT MAKRO- UND MIKROELEKTRODEN

DISPOSITIF DE DÉTECTION & DE SURVEILLANCE INTRACRÂNIENNES AYANT DES MACRO-ÉLECTRODES ET DES MICROÉLECTRODES

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(56) References cited:
WO-A1-2011/067297 US-A- 5 237 995
US-A1- 2010 292 602 US-B2- 7 536 215
US-B2- 7 945 330

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Description

FIELD OF THE INVENTION

[0001] This invention is related generally to intracranial sensing devices and, more particularly, to strip/grid and depth electrode sensing devices.

BACKGROUND OF THE INVENTION

[0002] Monitoring and surgical removal of epileptogenic brain is indicated for the treatment of many medically refractory focal seizure disorders. Such surgery demands a high degree of accuracy in identifying the epileptogenic foci. Various methods have been used in attempting to determine the location of these foci, and all involve sensing cortical electrical activity using electrical contacts applied in various ways.

[0003] While scalp contacts were customarily used for many years to identify epileptogenic foci, accurate localization of the foci was usually very difficult with the recordings obtained from such contacts. Therefore, it has become customary for medical centers to use intracranial recording techniques to better define regions of cortical epileptogenicity whereby the safety and effectiveness of epileptogenic brain monitoring and removal is enhanced.

[0004] Intracranial recording techniques have typically involved one of two different types of sensing devices - intracortical depth electrodes or cortical strip/grid electrodes. Depth electrodes are necessary in certain circumstances and applications. Techniques using cortical strip/grid electrodes have been shown to be relatively safe and serve as an alternative to depth electrodes.

[0005] Cortical strip/grid electrodes are not invasive of brain tissue. Depth electrodes are narrow, typically cylindrical dielectric structures with contact bands spaced along their lengths. Such electrodes are inserted into the brain in order to establish good electrical contact with different portions within the brain. Cortical strip/grid electrodes, on the other hand, are flat strips that support contacts spaced along their lengths. Such strip/grid electrodes are inserted between the dura and the brain, along the surface of and in contact with the brain, but not within the brain.

[0006] Examples of such electrodes include but are not limited to electrodes described in United States Patent Nos. 4,735,208 (Wyler, et al.), 4,805,625 (Putz), 4,903,702 (Putz), 5,044,368 (Putz), and 5,097,835 (Putz).

[0007] A cortical strip/grid electrode has a flexible dielectric strip within which a plurality of spaced aligned flat contacts and their lead wires are enclosed and supported in place between front and back layers of the material forming the dielectric strip. Each flat contact has a face or main contact surface which is exposed by an opening in the front layer of the dielectric strip. Insulated lead wires, one for each contact, are secured within the strip and exit the strip from a proximal end. The dielectric ma-

terial used in such cortical strip/grid electrodes is typically a flexible, bio-compatible material such as silicone.

[0008] While the "typical" cortical strip/grid electrode works fine in many situations, there are applications for which its structure is not well suited. For instance, it may be desirable to sense and record both cellular activity within the brain with a microelectrode while simultaneously monitoring/recording standard electroencephalography (EEG) activity of the brain with a macroelectrode. One example for a comparable device carrying distinct microelectrodes and macroelectrodes is known from US Patent Application US 2010/0292602 A1. However, the respective microelectrodes and macroelectrodes of said device are arranged at some distance from each other. Cortical sensing devices that allow sensing elements such as electrical contacts to simultaneously sense/record both cellular and EEG activity in an easy and safe manner would be an improvement over the current state of the art.

OBJECTS OF THE INVENTION

[0009] It is an object of the invention to provide an improved cortical sensing device that simultaneously monitors/records both cellular and EEG activity in an easy and safe manner.

[0010] Another object of the invention is to provide a cortical sensing device that is easy to place at a desired position on the brain surface.

[0011] Another object of the invention is to provide a cortical sensing device that anchors itself to the brain surface so as to prevent unintentional movement of the sensing device with respect to the brain surface.

[0012] Another object of the invention is to provide a cortical sensing device that provides a large surface area contacting the brain.

[0013] Another object of the invention to provide a method of accurately positioning a cortical sensing device upon the brain surface.

[0014] These and other objects of the invention will be apparent from the following descriptions and from the drawings.

SUMMARY OF THE INVENTION

[0015] The invention is for an improved cortical sensing device for contact with the surface of the brain at a desired position on a brain surface. The sensing device includes a support member of a flexibly-conformable material and having a first surface. The support member is substantially thin and made from material that is flexibly-conformable. Flexibly-conformable refers to the ability of the support member to easily conform to the contours of the brain surface where the sensing device is placed while being able to recover its original shape and size when removed. The sensing device also includes at least one macroelectrode sensing element secured with respect to the support member and having a macroelectrode brain-con-

tact surface as well as at least one microelectrode sensing element secured with respect to the macroelectrode and having a microelectrode brain-contact surface surrounded by the macroelectrode brain-contact surface. The first surface, the macroelectrode brain-contact surface and the microelectrode brain-contact surface are substantially co-planar to abut the surface of the brain for sensing and monitoring.

[0016] The microelectrode sensing element is a micro-wire insulated therealong to the microelectrode brain-contact surface with a bio-compatible material to prevent electrical interaction between the microelectrode sensing element and macroelectrode sensing element. Preferred is that the macroelectrode sensing element includes a lead wire extending from it. A highly preferred embodiment finds the lead wire and the micro-wire being imbedded in and extending along the support member to exit therefrom for remote electrical connection.

[0017] Most preferred is that the microelectrode sensing element is adapted to monitor cellular neuron activity signals within the brain, while the macroelectrode sensing element is adapted to monitor EEG brain activity signals from the brain.

[0018] A highly preferred embodiment includes the macroelectrode sensing element being a flat member which has peripheral portions engaged by the support member. Another highly preferred embodiment includes the macroelectrode sensing element having a recessed flange thereabout engaged by the support member such that the macroelectrode brain-contact surface is substantially co-planar with the first surface of the support member.

[0019] It is preferred that the macroelectrode sensing element has a rear surface opposite the macroelectrode brain-contact surface with bio-compatible epoxy thereon further securing the microelectrode sensing element to the macroelectrode sensing element. More desirable is that the support member be formed from a dielectric, bio-compatible material, most preferably a medical or implant grade silicone, polyurethane or other biocompatible elastomer.

[0020] A highly desirable embodiment includes a plurality of microelectrode sensing elements spaced from one another on the macroelectrode sensing element. Also highly preferred is that the support member is an elongate strip or grid array having a plurality of macroelectrode sensing elements therealong, each having at least one of the microelectrode sensing element. Preferably the support member includes a center portion which has the macroelectrode sensing element and its related microelectrode sensing element(s) and has a peripheral portion and a plurality of flexible pads thereabout. Preferably each pad is located along the peripheral portion and has its own center, the plurality of pads are positioned such that the centers are not collinear. The flexible pads facilitate engagement of the sensing device with brain surface. In this manner, the sensing device is substantially clover-shaped.

[0021] Most desirable is that the macroelectrode sensing element be comprised of a single layer of material having a thickness of about 0.0005-0.004 inches and a diameter of about 1.0 mm.-10.0 mm. Also desirable is that the material is stainless steel or a noble alloy selected from the group consisting of platinum, gold, palladium, iridium and ruthenium alloys and combinations thereof.

[0022] It is desirable that the microelectrode brain-contact surface has a diameter of about 10-250 microns. Also desirable is that the microelectrode sensing element be comprised of a noble alloy selected from the group consisting of platinum, gold, palladium, iridium and ruthenium alloys and combinations thereof.

[0023] Another highly preferred embodiment for a sensing device for contact with brain tissue includes a flexible support sleeve having an outer surface and inner surface defining a cavity. The highly preferred embodiment also includes at least one macroelectrode sensing element secured with respect to the outer surface and having a macroelectrode brain-contact surface as well as a lead wire secured to each macroelectrode sensing element and extending into and along the cavity. The highly preferred embodiment further includes at least one microelectrode sensing element secured with respect to the macroelectrode sensing element and having a microelectrode brain-contact surface surrounded by the macroelectrode brain-contact surface as well as a micro-wire secured to each macroelectrode sensing element and extending into and along the cavity. It is most preferred that the macroelectrode brain-contact surface and the microelectrode brain-contact surface are in substantially the same curved surface to abut brain tissue for sensing and monitoring.

[0024] The sensing device includes the features as described above, and also includes a linear-array plural-contact tail on the end of the electrode which is not implanted in the brain (this is the end distal from the macroelectrode sensing element and microelectrode sensing element). In highly preferred embodiments, the plural contacts of the plural-contact tail are annular sleeves having necked-in (e.g., crimped) ends. This configuration of a plural-contact tail allows connection with a medical connector and monitoring device remote from the patient.

[0025] Other objects, advantages and features will become apparent from the following specification when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026]

FIG. 1 is a top view of a cortical sensing device shown in the grid/strip electrode embodiment, in accordance with this invention.

FIG. 2 is a close-up view of the sensing device of FIGURE 1, showing the lead wire and micro-wires as well as the plural-contact tail.

FIG. 3 is a cross-sectional view of the cortical sensing

device taken substantially along line 3-3 of FIG. 2. FIG. 4 is a cross-sectional view of the cortical sensing device of FIGURE 1, showing the macroelectrode sensing element as a flat member.

FIG. 5 is a top view of an embodiment of the sensing device of FIGURE 1, illustrating the pads.

FIG. 6 is a cross-sectional view of the cortical sensing device taken substantially along line 6-6 of FIG. 5.

FIG. 7 is a cross-sectional view of the cortical sensing device of FIGURE 1, showing the macroelectrode sensing element as a flat member.

FIG. 8 is a perspective view of an alternative embodiment of the sensing device of FIGURE 1, illustrating the flexible support sleeve.

FIG. 9 is a cross-sectional view of the sensing device taken substantially along line 9-9 of FIG. 8.

FIG. 10 is a cross-sectional view of the sensing device taken substantially along line 10-10 of FIG. 9.

FIG. 11 is a cross-sectional view of the sensing device taken substantially along line 11-11 of FIG. 10.

FIG. 12 is a cross-sectional view of the sensing device of FIGURE 8.

FIG. 13 is a cross-sectional view of the sensing device taken substantially along line 13-13 of FIG. 12.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0027] FIGURES 1-2 are top views of a cortical sensing device 10 having a preferred embodiment in accordance with this invention. Cortical sensing device 10 includes a support member 14 made of a flexibly-conformable material. Support member 14 has a first surface 16 for contact with a surface of the brain 12. Device 10 also includes at least one macroelectrode sensing element 18 secured with respect to support member 14. Macroelectrode sensing element 18 has a macroelectrode brain-contact surface 20. Device 10 includes at least one microelectrode sensing element 22 which is secured with respect to macroelectrode 18 and has a microelectrode brain-contact surface 24 surrounded by macroelectrode brain-contact surface 20. First surface 16, macroelectrode brain-contact surface 20 and microelectrode brain-contact surface 24 are substantially co-planar to abut the surface of brain 12 for sensing and monitoring. FIGURES 1-2 illustrate sensing device 10 as a grid/strip electrode.

[0028] FIGURES 3-4 illustrate that microelectrode sensing element 22 is a micro-wire 26 which is insulated along its length up to microelectrode brain-contact surface 24. Micro-wire 26 is insulated with a bio-compatible material 28 to prevent electrical interaction between microelectrode sensing element 22 and macroelectrode sensing element 18. It is important to note that each macroelectrode sensing element 18 has one or more microelectrode sensing elements 22. By way of example only, FIGURES 1-11 illustrate two microelectrode sensing elements 22 for each macroelectrode sensing elements

18.

[0029] FIGURES 3-4 also illustrate that a lead wire 30 extends from macroelectrode sensing element 18. Lead wire 30 and micro-wire(s) 26 are imbedded in and extend along support member 14 to exit therefrom for remote electrical connection as shown in FIGURES 2 and 5. Microelectrode sensing element 22 is adapted to monitor cellular neuron activity signals within the brain, while macroelectrode sensing element 18 is adapted to monitor EEG brain activity signals from the brain. Microelectrode sensing element 22 operates at a higher frequency than macroelectrode sensing element 18.

[0030] Macroelectrode sensing element 18 can be a flat member with peripheral portions 34 engaged by support member 14 as shown in FIGURES 4 and 7. Macroelectrode sensing element 18 can also have a recessed flange 36 which engages support member 14 such that macroelectrode brain-contact surface 20 is substantially co-planar with first surface 16 of support member 14 as seen in FIGURES 3 and 6. Both the flat member and recessed flange 36 configurations of macroelectrode sensing elements 18 have a diameter of 1.0 to 10.0 mm that is exposed to surface of brain 12.

[0031] FIGURES 3-4 and 6-7 illustrate that macroelectrode sensing element 18 has a rear surface 38 opposite macroelectrode brain-contact surface 20. Rear surface 38 has bio-compatible epoxy 40 thereon to further secure microelectrode sensing element 22 to macroelectrode sensing element 18. Microelectrode sensing element 22 and macroelectrode sensing element 18 are also secured through frictional engagement.

[0032] Support member 14 is preferably of a medical or implant grade silicone, polyurethane or other biocompatible elastomer. Support member 14 is formed from a single thin and substantially planar layer of a dielectric material that is both flexible and bio-compatible (see FIGURES 1-2). A silicone material such as a medical grade of SILASTIC® is preferred although an equivalent dielectric elastomer can also be used. The material is also preferably transparent to enable the underlying features of the cortical surface to be visualized when sensing device 10 is placed upon the brain.

[0033] FIGURE 1 shows that device 1 includes one or a plurality of microelectrode sensing elements 22 spaced from one another on macroelectrode sensing element 18. Support member 14 can be an elongate strip or grid array which has a plurality of macroelectrode sensing elements 18 therealong, each having at least one or many microelectrode sensing elements 22 as seen in FIGURES 1-2.

[0034] Cortical sensing device 10 is also provided with three substantially similar circular pads 46 extending outward from support member 14 as illustrated in FIGURE 5. FIGURE 5 illustrates that support member 14 has a center portion 42 which includes macroelectrode sensing element 18 and its related microelectrode sensing element(s) 22. Center portion 42 has a peripheral portion 44. A plurality of flexible pads 46 surround peripheral

portion 44, each pad 46 being located along peripheral portion 44 and having its own center 48. The plurality of pads 46 are positioned such that the centers 48 are not collinear. Flexible pads 46 facilitate engagement of sensing device 10 with the brain surface. Pads 46 interact with brain surface 12 so that sensing device 10 clings to the cortex. Lateral movement of sensing device 10 is avoided once device 10 has been individually positioned at a desired specific location that is selected by the physician for that device 10 to perform a certain procedure such as sensing brain activity.

[0035] As illustrated best in FIGURES 1-2 and 5, macroelectrode sensing element 18 is comprised of a single layer of material having a thickness of about 0.0005-0.004 inches and a diameter of about 1.0 mm.-10.0 mm. Microelectrode brain-contact surface 24 preferably has a diameter of about 10-250 microns.

[0036] The thickness and diameter of support member 14 are substantially uniform throughout the strip, preferably about 0.006 in. In the support member 14 embodiment with pads 46, the center 48 of each pad 46 is equidistant from the centers of the other two pads, thereby forming a clover-like shape. Each pad 46 is attached to support member 14 along an arc as seen in FIGURE 5.

[0037] Pads 46 do not need to be sandwiched between the dura and the cortex to remain in place. Moreover, given the size and shape of sensing device 10, one can clearly understand that the weight of sensing device 10 is less of a factor in its ability to stay in one spot than is the case for the heavier strip sensing devices in the prior art.

[0038] The thinness of pads 46, the length of arcs, and the nature of the material selected for support member 14 each contribute to the ability of pads 46 to retain their shape but still be sufficiently flexible to conform to an area of brain surface 12 of comparable size.

[0039] Macroelectrode sensing element 18 and microelectrode sensing element 22 are preferably constructed from a noble alloy such as platinum, gold, palladium, iridium and ruthenium alloys and combinations thereof. Macroelectrode sensing element 18 can be also constructed of stainless steel.

[0040] As seen in FIGURES 8-11, another embodiment of device 10 is commonly referred to as a depth electrode for contact with brain tissue. In this embodiment device 10 includes a flexible support sleeve 50 as seen best in FIGURE 8. Support sleeve 50 has an outer surface 52 and an inner surface 54 which define cavity 56 as illustrated in FIGURE 10. Preferably, support sleeve 50 is constructed of a one-piece body so as to be a seamless component as illustrated in FIGURES 12-13. Macroelectrode sensing element 18 is preferably flush with support sleeve 50, however, an alternative embodiment is to have macroelectrode sensing element 18 slightly recessed inward from support sleeve 50 as seen in FIGURES 9-10 and 12-13.

[0041] In this embodiment, at least one macroelectrode sensing element 18 is secured with respect to outer

surface 52 and has a macroelectrode brain-contact surface 20 as illustrated in FIGURES 9-10. Lead wire 30 is secured to each macroelectrode sensing element 18 and extends into and along cavity 56 as shown in FIGURES 10-11. At least one microelectrode sensing element 22 is secured with respect to macroelectrode sensing element 18 and microelectrode sensing element 22 includes a microelectrode brain-contact surface 24 surrounded by macroelectrode brain-contact surface 20. This embodiment also includes a micro-wire 26 secured to each macroelectrode sensing element 18 as seen best in FIGURE 10. Micro-wire 26 extends into and along cavity 56. Macroelectrode brain-contact surface 20 and microelectrode brain-contact surface 24 are in substantially the same curved surface to abut brain tissue 12 for sensing and monitoring. In this embodiment, macroelectrode sensing element 18 is comprised of a single layer of material having a thickness of about 0.0005-0.004 inches and a diameter of about 0.3 mm.-5.0 mm.

[0042] Device 10, whether in a strip/grid configuration or depth electrode configuration, typically includes a linear-array plural-contact tail 58 on the end of device 10 which is not implanted in the brain (this is the end distal from the macroelectrode sensing element 18 and microelectrode sensing element 22) as shown in FIGURES 1-2 and 8. Plural contacts 60 of plural-contact tail 58 are annular sleeves having necked-in (e.g., crimped) ends. This configuration of a plural-contact tail 58 allows connection with a medical connector and external monitoring device remote from the patient. Where device 10 is intended to monitor electrical brain activity, external monitoring device will preferably consist of a conventional monitoring device with output display and a suitable power source to record or display information communicated by sensing device 10.

[0043] Device 10 is also provided with numerical indicia (not shown) to use to distinguish one device 10 from the others as numerous devices 10 maybe used at one time. The numerical indicia allows individual users to more quickly, easily and with greater assurance associate each device 10 with a corresponding external device

[0044] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art.

Claims

1. A cortical sensing device (10) for contact with the surface of the brain comprising:

a support member (14) of a flexibly-conformable material and having a first surface (16);
at least one macroelectrode sensing element (18) secured with respect to the support member (14) and having a macroelectrode brain-contact surface (20); and

- at least one microelectrode sensing element (22) secured with respect to the macroelectrode, and having a microelectrode brain-contact surface (24), wherein the first surface (16), the macroelectrode brain-contact surface (20) and the microelectrode brain-contact surface (24) are substantially co-planar to abut the surface of the brain for sensing and monitoring;
- characterized in that**
- on each macroelectrode sensing element (18) there is included one or a plurality of microelectrode sensing elements (22) spaced from one another so that the microelectrode brain-contact surface (24) is surrounded by the macroelectrode brain-contact surface (20); and the microelectrode sensing element (22) is a micro-wire (24) insulated therealong to the microelectrode brain-contact surface (24) with a bio-compatible material (28) to prevent electrical interaction between the microelectrode sensing element (22) and macroelectrode sensing element (18).
2. The sensing device (10) of claim 1 further including a lead wire (30) extending from the macroelectrode sensing element (18), the lead wire (30) and the micro-wire (26) being imbedded in and extending along the support member (14) to exit therefrom for remote electrical connection.
 3. The sensing device of claim 1 wherein the microelectrode sensing element (22) is adapted to monitor cellular neuron activity signals within the brain, while the macroelectrode sensing element (18) is a flat member with peripheral portions (34) engaged by the support member (14) and adapted to monitor EEG brain activity signals from the brain.
 4. The sensing device (10) of claim 1 wherein the macroelectrode sensing element (18) has (a) a recessed flange (36) thereabout engaged by the support member (14) such that the macroelectrode brain-contact surface (20) is substantially co-planar with the first surface (16) of the support member (14); and (b) a rear surface (38) opposite the macroelectrode brain-contact surface (20) with bio-compatible epoxy (40) thereon further securing the microelectrode sensing element (22) to the macroelectrode sensing element (18).
 5. The sensing device (10) of claim 1 wherein the support member (14) is formed from a dielectric, bio-compatible material or is of a medical or implant grade silicone, polyurethane or other biocompatible elastomer.
 6. The sensing device (10) of claim 1 further including a plurality of the microelectrode sensing elements (22) spaced from one another on the macroelectrode sensing element (18).
 7. The sensing device (10) of claim 1 wherein the support member (14) is an elongate strip or grid array having a plurality of macroelectrode sensing elements (18) therealong, each having at least one of the microelectrode sensing element (22).
 8. The sensing device (10) of claim 1 wherein the support member (14) comprises:
 - a center portion (42) which includes the macroelectrode sensing element (18) and its related microelectrode sensing element(s) (22) and has a peripheral portion (44); and
 - a plurality of flexible pads (46) thereabout, each pad (46) located along the peripheral portion (44) and having its own center (48), the plurality of pads (46) being positioned such that the centers (48) are not collinear, whereby the flexible pads facilitate (46) engagement of the sensing device (10) with brain surface.
 9. The sensing device (10) of claim 1 wherein the macroelectrode sensing element (18) is comprised of a single layer of material having a thickness of about 0,0127 mm - 0,1 mm and a diameter of about 1.0 mm.-10.0 mm and the material is stainless steel or a noble alloy selected from the group consisting of platinum, gold, palladium, iridium and ruthenium alloys and combinations thereof.
 10. The sensing device (10) of claim 1 wherein the microelectrode brain-contact surface (24) has a diameter of about 10-250 microns and is comprised of a noble alloy selected from the group consisting of platinum, gold, palladium, iridium and ruthenium alloys and combinations thereof.

Patentansprüche

1. Kortikale Messvorrichtung (10) zum Kontaktieren der Oberfläche des Gehirns, mit:
 - einem Trägerelement (14) aus einem flexibel anpassbaren Material, das eine erste Oberfläche (16) aufweist;
 - mindestens einem Makroelektroden-Messelement (18), das bezüglich des Trägerelements (14) befestigt ist und das eine Makroelektroden-Gehirnkontaktfläche (20) aufweist; und
 - mindestens einem Mikroelektroden-Messelement (22), das bezüglich der Makroelektrode befestigt ist und das eine Mikroelektroden-Gehirnkontaktfläche (24) aufweist, wobei die erste

- Oberfläche (16), die Makroelektroden-Gehirnkontaktfläche (20) und die Mikroelektroden-Gehirnkontaktfläche (24) im Wesentlichen derart in einer Ebene liegend angeordnet sind, dass sie an der Oberfläche des Gehirns zur Messung und zur Überwachung anliegen;
- dadurch gekennzeichnet, dass**
- an jedem Makroelektroden-Messelement (18) ein oder eine Mehrzahl von Mikroelektroden-Messelementen (22), die voneinander beabstandet sind, vorhanden ist, so dass die Mikroelektroden-Gehirnkontaktfläche (24) von der Makroelektroden-Gehirnkontaktfläche (20) umgeben ist; und
- das Mikroelektroden-Messelement (22) ein Mikro-Draht (24) ist, der entlang seiner Länge von der Mikroelektroden-Gehirnkontaktfläche (24) mit einem biologisch verträglichen Material (28) isoliert ist, um eine elektrische Interaktion zwischen dem Mikroelektroden-Messelement (22) und dem Makroelektroden-Messelement (18) zu verhindern.
2. Messvorrichtung (10) nach Anspruch 1, die des Weiteren einen Führungsdraht (30) aufweist, der sich von dem Makroelektroden-Messelement (18) erstreckt, wobei der Führungsdraht (30) und der Mikro-Draht (26) in dem Trägerelement (14) eingebettet sind und sich entlang diesem so erstrecken, dass sie dieses zum entfernt liegend elektrischen Anschließen verlassen.
 3. Messvorrichtung nach Anspruch 1, wobei das Mikroelektroden-Messelement (22) dazu eingerichtet ist, dass es zelluläre neuronale Aktivitätssignale innerhalb des Gehirns überwacht, wobei das Makroelektroden-Messelement (18) ein flaches Element mit Umfangsabschnitten (34) ist, die mit dem Trägerelement (14) in Eingriff sind und eingerichtet sind, um EEG-Gehirnaktivitätssignale des Gehirns zu überwachen.
 4. Messvorrichtung (10) nach Anspruch 1, wobei das Makroelektroden-Messelement (18) (a) einen vertieften Flansch (36) um dieses herum aufweist, der mit dem Trägerelement (14) derart in Eingriff steht, dass die Makroelektroden-Gehirnkontaktfläche (20) mit der ersten Oberfläche (16) des Trägerelements (14) im Wesentlichen in einer Ebene liegend angeordnet ist; und (b) eine hintere Oberfläche (38) gegenüber liegend der Makroelektroden-Gehirnkontaktfläche (20) mit einem biologisch verträglichen Epoxidharz (40) daran zum weiteren Verbinden des Mikroelektroden-Messelements (22) mit dem Makroelektroden-Messelement (18) aufweist.
 5. Messvorrichtung (10) nach Anspruch 1, wobei das Trägerelement (14) aus einem dielektrischen, biologisch verträglichen Material, oder aus einem medizinischen oder einem als Implantat eingestuften Silikon, einem Polyurethan oder einem anderen biologisch verträglichen Elastomer hergestellt ist.
 6. Messvorrichtung (10) nach Anspruch 1, das des Weiteren eine Mehrzahl von Mikroelektroden-Messelementen (22) aufweist, die an dem Makroelektroden-Messelement (18) voneinander beabstandet sind.
 7. Messvorrichtung (10) nach Anspruch 1, wobei das Trägerelement (14) ein länglicher Streifen oder ein Netz-Array ist, der bzw. das eine Mehrzahl von Makroelektroden-Messelementen (18) daran entlang aufweist, die jeweils mindestens eines der Mikroelektroden-Messelemente (22) aufweisen.
 8. Messvorrichtung (10) nach Anspruch 1, wobei das Trägerelement (14) aufweist:
 - einen zentralen Abschnitt (42), der das Makroelektroden-Messelement (18) und das bzw. die ihm zugeordneten Mikroelektroden-Messelemente (22) aufweist und der einen Umfangsabschnitt (44) hat; und
 - eine Mehrzahl von elastischen Pads (46) um diesen herum, wobei jedes Pad (46) entlang dem Umfangsabschnitt (44) angeordnet ist und seinen eigenen Mittelpunkt (48) hat, wobei die Mehrzahl der Pads (46) so angeordnet ist, dass die Mittelpunkte (48) nicht kollinear sind, wobei die elastischen Pads (46) die Verbindung der Messvorrichtung (10) mit der Gehirnoberfläche erleichtern.
 9. Messvorrichtung (10) nach Anspruch 1, wobei das Makroelektroden-Messelement (18) aus einer einzelnen Schicht aus einem Material mit einer Dicke von in etwa 0,0127 mm - 0,1 mm und einem Durchmesser von in etwa 1,0 mm - 10,0 mm besteht und das Material ein rostfreier Stahl ist oder eine Edelmetalllegierung ist, die aus einer Gruppe bestehend aus Platin-, Gold-, Palladium-, Iridium- und Rutheniumlegierung und Kombinationen davon ausgewählt ist.
 10. Messvorrichtung (10) nach Anspruch 1, wobei die Mikroelektroden-Gehirnkontaktfläche (24) einen Durchmesser von in etwa 10-250 μm hat und aus einer Edelmetalllegierung besteht, die aus einer Gruppe ausgewählt ist, die aus Platin-, Gold-, Palladium-, Iridium- und Rutheniumlegierung und Kombinationen daraus besteht.

Revendications

1. Dispositif de détection corticale (10) conçu pour entrer en contact avec la surface du cerveau comprenant :

un élément de support (14) constitué d'un matériau conforme de façon flexible et ayant une première surface (16) ,

au moins un élément de détection de macro-électrode (18) fixé par rapport à l'élément de support (14) et ayant une surface en contact avec le cerveau de macro-électrode (20) et

au moins un élément de détection de microélectrode (22) fixé par rapport à la macro-électrode, et ayant une surface en contact avec le cerveau de microélectrode (24), dans lequel la première surface (16), la surface en contact avec le cerveau de macro-électrode (20) et la surface en contact avec le cerveau de microélectrode (24) sont sensiblement coplanaires pour venir en butée contre la surface du cerveau afin de réaliser une détection et une surveillance,

caractérisé en ce que

sur chaque élément de détection de macro-électrode (18) se trouve un ou une pluralité d'élément(s) de détection de microélectrode (22) espacés les uns des autres de telle sorte que la surface en contact avec le cerveau de microélectrode (24) est entourée par la surface en contact avec le cerveau de macro-électrode (20) et

en ce que

l'élément de détection de microélectrode (22) est un micro-fil (24) isolé le long de celui-ci par rapport à la surface en contact avec le cerveau de microélectrode (24) avec un matériau biocompatible (28) afin d'empêcher toute interaction électrique entre l'élément de détection de microélectrode (22) et l'élément de détection de macro-électrode (18).

2. Dispositif de détection (10) selon la revendication 1, comprenant en outre un fil de connexion (30) qui s'étend à partir de l'élément de détection de macro-électrode (18), le fil de connexion (30) et le micro-fil (26) étant encastrés dans l'élément de support (14) et s'étendant le long de celui-ci pour en sortir afin d'être reliés par une connexion électrique distante.

3. Dispositif de détection (10) selon la revendication 1, dans lequel l'élément de détection de microélectrode (22) est conçu pour surveiller les signaux d'activité neuronale cellulaire à l'intérieur du cerveau, alors que l'élément de détection de macro-électrode (18) est un organe plat muni de parties périphériques (34) sur lesquelles s'engage l'élément de support (14) et conçu pour surveiller les signaux de l'activité cérébrale EEG émis par le cerveau.

4. Dispositif de détection (10) selon la revendication 1, dans lequel l'élément de détection de macro-électrode (18) a (a) une bride en creux (36) autour de celui-ci, sur lequel s'engage l'élément de support (14) de telle sorte que la surface en contact avec le cerveau de macro-électrode (20) est sensiblement coplanaire avec la première surface (16) de l'élément de support (14), et (b) une surface arrière (38) opposée à la surface en contact avec le cerveau de macro-électrode (20) avec de l'époxy biocompatible (40) sur celui-ci qui fixe en outre l'élément de détection de microélectrode (22) sur l'élément de détection de macro-électrode (18).

5. Dispositif de détection (10) selon la revendication 1, dans lequel l'élément de support (14) est composé d'un matériau diélectrique biocompatible ou de silicone, polyuréthane de qualité médicale ou pour implant, ou d'un autre élastomère biocompatible.

6. Dispositif de détection (10) selon la revendication 1, comprenant en outre une pluralité des éléments de détection de microélectrode (22) espacés les uns des autres sur l'élément de détection de macro-électrode (18) .

7. Dispositif de détection (10) selon la revendication 1, dans lequel l'élément de support (14) est une bande allongée ou une grille matricielle ayant une pluralité d'éléments de détection de macro-électrode (18) le long de celle-ci, chacune ayant au moins l'un des éléments de détection de microélectrode (22).

8. Dispositif de détection (10) selon la revendication 1, dans lequel l'élément de support (14) comprend :

une partie centrale (42) qui inclut l'élément de détection de macro-électrode (18) et son ou ses élément(s) de détection de microélectrode (22) et possède une partie périphérique (44) et une pluralité de coussinets souples (46) autour de celle-ci, chaque coussinet (46) étant situé le long de la partie périphérique (44) et ayant son propre centre (48), la pluralité de coussinets (46) étant positionnés de telle manière que les centres (48) ne soient pas colinéaires, grâce à quoi les coussinets souples facilitent (46) l'engagement du dispositif de détection (10) sur la surface du cerveau.

9. Dispositif de détection (10) selon la revendication 1, dans lequel l'élément de détection de macro-électrode (18) est constitué d'une seule couche d'un matériau ayant une épaisseur d'environ 0,0127 mm - 0,1 mm et un diamètre d'environ 1,0 mm - 10,0 mm et le matériau est de l'acier inoxydable ou un alliage noble choisi dans le groupe consistant en les alliages de platine, d'or, de palladium, d'iridium et de ruthé-

nium et des combinaisons de ceux-ci.

- 10.** Dispositif de détection (10) selon la revendication 1, dans lequel la surface en contact avec le cerveau de microélectrode (24) a un diamètre d'environ 10 - 250 microns et est constituée d'un alliage noble choisi dans le groupe consistant en les alliages de platine, d'or, de palladium, d'iridium et de ruthénium et des combinaisons de ceux-ci.

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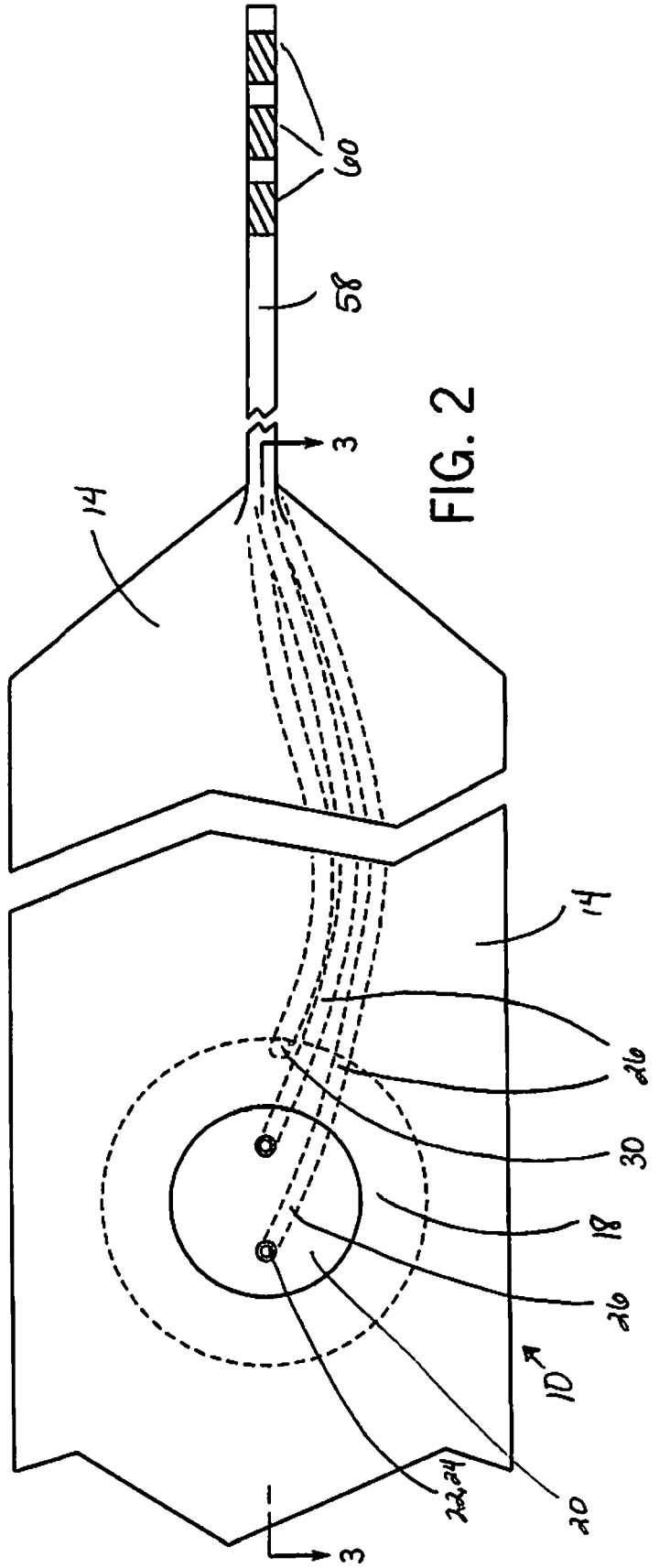
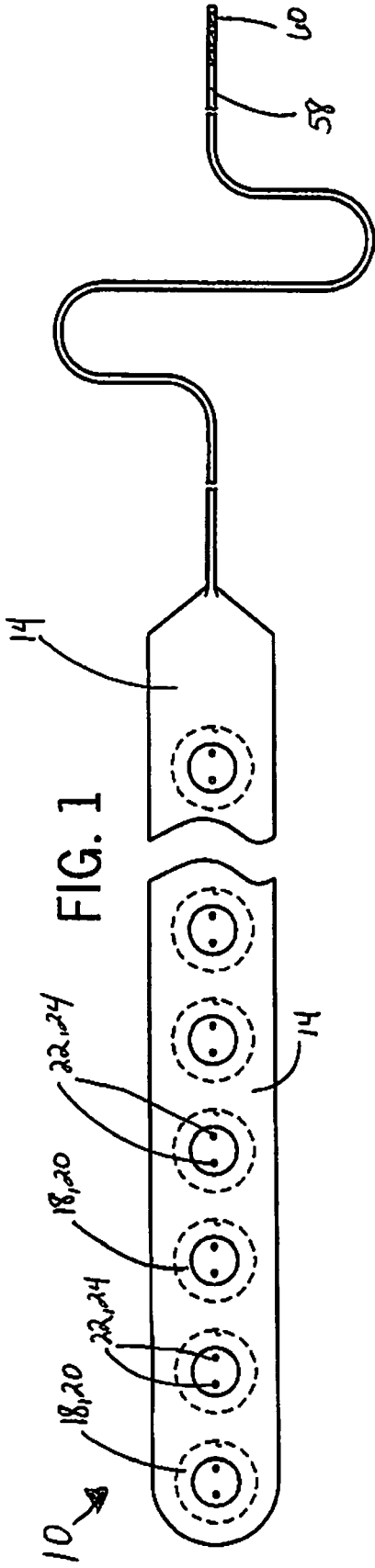
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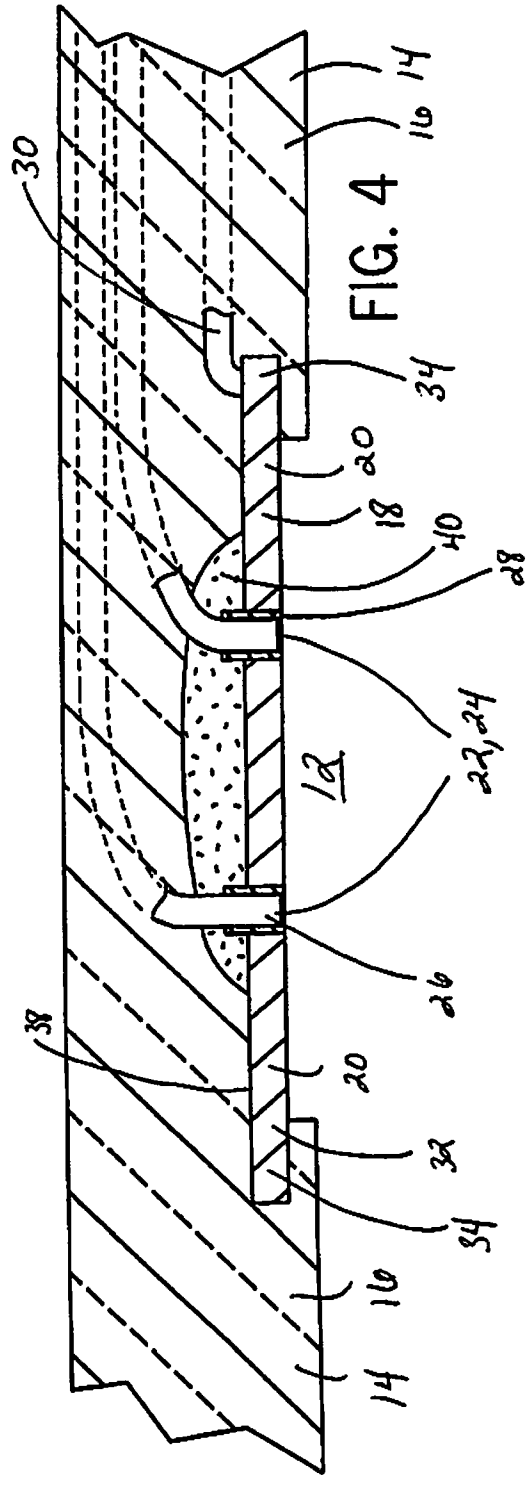
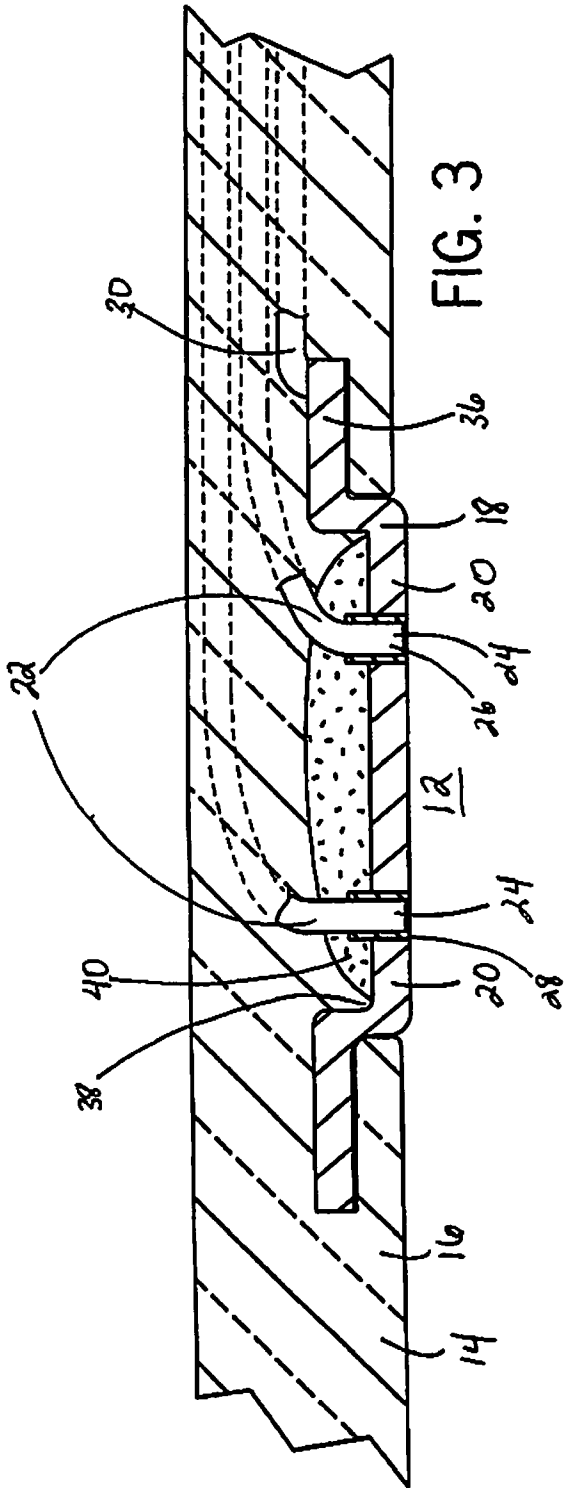
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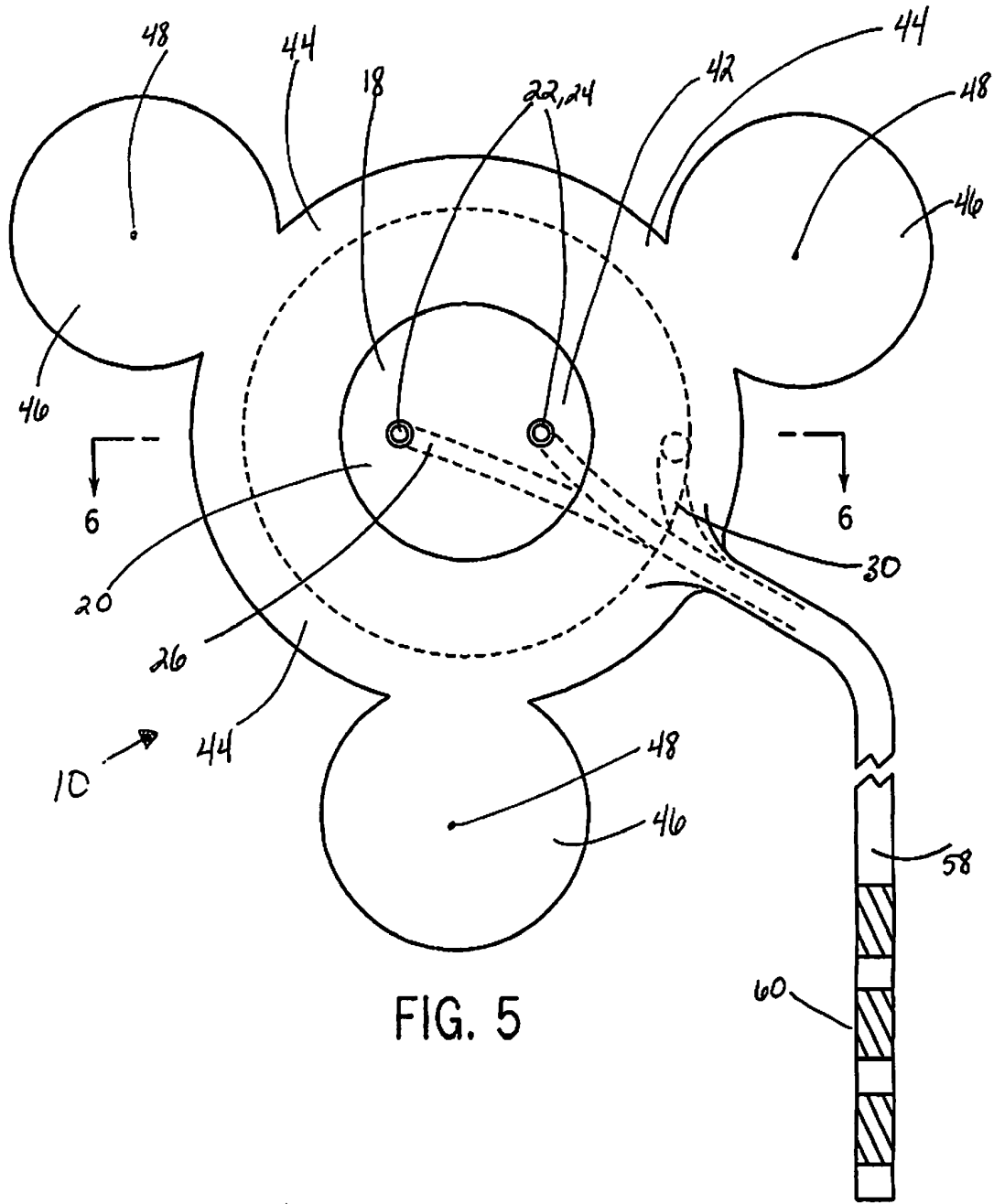


FIG. 5

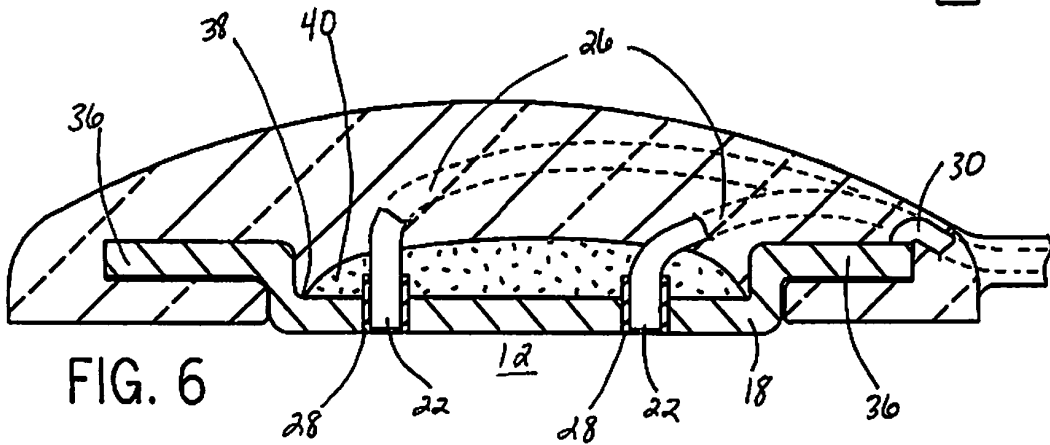


FIG. 6

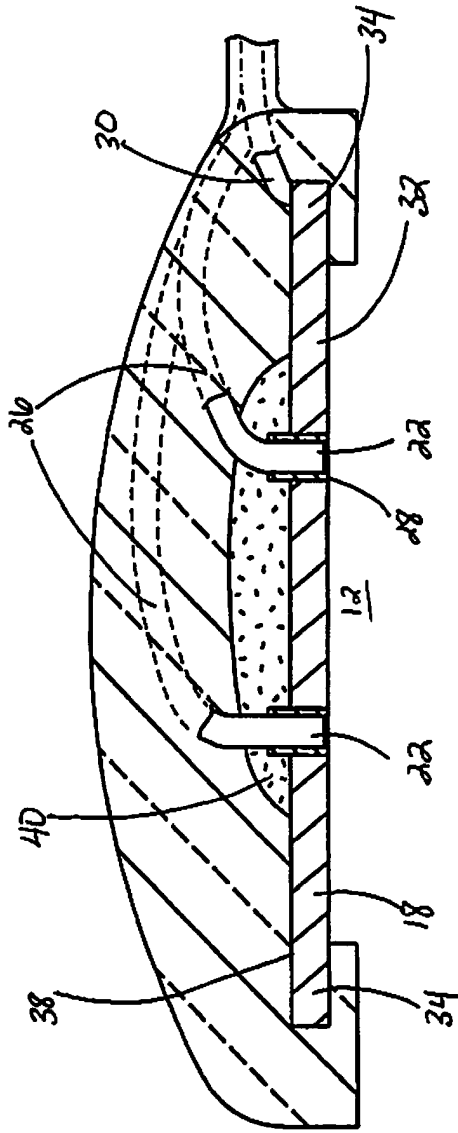


FIG. 7

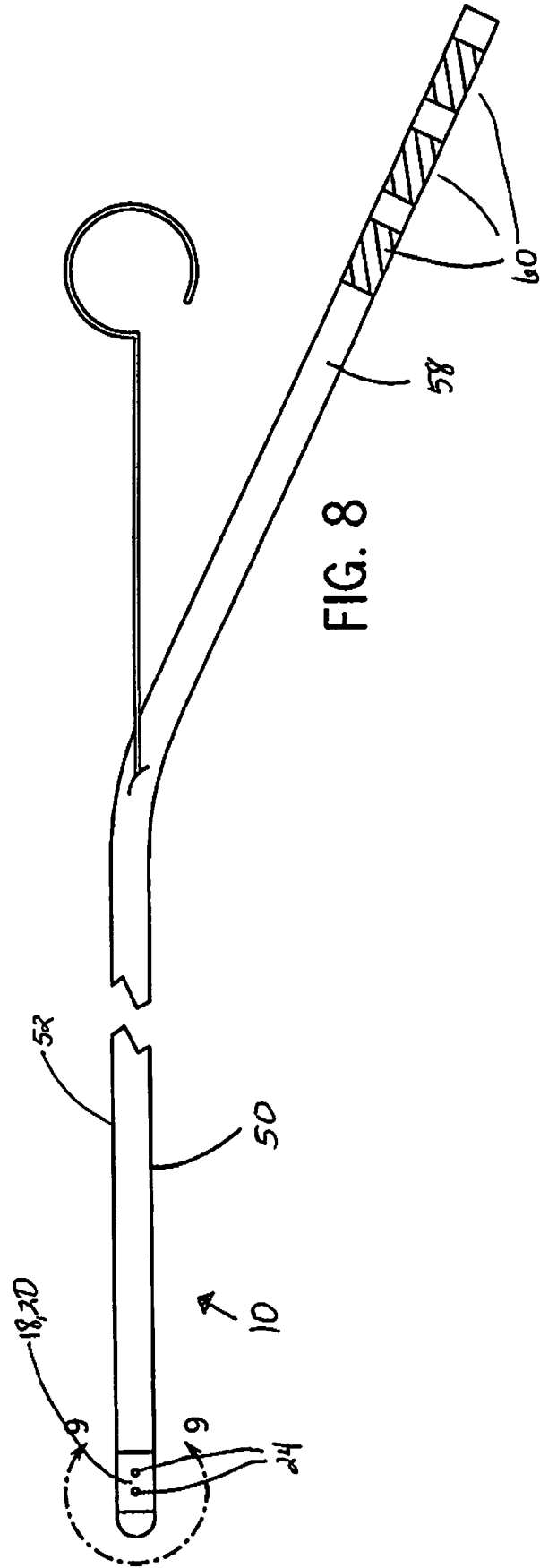


FIG. 8

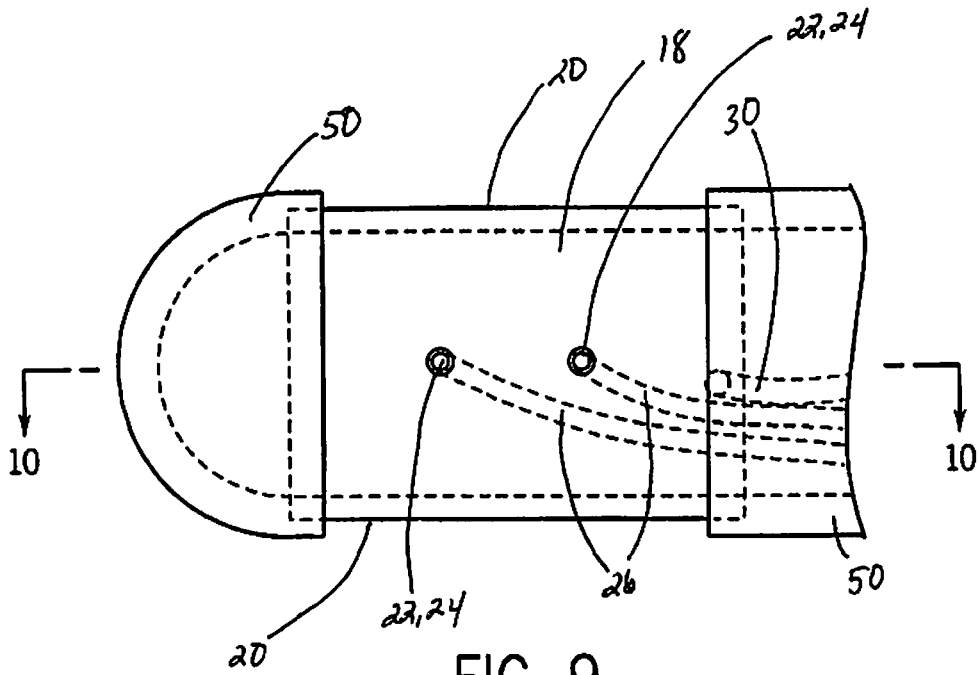


FIG. 9

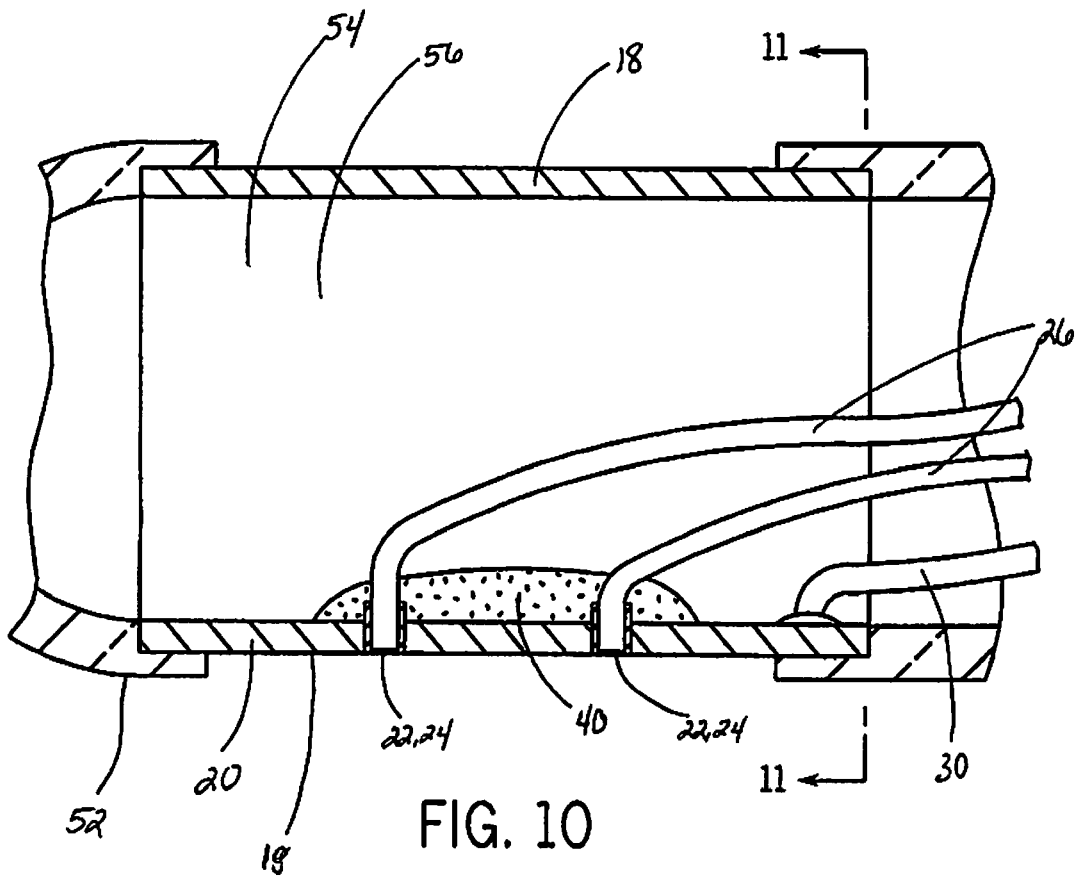


FIG. 10

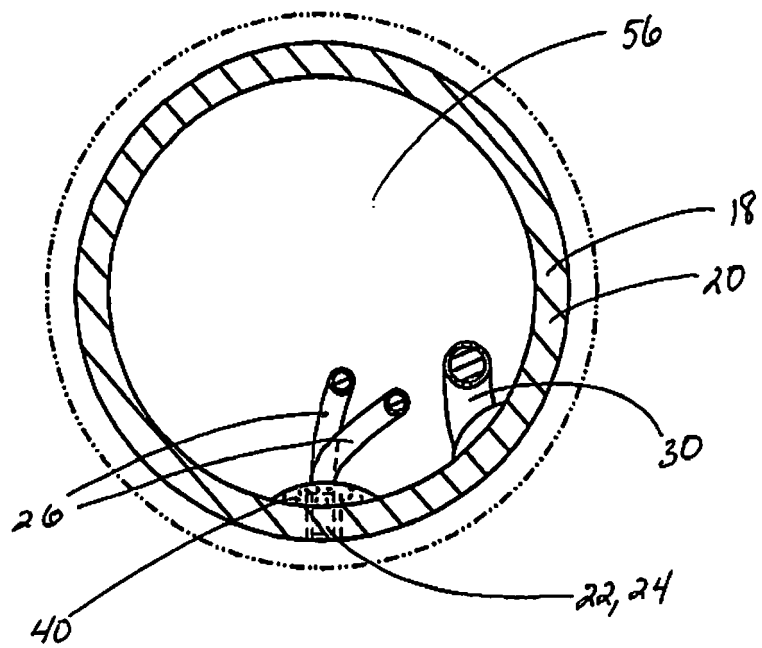


FIG. 11

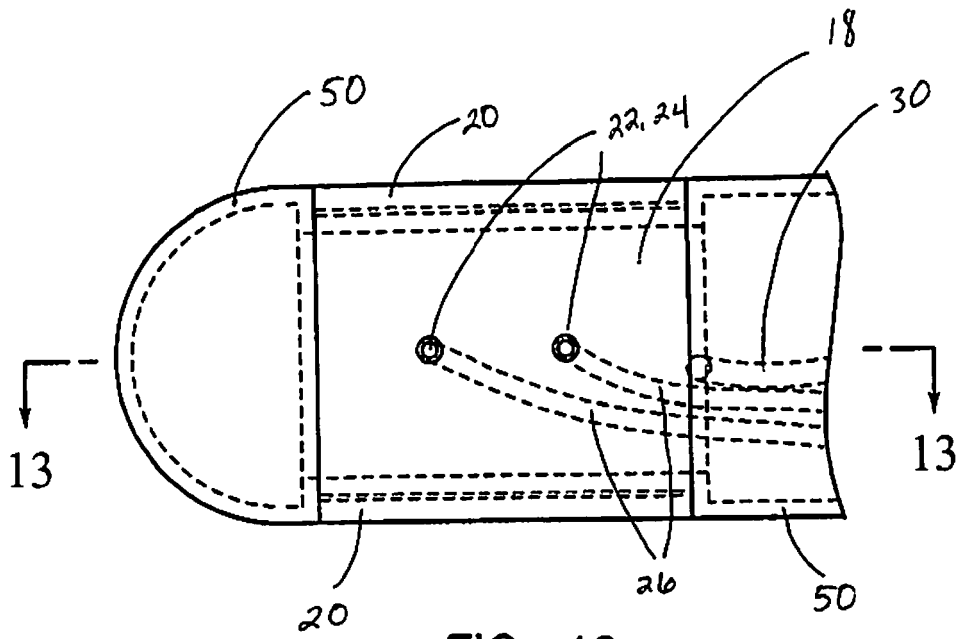


FIG. 12

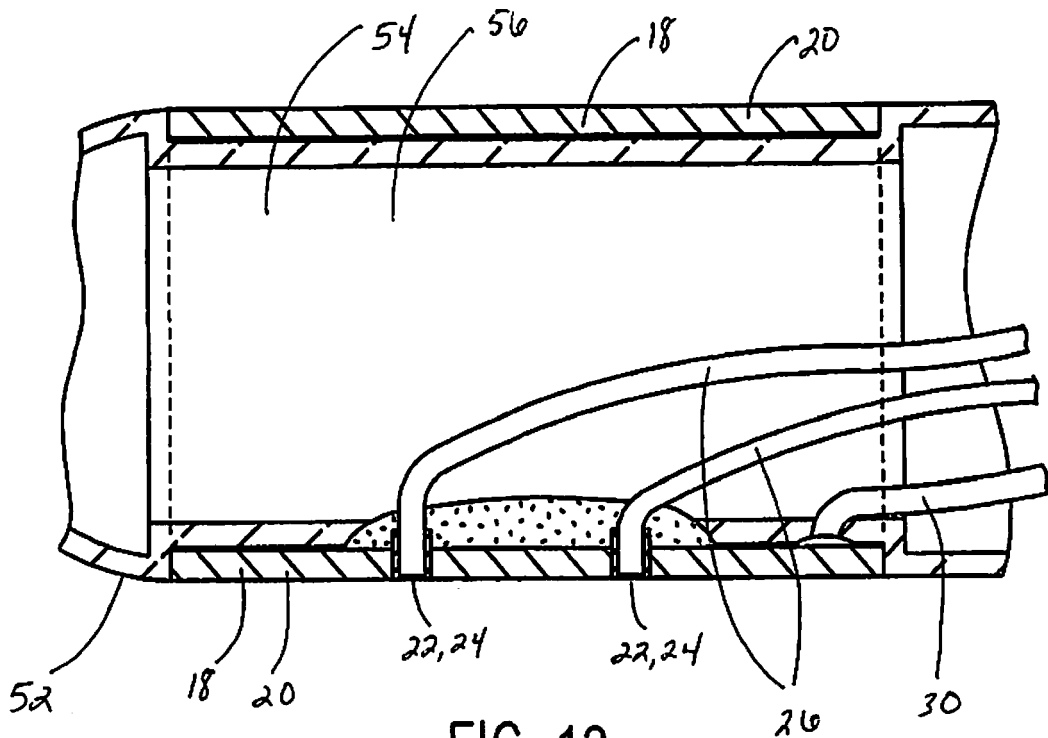


FIG. 13

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 4735208 A, Wyler [0006]
- US 4805625 A, Putz [0006]
- US 4903702 A, Putz [0006]
- US 5044368 A, Putz [0006]
- US 5097835 A, Putz [0006]
- US 20100292602 A1 [0008]

专利名称(译)	具有宏观和微电极的颅内感知和监测装置		
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当前申请(专利权)人(译)	AD-高科技医疗仪器公司		
[标]发明人	PUTZ DAVID A		
发明人	PUTZ, DAVID A.		
IPC分类号	A61B5/04 A61B5/0478 A61B5/0476 A61B5/00		
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优先权	13/434300 2012-03-29 US		
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外部链接	Espacenet		

摘要(译)

提供了一种用于与脑表面接触的皮质感测装置，其包括支撑构件，相对于支撑构件固定的至少一个宏电极感测元件和相对于大电极固定的至少一个微电极感测元件。支撑构件基本上是薄的并且由柔性适形材料制成，以将传感装置准确且安全地放置在脑表面上。微电极感测元件被宏电极感测元件的宏电极脑接触表面围绕。支撑构件的第一表面，大电极脑接触表面和微电极脑接触表面基本上共面，以邻接大脑表面以进行感测和监测。

