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(54) SET FOR APPLYING A FLAT, FLEXIBLE TWO-DIMENSIONAL THIN-FILM STRIP INTO LIVING TISSUE

SET ZUM EINSETZEN EINES FLACHEN, FLEXIBLEN, ZWEIDIMENSIONALEN DÜNNSCHICHTSTREIFENS IN LEBENDES GEWEBE

ENSEMBLE POUR APPLIQUER UNE BANDE DE FILM MINCE PLATE, FLEXIBLE ET BIDIMENSIONNELLE SUR UN TISSU VIVANT

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Description

[0001] The use of sensor and effector arrays on flexible substrates is of growing relevance for biomedical applications. The ability to construct diverse devices on biocompatible substrates which are tolerated over long time scales will allow enhanced therapeutic and diagnostic interventions as well as improvements in brain/machine interfaces. However, it is currently difficult to implant these devices into the body in a minimally invasive way because of their otherwise desirable flexibility.

[0002] The term thin-film strip as used hereinafter indicates a strip of thin film that is flexible and therefore cannot be inserted into living tissue by itself due to mechanical barriers like the dura mater if considering the brain as exemplified. The strip carries components that are to be deposited in the living tissue as e. g. electronic circuits, light guides, fluid vias and the like.

[0003] Multi-electrode arrays are currently revolutionizing basic and clinical neuroscience due to their unprecedented ability to record from and stimulate in dense populations of neurons. One of the most promising technologies for fabricating multi-electrode arrays relies on the application of Micro-Electro-Mechanical Systems (MEMS) lithographic processes to realize dense arrays with arbitrary geometries on flexible, polyimide-based or parylene-based films. Such MEMS are considered as an example of flat, flexible two-dimensional thin-film strips within the scope of the present application besides others. Such techniques have been widely adopted for surface recording from the brain because they offer freedom in design, biocompatibility over long time scales, and are minimally invasive. However, many areas of the brain of especial interest for both research and clinical applications are not accessible from such surface recordings, and the targets desirable for therapeutic stimulation often lie tens of millimeters from the brain's surface. In order to achieve access to such areas, it is desirable to penetrate the brain tissue in a minimal fashion. However, current designs to achieve this goal are either macroscopic (on the order of a millimeter) or use brittle electrode substrates, such as silicon. Existing technologies thus risk unnecessary damage to the brain both during implantation, as well as in the lifetime of the implanted device.

[0004] RUBEHN, B., et al. "Flexible shaft electrodes for transdural implantation and chronic recording". In: Proceedings of the 15th Annual Conference of the IFESS. Vienna. 2010 propose for fulfilling the contradicting requirements of stiffness of a thin-film strip to be applied during insertion and flexibility during the course of a long-term implantation a custom insertion tool for the thin-film strips, in this case for shaft electrodes. While the shaft itself is flexible, an insertion tool is used to penetrate the dura mater. The tool comprises a tungsten rod with a diameter of 100 microns and a tapered tip, and two rods with diameters of 50 microns and blunt tips. The thicker rod is glued between the two thinner ones protruding beyond them. For the implantation it is proposed that the tapered rod slides into a U-shaped profile which is glued to the back of the shaft's tip. The whole assembly is intended to be inserted into the brain, with the tapered tip of the rod penetrating the dura mater while the two blunt rods bear against the back of the U-profile, pushing it through the hole in the dura mater and into the tissue. Since it is attached to the U-profile, the flexible shaft is inserted into the brain matter. After placing the shaft at the right position, the tungsten insertion tool is withdrawn, leaving the micromachined polyimide foil (the thin-film strip) and the U-profile in the brain.

[0005] The authors themselves observe that whilst the thin-film strip could be inserted into the cortex, it was not possible to insert it through the closed dura or pia mater. Moreover, leaving the U-profile in the brain behind can be cause for undesirable damages to the tissue. US2011/0224682 A1 discloses an instrument for implanting an electrode which forms the basis of the preamble of claim 1.

[0006] The invention is defined by claim 1 and the dependent claims disclose the preferred embodiments. It is the object of the present invention to propose a set for applying a flat, flexible two-dimensional thin-film strip into living tissue, in particular brain, avoiding the above mentioned drawbacks as far as possible.

[0007] The aforementioned object is achieved by a set comprising

- the thin-film strip itself to be applied,
- an application tool removable and exclusively mechanically connectable to the thin-film strip by means of a coupling device, wherein after application of the thin-film strip in the target location the application tool is removable from the tissue without residue by mechanically disengaging the coupling device itself thereby leaving the thin-film strip behind.

[0008] The benefits of such a system include :

- the ability to target deep brain structures with flexible devices that could otherwise not penetrate at all or that could not be targeted precisely,
- implantation of the thin-film strip through minimally invasive means,
- removal of the rigid implantation device without leaving any residue so that damage to brain tissue is minimized over the lifetime of the implant,
- free determination of the timing of the insertion, i.e. the length of the penetration and the speed of release of the flexible device.

[0009] In a particular preferred embodiment the thin-film strip is a micro-electromechanical system (MEMS) in the form of a flexible multi electrode array. The set of this embodiment of the present invention allows application of such MEMS enabling neuroscientifical measurements as mentioned above.

[0010] It is preferred that the flexible thin-film strip is

polyimide-based or parylene-based which is known per se in the field of the present invention.

[0011] According to one preferred embodiment the flexible thin-film strip has a reinforced retaining hole in the distal end and the application tool consists of an insertion needle having an inner bore and a window on one side next to its distal end opening towards the bore and of a retaining wire designed to pass through the inner bore of the insertion needle and through said retaining hole in the thin-film strip lying in said window during insertion of the thin-film strip into the tissue, thereby removably locking up the flexible thin-film strip to the insertion needle.

[0012] Preferably, the insertion needle is a micro-machined, surgical-grade steel tubing with an outer diameter of 200 microns and a bore of 100 microns diameter.

[0013] In a preferred embodiment the insertion needle has a conical tip (the "insertion tip") that is sharp enough (~18 degrees) to allow penetration of the dura mater and brain tissue.

[0014] Preferably, the retaining wire is a surgical grade stainless steel wire of 70 microns diameter that can pass through the bore of the insertion needle.

[0015] The insertion tool is used to insert the thin-film strip into the brain. Said thin-film strip also will be referred to as the flexshaft hereinafter. For insertion, the flexshaft is coupled to the insertion needle and then released after being positioned at the target location. For coupling of the flexshaft to the insertion needle, the flexshaft is equipped with the reinforced retaining hole close to its end. This hole can have a diameter of 80 microns and aids in retaining the flexshaft on the insertion needle. The flexshaft is laid into the window on the side of the insertion needle such that the retaining hole fits precisely over the bore of the insertion needle as exposed through the window. The retaining wire is then threaded through the retaining hole and further into the tip of the insertion needle on the other end of the window. Thereby, the flexshaft is firmly attached to the insertion needle.

[0016] In order to form an abutment for the retaining wire the distal end of the insertion needle should be shut. Once the multi-electrode array has been placed in the area of interest, the retaining wire can then be removed, freeing the flexshaft, and subsequently, the insertion needle can be withdrawn without residue, leaving the flexshaft in place.

[0017] According to another preferred embodiment the flexible multi-electrode array tapers into a retaining thread next to its distal end consisting of a polyimide thread and the application tool consists of a solid insertion needle having a through bore in its distal end, the polyimide thread being designed to be threaded through said through bore in the insertion needle before applying the multi-electrode array.

[0018] In this approach, the polyimide flexshaft is coupled with the insertion needle by means of the polyimide thread. This technique allows for smaller dimensions of the insertion needle and sharper tips for penetrating tougher tissue. The insertion needle is preferably constructed from a 200 microns diameter steel rod. Preferably, the insertion needle is tapered in the initial 5.75 mm with a 3 degree angle and in the final millimeter to a 10 degree tip. It has a hole bored through the angled plane about 1 mm from the end The typical flexshaft for use with this insertion needle ends with a 5 cm long and 100 microns wide thread of polyimide which is narrowed further to 40 microns where it meets the flexshaft. This reduced polyimide retaining thread allows the flexshaft to be coupled to the insertion needle for implantation, but can be separated from the flexshaft mechanically once the device is implanted. The retaining thread is introduced through the hole in the insertion needle, coupling the flexshaft to the insertion needle. The flexshaft and retaining thread are produced from a single piece of polyimide and lie flush to the insertion needle. The flexshaft is inserted in this manner. Once the flexshaft has been inserted, the retaining thread is mechanically separated from the flexshaft by simply pulling on the retaining thread. The insertion needle can then be withdrawn without residue, while the flexshaft remains in place.

[0019] According to still another preferred embodiment the flexible multi-electrode array has a retaining hole next to its distal end and the application tool consists of an insertion needle having a through bore in its distal end and of a separate polyimide thread being designed to be threaded through said through bore in the insertion needle as well as through the retaining hole of the flexible multi-electrode array before applying the multi-electrode array.

[0020] In this approach, the flexshaft is coupled to the insertion needle by means of the polyimide thread. This embodiment is therefore a combination of the flexshaft of the first embodiment and the insertion needle of the second embodiment, the retaining wire of the first embodiment being replaced by the separate polyimide thread. The handling of this third embodiment is similar to the handling of the second embodiment. Before applying the flexshaft into the brain tissue the flexshaft is connected to the insertion needle by means of the separate thread by threading it through the retaining hole and through the through bore in the insertion needle. Once the flexshaft has been inserted, the polyimide thread is pulled and the mechanical connection to the flexshaft is separated such that the insertion needle and the polyimide thread can be pulled out from the surgery area without residue.

[0021] In still another preferred embodiment the flexible multi-electrode array has a reinforced retaining hole in the distal end and the application tool consists of an insertion needle having two through bores in its distal end and of a separate polyimide thread being designed to be threaded through said through bores in the insertion needle in a loop-like manner before applying the multi-electrode array the through bores serving as loop thread guide.

[0022] This forth embodiment is closely related to the

third embodiment as described before. The handling is also very similar except for forming the loop from the polyimide thread through the through bores in the tip of the insertion needle.

[0023] The set of the present invention and in particular all of the aforementioned embodiments can preferably be further developed by a removable guidetube which encases at least parts of the coupling device and the application tool prior to applying the assembly of application tool, coupling device and thin-film strip.

[0024] The guidetube allows for smaller diameter insertion needles and increases the precision of localization when targeting very deep structures. This is due to the additional mechanical stability of the assembly granted by the guidetube.

[0025] According to one embodiment, it is preferred that the tip of the guidetube has a sharp cannula-type cutting shape. This sharp-ended guidetube can penetrate through the tissue for some defined distance, prior to implantation of the application and the thin-film strip. This allows penetration of tough tissues and insures accurate targeting of very deep structures, for which the length of the application tool necessary to reach the target would result in potential bending of the application tool and subsequent misplacement.

[0026] According to an alternative embodiment, the tip of the guidetube can have a blunt or flat shape. The blunt-ended guidetube can be positioned against the dura mater and the application tool and the thin-film strip can be implanted through the dura mater and tissue. Again, this allows deep targets to be reached while providing stability and maintaining the structural integrity of the application tool.

[0027] Preferably, the guidetube consists of steel tube having an inner diameter of 220-260 micron and an outer diameter of 300-400 micron.

[0028] According to a very much preferred embodiment, the guidetube is provided with a channel cut into the outside thereof for the reception of the thin-film strip allowing the thin-film strip to stay on the outside of the guidetube during its insertion into the living tissue. In use, the application tool is placed inside the guide tube whereas the thin-film strip is affixed to the application tool through the channel. Said channel allows the thin-film strip to remain in place later after the application tool and the guidetube have been removed.

[0029] The invention will now be described in greater detail using the embodiments according to the drawing figures.

Fig. 1 shows a first embodiment of the set according to the invention, in particular
Fig.1a an insertion needle,
Fig 1b a retaining wire,
Fig.1c schematically a thin-film strip in the form of a flexible multi-electrode array, and
Fig 1d the set as put together, ready for use,

Fig. 2 shows a second embodiment of the set, in particular
Fig. 2a a sectional view of an insertion needle,
Fig. 2b a top view of the insertion needle,
Fig. 2c schematically a flexible multi-electrode array, tapering to a thread in its distal section,
Fig. 2d the set as put together,

Fig. 3 shows a third embodiment of the set, in particular
Fig. 3a an insertion needle (sectional and top view),
Fig. 3b schematically a flexible multi-electrode array,
Fig. 3c the set as put together,

Fig. 4 shows a fourth embodiment of the set, in particular
Fig. 4a an insertion needle (sectional and top view),
Fig. 4b schematically a flexible multi-electrode array,
Fig. 4c the set as put together,

Fig. 5 shows the embodiment of Fig. 1d) completed by a guidetube having a tip with a sharp cannula-type cutting shape, and

Fig. 6 shows the embodiment of Fig. 4c) completed by a guidetube having a tip showing a blunt shape.

[0030] Fig. 1 shows a first example of the set. It comprises three parts, namely the flexshaft 9, an insertion needle 10 as application tool 7and a retaining wire 13.

[0031] The flexshaft 9 is shown schematically, only. It has a reinforced retaining hole 8 in its distal end. The retaining hole 8 is provided for the accommodation of the retaining wire 13 prior to and during the application of the set. The retaining wire 13 arrests the flexshaft 9 lying within a window 12 on one side of the insertion needle 10 next to its distal end to the insertion needle 10. For this purpose the window 12 opens towards the inner bore 11 of the insertion needle 10 allowing the retaining wire 13 to be threaded through the retaining hole 8 of the flexshaft 9. In this case the coupling device is formed by the retaining wire 13 in interaction with the retaining hole 8 and the insertion needle 10.

[0032] To ease the penetration of the dura mater the insertion needle 10 has a conical tip 14 at its distal end.

[0033] Fig. 2 shows an example for the second embodiment of the set. As shown the application tool 7 consists of an solid insertion needle 15, preferably constructed from a steel rod (without an inner bore). However it has a through bore 16 in its distal end. The through bore 16 is designed to accommodate a flexible multi-electrode array 17 or flexshaft. The flexshaft is tapering towards its distal end 18 from for example 100 micron to 40 micron

(see detail Z) forming a polyimide thread.

[0034] Prior to use of the application tool the set is prepared by threading the flexshaft 17 through the through bore 16 in the insertion needle 15 such that the tapered section of the flexshaft 17 is held in the area of the through bore 16. In this combination a predetermined breaking point is created for the polyimide thread of flexshaft 17. Once the flexshaft 17 has been positioned in the area of interest the retaining thread of flexshaft 17 is separated from the flexshaft by simply pulling on its distal end 18, the retaining thread, which will lead to its breaking in the through bore 16. Then the insertion needle 15 can be pulled out from the surgery area without residue. Accordingly, the coupling device is formed by the distal end 18 of the flexible multi-electrode array 17 in interaction with the through bore 16 in the insertion needle 15.

[0035] Fig. 3 shows a further embodiment of the set. Here, the application tool 7 consists of a solid insertion needle 25 which can be constructed similar to insertion needle 15 of the aforementioned embodiment of the set. This does mean that insertion needle 25 is preferably constructed from a steel rod having a through bore 26 in its distal end. A further component of the set in this embodiment is a separate polyimide thread 29. The polyimide thread 29 enables the releasable and exclusively mechanical connection of a flexible multi-electrode array 24 to the insertion needle 25. For this reason the flexible multi-electrode array 24 resembles the flexible multi-electrode array 9 of the first embodiment and has a retaining hole 23 in the distal end. Now, for preparation of the application tool the separate polyimide thread 29 is threaded through the retaining hole 23 of the flexible multi-electrode array 24 and through the through bore 26 in the insertion needle 25. The connection of the flexible multi-electrode array 24 to the insertion needle 25 during insertion of the flexible multi-electrode array 24 into a brain is tougher as compared to the connections in the other embodiments.

[0036] Once the flexible multi-electrode array 24 has reached the desired position in the tissue the polyimide thread 29 is simply pulled on and cracks. Both ends of the cracked polyimide thread 29 as well as the insertion needle 25 can be pulled out from the surgery area leaving no residue behind. Accordingly, the coupling device in this case is formed by the polyimide thread 29 in interaction with the retaining hole 23 in the flexible multi-electrode array 24 and the through bore 26 in the insertion needle 25.

[0037] An even tougher connection between a flexible multi-electrode array and an insertion needle can be achieved by means of the embodiment according to Fig. 4.

[0038] This embodiment is very similar to the aforementioned embodiment. This is the reason why merely the differences will be highlighted hereinafter. Apart from that reference is made to the details of embodiment 3.

[0039] Here, the solid insertion needle has two through bores 36, 37 in its distal end. The separate polyimide thread 29 now needs to be threaded through both through bores 36, 37 as well as through retaining hole 23 in the flexible multi-electrode array 24. The result is a very tight and robust positioning of the array allowing it to be placed into the brain even if hard dura mater needs to be passed.

[0040] Embodiments 3 and 4 allow to reuse the flexshaft. The flexshaft is costly and can be reused for instance in animal experiments. In contrast thereto the flexshaft in embodiment 2 needs the thin thread at the distal end 18. Once this thread has been mechanically separated, one needs to use an entirely new flexshaft with thread since it seems impossible to fix a new thread to the already used flexshaft.

[0041] Embodiment 4 is preferably applied when it is desirable to record electric potentials from the flexshaft electrodes during its insertion into the tissue since no separate thread runs over the flexshaft 24.

[0042] Fig. 5 shows the embodiment of Fig. 1d. Therefore, reference is made to the respective description. However, here the embodiment has been completed by a guidetube 40 providing enhanced mechanical stability to the set. As can be seen, the retaining wire 13 and the insertion needle 10 are placed inside the guidetube 40 whereas the flexshaft 9 is placed outside of the guidetube 40. In this embodiment the guidetube 40 has tip 42 having a sharp cannula-type cutting shape.

[0043] In Fig. 6 the embodiment of Fig. 4c) is shown. For the minutes reference is made to the description thereof. However, here a guidetube 41 has been added to the assembly of the other components. Clearly, the insertion needle 35 as well as the polyimide thread 29 are placed inside the guidetube 41 whereas the flexible multi-electrode array is placed outside of the guidetube 41. Here the guidetube 41 has a tip 43 with a blunt shape.

Reference signs

[0044]

6	flexible thin-film strip
7	application tool
8	retaining hole
9	flexible multi-electrode array
10	insertion needle
11	inner bore
12	window
13	retaining wire
14	conical tip
15	insertion needle
16	through bore
17	flexible multi-electrode array
18	distal end
23	retaining hole
24	flexible multi-electrode array
25	insertion needle
26	through bore
29	polyimide thread
35	insertion needle

36 through bore
37 through bore
40 guidetube
41 guidetube
42 tip
43 tip

Claims

1. Set for applying a flat, flexible two-dimensional thin-film strip into living tissue, in particular brain comprising

- the thin-film strip (6) itself to be applied,
- an application tool (7) removable and exclusively mechanically connectable to the thin-film strip (6) by means of a coupling device (8,13;15,16,18;23,29;29,36,37), wherein:

a thread (29), wire (13) or needle (15, 25, 35) is configured to couple the thin-film strip (6) to the application tool (7) by means of a retaining hole (8, 23) in the thin-film, such that withdrawal or removal of the thread (29), wire (13) or needle (15, 25, 35) releases the thin-film strip from the application tool; or
the thin-film strip (6) tapers into a retaining thread configured to thread through a through bore (16) in the application tool (7), such that the thin-film strip (6) is releasable from the application tool (7) by pulling the thread and thereby separating the thread from the rest of the thin-film strip (6);

so that after application of the thin-film strip (6) in the target location the application tool (7) is removable from the tissue without residue by mechanically disengaging the coupling device (8,13;15,16,18;23,29;29,36,37) itself thereby leaving the thin-film strip (6) behind.

2. The set of claim 1, wherein the thin-film strip (6) is a micro-electromechanical system (MEMS) in the form of a flexible multi electrode array.

3. The set of claim 1 or 2, wherein the flexible thin-film strip (6) is polyimide-based or parylene-based.

4. The set of claim 1, 2 or 3, wherein the flexible thin-film strip (6) has a reinforced retaining hole (8) in the distal end and wherein the application tool (7) consists of an insertion needle (10) having an inner bore (11) and a window (12) on one side next to its distal end opening towards the inner bore (11) and of a retaining wire (13) designed to pass through the inner bore (11) of the insertion needle (10) and through said retaining hole (8) in the thin-film strip (6) lying in said window (12) during insertion of the thin-film strip (6) into the tissue, thereby removably locking up the thin-film strip (6) to the insertion needle (10).

5. The set of claim 4, wherein the insertion needle (10) is a micro-machined surgical-grade steel tubing with an outer diameter of 200 micron with an inner bore (11) of 100 micron diameter.

6. The set of claim 4 or 5, wherein the insertion needle (10) has a conical tip (14) which is sharp enough to allow penetration of the dura mater and brain tissue.

7. The set of claims 4, 5 or 6, wherein the retaining wire is a surgical-grade stainless steel wire having a diameter of 70 micron.

8. The set of claim 1, 2 or 3, wherein the flexible thin-film strip (6) tapers into a retaining thread next to its distal end (18) consisting of a polyimide thread and wherein the application tool consists of a solid insertion needle (15) having a through bore (16) in its distal end the polyimide thread being designed to be threaded through said through bore (16) in the insertion needle (15) before applying the thin-film strip (6).

9. The set of claim 1, 2 or 3, wherein the flexible thin-film strip (6) has a reinforced retaining hole (23) in the distal end and wherein the application tool consists of a solid insertion needle (25) having a through bore (26) in its distal end and of a separate polyimide thread (29) being designed to be threaded through said through bore (26) in the insertion needle (25) and through the retaining hole (23) in the flexible thin-film strip (6) before applying the thin-film strip.

10. The set of claim 1, 2 or 3, wherein the flexible thin-film strip (6) has a reinforced retaining hole (23) in the distal end and wherein the application tool consists of a solid insertion needle (35) having two through bores (36,37) in its distal end and of a separate polyimide thread (29) being designed to be threaded through said through bores (36,37) in the insertion needle (25) in a loop-like manner as well as through the retaining hole (23) of the flexible thin-film strip (6) before applying the thin-film strip, the through bores serving as loop thread guide.

11. The set of claim 8, 9 or 10, wherein the insertion needle is constructed from a 200 micron diameter steel rod.

12. The set of claim 8, 9, 10 or 11, wherein the insertion needle is tapered in the initial 5,75 mm with a 3° angle and in the final distal millimeter to a 10°tip.

13. The set of any preceding claims, wherein at least

parts of the coupling device (13;18;29) and the application tool (7) are encased in a removable guidetube (40;41) prior to applying the assembly of application tool (7), coupling device (13;18;29) and the thin-film strip (6).

14. The set of claim 13, wherein the tip (42) of the guidetube (40) has a sharp cutting shape.

15. The set of claim 13, wherein the tip (43) of the guidetube (41) has a blunt shape.

16. The set of any of the claims 13, 14 or 15, wherein the guidetube (40;41) consists of steel tube having an inner diameter of 220-260 micron and an outer diameter of 300-400 micron.

17. The set of any of the claims 13 through 16, wherein the guidetube (40;41) has a channel cut into the outside for the reception of the thin-film strip (6) allowing the thin-film strip (6) to remain on the outside of the guidetube (40;41) during its insertion into the living tissue.

Patentansprüche

1. Set zum Applizieren eines flachen, flexiblen zweidimensionalen Dünnschichtstreifens in lebendes Gewebe, insbesondere Gehirn, mit:

dem zu applizierenden Dünnschichtstreifen (6) selbst; und
einem Applikationswerkzeug (7), das mittels einer Kopplungseinrichtung (8, 13; 15, 16, 18; 23, 29; 29, 36, 37) lösbar und ausschließlich mechanisch mit dem Dünnschichtstreifen (6) verbindbar ist, wobei:

ein Faden (29), ein Draht (13) oder eine Nadel (15, 25, 35) dafür konfiguriert ist, den Dünnschichtstreifen (6) mit dem Applikationswerkzeug (7) mittels eines Haltelochs (8, 23) in der Dünnschicht zu koppeln, so dass durch Herausziehen oder Entfernen des Fadens (29), des Drahts (13) oder der Nadel (15, 25, 35) der Dünnschichtstreifen vom Applikationswerkzeug freigegeben wird, oder
der Dünnschichtstreifen (6) sich zu einem Haltefaden verjüngt, der dafür konfiguriert ist, durch ein Durchgangsloch (16) im Applikationswerkzeug (7) gefädelt zu werden, so dass der Dünnfilmstreifen (6) durch Ziehen des Fadens, wodurch der Faden vom Rest des Dünnschichtstreifens (6) getrennt wird, vom Applikationswerkzeug (7) ablösbar ist,

so dass nach dem Applizieren des Dünnschichtstreifens (6) an der Zielstelle das Applikationswerkzeug (7) durch mechanisches Außereingriffbringen der Kopplungseinrichtung (8, 13; 15, 16, 18; 23, 29; 29, 36, 37) selbst rückstandsfrei aus dem Gewebe entfernt werden kann und der Dünnschichtstreifen (6) zurückbleibt.

2. Set nach Anspruch 1, wobei der Dünnschichtstreifen (6) ein mikroelektromechanisches System (MEMS) in Form eines flexiblen Mehrelektrodenarrays ist.

3. Set nach Anspruch 1 oder 2, wobei der flexible Dünnschichtstreifen (6) auf Polyimid oder Parylen basiert.

4. Set nach Anspruch 1, 2 oder 3, wobei der flexible Dünnschichtstreifen (6) im distalen Ende ein verstärktes Halteloch (8) aufweist, und wobei das Applikationswerkzeug (7) aus einer Einführnadel (10) mit einer Innenöffnung (11) und einem Fenster (12) an einer Seite in der Nähe seines distalen Ende, das sich zur Innenöffnung (11) hin öffnet, und einem Haltedraht (13) besteht, der derart konfiguriert ist, dass er sich durch die Innenöffnung (11) der Einführnadel (10) und durch das Halteloch (8) im Dünnschichtstreifen (6) erstreckt, der in dem Fenster (12) liegt, während der Dünnschichtstreifen (6) in das Gewebe eingeführt wird, wodurch der Dünnschichtstreifen (6) mit der Einführnadel (10) entfernbar verriegelt wird.

5. Set nach Anspruch 4, wobei die Einführnadel (10) ein mikrobearbeitetes Röhrchen aus chirurgischem Stahl mit einem Außendurchmesser von 200 μm und einer Innenöffnung (11) mit einem Durchmesser von 100 μm ist.

6. Set nach Anspruch 4 oder 5, wobei die Einführnadel (10) eine konische Spitze (14) aufweist, die scharf genug ist, so dass sie die Dura mater und das Gehirngewebe durchdringen kann.

7. Set nach Anspruch 4, 5 oder 6, wobei der Haltedraht ein Draht aus chirurgischem Edelstahl mit einem Durchmesser von 70 μm ist.

8. Set nach Anspruch 1, 2 oder 3, wobei der flexible Dünnschichtstreifen (6) sich in der Nähe seines distalen Ende (18) zu einem Haltefaden verjüngt, der aus einem Polyimidfaden besteht, und wobei das Applikationswerkzeug aus einer festen Einführnadel (15) besteht, die an ihrem distalen Ende eine Durchgangsöffnung (16) aufweist, wobei der Polyimidfaden dafür konfiguriert ist, vor dem Applizieren des Dünnschichtstreifens (6) durch die Durchgangsöffnung (16) der Einführnadel (15) gefädelt zu werden.

9. Set nach Anspruch 1, 2 oder 3, wobei der flexible

Dünnschichtstreifen (6) im distalen Ende ein verstärktes Halteloch (23) aufweist, und wobei das Applikationswerkzeug aus einer festen Einführnadel (25), die eine Durchgangsöffnung (26) in ihrem distalen Ende aufweist, und einem separaten Polyimidfaden (29) besteht, der dafür konfiguriert ist, durch die Durchgangsöffnung (26) in der Einführnadel (25) und durch das Halteloch (23) im flexiblen Dünnschichtstreifen (6) gefädelt zu werden, bevor der Dünnschichtstreifen appliziert wird.

10. Set nach Anspruch 1, 2 oder 3, wobei der flexible Dünnschichtstreifen (6) ein verstärktes Halteloch (23) im distalen Ende aufweist, und wobei das Applikationswerkzeug aus einer festen Einführnadel (35) mit zwei Durchgangsöffnungen (36, 37) in ihrem distalen Ende und einem separaten Polyimidfaden (29) besteht, der dafür konfiguriert ist, auf eine schleifenartige Weise durch die Durchgangsöffnungen (36, 37) in der Einführnadel (25) sowie durch das Halteloch (23) des flexiblen Dünnschichtstreifens (6) gefädelt zu werden, bevor der Dünnschichtstreifen appliziert wird, wobei die Durchgangsöffnungen als Schleifenfädelungsführung dienen.

11. Set nach Anspruch 8, 9 oder 10, wobei die Einführnadel aus einem stabförmigen Stahlelement mit einem Durchmesser von 200 μm konstruiert ist.

12. Set nach Anspruch 8, 9, 10 oder 11, wobei sich die Einführnadel in den anfänglichen 5,75 Millimetern mit einem Winkel von 3° und im letzten distalen Millimeter zu einer 10°-Spitze verjüngt.

13. Set nach einem der vorangehenden Ansprüche, wobei mindestens Teile der Kopplungseinrichtung (13; 18; 29) und des Applikationswerkzeugs (7) vor dem Applizieren der Einheit aus dem Applikationswerkzeug (7), der Kopplungseinrichtung (13; 18; 29) und dem Dünnschichtstreifen (6) in ein entfernbares Führungsrohr (40; 41) eingekapselt werden.

14. Set nach Anspruch 13, wobei die Spitze (42) des Führungsrohrs (40) eine scharfe Schneidform aufweist.

15. Set nach Anspruch 13, wobei die Spitze (43) des Führungsrohrs (41) eine stumpfe Form aufweist.

16. Set nach einem der Ansprüche 13, 14 oder 15, wobei das Führungsrohr (40; 41) aus einem Stahlrohr mit einem Innendurchmesser von 220 - 260 μm und einem Außendurchmesser von 300 - 400 μm besteht.

17. Set nach einem der Ansprüche 13 bis 16, wobei das Führungsrohr (40; 41) einen in der Außenseite ausgebildeten Kanal zum Aufnehmen des Dünnschichtstreifens (6) aufweist, um zu ermöglichen, dass der Dünnschichtstreifen (6) auf der Außenseite des Führungsrohrs (40; 41) verbleibt, während er in das lebende Gewebe eingeführt wird.

Revendications

1. Ensemble destiné à appliquer une bande de film mince bidimensionnelle, plate, souple à l'intérieur d'un tissu vivant, en particulier le cerveau, comprenant

- la bande de film mince (6) elle-même à appliquer,
- un outil d'application (7) amovible et raccordable exclusivement mécaniquement à la bande de film mince (6) au moyen d'un dispositif de couplage (8, 13 ; 15, 16, 18 ; 23, 29 ; 29, 36, 37), dans lequel :

un fil (29), un fil métallique (13) ou une aiguille (15, 25, 35) est configuré pour coupler la bande de film mince (6) à l'outil d'application (7) au moyen d'un trou de retenue (8, 23) dans le film mince, de telle sorte que la rétractation ou le retrait du fil (29), du fil métallique (13) ou de l'aiguille (15, 25, 35) libère la bande de film mince de l'outil d'application ; ou
la bande de film mince (6) se recroqueville à l'intérieur d'un fil de retenue configuré pour passer à travers un alésage traversant (16) dans l'outil d'application (7), de telle sorte que la bande de film mince (6) peut être libérée de l'outil d'application (7) en tirant le fil et en séparant ainsi le fil du reste de la bande de film mince (6) ;

de telle sorte qu'après l'application de la bande de film mince (6) à l'emplacement cible, l'outil d'application (7) peut être retiré du tissu sans résidu par désaccouplement mécanique du dispositif de couplage (8, 13 ; 15, 16, 18 ; 23, 29 ; 29, 36, 37) lui-même, laissant ainsi la bande de film mince (6) derrière.

2. Ensemble de la revendication 1, dans lequel la bande de film mince (6) est un système microélectromécanique (MEMS) sous la forme d'un réseau multiélectrodes souple.

3. Ensemble de la revendication 1 ou 2, dans lequel la bande de film mince souple (6) est à base de polyimide ou à base de parylène.

4. Ensemble de la revendication 1, 2 ou 3, dans lequel la bande de film mince souple (6) a un trou de retenue renforcé (8) dans l'extrémité distale et dans lequel l'outil d'application (7) se compose d'une aiguille

d'insertion (10) ayant un alésage interne (11) et une fenêtre (12) sur un côté voisine de son extrémité distale s'ouvrant vers l'alésage interne (11) et d'un fil métallique de retenue (13) conçu ou réalisé pour passer à travers l'alésage interne (11) de l'aiguille d'insertion (10) et à travers ledit trou de retenue (8) dans la bande de film mince (6) se situant dans ladite fenêtre (12) pendant l'insertion de la bande de film mince (6) dans le tissu, bloquant ainsi de façon amovible la bande de film mince (6) sur l'aiguille d'insertion (10).

5. Ensemble de la revendication 4, dans lequel l'aiguille d'insertion (10) est un tubage en acier de qualité chirurgicale micro-usiné avec un diamètre externe de 200 μm avec un alésage interne (11) de 100 μm de diamètre.

6. Ensemble de la revendication 4 ou 5, dans lequel l'aiguille d'insertion (10) a une pointe conique (14) qui est suffisamment pointue pour pouvoir pénétrer dans la dure-mère et le tissu cérébral.

7. Ensemble des revendications 4, 5 et 6, dans lequel le fil métallique de retenue est un fil en acier inoxydable de qualité chirurgicale ayant un diamètre de 70 μm.

8. Ensemble de la revendication 1, 2 ou 3, dans lequel la bande de film mince souple (6) se recroqueville à l'intérieur d'un fil de retenue à côté de son extrémité distale (18) consistant en un fil de polyimide et dans lequel l'outil d'application consiste en une aiguille d'insertion pleine (15) ayant un alésage traversant (16) dans son extrémité distale, le fil de polyimide étant conçu ou réalisé pour être passé à travers ledit alésage traversant (16) dans l'aiguille d'insertion (15) avant l'application de la bande de film mince (6).

9. Ensemble de la revendication 1, 2 ou 3, dans lequel la bande de film mince souple (6) a un trou de retenue renforcé (23) dans l'extrémité distale et dans lequel l'outil d'application se compose d'une aiguille d'insertion pleine (25) ayant un alésage traversant (26) dans son extrémité distale et d'un fil de polyimide séparé (29) conçu ou réalisé pour être passé à travers ledit alésage traversant (26) dans l'aiguille d'insertion (25) et à travers le trou de retenue (23) dans la bande de film mince souple (6) avant l'application de la bande de film mince.

10. Ensemble de la revendication 1, 2 ou 3, dans lequel la bande de film mince souple (6) a un trou de retenue renforcé (23) dans l'extrémité distale et dans lequel l'outil d'application se compose d'une aiguille d'insertion pleine (35) ayant deux alésages traversants (36, 37) dans son extrémité distale et d'un fil de polyimide séparé (29) conçu ou réalisé pour être passé à travers lesdits alésages traversants (36, 37) dans l'aiguille d'insertion (25) à la manière d'une boucle ainsi qu'à travers le trou de retenue (23) dans la bande de film mince souple (6) avant l'application de la bande de film mince, les alésages traversants servant de guide de guide-fil en forme de boucle.

11. Ensemble de la revendication 8, 9 ou 10, dans lequel l'aiguille d'insertion est construite à partir d'une tige d'acier de 200 μm de diamètre.

12. Ensemble de la revendication 8, 9, 10 ou 11, dans lequel l'aiguille d'insertion est effilée dans les 5,75 mm initiaux avec un angle de 3° et dans le millimètre distal final jusqu'à une pointe de 10°.

13. Ensemble d'une quelconque revendication précédente, dans lequel au moins des parties du dispositif de couplage (13 ; 18 ; 29) et l'outil d'application (7) sont enfermés dans un tube de guidage amovible (40 ; 41) avant l'application de l'assemblage de l'outil d'application (7), du dispositif de couplage (13 ; 18 ; 29) et de la bande de film mince (6).

14. Ensemble de la revendication 13, dans lequel la pointe (42) du tube de guidage (40) a une forme de coupe tranchante.

15. Ensemble de la revendication 13, dans lequel la pointe (43) du tube de guidage (41) a une forme contondante.

16. Ensemble de l'une quelconque des revendications 13, 14 et 15, dans lequel le tube de guidage (40 ; 41) consiste en un tube en acier ayant un diamètre interne de 220-260 μm et un diamètre externe de 300-400 μm.

17. Ensemble de l'une quelconque des revendications 13 à 16, dans lequel le tube de guidage (40 ; 41) a une découpe en canal dans l'extérieur pour la réception de la bande de film mince (6) permettant à la bande de film mince (6) de rester sur l'extérieur du tube de guidage (40 ; 41) pendant son insertion dans le tissu vivant.

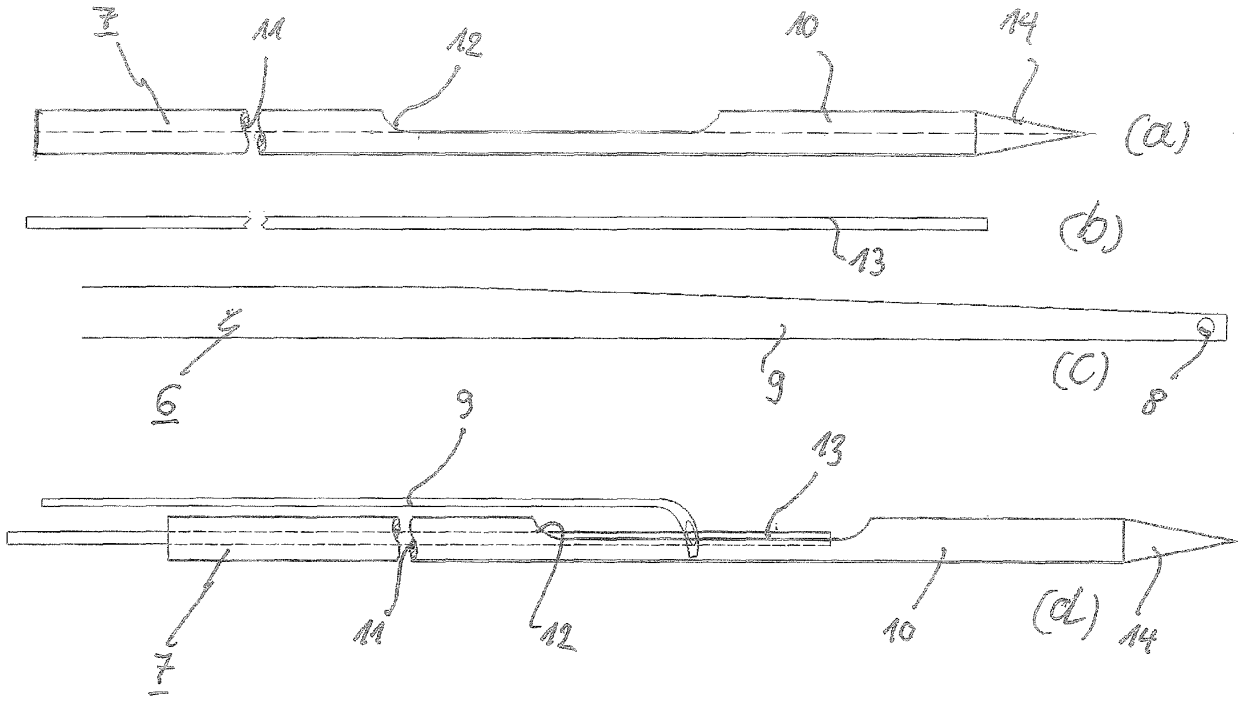

Fig. 1

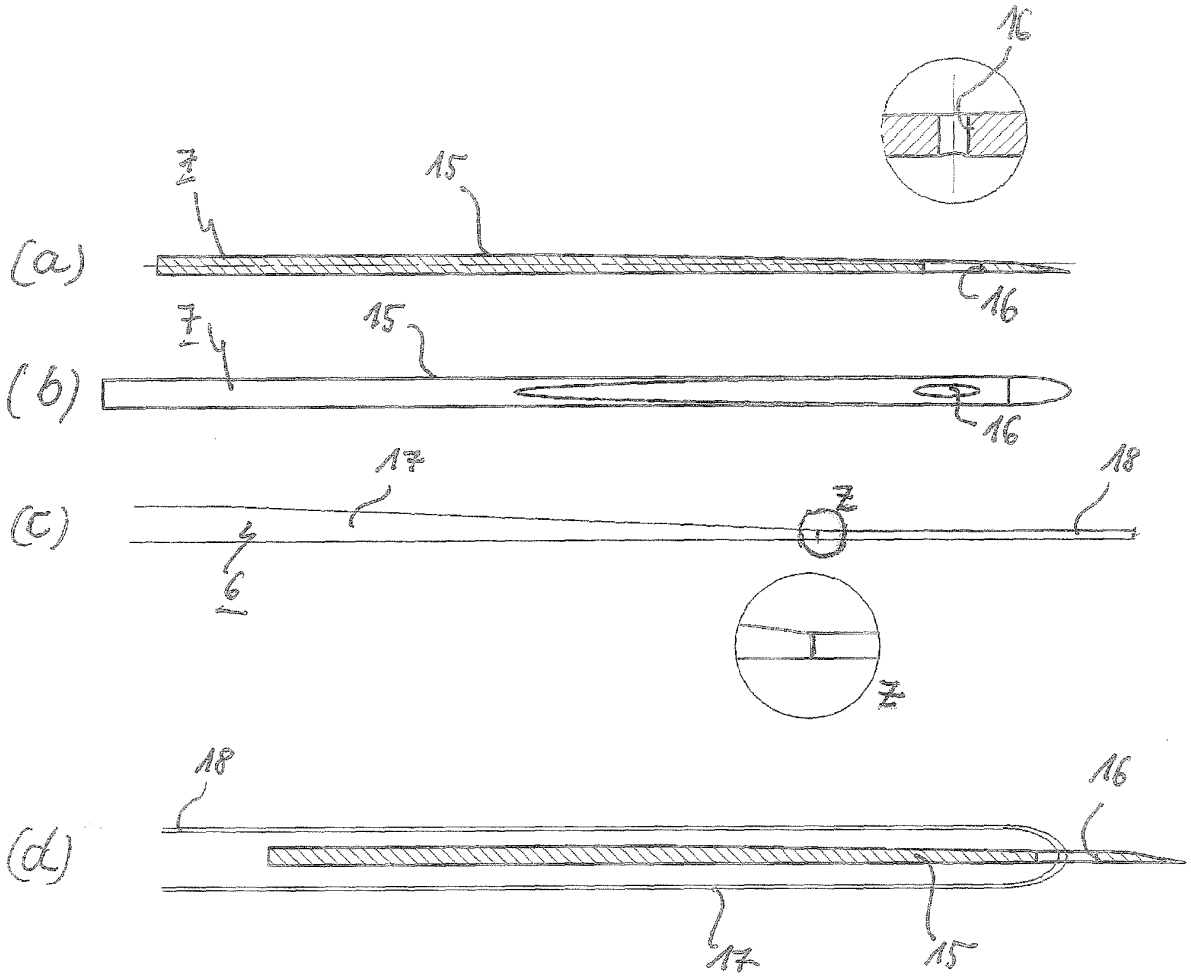

Fig. 2

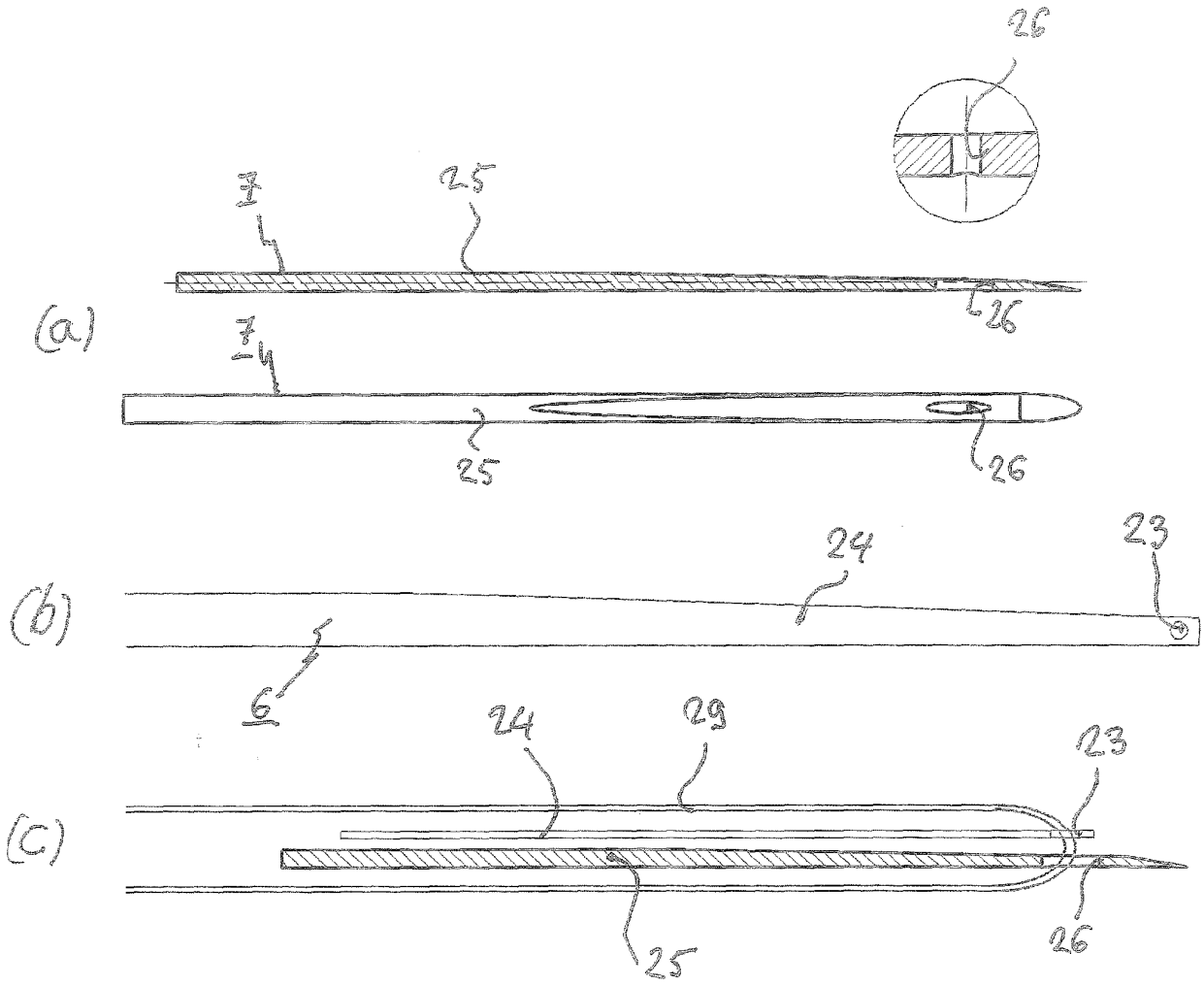

Fig. 3

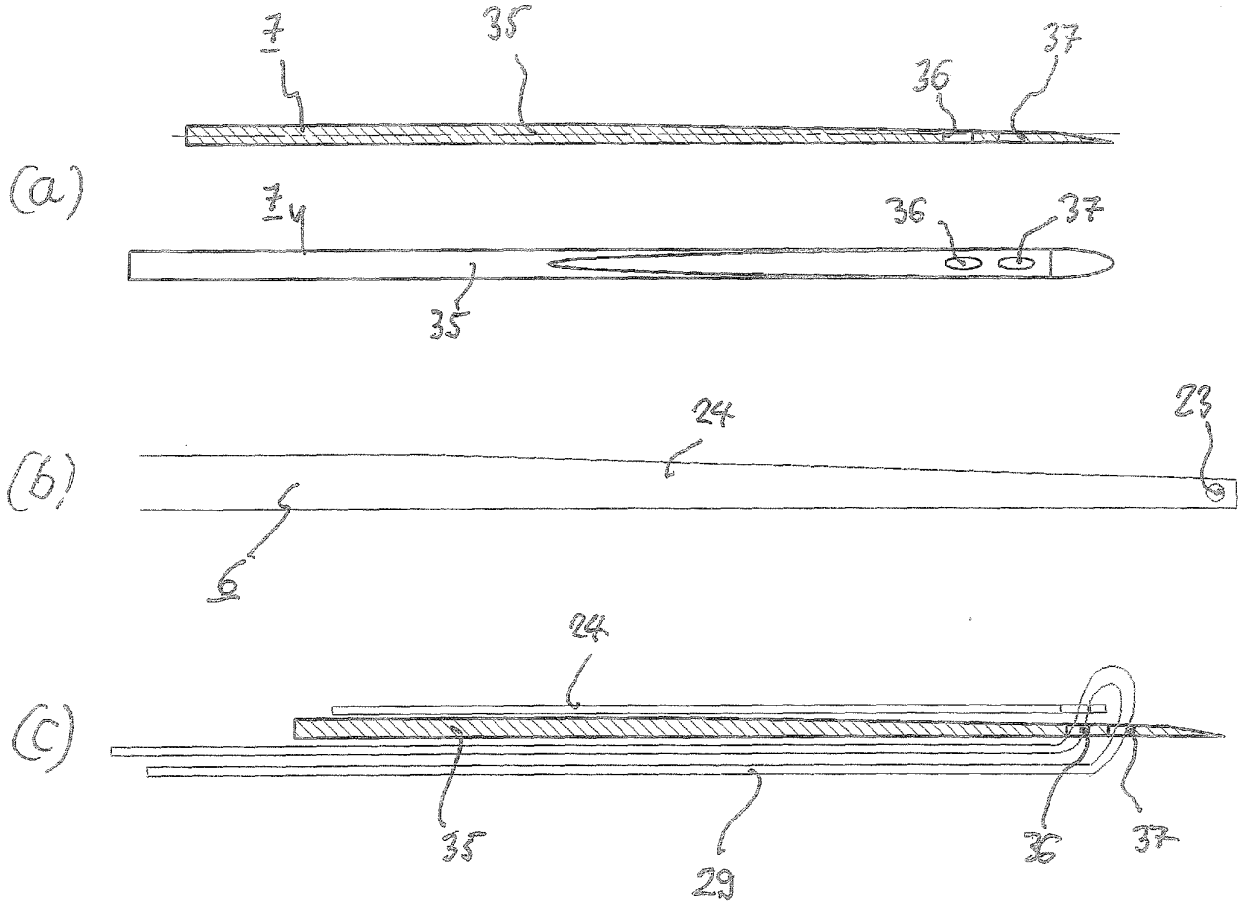

Fig. 4

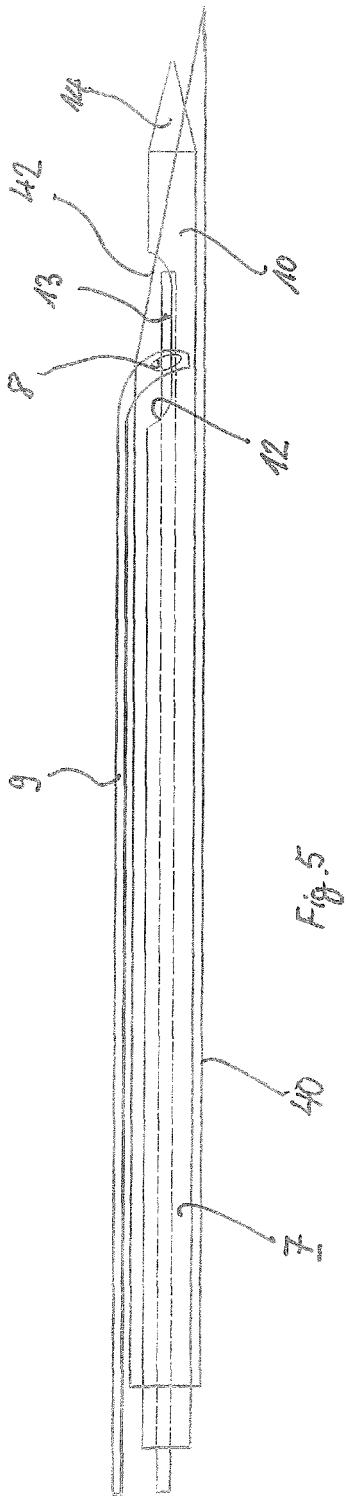

Fig. 5

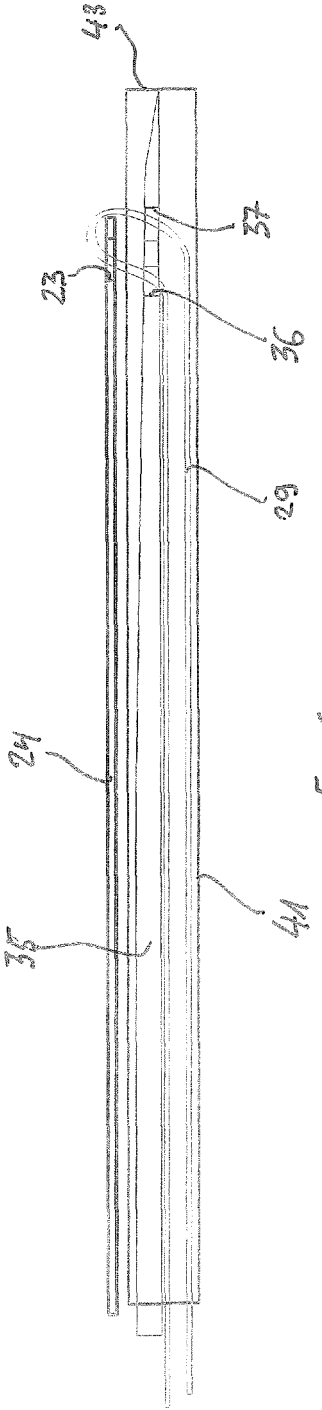

Fig. 6

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于将扁平，柔韧的二维薄膜条带应用于活组织		
公开(公告)号	EP3148454A1	公开(公告)日	2017-04-05
申请号	EP2015703789	申请日	2015-02-12
[标]申请(专利权)人(译)	严重strungmann院……		
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优先权	2014169867 2014-05-26 EP		
其他公开文献	EP3148454B1		
外部链接	Espacenet		

摘要(译)

提供了一种用于将平坦的，柔性的二维薄膜带施加到活组织中，尤其是脑组织中的套件。该套件包括要被施加的薄膜条本身和施加工具，该施加工具是可移除的并且可以通过联接装置机械地连接到薄膜条。在原位施加薄膜条之后，可通过机械脱开耦合装置本身，而将薄膜条从后面移开，从而从组织上移除施加工具而没有残留物。