

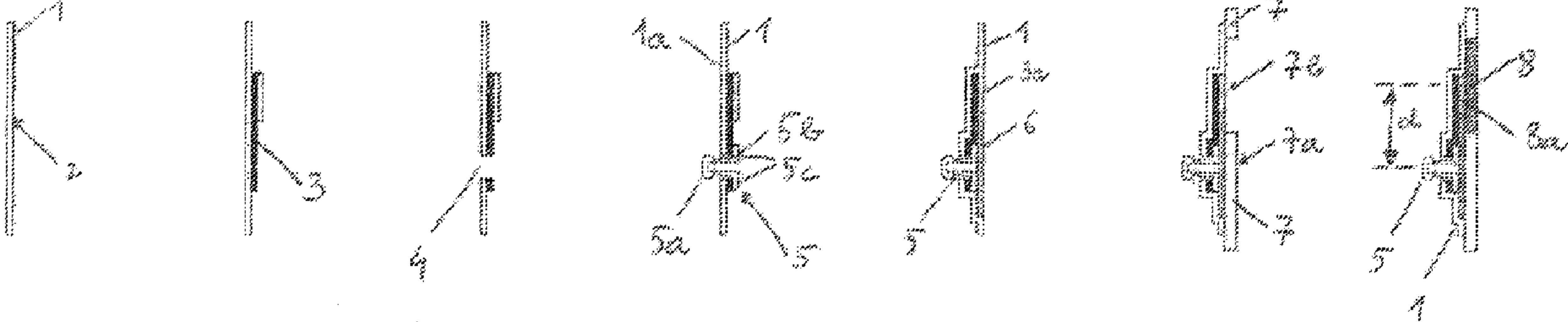


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(54) Titre : ELECTRODE A APPLIQUER SUR LA PEAU HUMAINE
(54) Title: ELECTRODE FOR APPLICATION TO HUMAN SKIN

FIG. 3



(57) **Abrégé/Abstract:**
Disclosed is an electrode for application to the human skin, comprising an electrically non-conductive support which on its upper side, facing away from the skin, has a protruding, electrically conductive connecting element with a terminal for removable connection of a signal conductor; a transverse conductor is provided which extends at least partially on the opposite, lower side of the support and is electrically coupled to the connecting element and to a contact medium facing the skin; the connecting element (5) is made of a single piece, which on the one hand is connected to the transverse electrical conductor (3) and on the other hand has the terminal (5a) for releasable connection of a separate signal conductor.

Abstract

Disclosed is an electrode for application to the human skin, comprising an electrically non-conductive support which on its upper side, facing away from the skin, has a protruding, electrically conductive connecting element with a terminal for removable connection of a signal conductor; a transverse conductor is provided which extends at least partially on the opposite, lower side of the support and is electrically coupled to the connecting element and to a contact medium facing the skin; the connecting element (5) is made of a single piece, which on the one hand is connected to the transverse electrical conductor (3) and on the other hand has the terminal (5a) for releasable connection of a separate signal conductor.

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Electrode for application to the human skin

5 The invention concerns an electrode according to the classifying portion of claim 1. The invention further concerns a method of producing an electrode.

Such medical skin electrodes can be used as measuring electrodes which derive electrical signals from the human body. They can however also be used as therapy electrodes for feeding currents to the human body. The electrodes are glued
10 to the skin for this purpose and generally have on their underside an electrically conductive gel or another electrical contact medium which is in galvanic contact with a connecting element of the electrode. An electrical signal conductor can be connected to that connecting element, by way of which currents can be derived from the electrode or can be supplied to the electrode.

15 One type of electrodes has at the top side facing away from the skin a projecting electrically conductive connecting element with a connection location which is usually substantially in the form of a spherical head adjoined by a neck.

In the previous structure of electrodes of that type the connecting element was made in two parts. The upper part (top knob, stud) serves as a contact and anchor
20 element for commercially available signal conductors, for example ECG cables. Substantially beneath the carrier, that is to say on the side facing the skin, there is a lower knob (eyelet) which serves to take electrical potential directly from the gel (contact medium) or transfer it to the gel. In that case the eyelet is connected both electrically and mechanically to the stud and more specifically in general by riveting the
25 two parts in such a way that the carrier material of the electrode is firmly clamped between a flange-like laterally projecting holding region of the stud and a similar holding region of the eyelet,. On the one hand such a structure provides a good mechanical hold for the connecting element on the carrier of the electrode and on the other hand makes it possible to manufacture the eyelet from materials which have
30 favourable electrical properties for a signal electrode, for example for that purpose it can be coated with silver, the silver layer in turn being covered over the entire surface or at least in a partial area which is in contact with the gel, with a layer of silver/silver chloride (Ag/AgCl). There is also the possibility of the eyelet not touching the gel directly. Then a transverse conductor is provided in these so-called off-centre signal
35 electrodes, which connects the eyelet to the gel.

However the electrodes in the state of the art are expensive - in which respect minor price differences are already a significant factor in such mass-produced articles.

The object of the invention is therefore to provide an electrode of the kind set forth in the opening part of this specification, which can be produced more cheaply and
5 nonetheless provides good mechanical anchoring of the connecting element in the electrode and good electrical properties.

According to the invention that is achieved by an electrode according to claim 1.

In contrast to the previously usual two-part structure in which the connecting
10 element consists of two parts (stud and eyelet) riveted together, according to the invention there is now a single part as a connecting element, which on the one hand provides the connection location for releasably connecting a signal conductor and on the other hand is connected to the electrical transverse conductor (preferably galvanically). In this case the single part of the connecting element may itself comprise
15 a plurality of materials, for example nickel-plated brass or a plastic doped with conductive material (in particular carbon fibres). However, in contrast to the previous two-part structure of eyelet and stud it represents a structural unit in the sense of a single part.

A particularly preferred embodiment of the connecting element is one in which
20 it is of such a configuration that the connecting element has a substantially spherical head, an adjoining reduced-diameter neck and a flange-shaped laterally projecting holding region at the end of the neck remote from the head. Standard signal conductors can be easily releasably connected by way of the spherical head. The reduced-diameter neck is guided (preferably without lateral contact) through an
25 opening in the carrier while the flange-shaped laterally projecting holding region is connected, preferably glued, to the underside of the carrier or to a layer-shaped transverse conductor mounted thereto. The enlarged-diameter flange-shaped laterally projecting holding region also securely holds the connecting element firmly to the carrier material with high tensile loads.

30 In order to ensure a good hold even under pressure loads on the connecting element it is preferably provided that the connecting element has a laterally projecting holding region which is arranged between a support layer and the carrier, wherein the support layer laterally extends beyond the holding region of the connecting element and is there firmly connected to the carrier - preferably glued.

Forces exerted on the connecting element by pressure loads are carried on the one hand by the gluing of the holding region to the underside of the carrier or the transverse conductor provided there, and on the other hand by the supporting layer which diverts those forces laterally into the carrier.

5 No high demands are made on the electrical properties of the holding element in the subject-matter of the invention. It can therefore comprise inexpensive material, for example a simple sheet metal. More specifically the holding element does not need to have any special electrical properties for only the transverse conductor which is connected to the electrical contact medium can have those electrical properties which
10 are desirable for bioelectrodes.

 Redox pairs are currently used to achieve low noise and depolarisation in an electrode in the event of defibrillation. Those can be oxidized or reduced and in that case absorb at least one electron or release at least one electron. At the present time the most widely varying substances are used for such depolarisation. Silver/silver
15 chloride and tin/tin chloride are most frequently used. All redox pairs are conceivable for the present invention however, which allow depolarisation of the electrode. The redox pairs can be actively incorporated or possibly generated in situ by reactions.

 As for example silver/silver chloride is a relatively expensive substance it is sufficient if, according to a further aspect of the invention, it is provided that the
20 transverse conductor has at least two different electrically conductive materials, one of which is galvanically connected to the connecting element and one another is galvanically connected to the contact medium.

 Making the transverse conductor of at least two different materials makes it possible further to save costs. The actual transverse conductor can be made more
25 specifically from relatively inexpensive materials, for example metal or plastic provided with conductive carbon fibres while a second material like for example silver/silver chloride can be used at the transitional region, that is critical in regard to the desirable electrical properties of the bioelectrode, to the electrical contact medium (especially gel). It is sufficient if that material is present only locally in that region.

30 Overall the invention is based on the basic idea of designing the connecting element for the signal conductor in such a way that it is securely anchored in the electrode while the electrical properties are less important and therefore cost-effective materials can be used. On the other hand the more expensive materials provided for favourable electrical signal conduction can be used only in the electrically critical
35 region at the transition to the electrical contact medium (gel). This task is performed by

the transverse conductor. In brief terms it would be said that the electrically conductive connecting element is primarily responsible for the "mechanics", apart from the basic property of electrical conduction. It is the other way around with the transverse conductor: it does not need to fulfil any special mechanical properties and it is only in
5 the region of the transitional location to the electrical contact medium (gel) that it comprises materials which are appropriate for that purpose. In that respect the transverse conductor is responsible for the "electrics" without any special mechanical functions for it to perform.

Further advantages and details of the invention are described more fully with
10 reference to the following description of the Figures:

Figure 1 shows in a diagrammatic view from below (later the side towards the skin) the production steps of an embodiment of an electrode according to the invention to the finished electrode,

Figure 2 shows a corresponding plan view, wherein only a part of the method
15 steps is shown in a plan view,

Figure 3 shows the sequence of sections along the line A - A of Figure 1, wherein the representation is to be interpreted for better visualization as a diagrammatic illustration. In reality the layer sequence can be of different dimensioning, as is usual with medical electrodes,

20 Figures 4, 5 and 6 show substantially the same illustrations as in Figures 1, 2 and 3, but for another embodiment, and

Figures 7 and 8 show a view from below of embodiments of an electrical connecting element.

The method for producing an embodiment of an electrode for application to the
25 human skin according to the invention will now be described in greater detail with reference to Figures 1 to 3.

The basic starting point is an electrically non-conductive carrier 1. The carrier material serves to anchor the electrical components of the electrode. It may for example comprise a (flexible) film (for example, PET or TPU), which is coated on the
30 underside facing upwardly in the drawing of Figure 1 with an adhesive 2 which for example can be self-adhesive (pressure sensitive adhesive) or thermally activatable (hot melt).

A strip-shaped transverse conductor 3 is now attached, in particular glued, to the carrier material, in a next step. According to a preferred variant of the invention the
35 transverse conductor has two differently electrically conductive materials, one of which

is later galvanically connected to the electrical connecting element and while the other is galvanically connected to the contact medium (gel).

The illustrated embodiment is a strip-shaped conductor shown in black, made of a plastic doped with conductive carbon fibres. In the region of the later contact location with the electrical contact medium (gel) the transverse conductor 3 (first material) is coated with a second electrically conductive material, for example, a layer 3a of silver/silver chloride or tin/tin chloride or another redox pair.

Preferably that layer 3a provided for the appropriate electrical properties from the contact location to the later gel is only provided where the gel is later provided. Otherwise a "normal" conductor 3, which is considerably less expensive, is sufficient to produce the electrical connection to the electrical connecting element described below.

In a further step a bore 4 is now provided through the electrical transverse conductor 3 and the carrier 1. This can be done for example by punching. There then follows the introduction of the electrically conductive connecting element 5 which has a substantially spherical-head-shaped connection location 5a for releasably connecting a commercially usual signal conductor (not shown) and which projects beyond the top side 1a of the carrier 1.

In the illustrated embodiment adjoining the substantially spherical head 5a the electrical connecting element has a reduced-diameter neck 5b on which finally a flange-like laterally projecting holding region 5c is disposed at the end facing away from the head 5a.

Overall the laterally projecting flange-shaped holding region 5c is of a substantially plate-shaped configuration. On the one hand it serves for making electrical contact with the transverse conductor 3, by being "clamped" between the carrier 1 and the plate-shaped flange 5c. On the other hand the plate-shaped flange serves for producing the mechanical hold of the electrical connecting element, in particular against tensile loads which can be exerted by a signal cable on the head 5a and thus the entire connecting element 5.

It is preferably provided that an electrically conductive adhesive is provided between the transverse conductor 3 and the connecting element 5 or a flange 5c projecting laterally therefrom.

In contrast to the hitherto usual riveted two-piece connecting elements comprising the upwardly projecting stud (top knob) and the subjacent eyelet (lower knob), according to the invention a connecting element 5 is used, which comprises a single part, which is connected on the one hand to the electrical transverse conductor

3 and on the other hand has the connection location 5a for releasably connecting a signal conductor (not shown here). This permits cost-effective production of the electrode because the mostly expensive eyelet (lower knob) can be omitted. The one-part design of the connecting element is sufficient for the mechanical anchoring effect.

5 The demands in terms of the electrical properties are low. This means simple structures, for example a deep-drawn metal part, can be used as a connecting element 5. The somewhat more difficult electrical functions are therefore not performed here by the otherwise usual eyelet (lower knob) but that end of the transverse conductor 3, which is in communication with the subsequently applied
10 electrical contact medium (gel). This therefore involves a separation of tasks. Apart from the basic property of being electrically conductive the electrical connecting element is substantially responsible for the mechanical hold in the electrode while the transverse conductor is largely free of mechanical tasks. This makes it possible to make a favourable choice of material. In particular, it is possible to provide more
15 expensive materials – which are favourable from an electrical point of view - only (location 3a) where contact with the gel later takes place.

 The electrically conductive connecting element can comprise a deep-drawn metal sheet, - as already mentioned. It is then at least partially hollow inside. It may however also consist of a conductive plastic, for example, ABS, which is doped with
20 conductive carbon fibres.

 Desirably the connecting element will be substantially rotationally symmetrical. Other variants are also possible.

 In order to fix the electrical connecting element 5c definitively in the electrode and in particular to secure it against pressure loads on the head 5a a support layer 6 is applied in a next step. The support layer 6 may for example comprise a double-sided
25 adhesive tape which is glued on the underside in Figure 1 to the connecting element 5 (specifically to the plate-shaped holding region 5c) and to regions of the underside 1a of the carrier 1.

 In that case pressure can be exerted on the layers so that they are
30 correspondingly contoured and connect with each other. However the cross section shown in Figure 3 after attaching the support layer 6 with the edges shown there is only to be seen as a diagrammatic representation. In actual fact the layer thicknesses are usually smaller and the layouts of the layers are substantially more rounded.

 The double-sided adhesive tape 6 which is glued to the carrier 1, the electrical
35 transverse conductor 3 and the holding region 5c of the electrical connecting element

5 on the one side, is now glued on the other side with a plaster layer 7, wherein the plaster layer can be glued to the skin, preferably by means of a patient-side coating made of biocompatible adhesive to fix the electrode.

Contrary to the illustrated embodiments the support layer can also be formed
 5 directly from the plaster layer (without interposed double-sided adhesive tape). In that case it is also possible to glue the plaster layer to the carrier 1 and the holding region 5c of the connecting element 5 by way of a layer of self-adhesive applied to it or a thermally activatable adhesive.

Going back now to the embodiment of Figures 1 to 3. The plaster material 7
 10 shown there is firmly connected to the carrier 1 not only by way of the double-sided adhesive tape 6 but also the adhesive on the underside 2 of the carrier 1.

The plaster material finally serves to fix the electrode on the patient's skin. Suitable plaster materials may for example comprise a film (for example PE), a foam tape (for example PE foam) or non-woven materials. The plaster materials are usually
 15 coated on the patient side with a biocompatible adhesive 7a.

A final production step of the electrode shown in Figures 1 to 3 involves the introduction of the electrical contact medium into a recess 7b provided in the plaster material 7 for that purpose. The electrical contact medium allows the (preferably ion-based) conduction of body-generated electrical potentials or device-generated
 20 measurement or stimulation currents from the body surface (skin) to the electrical contact element and vice versa. The contact medium may comprise for example a chloride-doped gel which is present either in more or less liquid form (more or less gelled) or as a crosslinked polymer matrix (hydrogel). However it is also possible to produce the electrical contact medium by other means, for example as a conductive
 25 adhesive or as a saline-filled sponge.

At any event the electrical contact medium 8, as is shown by the last step in Figures 1 to 3, is introduced into the recess 7b. It contacts therein the end region 3a (there is the second material of the transverse conductor, in particular silver/silver chloride).

30 The co-operation of the especially designed end region of the transverse conductor 3, in particular the coating with silver/silver chloride or another suitable material on the one hand and the material of the electrically conductive contact medium 8 on the other hand makes it possible to achieve favourable electrical properties of the electrode, for example noise-free signal transmission or depolarising
 35 effects, wherein the use of the relatively expensive second material 3a at the end of

the transverse conductor 3 can remain restricted to that region in which contact with the contact medium 8 takes place. This further reduces the costs.

Overall the production as shown in Figures 1 to 3 gives a "decentralised" electrode, in which the connecting element 5 on the one hand and the contact medium 8 (gel) on the other hand are arranged on the carrier 1 at laterally mutually displaced locations (distance d).

The method steps essential for the embodiment shown in Figures 1 to 3 are the following:

- applying, preferably by thermally activated gluing, a strip-shaped transverse conductor to the underside facing the skin of an electrically non-conductive carrier,
 - producing, preferably by punching, a through opening through the transverse conductor and the carrier,
 - introducing a one-piece connecting element from the underside of the carrier into the opening, such that a connection location for a signal conductor projects on the opposite top side of the carrier and the connecting element bears with a laterally projecting - preferably plate-shaped holding region against the transverse conductor, and
 - covering the holding region of the connecting element with a support layer which is glued to the carrier laterally beside the holding region.
- Finally, the following steps are then also effected to complete the electrode:
- applying, - preferably gluing -, a plaster layer which is adhesive on the skin side to the carrier and/or the support layer, and
 - introducing an electrical contact medium - preferably a gel - into a recess of the plaster layer such that the subjacent transverse conductor is contacted.

In the embodiment illustrated in Figures 4 to 6, most of the method steps are the same as those in Figures 1 to 3, for which reason the same reference numerals denote the same parts.

The difference is essentially in step 5. Specifically as shown in Figure. 4 two incisions 9 are made through the entire composite. In the next step 6 the plaster material 7 is then glued only in the upper region and at the bottom to the "wings" (for example, by local thermal activation), but not in the region of the flap which thereby remains movable.

Overall the embodiment shown in Figures 4 to 6 involves a movable flap 10 which carries the connecting element 5 with the connection location 5a. The movable flap can compensate for tensile loads on the signal conductor (not shown) and thus on

the connection location 5a, so that same is not transmitted fully to the electrode. Overall this improves the adhesion of the electrode to the skin of the patient.

Figure 7 shows an embodiment by way of example of a holding region 5c which projects laterally from the connecting element 5 in the form of a flange. This
5 holding region or flange has bores 5d. When gluing the electrode adhesive penetrates into those bores and thus improves the adhesion and resistance to rotation of the connecting element with the parts of the rest of the electrode.

The embodiment shown in Figure. 8 serves for the same purpose. Here indentations 5e are provided at the peripheral edge of the plate-shaped holding region.
10 The hot melt adhesive also penetrates thereinto and thus improves adhesion.

The signal conductor (not shown) is of a known configuration and usually comprises an insulated flexible cable which leads from an evaluation device or power supply to the electrode. The signal conductor itself is not part of the electrode, that is to say it is formed separately from same and its connecting element. At its electrode
15 end the signal conductor usually carries a coupling portion, by way of which it is mechanically and electrically releasably connectable to the connection location of the connecting element of the electrode, which in turn is preferably pre-mounted on the electrode and permanently connected thereto.

CLAIMS

1. An electrode for application to the human skin comprising an electrically non-conductive carrier having on its top side remote from the skin a projecting, electrically
 5 conductive connecting element with a connection location for releasably connecting a signal conductor, wherein there is provided a transverse conductor extending at least partially on the opposite underside of the carrier, being electrically connected to the connecting element and a contact medium facing the skin, characterised in that the
 10 connecting element (5) comprises a single part which on the one hand is in connected relationship with the electrical transverse conductor (3) and on the other hand has the connection location (5a) for releasably connecting a separate signal conductor.

2. An electrode according to claim 1 characterised in that the connecting
 15 element (5) comprises metal, preferably a deep-drawn metal sheet, or conductive plastic, preferably doped with conductive carbon fibres ABS.

3. An electrode according to claim 1 characterised in that the connecting
 element (5) has a substantially spherical head (5a), an adjoining reduced-diameter
 20 neck (5b) and a flange-shaped laterally projecting holding region (5c) at the end of the neck (5b) remote from the head (5a).

4. An electrode according to claim 3 characterised in that the laterally
 projecting flange-like holding region (5c) is plate-shaped.

25 5. An electrode according to one of claims 1 to 4 characterised in that the connecting element (5) is overall of a substantially rotationally symmetrical configuration.

6. An electrode according to one of claims 1 to 5 characterised in that the
 30 connecting element (5) on the one hand and the contact medium (8) on the other hand are arranged at laterally mutually displaced locations (distance d) on the carrier (1).

7. An electrode according to one of claims 1 to 6 characterised in that the
 contact medium (8) - preferably arranged in a recess (7b) of a plaster layer (7) - is a

gel preferably doped with chlorides, is in the form of a conductive adhesive or a saline-filled sponge.

8. An electrode according to one of claims 1 to 7 characterised in that the
5 connecting element (5) - preferably with a reduced-diameter neck (5b) - projects through an opening (4) in the carrier (1).

9. An electrode according to claim 8 characterised in that the connecting
10 element (5) - apart from possible lateral contact in the region of the opening - is connected to the carrier (1) only on the underside of the carrier (1), that is towards the skin - preferably with the interposition of a flat transverse conductor (3).

10. An electrode according to one of claims 1 to 9 characterised in that the
15 connecting element (5) has a laterally projecting holding region (5c) which is arranged between a support layer (6) and the carrier (1), wherein the support layer (6) extends laterally beyond the holding region (5c) of the connecting element (5) and is there firmly connected to the carrier (1) - preferably glued.

11. An electrode according to claim 10 characterised in that the support layer
20 (6) is in the form of a double-sided adhesive tape or a tape made of a thermally activatable adhesive or a tape made of a thermoplastic material suitable for direct thermoplastic connection to the carrier, which is glued on the one side with the connecting element (5) and the carrier (1).

25 12. An electrode according to claim 11 characterised in that the double-sided adhesive tape (6) is glued on the other side with a plaster layer (7), wherein the plaster layer (7) - preferably by means of a patient-side coating (7a) made of biocompatible adhesive - can be glued on the skin to fix the electrode.

30 13. An electrode according to claim 10 characterised in that the support layer (6) is formed by a plaster layer (7), wherein the plaster layer - preferably by means of a patient-side coating (7a) made of biocompatible adhesive - can be glued on the skin to fix the electrode.

14. An electrode according to claim 13 characterised in that the plaster layer (7) is glued to the carrier (1) and the holding region (5c) of the connecting element (5) by means of a layer applied thereto of self-adhesive or a thermally activatable adhesive.

5

15. An electrode according to one of claims 1 to 14 characterised in that the carrier material (1) comprises a dimensionally stable film, in particular of PET.

16. An electrode according to one of claims 1 to 15 characterised in that the carrier material (1) is coated on the side facing the skin with adhesive (2) which is preferably self-adhesive or thermally activatable.

17. An electrode according to the classifying portion of claim 1 and in particular according to one of claims 1 to 16 characterised in that the transverse conductor (3) comprises at least two different electrically conductive materials, one of which (3) is galvanically connected to the connecting element (5) and another (3a) is galvanically connected to the contact medium (8).

18. An electrode according to claim 17 characterised in that the transverse conductor (3) is in the form of a preferably strip-shaped layer of a first electrically conductive material which in the region of the contact medium (8) - and preferably only there - is provided, preferably coated, with a second electrically conductive material (3a).

19. An electrode according to claim 18 characterised in that the first electrically conductive material (3) is a metal or a metal alloy, a plastic film which is conductive throughout or superficially, for example by conductive carbon fibres, or a textile material which is conductive throughout or superficially.

20. An electrode according to claim 18 or claim 19 characterised in that the second material (3a) is formed by a pair of silver/silver chloride or tin/tin chloride or another redox pair suitable for depolarising the electrode.

21. An electrode according to one of claims 1 to 20 characterised in that the connecting element (5) in a holding region (5c) in which it is connected, preferably

35

glued, to the rest of the electrode, has at least one recess (5e) and/or a bore (5d) in its surface.

22. An electrode according to claims 4 and 21 characterised in that the bores
5 (5d) pass through the plate-shaped holding region (5c).

23. An electrode according to claim 4 and claim 5 and according to claim 21
characterised in that the recesses (5e) at the peripheral edge of the plate-shaped
holding region (5c) are tooth-shaped and/or wave-shaped.

10

24. An electrode according to one of claims 1 to 23 characterised in that carrier
(1) together with a support layer (6) possibly connected thereto has at least one
incision (9) in the region beside the connecting element (5), which incision allows
mobility of the connecting element (5) with respect to a plaster layer (7) provided for
15 gluing to the skin.

25. An electrode according to one of claims 1 to 24 characterised in that an
electrically conductive adhesive is provided between the transverse conductor (3) and
the connecting element (5) or a flange (5c) projecting laterally therefrom.
20

26. An electrode according to one of claims 1 to 25 characterised in that the
connecting element (5) is pre-mounted on the electrode and permanently connected
thereto.

27. A method of producing an electrode for application to the human skin, in
particular according to one of claims 1 to 26, characterised by the following steps

- applying, preferably by thermally activated gluing, a strip-shaped transverse
conductor to the underside facing the skin of an electrically non-conductive carrier,
- producing, preferably by punching, a through opening through the transverse
30 conductor and the carrier,

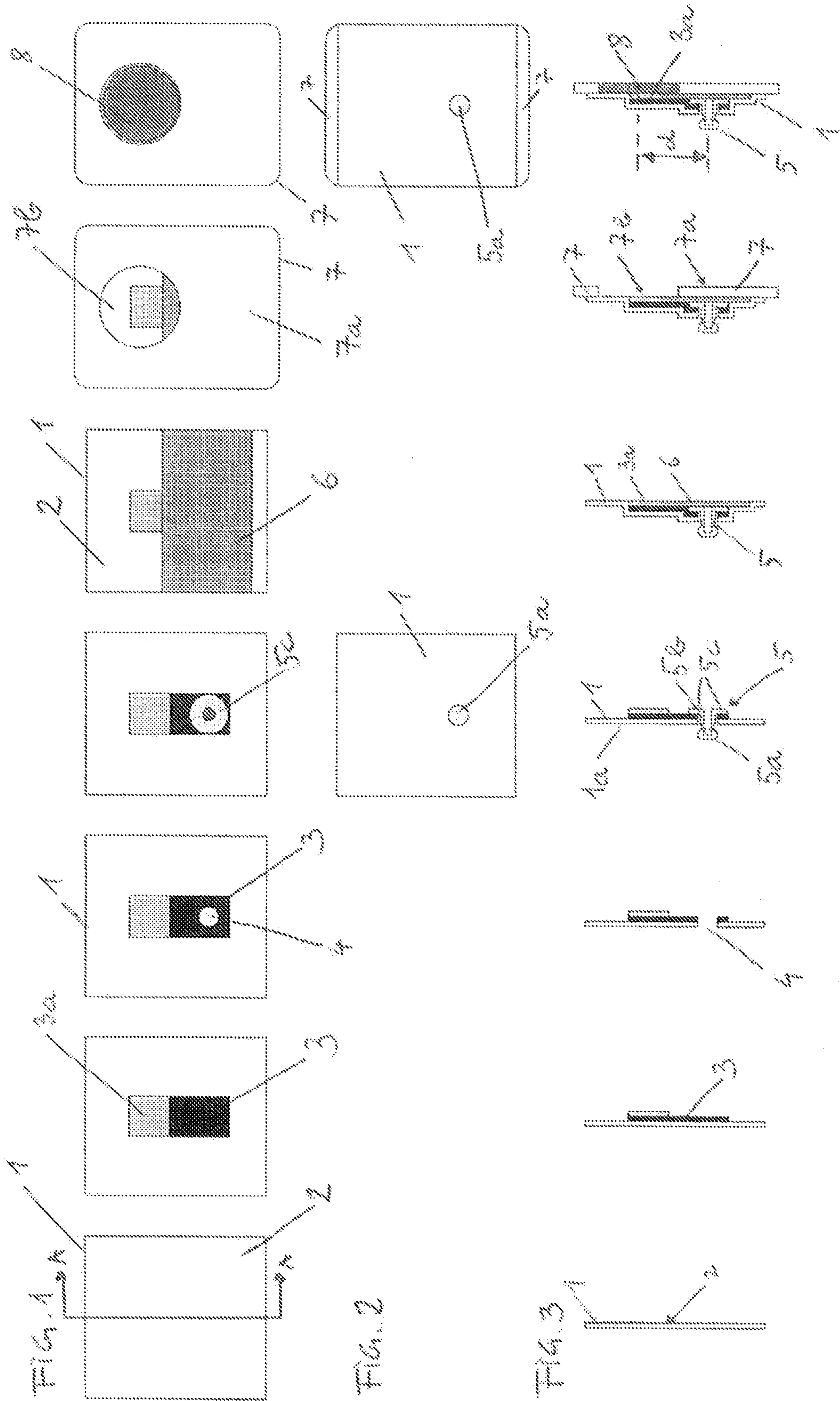
- introducing a one-piece connecting element from the underside of the carrier
into the opening, such that a connection location for a signal conductor projects on the
opposite top side of the carrier and the connecting element bears with a laterally
projecting - preferably plate-shaped holding region against the transverse conductor,
35 and

- covering the holding region of the connecting element with a support layer which is glued to the carrier laterally beside the holding region.

28. A method according to claim 27 characterised by the following further
5 steps:

- applying - preferably gluing - a plaster layer which is adhesive on the skin side to the carrier and/or the support layer, and

- introducing an electrical contact medium - preferably a gel - into a recess in the plaster layer such that the subjacent transverse conductor is contacted.



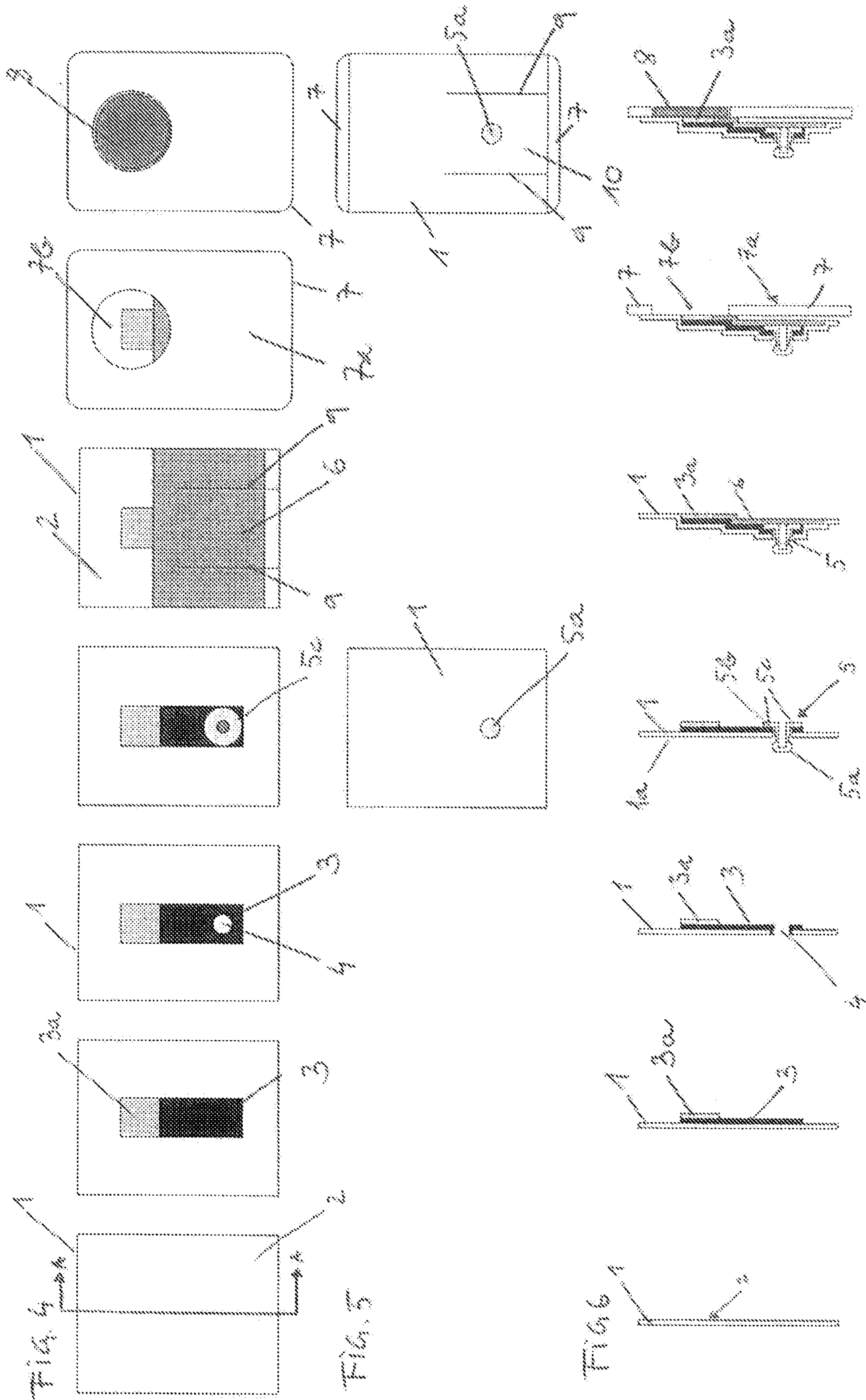


Fig. 7

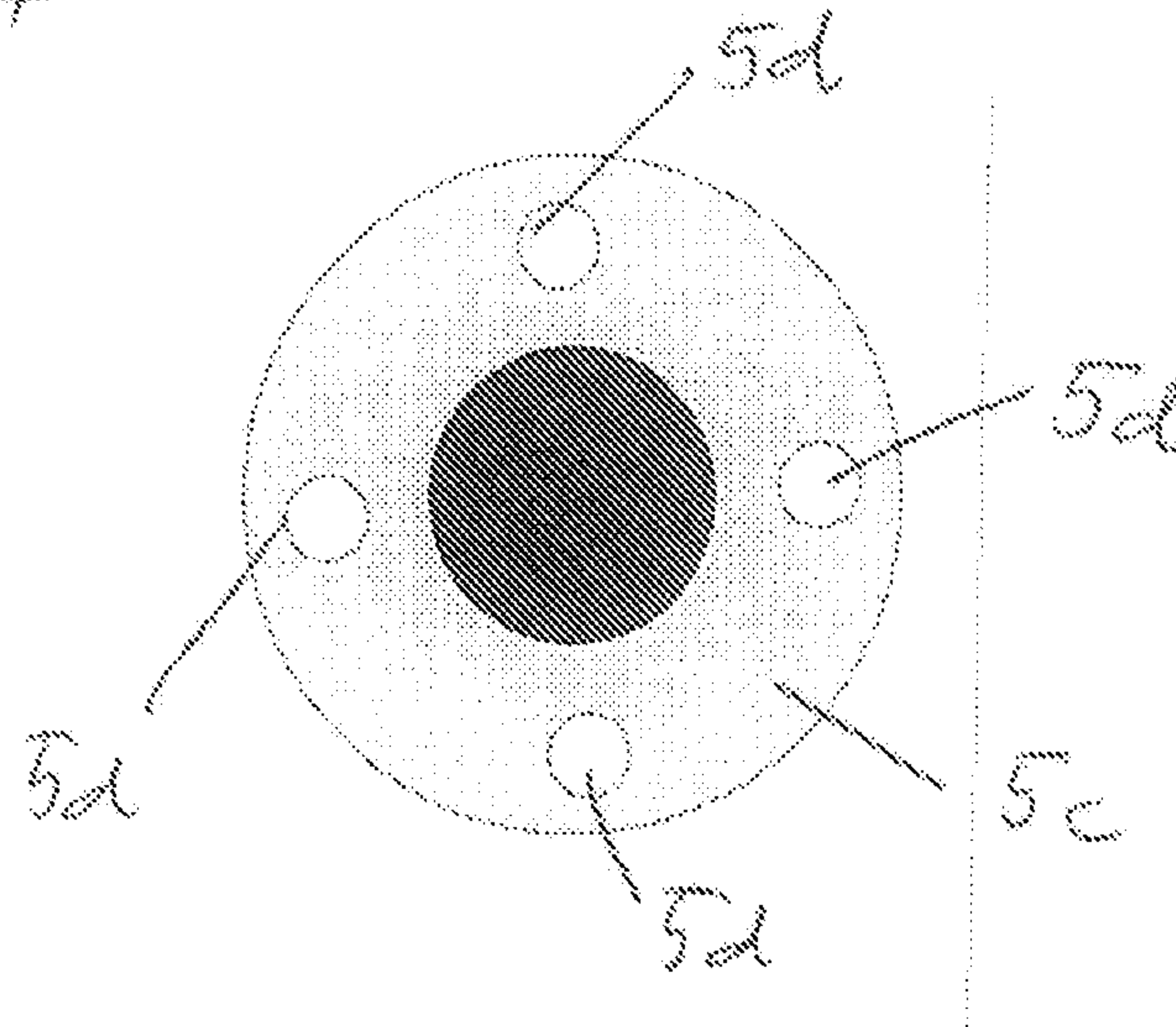


Fig. 8

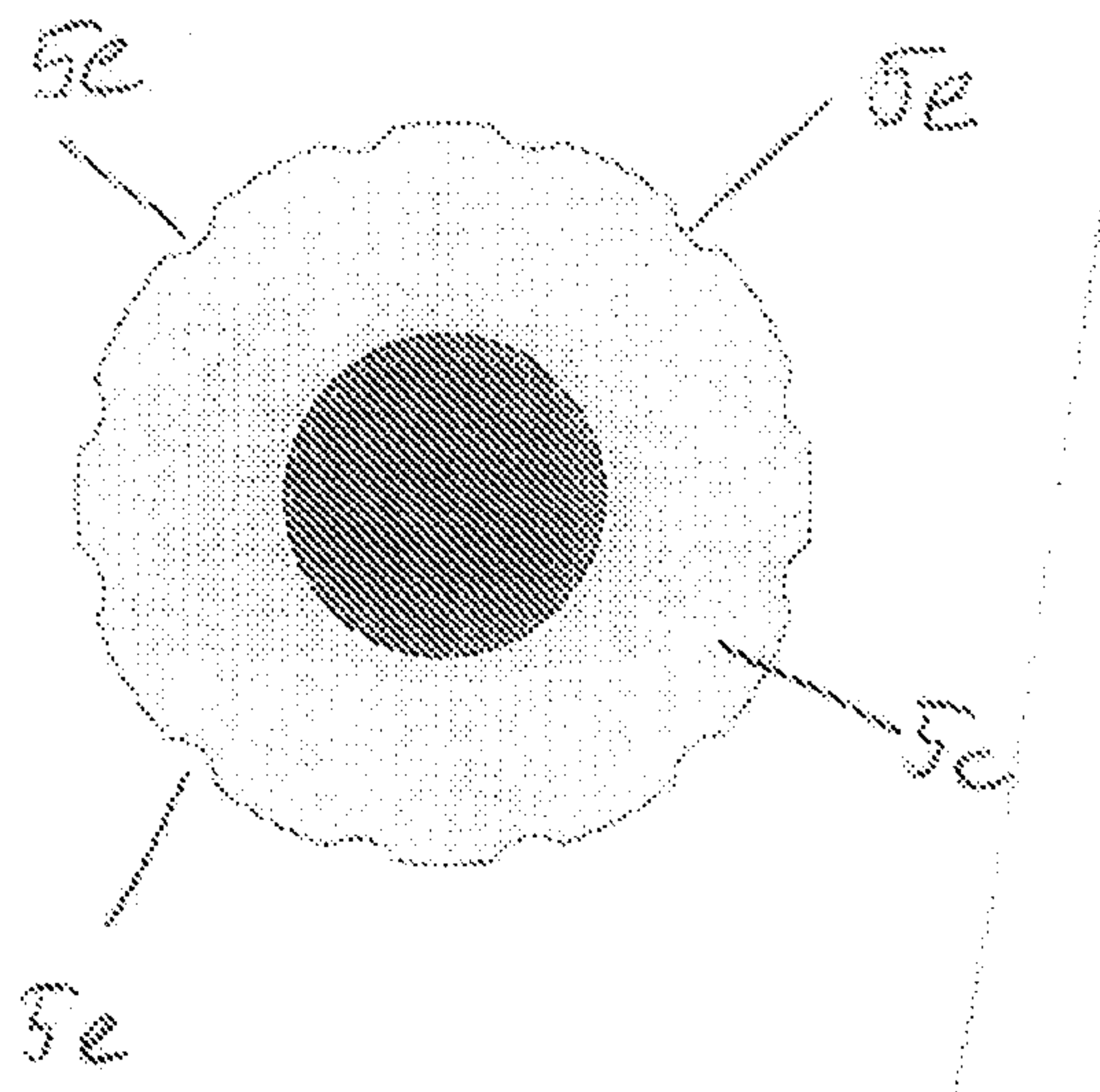


Fig. 3

