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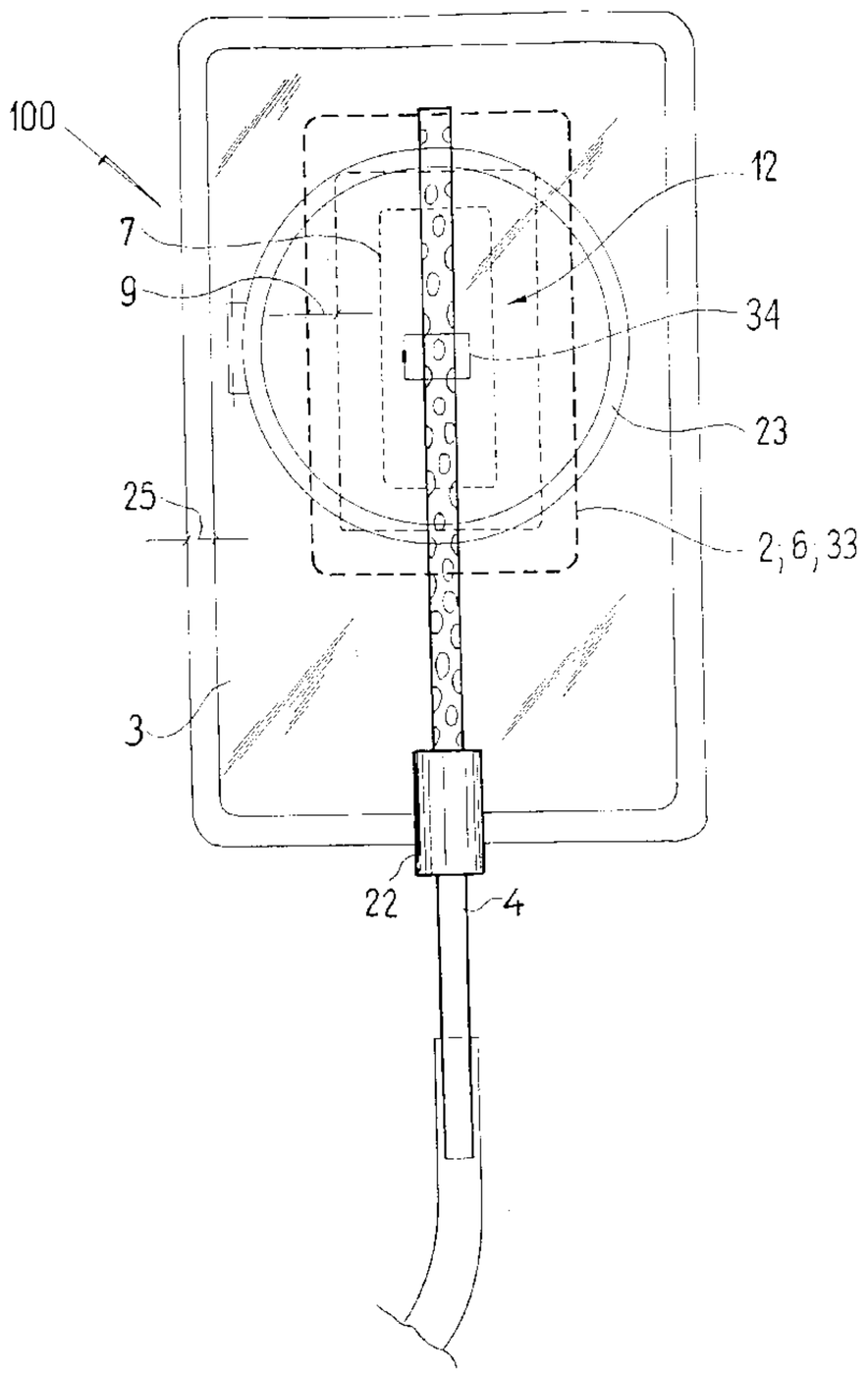
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(54) Titre : DISPOSITIF DE DRAINAGE SERVANT A SOIGNER DES PLAIES PAR L'APPLICATION D'UNE PRESSION NEGATIVE

(54) Title: DRAINAGE DEVICE FOR THE TREATMENT OF WOUNDS WITH APPLICATION OF A VACUUM



(57) Abrégé/Abstract:
The invention relates to a drainage device (100), for the treatment of wounds with application of a vacuum, comprising: a gas-tight wound dressing element (3), which when applied to the body of the patient is fixed around the wound region to the skin surface by

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(57) Abrégé(suite)/Abstract(continued):
adhesive and forms a remaining wound space between the wound and the wound dressing element (3), at least one drainage tube (4) which may be connected to the vacuum generation means and which may be inserted in the wound chamber roughly parallel to the wound dressing element (3) and at least one absorption body (2) in the form of at least one layer (7) of a piece of textile (33), interspersed with superabsorbent particles, set in an envelope. The absorbed wound secretions, depending on the pore size of the envelope, remaining within the absorption body (2) and hence under the wound dressing element (3), until removal of the absorption body from the wound space. An air passage (34) is provided for the wound dressing element (3).

ABSTRACT OF THE DISCLOSURE

The invention relates to a drainage device (100) for the treatment of wounds using reduced pressure, comprising a gas-type wound-covering element (3), which, in the state in contact with the body of the patient, is fastened cohesively at the skin surface around the region of the wound and forms a sealed wound space, remaining between the respective wound and the wound-covering element (3), at least one drainage tube (4), which can be connected to means generating the reduced pressure and can be inserted into the wound space approximately parallel to the wound-covering element (3), and at least one absorption body (2) in the form of at least one layer (7) of a textile section (33), which is interspersed with super-absorbing particles and enclosed in an envelope. Due to the size of the pores of the envelope, the absorbed wound secretions remain within the absorption body (2) and, with that, underneath the wound-covering element (3) until the absorption body is removed from the wound space. An air opening (34) is provided for the wound-covering element (3).

DRAINAGE DEVICE FOR THE TREATMENT OF WOUNDS WITH APPLICATION OF A VACUUM

The invention relates to a drainage device for treating wounds using a reduced pressure, comprising:

a gas-tight wound-covering element, which consists of a sheet-like material and, when placed in contact with the body of the patient, is fastened adhesively to the surface of the skin about the region of the wound, forming a sealed, wound space remaining between the respective wound and the wound-covering element, and at least one drainage tube, which can be connected to a means, such as a vacuum pump, for producing the reduced pressure and can be inserted prone into the wound space approximately parallel to the wound-covering element and over which the materials in the wound space can be evacuated,

and at least one absorption body, which is disposed in the wound space and absorbs the wound secretions.

A device of the type named above is known from the DE 195 17 699. The known device has a covering sheet for covering the wound flat and closing it off air-tight, so that a wound space, into which an insert of a foam material and a drainage hose, which is pulled into this insert, are

inserted, is formed underneath the covering sheet in the region of the wound. With the help of the insert of foam material, the wound secretions are to be withdrawn uniformly over the whole of the wound surface. A collecting container with a vacuum pump for producing the reduced pressure is, in turn, connected to the drainage tube. The whole device is disposed of when the collecting container is filled with wound secretion. The purpose of the disposable device is to pass the wound secretions continuously through the drainage tube into the collecting container.

US patent 5,549,584 shows a device for vacuum treatments, which consists of a wound cover, a membrane pump, which is disposed at the suction tube, and a pouch-like collector, which is connected downstream from the membrane pump. A layer of material or a loose bed of liquid-absorbing fibers, which rest on a perforated layer and under which a further adhesive layer, in turn, is placed, is disposed underneath the wound covering. Furthermore, the fibers are covered by a liquid-permeable upper layer, which has several windows. Beneath each window, there is a section of material, which is also permeable to liquids. The suction tube is connected with a connecting piece, which is disposed above

the wound cover, and does not have any direct contact with the absorption material, which is located within the wound space. The device, so designed, seems complicated and expensive to produce.

The DE 299 53 373 C2 also discloses a device, which uses reduced pressure for the treatment of wounds and comprises a wound-covering element, a foam material insert underneath the wound-covering element and at least one flexible conduit, which communicates with the pores of the foam material insert. In the DE 38 50 798 T2, a sterile, rectangular, yet rigid cassette, in which a surgical dressing is accommodated, is shown. The lower edge of the cassette is fastened to the skin of the patient. For enclosing the surgical field at the patient, the cassette is open at the top and at the bottom.

US 50 86 763 A discloses a cassette-like wound-treating device, which is also fastened to the skin of the patient. An exchangeable wound dressing is placed at the underside of a swiveling lid.

A pouch-like wound-treating and wound drainage device, known from AT E33 446 B, has a lower, peripheral edge, by which it may be glued to the skin of a patient, a catheter

holder, two treatment openings with caps, which are disposed at an upper wall, as well as an opening at the lower wall of the pouch for enabling access to the wound. The publication describes only the construction of the pouch.

It is an object of the invention to design a cost-effective device for the vacuum treatment of wounds, the design of which is simplified.

This objective is accomplished by a device of the type named above, for which the absorption body is at least one textile section, in which super-absorbing particles are interspersed and which is enclosed in an envelope, the envelope being permeable to liquids and having pores, the size of which essentially does not exceed that of the super-absorbing particles, the absorption body, which is to be inserted in the wound space, having an initial volume, which enlarges in the course of the absorption process and assumes a final volume, so that the absorbed wound secretions, due to the size of the pores of the envelope, remain within the absorption body and, with that, below the wound-covering element until the absorption body is removed from the wound space.

The wound-covering element may be fastened over a flexible connecting plate, the so-called base plate, to the body of the patient. One or more openings, which are fitted to the wound area(s), are cut from the base plate before it is glued to the skin. It is, however, possible to do without the base plate, if a peripheral adhesive surface is applied, provided that the adhesive substance is harmless and an appropriate connection site for introducing the drainage hose is provided at the wound-covering element. However, a conventional commercial wound-repair pouch with a gas-tight treatment window and a drain, the side wall of which, opposite to the wound-covering element, is glued to the connection plate at the factory, is preferred.

It is important that at least one absorption body, which is enriched with super-absorbents and can be exchanged, and one drainage hose, which rests on the absorption body, are disposed within the wound-repair pouch.

The drainage tube may, however, also lie between two absorption bodies, which have the same or a different suction force and form a sandwich arrangement. For the sandwich arrangement, an absorption body, enriched with super-absorbents, and an additional absorption body, which is not provided with super-absorbents, such as a flat,

open-pored foam body, may be used. Different possibilities are provided here, namely, a sandwich arrangement, for which the foam body lies between the connecting plate and the absorption body, enriched with super-absorbents, or between the wound-covering element and the absorption body, which is enriched with super-absorbents.

An optimum wound-healing process can be "programmed" by the selection of absorption bodies and their suction force.

The enveloped absorption body and/or the additional and/or the additional foam-like absorption body and/or the abhesive film element may be provided with silver-, copper- or zinc-containing substances, for example, in nano-crystalline form, in order to kill germs.

It is also important that the area of the textile section of the absorption body, enriched with super-absorbent particles, is significantly smaller that that of the envelope, so that the absorption body, without being impeded in its cross section, can approach a circular form. The full utilization of the maximum or almost maximum filling capacity of the absorption body contributes to lowering the costs of treating the wound.

The wound-covering element may be transparent at least over a portion of its surface, so that the state of the wound-healing process may be observed. The drainage device may be provided with a liquid permeable, mucous membrane compatible protective element, which is disposed on a side of the absorption body, opposite to the wound-covering element and the surface area of which is approximately equal to that of the enveloped absorption body. The protective element may also be produced from a soft, open cell foam material or a very loose nonwoven fabric. Finally, the protective element may also be a loose bed of pieces of a nonwoven material or of a foam underneath the absorption body. At the end of the absorption process, these pieces are removed from the wound, for example with forceps. Moreover, a voluminous formation fulfills not only the function of protecting the mucous membrane, but also that of an absorber. The open cell foam or the nonwoven material may have pores, which are several times larger than those of the envelope, so that the larger particles of wound exudate may be taken up.

If the device is glued to the body of the patient, the reduced pressure in the wound space beneath the wound-covering element can be produced manually or mechanically

or electrically. A most simple manual production of vacuum can be brought about, for example, with the help of a so-called scissors grip vacuum pump or a known rubber bellows ("ball pump"), which can be compressed by hand. Different conventional, commercial vacuum pumps, which can be supplied, for example, together with a tube and a pressure regulator, are suitable for producing a vacuum electrically.

For an in-patient, for example, post-operative treatment of a wound, the reduced pressure can be produced by connecting the drainage device to an existing, stationary vacuum installation, optionally by way of a pressure regulator.

In a plan view of its flat side, the device may be polygonal, oval or circular or it may also be pouch-shaped, similar to the known wound-repair pouches.

The envelope consists of a liquid-permeable, mucous membrane-compatible natural material or plastic, to which the wound secretions adhere hardly, if at all. This enables liquid wound secretions to be transported into the absorption material. The wound secretions pass through the envelope and are absorbed by the absorption material, which has been enriched with super-absorbents.

Advantageously, a peripheral overhang of envelope material is provided at the envelope of the absorption body, so that any painful contact of the relative hard seam with the surface of the wound can be limited or even avoided. The envelope material a peripheral seam and the outer extent of the envelope is understood to be the overhang here.

The envelope of the absorption body many be provided with pulling means, so that the consumed, swollen absorption body can be pulled more easily out of the wound region.

The envelope, as well as the absorption material within the envelope may be provided with an odor-inhibiting and/or odor-neutralizing or odor-masking additive, such as activated charcoal.

It is of great advantage that, during the evacuation of the gases, wound secretion particles are not carried along. These remain within the envelope of the absorption body until the whole device is removed from the body of the patient and disposed of or until the swollen absorption body is exchanged. Overall, a device is created for the treatment of wounds using a reduced pressure, for which the wound secretions are aspirated by the nonwoven material of the absorption body, which is interspersed with super

absorber, and remain within the envelope surrounding the absorption body without getting back from the envelope into the covered wound space. As the absorption increases, the cross sectional area of the absorption body increases greatly by a multiple and approaches a circular shape. Essentially, no wound secretions are carried along while the reduced pressure is being maintained with the help of a vacuum pump, which can be connected to the device, that is, when evacuating gases. Moreover, it is possible to do without an additional collecting container. If an excess of wound secretion is to be drained off, it is advisable to connect the drainage tube over a check valve to a collecting container, which, in turn, is connected upstream from a vacuum pump with a pressure manometer. In this case, the exchangeable absorption body acts as an intermediate storage device for the secretions emerging from the wound.

The inventive drainage device can also be used for compression therapy, for example, for the treatment of open legs.

An example of the invention is explained in greater detail by means of the drawing, in which

Figure 1 shows a drainage device in plan view of the wound-covering element.

Figures 2a to 2d show the device of Figure 1, glued to the skin of the patient, in a diagrammatic section.

Figure 3 shows the device of Figure 1, however with a neck, also in plan view of its flat side.

Figures 4a to 4c show a section A-A of Figure 3 with three different sandwich arrangements of two absorption bodies.

Figure 5 shows the device of Figures 1 or 3 in a diagrammatic longitudinal section, connected to a portable or a stationary vacuum installation.

Figure 6a shows a further embodiment of the drainage device in plan view of the wound-covering element.

Figure 6b shows a section, similar to that of Figure 6a.

Figures 1 and 2a to 2d show a drainage device 100 for the treatment of wounds using a reduced pressure is shown, comprising a rectangular and a sheet-like, transparent wound-covering 3, a connecting plate 10 of a hydrocolloid-like material, between which there is an absorption body 2,

and a drainage tube 4. An opening 11 (compare Figure 2a), the size of which corresponds to that of the wound, is cut out of the connecting plate 10, so that, when the device 100 is glued to the skin of the patient, a gas-tight wound space 5 results in the region of the wound (compare Figure 2b). A peripheral edge 25 of the wound-covering element 3 is glued firmly to the connecting plate 10.

The gas-tight wound space 5 is thus bounded by the wound surface, the wound covering element 3 and the inner edge of the opening 11 at the connecting plate. This wound space has a variable volume, since the wound-covering element 3 is not tensioned. The wound space, if it is considered as a reduced pressure space, also includes the interior of the drainage tube 4 up to the obstruction element, such as the check valve 17, shown diagrammatically in Figure 5.

The drainage tube 4 is pushed over an envelope piece 22, which is disposed at the edge of the wound-covering element 3, and under the wound covering element and rests on the absorption body 2, without contacting the wound surface.

Furthermore, at each of its two flat sides, the connecting plate 10 has a protective film 19, 24, of which the protective film 19, facing the later wound region, can be

pulled off. The other protective film 24 is finished to be adhesive on the side facing the wound-covering element 3.

The absorption body 2 is a layer 7 (compare Figure 2a) of a textile section 33, which is enriched with super-absorbents and surrounded by the liquid-permeable envelope 6. The envelope 6 has a peripheral overhang 9 of material at its periphery, the area of the layer 7 being about 40% smaller than that of the envelope 11.

A drainage device 200, similar to the one described above, is sharing in Figures 3 and 5. For this drainage device 200, the wound covering element 3 is part of a known wound-repair pouch 13 with a neck 27, the side wall 8 (compare Figure 5) of which, opposite the wound-covering element 3, is glued rigidly to the hydrocolloidal connecting plate 10, an outline 26 of the wound-repair pouch, placed flat, protruding beyond the connecting plate. The flat absorption body 2 is accommodated in the interior of the wound-repair pouch 13, which is glued to the skin of the patient. The wound contour 28 is outlined with a line 28 of dashes.

Figure 4a shows the drainage device 200 in the section A-A of Figure 3. A sandwich arrangement 20 of two absorption

bodies 2.1, 2.2, between which the drainage tube 4 is located, is a special feature of this embodiment. Figure 4b also shows a sandwich arrangement, for which an additional absorption body 32, which is not provided with super-absorbents, is located between the wound-covering element 3 and the absorption body 2, which is enriched with super-absorbents. In Figure 4c, once again a sandwich arrangement is shown, for which the additional absorption body 32 is located between the connecting plate 10 and the absorption body 2, which is enriched with super-absorbents. In the last two cases, the drainage tube 4 is disposed between the absorption bodies 2; 32, which differ from one another. The additional super-absorber-free absorption body 32 is present in the form of an open pore foam body.

A relatively wide, round treatment opening 12, through which the absorption body 2 or the additional absorption body 32 can be placed in or removed from the wound space 5, is incorporated at the wound covering element 3. The treatment opening 12 can be closed off gas-tied with a swiveling lid 23. An air opening 34, which is disposed in the center of the swiveling lid 23 and with which the reduced pressure can be regulated and adjusted in such a manner, that there may be a draft of air within the wound

space during the suction process, is shown diagrammatically in Figure 1. Figures 6a and 6b show a drainage device 300, which is essentially similar to that shown in Figure 1. The difference consists therein that the perforated part of the drainage tube 4 underneath the wound-covering element 3 is forked. A stable pressure distributor 40 results in this way, since the two branches 41.1, 41.2 rest on the absorption body 2 and press against a reinforced rim 42 of the swiveling lid 23.

A different pressure distributor 43 is present in the form of a flat, open cell foam piece 44 (compare Figure 4c). The foam piece 44 is hardly compressible and therefore retains its thickness, which defines a required distance A between the wound-covering element 3 and the absorption body 2.

In addition, a sterile, air-tight packaging (not shown) is provided for the device.

Function (see Figures 2a to 2d and 5):

A deep wound 29 is covered completely by gluing the drainage device (100) of Figure 1 to the skin of the patient. Previously, an opening 11 was cut out of the connecting plate 10 and, after that, the protective film 19,

shown in Figure 2a, was removed, so that an adhesive surface 30 at the underside of the connecting plate 10 is exposed.

To begin with, the mucous membrane-compatible, perforated, film-like protective element 1 and then the flat absorption body 2 together with the envelope 6 were carefully placed through the treatment opening 12 with sterilized forceps (not shown) onto the surface of the wound. The absorption body 2 has an initial volume V1. The drainage tube 4 is then pushed in over the envelope piece 22 and under the wound covering element 3 in such a manner that it rests on the envelope of the absorption body 2 (see Figure 2b). By gluing the drainage device to the skin, a gas-tight wound space 5 is formed between the wound-covering element 3 and the surface of the wound.

A vacuum pump 15, which can be operated by hand and is equipped with a pressure manometer 15 (see Figure 5), is connected over a line 31 with the drainage tube 4. Since the wound space 5 is sealed, the gases in the wound space 5 can be evacuated with the help of the vacuum pump 15. The state is shown in Figures 2b and 5. A reduced pressure of about 100 mm Hg was produced within the wound space 5 with the help of the vacuum pump 15. A check valve 17, which

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permits the flow of gases and possibly of liquid wound secretions only in the direction of a collection container 16, which is connected upstream from the vacuum pump 16, is disposed in the line 31 between the envelope piece 22 and the vacuum pump 14.

The wound secretions, emerging from the wound, reach the absorption body 2 and bring about a compression underneath the wound-covering element 3. After the aspiration of wound secretions, the absorption body 2 assumes a final volume V2 (see Figures 2c and 2d). All wound secretions, which have emerged from the wound, are absorbed by the absorption body 2. Basically, the outside of the envelope 6 remains dry.

The consumed absorption body 2 and the protective element 1 are now removed carefully from the region of the wound by raising the pivoting lid 23 with the help of forceps (see Figure 2d). If required, a new absorption body and a new protective element 1 can be placed on the wound. If the wounds discharge very heavily, there may be an excess of wound secretion, which is passed over the drainage tube 4 to the collecting container 16.

If the patient is to be subjected to an in-patient wound treatment, the reduced pressure can be produced in the wound space in the wound region by an existing, clinical vacuum installation 21 (Figure 5). For this purpose, it is advisable to incorporate a pressure regulator 18, with which the reduced pressure range can be adjusted, in the line between the drainage tube 4 and the vacuum installation 21.

List of reference numbers:

1 protective element

2 absorption body

3 wound-covering element

4 drainage tube

5 wound space

6 envelope

7 layer

8 side wall

9 overhang

10 connecting plate

11 opening (of 10)

12 treatment opening (of 3)

13 wound-repair pouch

14 vacuum pump

15 pressure manometer

16 collecting container

17 check valve

18 pressure regulator

19 protective film

20 sandwich arrangement

21 vacuum installation (stationary)

22 envelope piece

23 pivoting lid

24 protective film

25 edge (of 3)

26 outline (of 13)

27 neck (of 13)

28 wound contour

29 wound

30 adhesive surface

31 line

32 additional absorption body

33 textile section

34 air inlet

40 pressure distributor

41.1 branch

41.2 branch

42 rim

43 pressure distributor

100 drainage device

200 drainage device

300 drainage device

A distance

V1, V2 volumes

Claims

1. Drainage device (100; 200; 300) for the treatment of wounds using reduced pressure, comprising:

a gas-tight wound-covering element (3), which comprises a sheet-like material and, in the state placed in contact with the body of the patient, is fastened adhesively to the surface of the skin around the region of the wound and forms a sealed wound space (5) remaining between the respective wound and the wound-covering element (3)

at least one means, which produces a reduced pressure, such as a vacuum pump (14) and can be connected to the drainage tube (4), which can be inserted prone in the wound space (5) approximately parallel to the wound-covering element (3), by means of which the materials in the wound space (5) can be evacuated,

and at least one absorption body (2), which is disposed in the wound space (5) and absorbs the wound secretions,

characterized in that

the absorption body (2) is at least one layer (7), which is enclosed in an envelope (6), of a textile section (33)

interspersed with super-absorbing particles, the envelope (6) being permeable to liquids and having pores, the size of which essentially does not exceed that of the super-absorbing particles,

the absorption body (2), which is to be inserted in the wound space (5), having an initial volume (V1), which increases in the course of the absorption process and assumes a final volume (V2), so that, due to the pore size of the envelope (11), the absorbed wound secretions remain within the absorption body (2) and, with that, underneath the wound-covering element (3) until the absorption body is removed from the wound space.

2. The drainage device of claim 1, characterized in that, in plan view of its flat side, the layer (7) has an area, which is 3% to 90% smaller than that of the envelope (6), so that the absorption body can unimpededly approach a circular shape in cross section in the vicinity of its total filling capacity.

3. The drainage device of claim 1, characterized in that the wound-covering element (3) has a window-like treatment opening (12), through which the absorption body (2) can be placed into and removed out of the wound space (5), it

being possible to close off the treatment opening (12) gas-tied with a lid (23).

4. The drainage device of one of the claims 1 to 3, characterized in that at least one air opening (34), with which the reduced pressure within the wound space can be regulated, is disposed at the wound-covering element (3) or at the lid (23).

5. The drainage device of claim 1, characterized in that the textile section of the absorption body comprises a non-woven material of cellulose fibers.

6. The drainage device of claim 1, characterized in that it comprises a liquid-permeable mucous membrane-compatible protective element (1), which is disposed on a side of the absorption body (2), opposite to the wound covering element (3) and is approximately equal in area to the enveloped absorption body.

7. The device of claim 6, characterized in that the protective element (1) is in the form of a sheet.

8. The device of claim 6, characterized in that the protective element (1) is a section of textile material.

9. The device of claim 6, characterized in that the protective element (1) consists of a foam material.

10. The device of claim 6, characterized in that the protective element (1) is a bed of pieces of nonwoven material or of foam, lying underneath the absorption body (2).

11. The drainage device of claim 1, characterized in that the wound-covering element (3) is transparent at least at a portion of its surface.

12. The drainage device of one of the claims 1 to 11, characterized in that the wound-covering element (3) can be fastened over a flexible connecting plate (10) to the body of the patient, at least one opening (11) being incorporated in the flexible connecting plate (10).

13. The drainage device of one of the claims 1 to 12, characterized in that the wound-covering element (3) is part of a medical care pouch (13), the side wall (8) of which, lying opposite the wound-covering element, is glued at least partly to the connecting plate (10).

14. The drainage device of one of the claims 1 to 13, characterized in that the envelope (6) of the absorption body (2) is sewn by ultrasonic seams.

15. The drainage device of one of the preceding claims, characterized in that the absorption body has an overhang (9) of enveloping material at its periphery.

16. The drainage device of one of the preceding claims, characterized in that the drainage tube (4) is passed to a collecting container (16), which is connected upstream from the vacuum pump (14) and/or the pressure manometer (15).

17. The damaged device of one of the preceding claims, characterized in that the vacuum pump (14) is driven electrically or mechanically.

18. The drainage device of one of the preceding claims, characterized in that the drainage tube (4) lies between two absorption bodies (2.1, 2.2; 32) having the same or a different absorption power and forming a sandwich arrangement (20).

19. The drainage device of claim 18, characterized in that the sandwich arrangement (20) has an absorption body (2), which is interspersed with super-absorbents, and at least

one additional absorption body (32) which is not provided with super-absorbents.

20. The drainage device of claim 14, characterized in that the additional absorption body (32) is an open pore foam body.

21. The drainage device of claims 19 and 20, characterized in that the additional absorption body (32) lies between the connecting plate (10) and the absorption body (2), which is interspersed with super-absorbents.

22. The drainage device of claims 19 and 20, characterized in that the additional absorption body (32) lies between the wound-covering element (3) and the absorption body (2), which is interspersed with super-absorbance.

23. The drainage device of one of the preceding claims, characterized in that the absorption body (2), the additional foam-like absorption body (32) and/or the protective element (1) have silver-containing, copper-containing or zinc-containing substances, for example, in nanocrystalline form.

24. The drainage device of one of the preceding claims, characterized in that the absorption body (2), the

additional foam-like absorption body (32) and/or the protective element (1) is enriched with activated charcoal.

25. The device of one of the preceding claims, characterized in that a pressure distributor (40), contacting the envelope (11) of the absorption body (2), is disposed underneath the wound-covering element (3), but above the enveloped absorption body (2) or the additional foam-like absorption body (32).

26. The device of claim 25, characterized in that the pressure distributor (40) is a piece molded from a gas-permeable foam.

27. The device of claim 25, characterized in that the pressure distributor (40) is formed by the drainage tube (4) extending in forked, loop-like or meandering fashion underneath the wound-covering element (3).

28. The drainage device of one of the preceding claims, characterized in that this device can be connected over a pressure regulator (18) to an existing, stationary, clinical vacuum installation (21).

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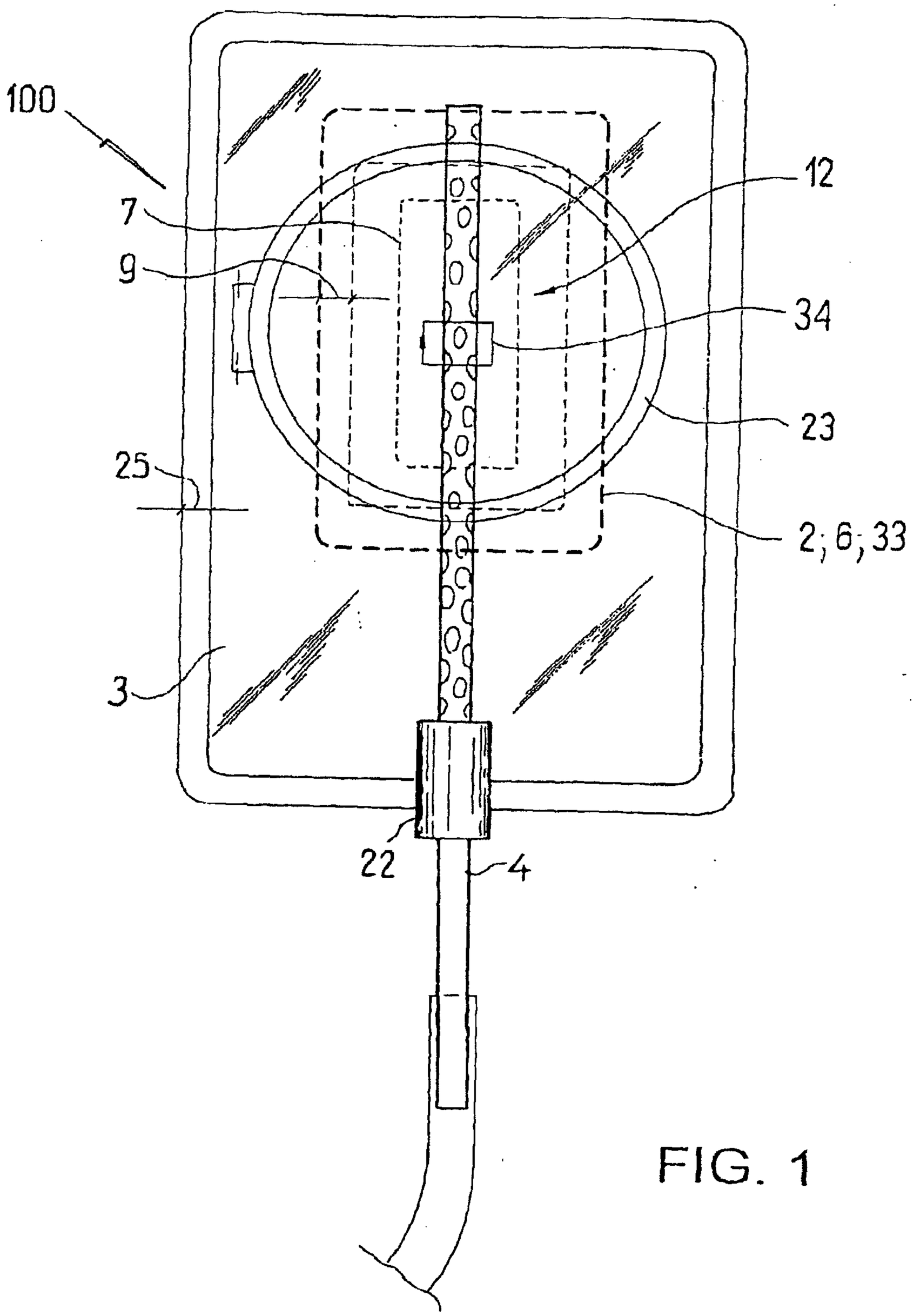


FIG. 1

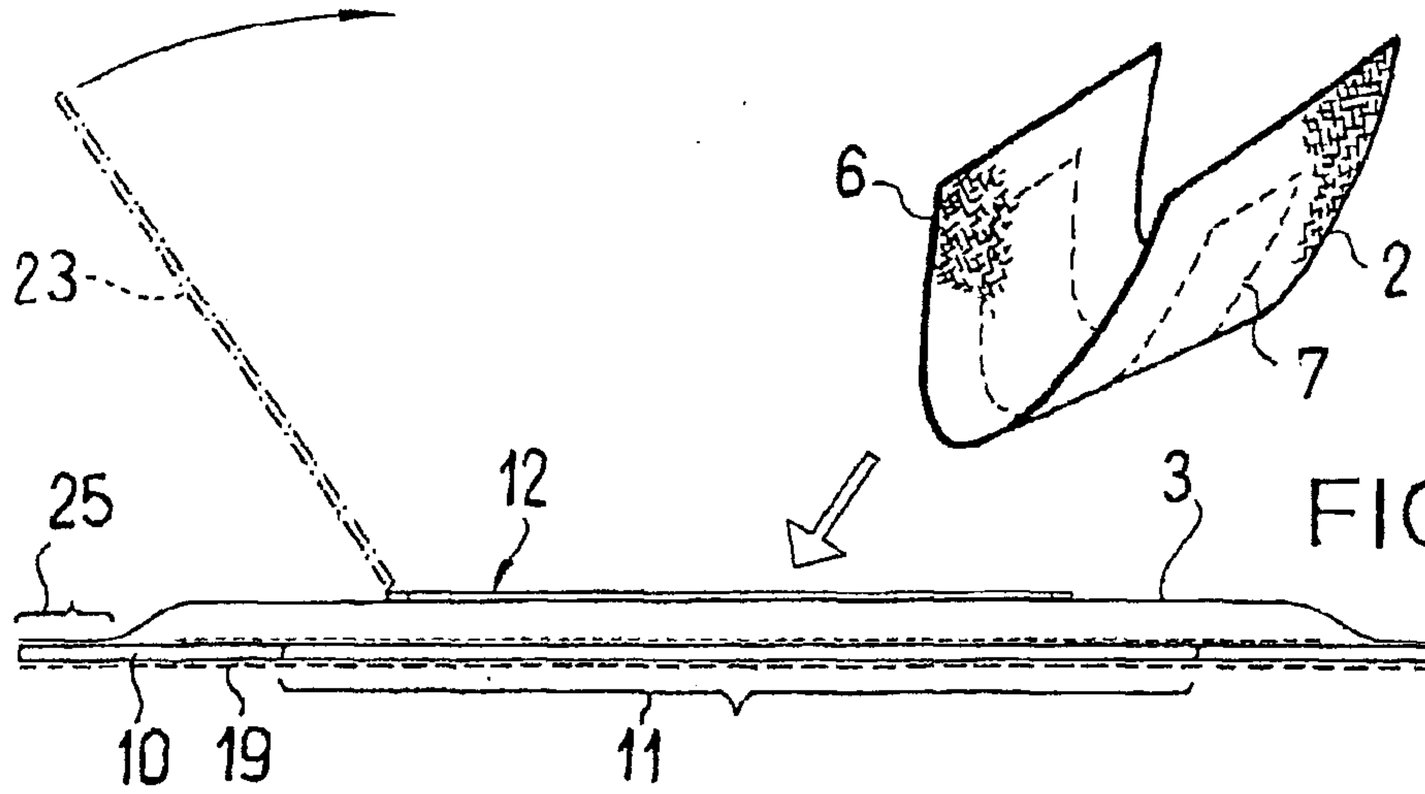


FIG. 2a

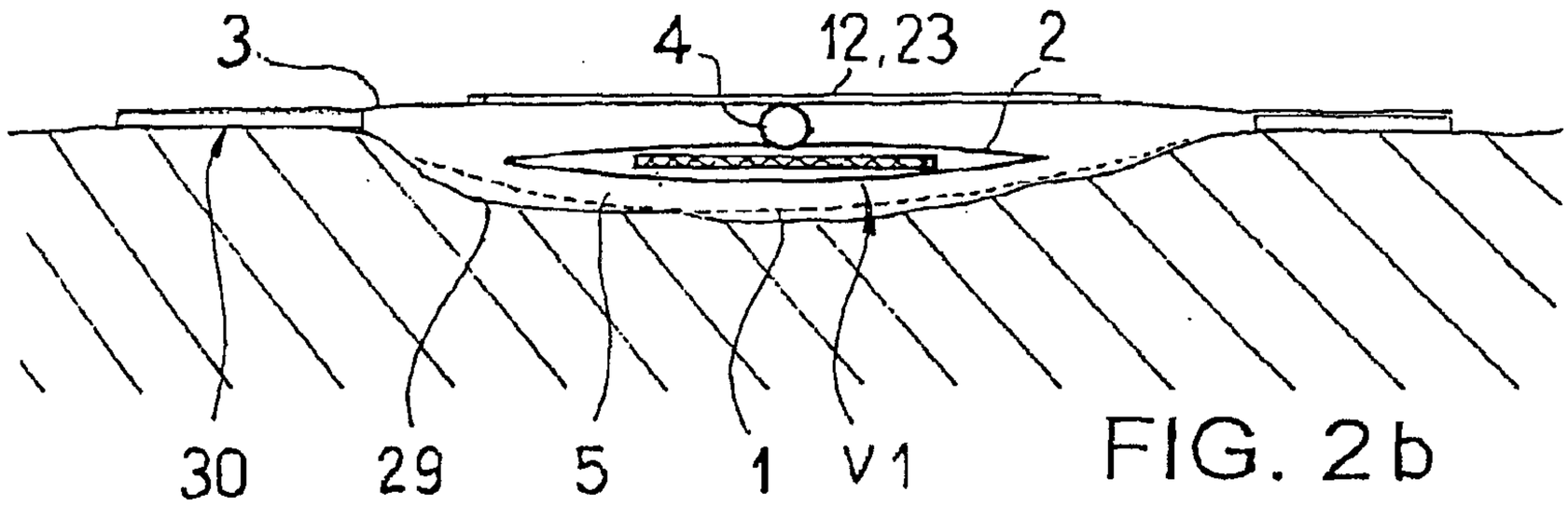


FIG. 2b

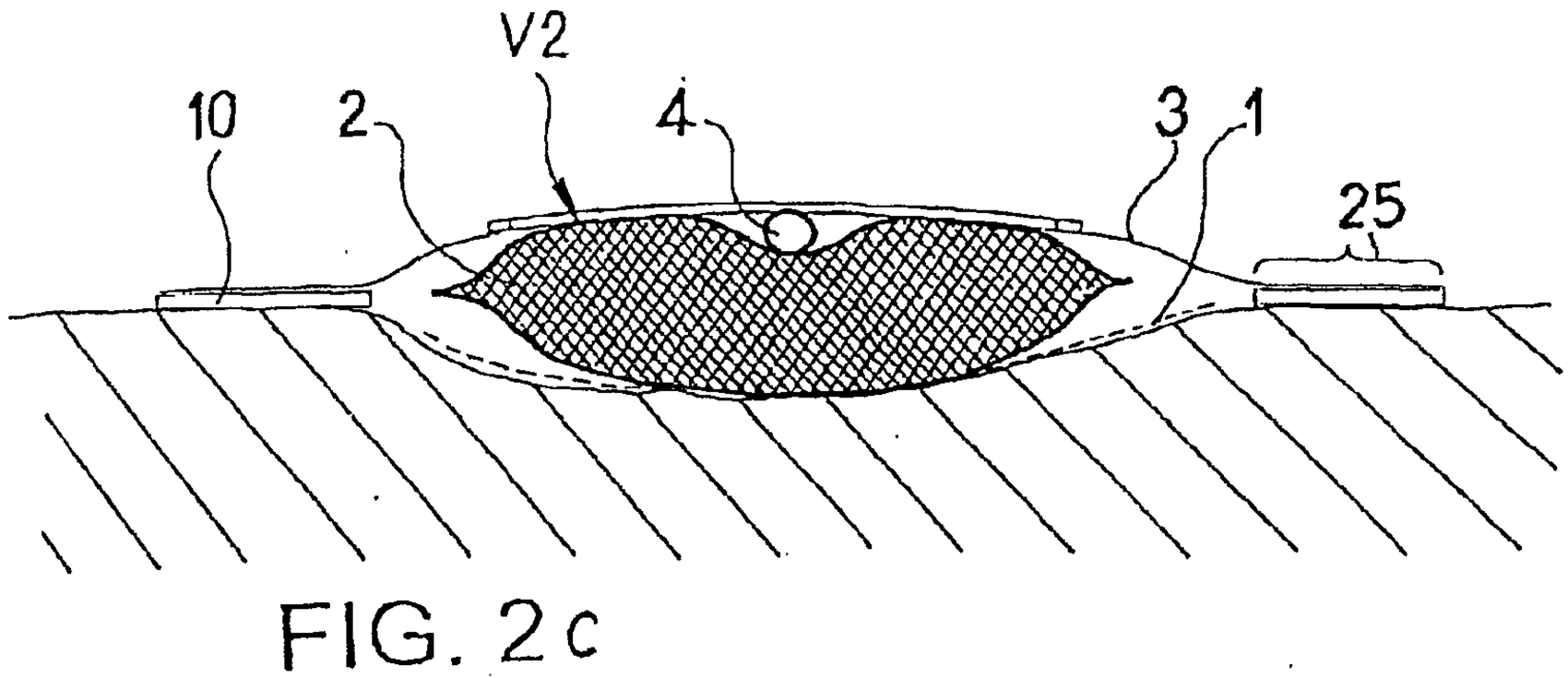


FIG. 2c

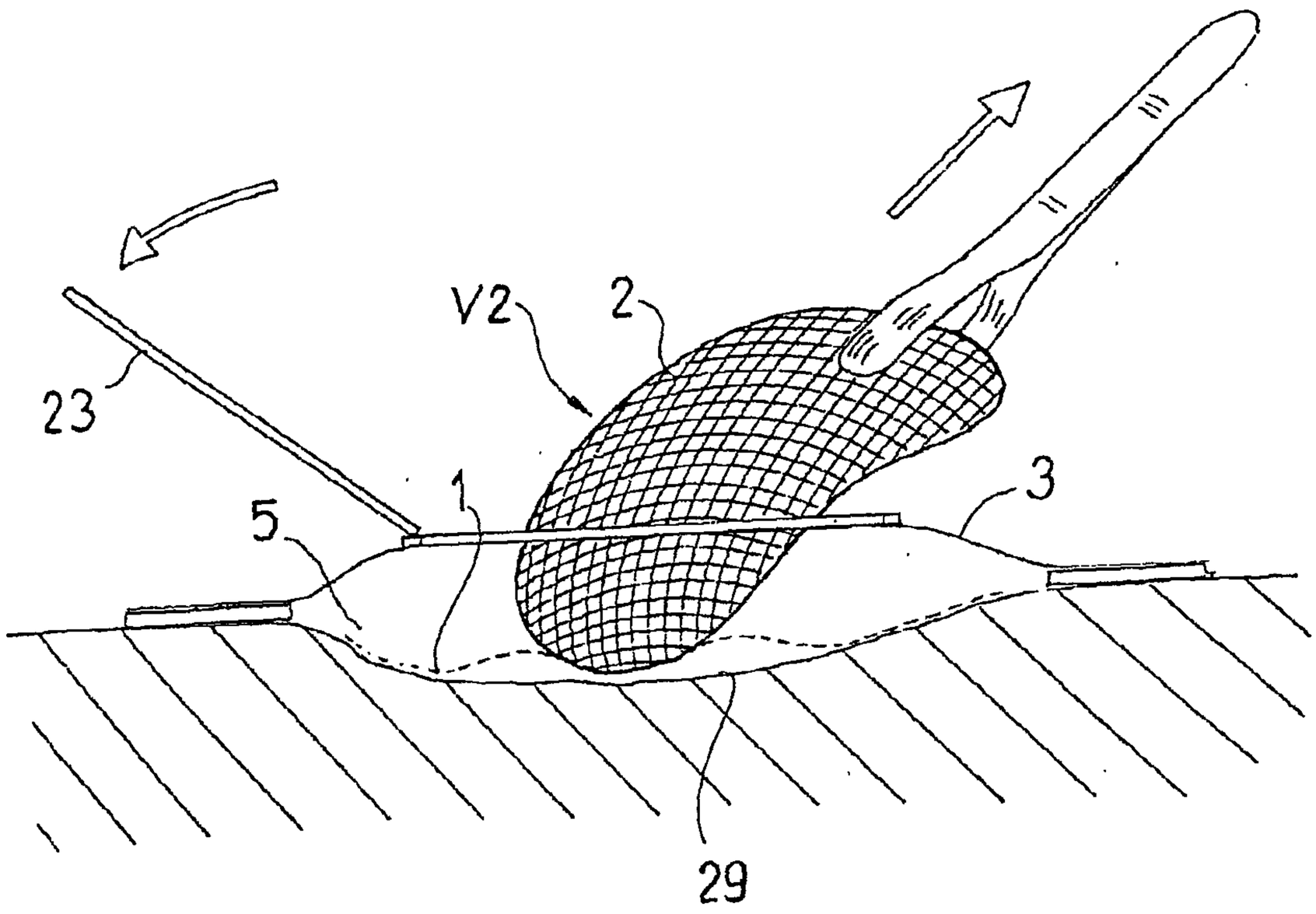


FIG. 2 d

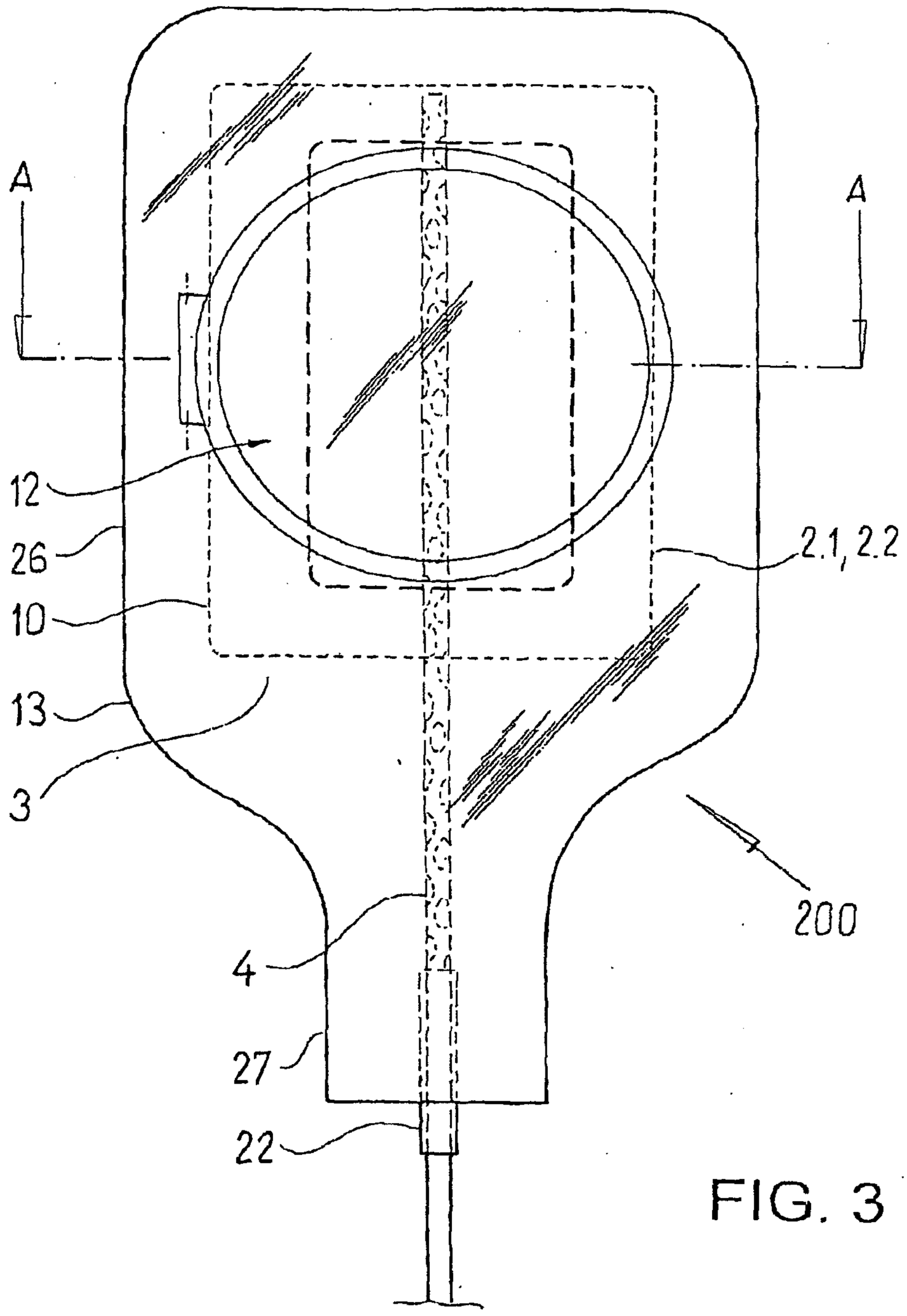


FIG. 3

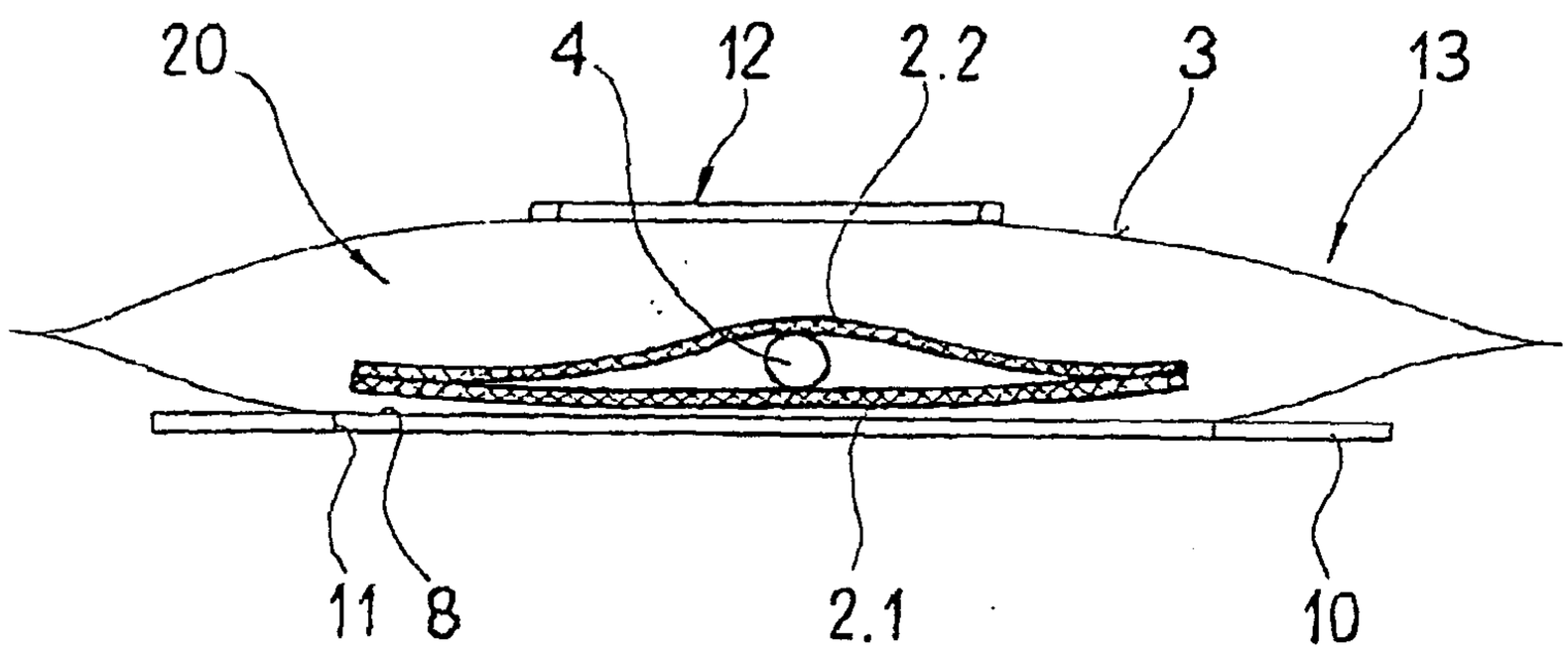


FIG. 4a

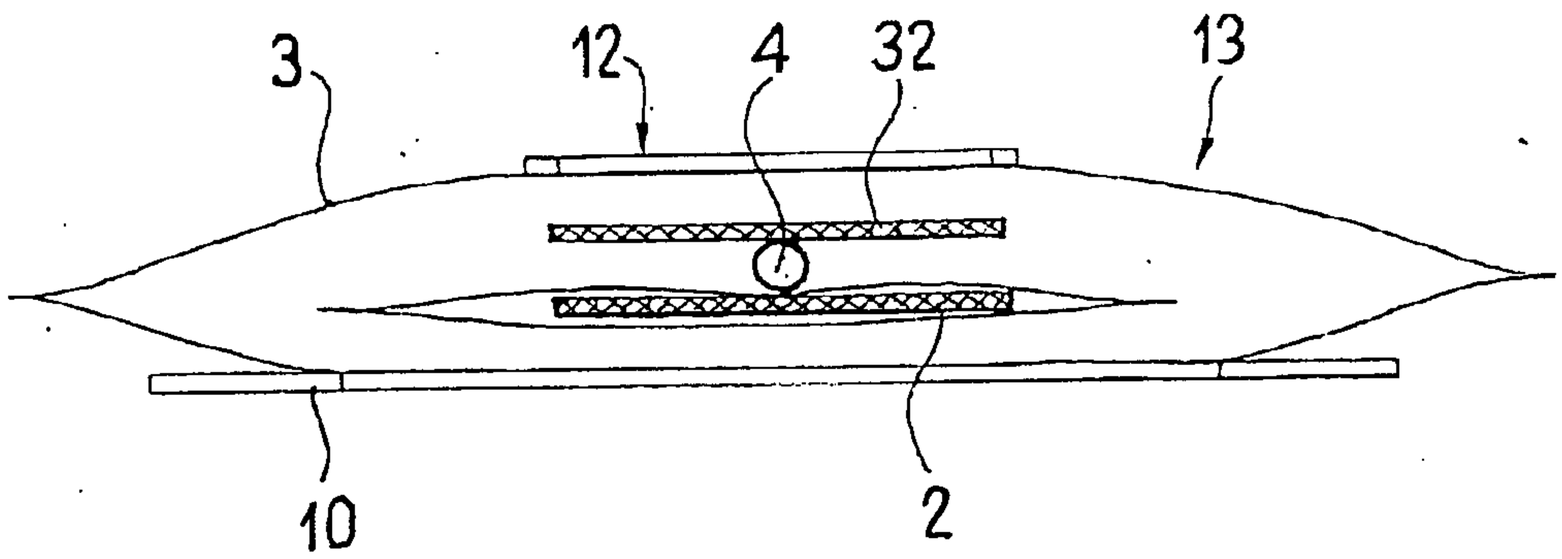


FIG. 4b

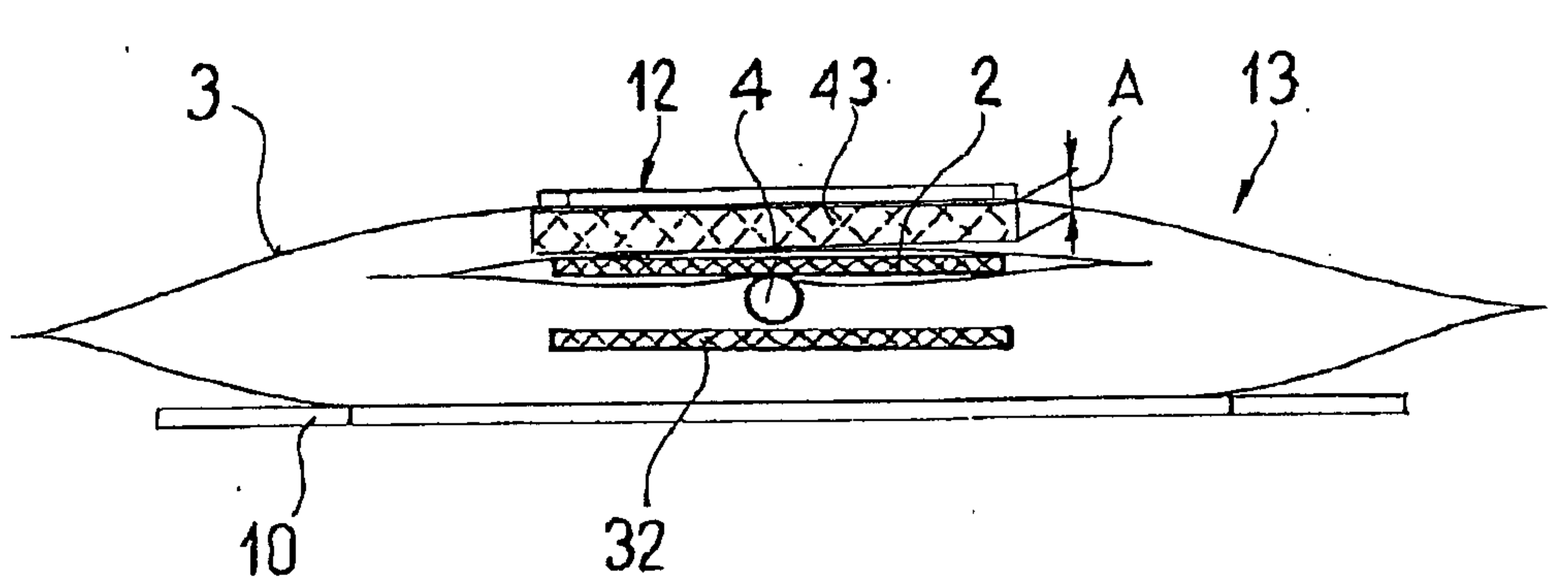
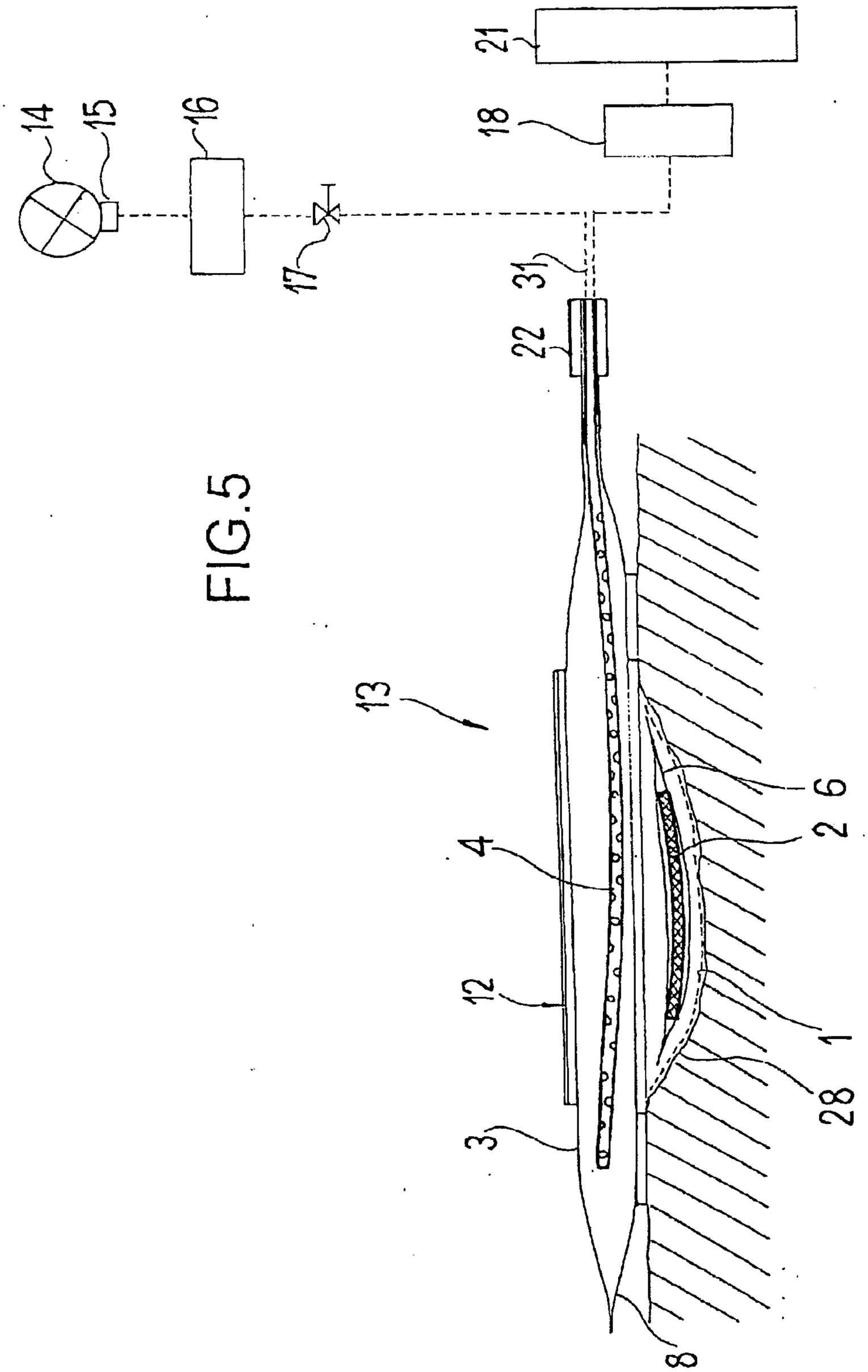


FIG. 4c

FIG.5



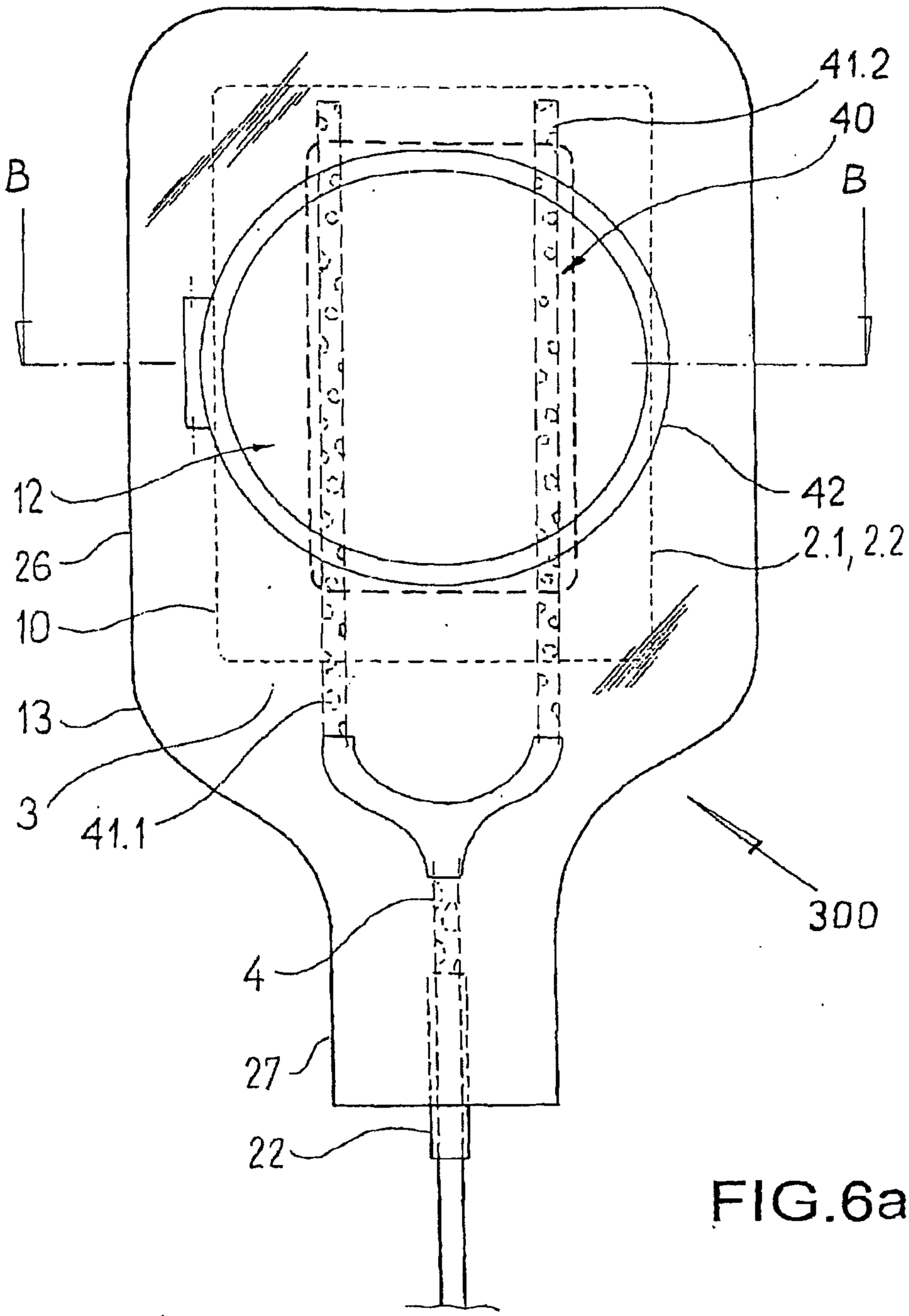


FIG.6a

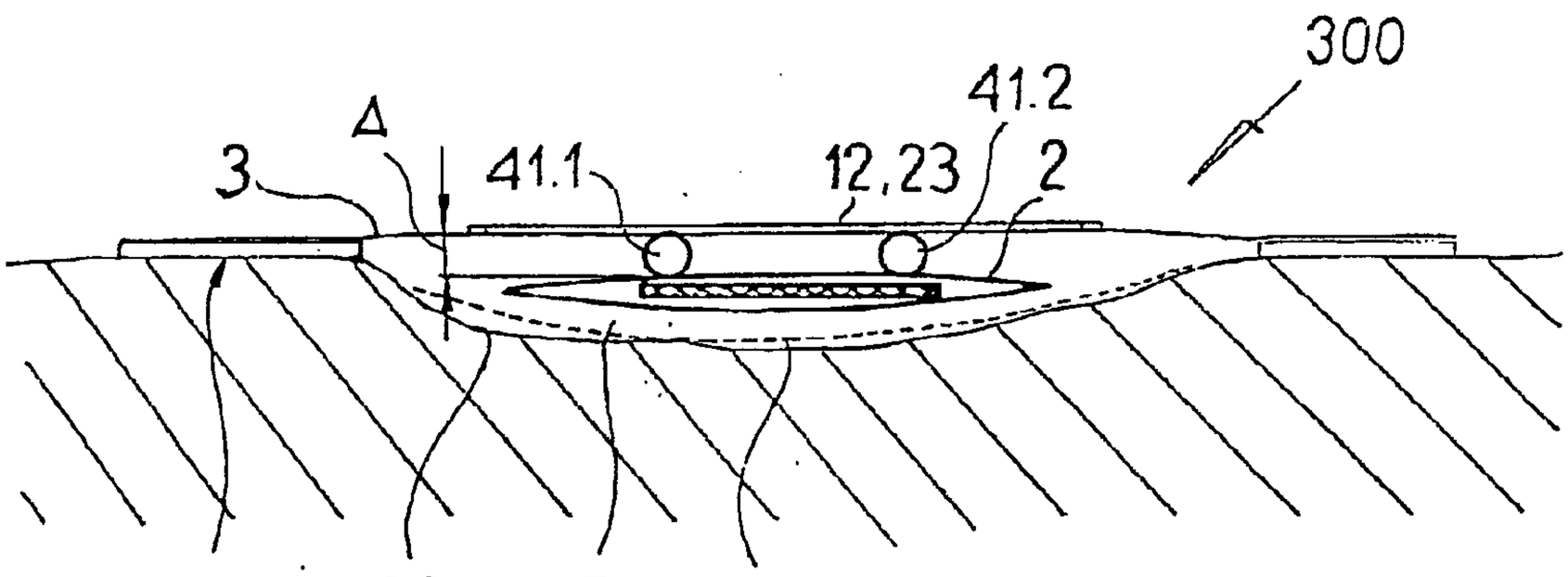
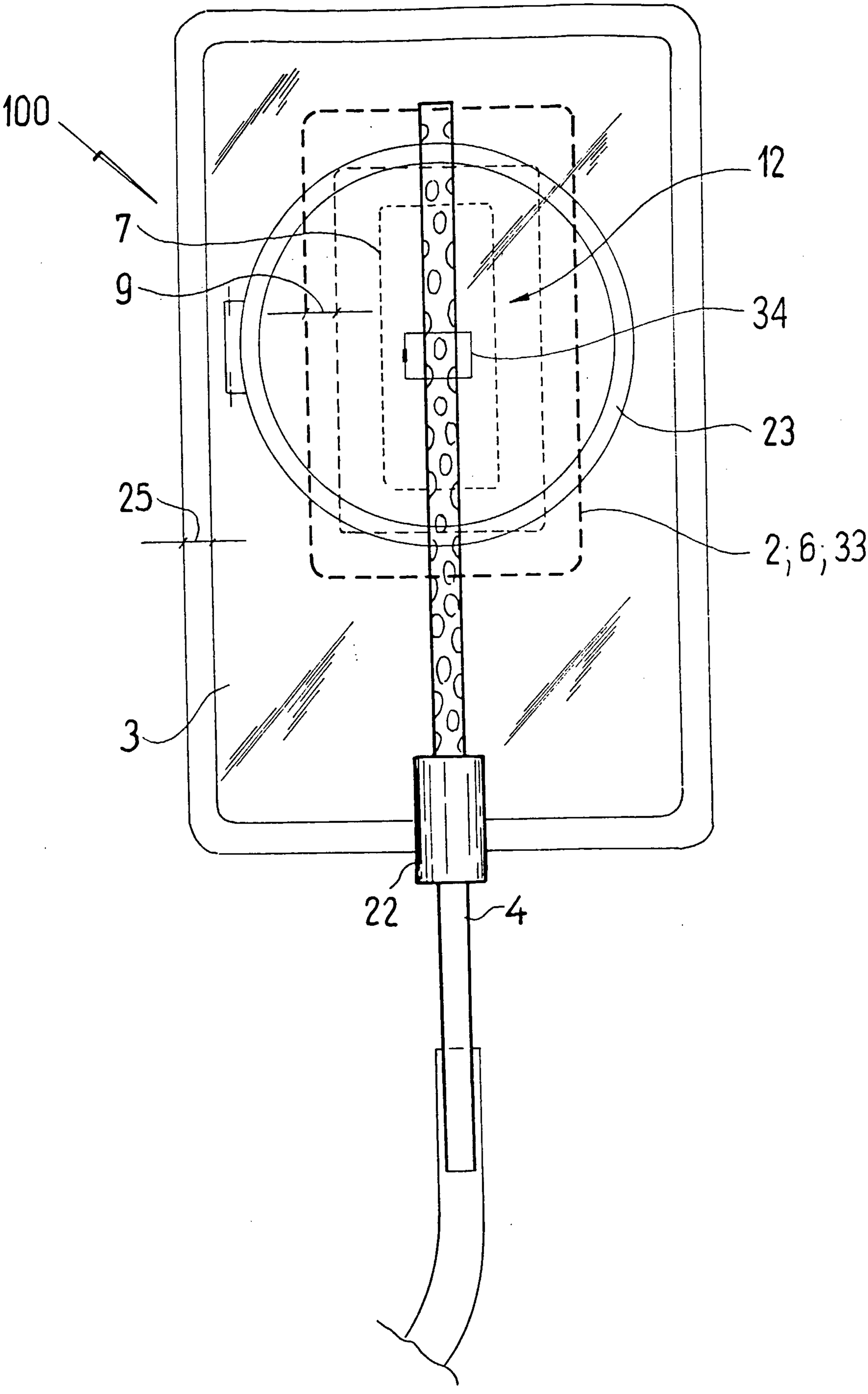


FIG.6 b


100
7
9
12
34
23
25
2;6;33
3
22
4