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(54) **COVER**

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(57) **ABSTRACT**

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A cover (101) for being located on an infusion device which cover (101) comprises an upper plate element (103) with an upper face (104) and a lower face (105) oriented towards the upper face of the infusion device, wherein the lower face (105) of the plate element (103) comprises attachment means (106), which means cooperate with elements on the infusion device.

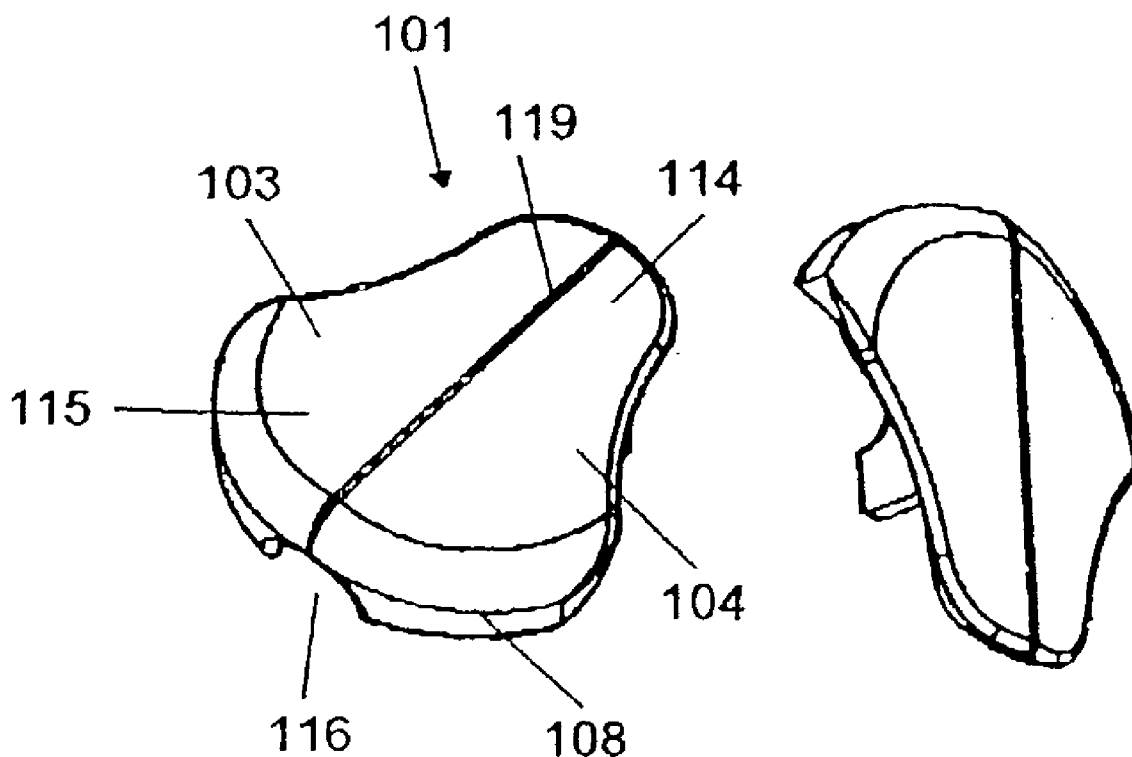
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Hereby the risk of bacteria and soil collected thereon penetrating into the construction is reduced considerably, and likewise the cover yields a smoother surface with an ensuing minimisation of the risk of the infusion device being torn off.

Publication Classification

(51) **Int. Cl.⁷ A61M 31/00**



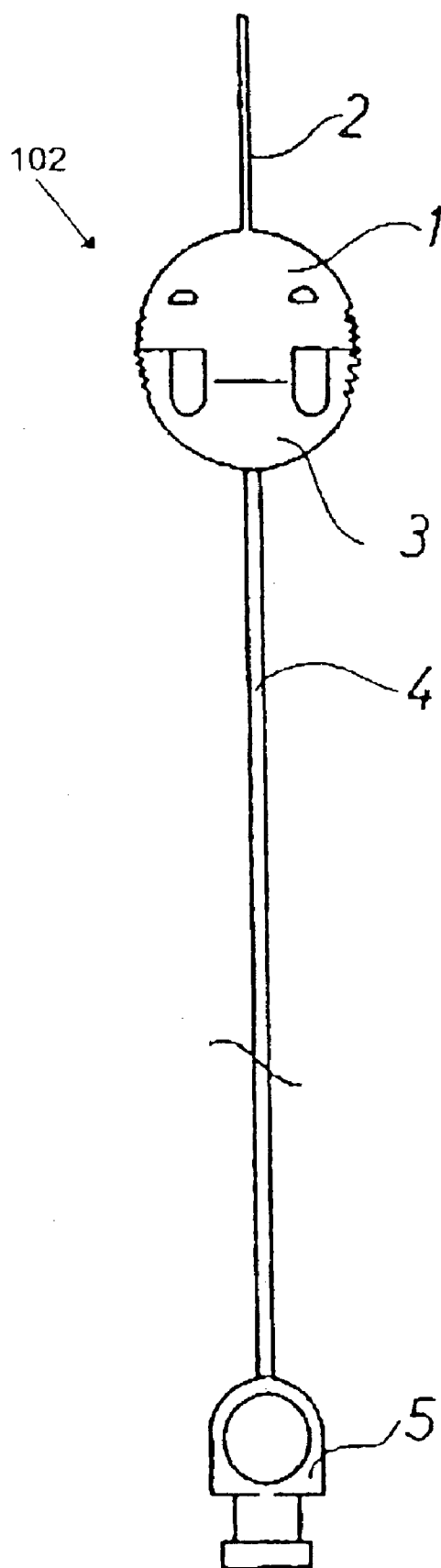


Fig. 1

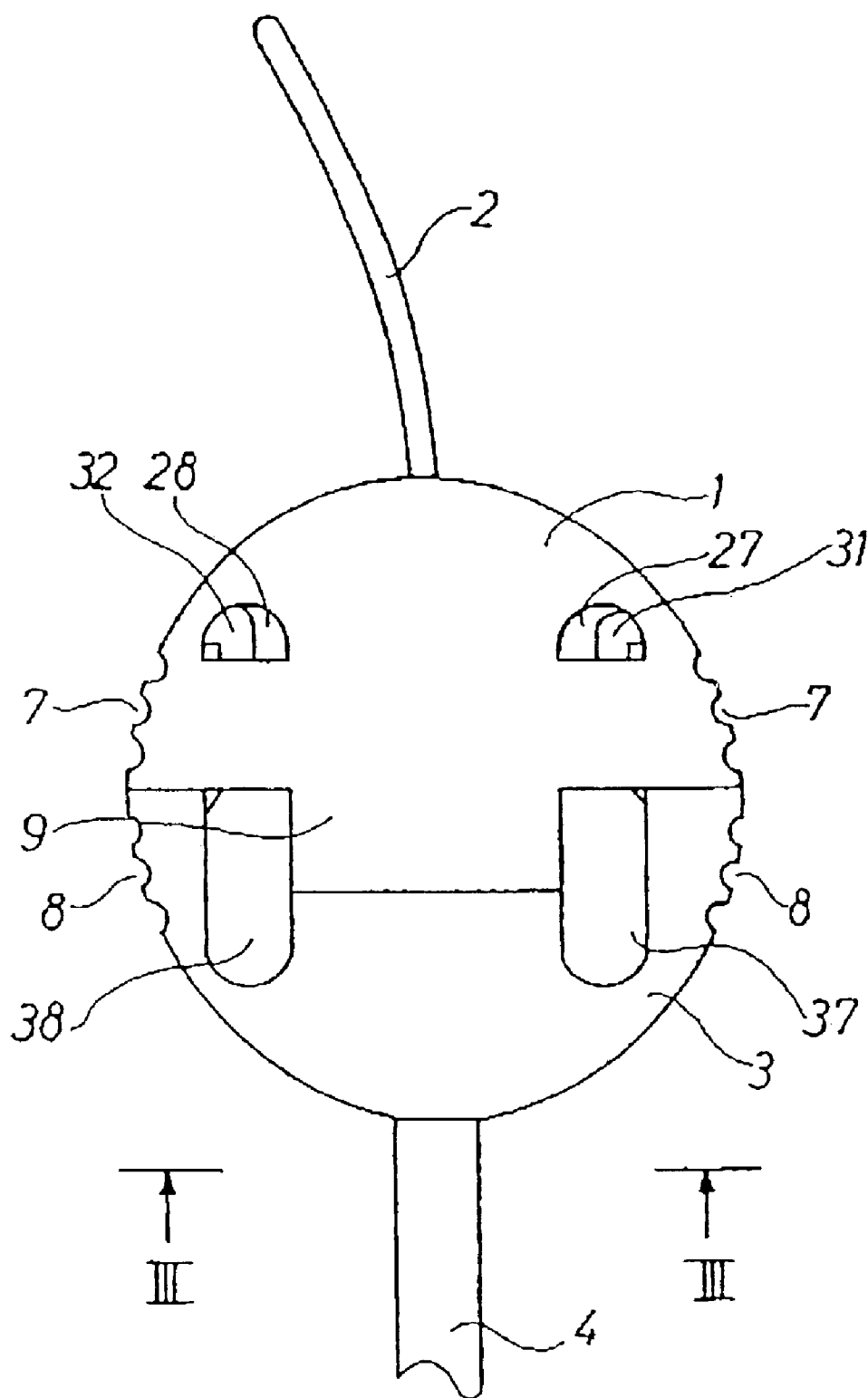


Fig. 2

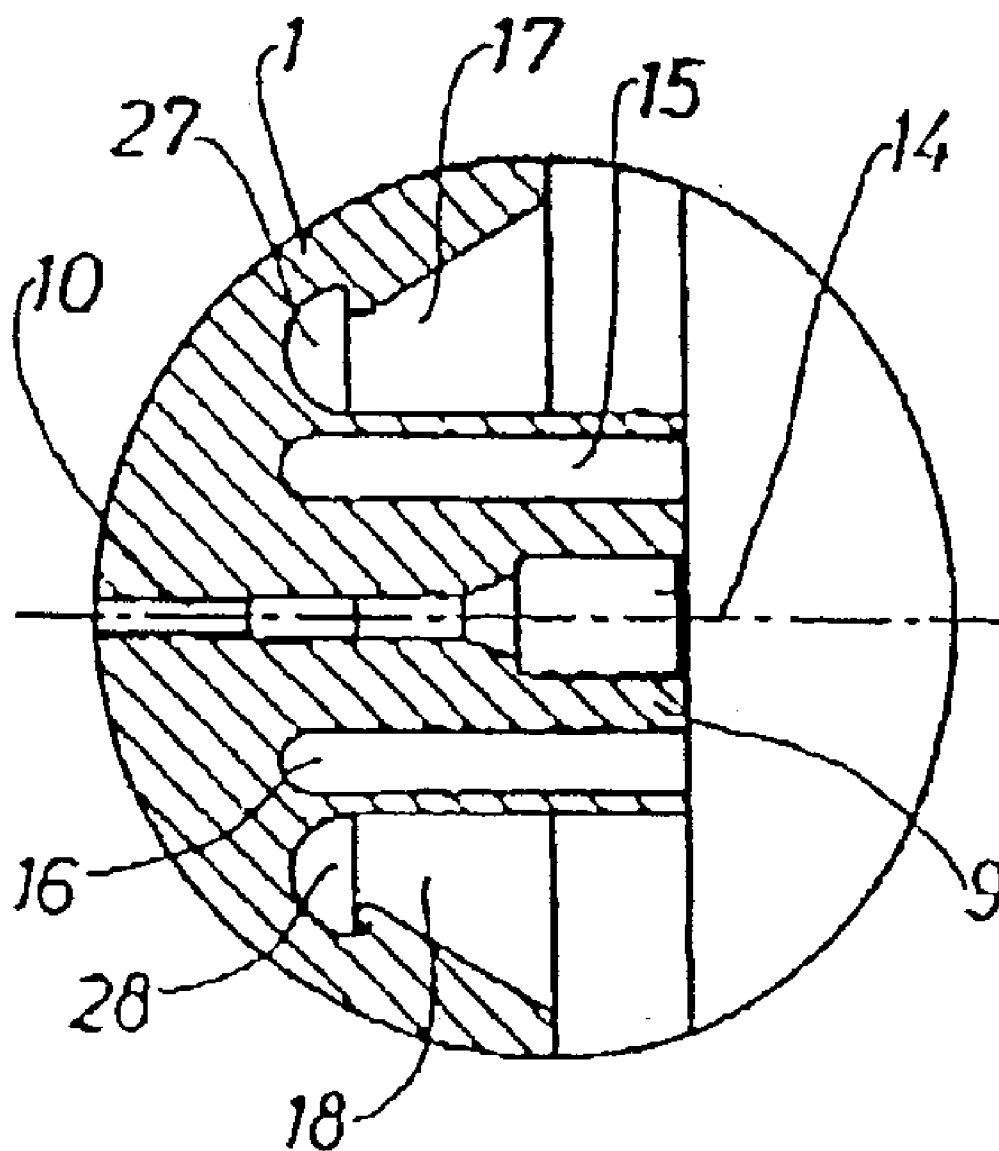


Fig. 3

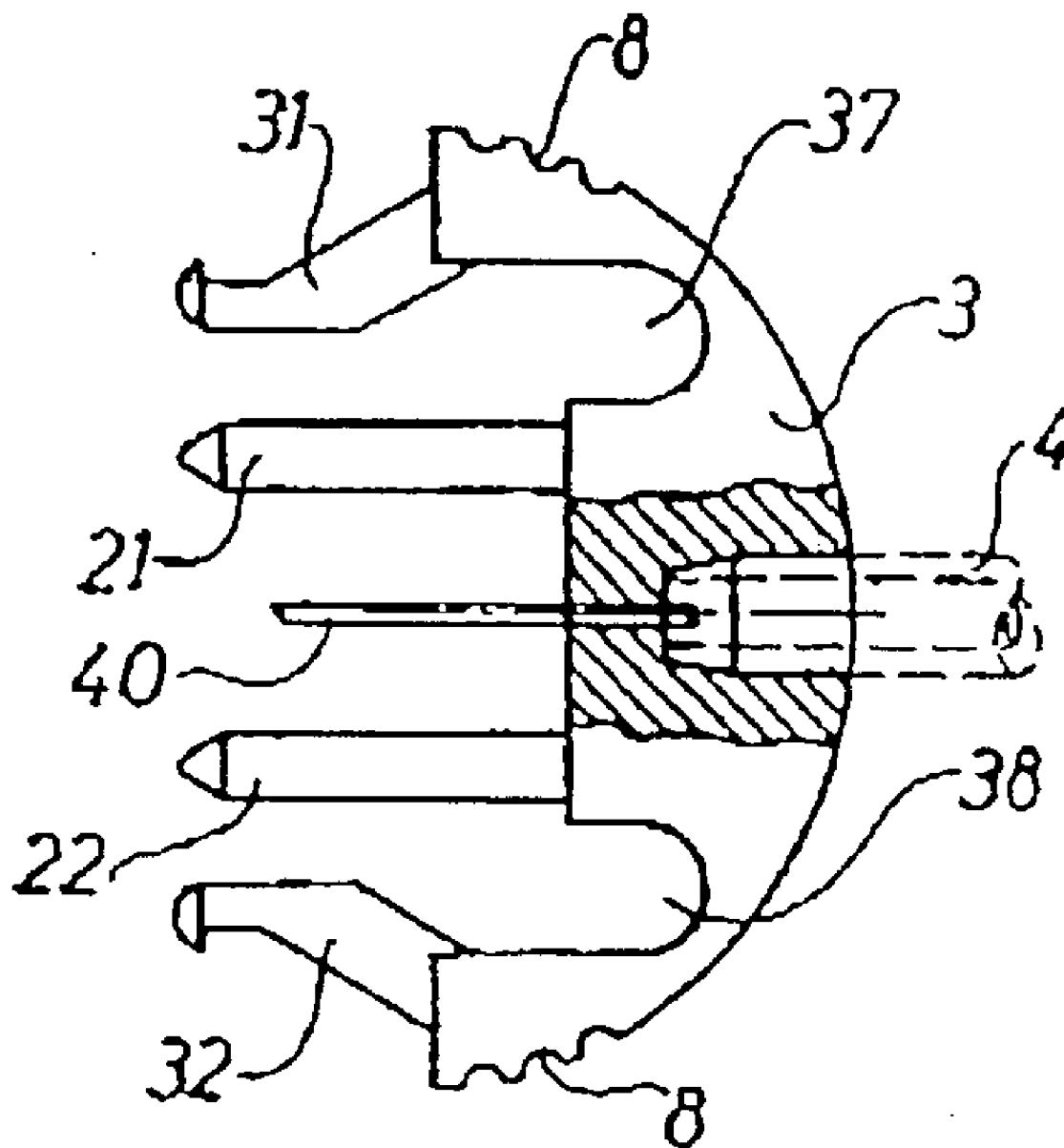


Fig. 4

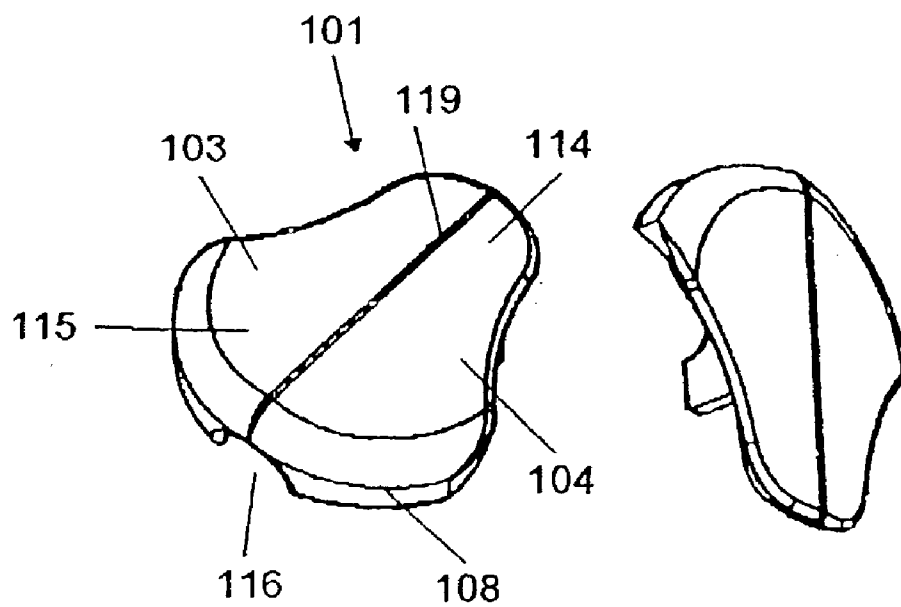


Fig. 5

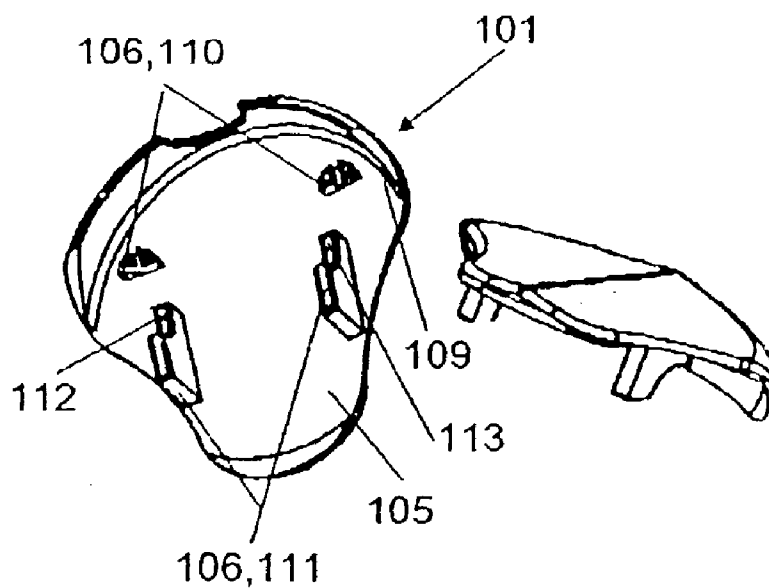


Fig. 6

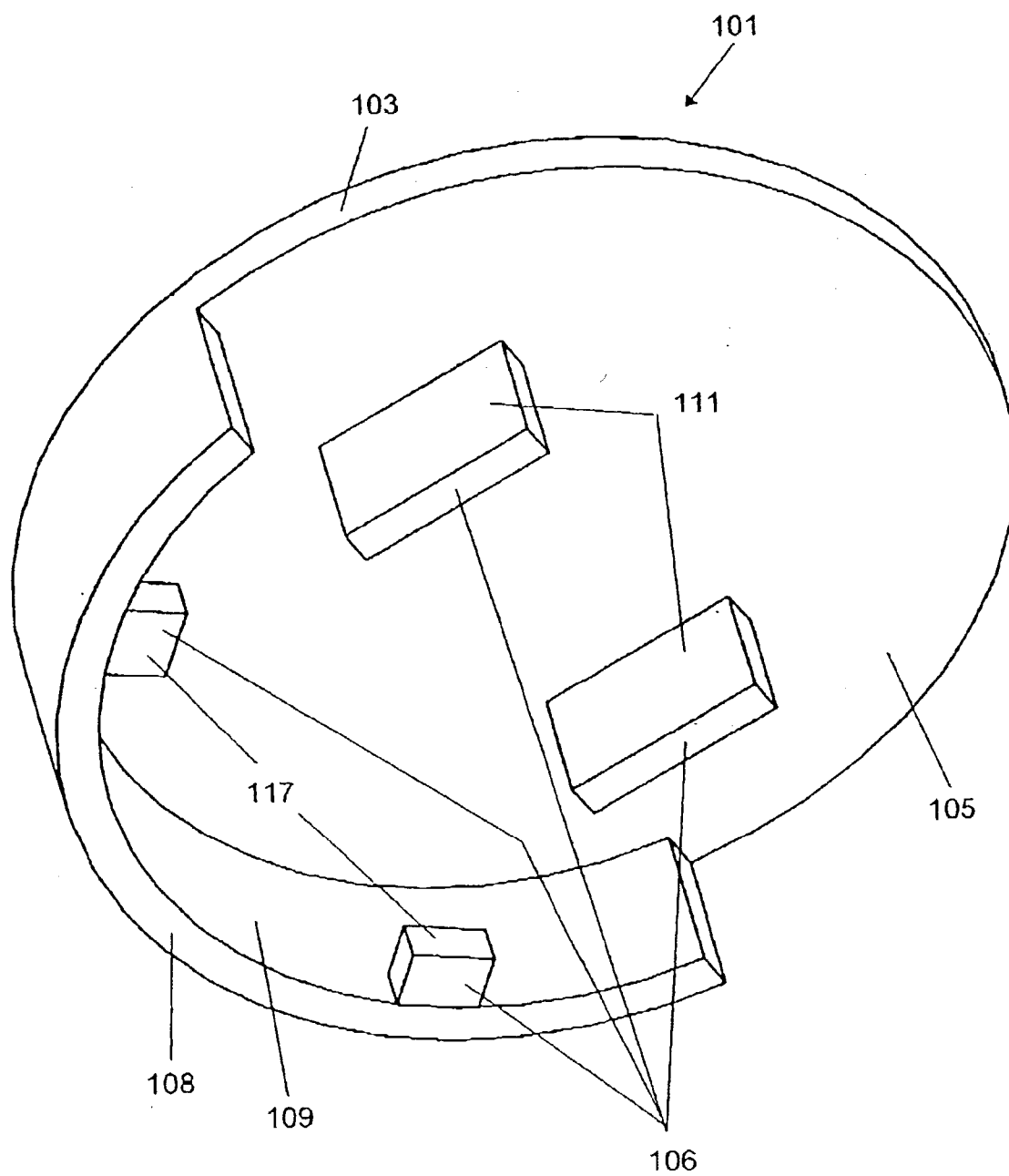


Fig. 7

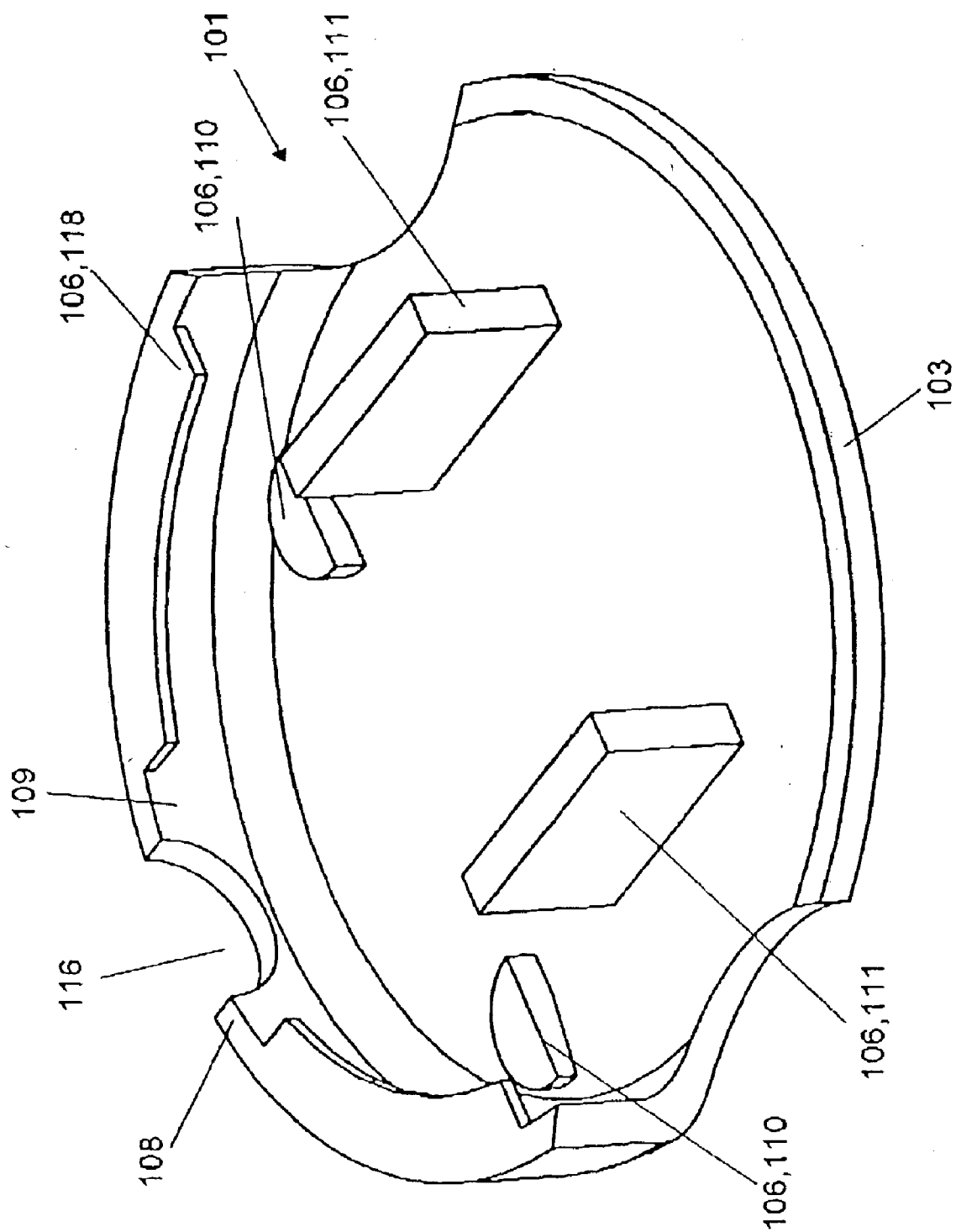


Fig. 8

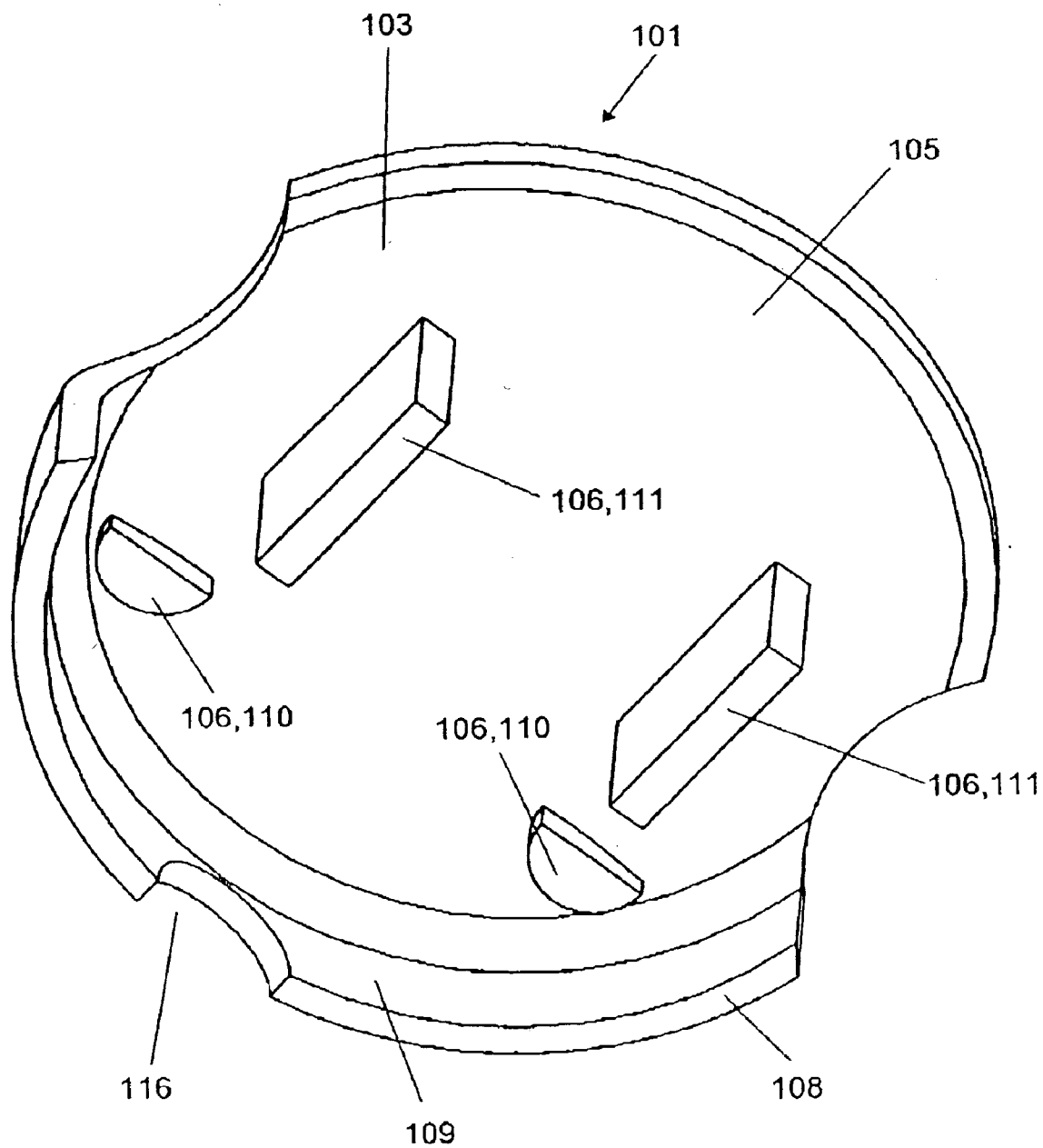


Fig. 9

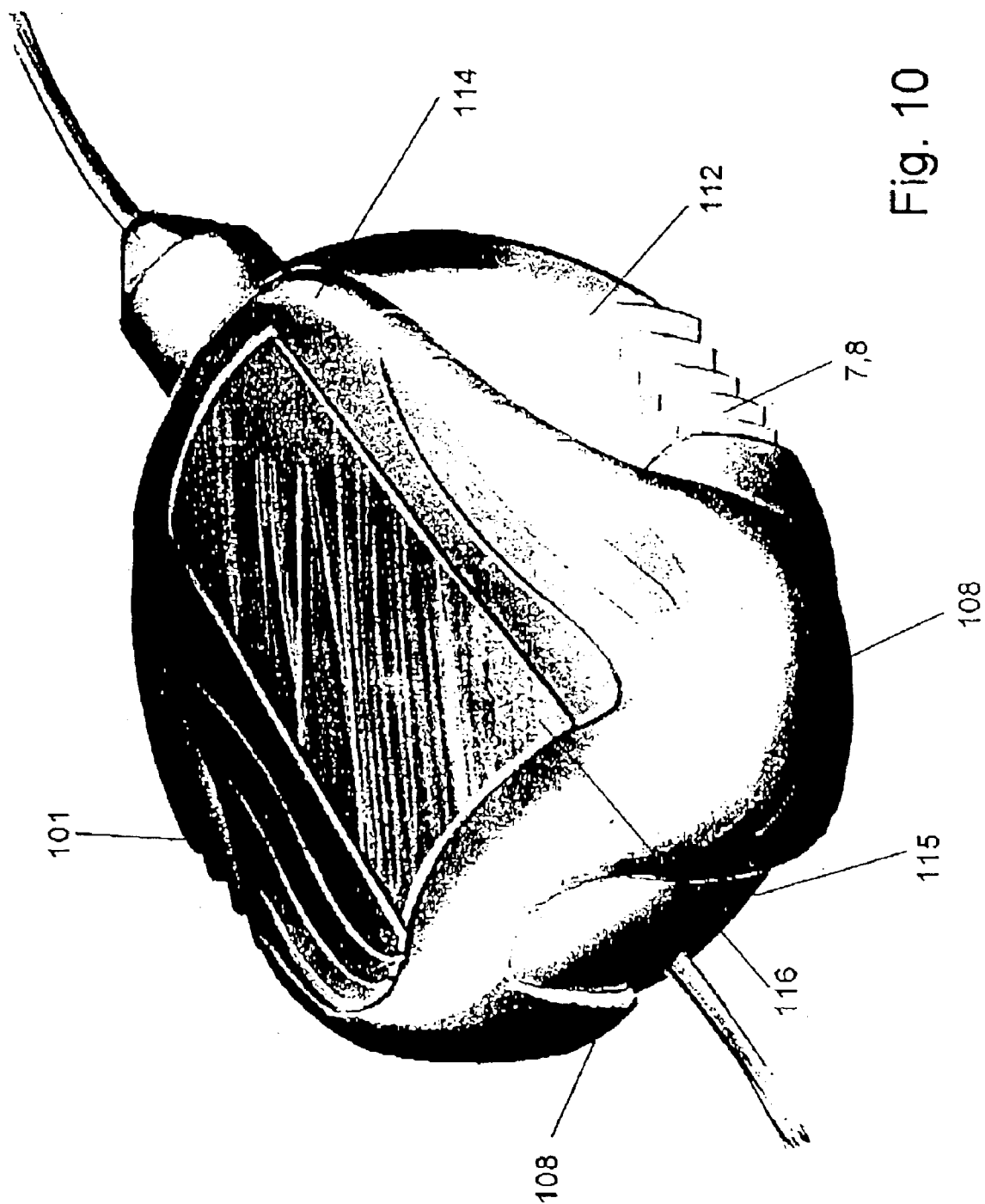


Fig. 10

COVER

[0001] The invention relates to a cover for being located on an infusion device, said cover comprising an upper plate element with an upper face and a lower face oriented towards the upper face of the infusion device.

[0002] In connection with an infusion device being located on the skin, it is known to shield it; such shielding, however, involving a complete covering of the infusion device and in such a manner that it becomes inaccessible to manipulation from the outside.

[0003] One example of this is known for instance from WO 87/06474. This discloses a device that can be strapped to the body over the location of insertion of an intravenous needle to shield the puncture area against contact and for anchoring the tube so that the needle will not be pulled out inadvertently.

[0004] However the construction necessitates use of an additional frame for securing the infusion device and also for securing the dome that shields the entire infusion device and is also manufactured to be very voluminous. There is thus a risk of it being torn off during use and, likewise, it prevents access to the infusion device and, furthermore, there is a risk of the adhesive effect ceasing and, likewise, it cannot be expected that adjustments of the shielding are possible as the adhesive effect will cease.

[0005] It is thus the object of the present invention to provide a cover that remedies the problems that may occur in connection with the prior art covers and whereby complete or partial shielding of the upper free face of the infusion set is enabled, but wherein the lower face is unshielded and the side faces are also partially unshielded, and wherein a shielding of the plate takes place directly on the infusion device. Hereby it is obtained that the risk of bacteria and soil collected thereon penetrating into the construction is reduced considerably, and likewise the cover enables a smoother surface with an ensuing minimisation of the risk of the infusion device being torn off.

[0006] This object is obtained by a cover like the one described in the preamble to claim 1 and wherein the lower face of the plate element also comprises attachment means, said means co-operating with elements on the infusion device.

[0007] Thus, the cover functions in that, by means of its attachment means that are provided on the lower free face, it fits into the upper face of the infusion device and by a press fitting ensures that the cover is securely attached onto the infusion device due to the clamping effect obtained between the individual attachment means and can be reinforced by the infusion device preferably comprising, as described in the attached claims, a side flange, and wherein this side flange cooperates with the attachment means to bring about a secure attachment of the cover on the infusion device.

[0008] Preferably the upper face of the infusion device is configured with recesses, on the one hand longitudinally extending recesses and rather rounded cavities, and consequently the attachment means match these cavities and bring about the attachment. The upper face of the cover is smooth throughout and the entire lower face of the cover is essentially congruent with the upper face of the infusion device, whereby the adaptation is optimised. The cover may be

removed by side flanges, if any, being seized thereby exposing the entire infusion device. The cover can be configured such that the upper plate does not cover the entire infusion device, but merely comprises a tongue portion that extends across a portion of the upper face of the infusion device and an essentially partially circular part that covers the remainder.

[0009] By providing a cover according to the invention and as further featured in claim 2, it is obtained that, in case the infusion device that consists of two parts is separated it is possible—due to the presence of the flange—for the cover to remain in place on the part designated the cannula part; the attachment means and the flange bringing about a squeezing effect that secures the cover in position.

[0010] By provision of a cover in accordance with the invention and as further featured in claim 3, an optimal complete or partial shielding of the infusion device is obtained.

[0011] Provision of a cover according to the invention and as further featured in claim 4 makes it possible to seize the exposed parts of the infusion device and thus to carry out a separation thereof.

[0012] Provision of a cover in accordance with the invention and as further featured in claim 5 enables close contact between the cover and the infusion device, and hereby a click-attachment is obtained.

[0013] Provision of a cover in accordance with the invention and as further featured in claims 5, 7 and 8 brings about a convenient shape of the attachment means.

[0014] Provision of a cover in accordance with the invention and as further featured in claim 9 enables separation of the hub and cannula part while simultaneously the cover remains in place on the cannula part.

[0015] The invention will now be explained in further detail with reference to the drawing wherein

[0016] FIGS. 1-4 show an infusion set as described in U.S. Pat. No. 5,522,803 and for which a cover in accordance with the invention can be used;

[0017] FIG. 5 shows a first exemplary embodiment of a cover according to the invention, seen in a perspective view from above;

[0018] FIG. 6 shows the cover shown in FIG. 5, in a perspective view seen from below;

[0019] FIG. 7 shows an alternative embodiment according to the invention, seen in perspective view from the bottom;

[0020] FIG. 8 shows a third exemplary embodiment in accordance with the invention, seen in perspective view and from the bottom;

[0021] FIG. 9 shows a fourth exemplary embodiment seen in perspective view and from the bottom;

[0022] FIG. 10 shows the cover shown in FIG. 5 located on an infusion set in accordance with FIG. 1.

[0023] The infusion set of FIG. 1 comprises a cannula housing 1 with a soft cannula 2 secured therein and manufactured in a conventional manner of a suitable plastics material. The infusion set further comprises a connecting hub 3 connected in a conventional manner through a hose 4

with a lower coupling member **5** to be used for the coupling thereof to an insulin pump (not shown).

[0024] FIG. 2 shows the cannula housing **1** and the connecting hub **3** on a larger scale and creating the infusion device **102**. It appears clearly that together they are of a relatively flat shape and of a uniform thickness and have a substantially plane rear side. When seen from the top, they are together of a substantially circular shape, said shape being interrupted only by recesses **7** and **8**, respectively, for facilitating a finger-handling. As illustrated in FIG. 2, the cannula housing **1** and the connecting hub **3** are divided substantially along a diametrical central plane, a central projection **9** being provided on said cannula housing **1** and projecting into a mating recess in the connecting hub **3**. In FIG. 3, the cannula **2** is slightly curved in order to illustrate that it is bendable.

[0025] As illustrated in FIG. 3, the cannula housing comprises two guide openings **16** and **15** and two locking openings **17** and **18** in addition to the rectilinear through bore **10**. These openings are symmetrically shaped about a plane including the central axis **14** of the through passageway **13** and extending perpendicular to the rear side **6**. The guide openings **15** and **16** are elongate openings adapted to receive mating guide pins **21** and **22** on the connecting hub **3**, cf. FIG. 4.

[0026] The locking openings **17** and **18** adjacent the guide openings **15** and **16** and the central through bore **10** follow a rectilinear course parallel to the central axis **14** and consequently also parallel to the guide openings **15** and **16**. The locking openings **17** and **18** at the bottom are connected to the surface of the cannula housing through a shaft or channel **27** and **28**, respectively, extending perpendicular from said locking openings **17** and **18**.

[0027] The locking openings **17** and **18** are adapted to receive mating symmetrically shaped locking pins **31** and **32** on the connecting hub **3**. As illustrated in FIG. 4, these locking pins **31** and **32** are engaging with the locking openings **17** and **18**.

[0028] As illustrated in FIGS. 2, curve-shaped recesses **37** and **38** are shaped on each side of the locking pins **21** and **22**. These recesses ensure that the locking pins **31** and **32** can be moved easily by means of a finger.

[0029] FIG. 4 shows furthermore that centrally the connecting hub **3** comprises a needle **40**. When inserted through a membrane in the cannula housing **1**, this needle provides a connection between the hose **4** of the infusion set and the through passageway **13** of the cannula housing **1**.

[0030] Reference now being made to FIGS. 5-9, the cover **101** will be described in further detail. FIG. 5 shows a first exemplary embodiment of a cover **101** seen from the top and comprising an upper plate portion **103** which is shaped to be essentially planar and has an upper face **104** which is plane and smooth. In this case, the upper plate portion **103** is configured as a partially circular element **115** that extends into a tongue part **114**. At the delimiting edge of the plate element corresponding to the partially circular area, it extends into a flange **108**, wherein flange and plate element form an essentially 90° wide angle—a first angle—to each other. Furthermore, this angle has a partially circular recess **116** essentially corresponding to the centre axis of the cover and arranged symmetrically thereabout, said recess **116**

ensuring that hoses can freely and unimpededly extend from whatever infusion device shielded by the cover. Thus the cover is configured symmetrically about its longitudinally extending centre axis **119**. Typically the upper plate portion **103** will have a thickness within the range 1.5-2 mm. Typically the flange will assume approximately the same thickness, however, optionally thicker in the transition area between plate and flange.

[0031] FIG. 6 shows the cover shown in FIG. 5, seen from below, from where the lower face **105** of the plate element **103** will appear which is essentially plane, optionally slightly curved; such, however, that this face is congruent with the infusion device on top of which it is to be located. This face comprises attachment means **106** that comprise in this case two types, viz two plate elements **111** and two partially cylindrical elements **110**. The two plate elements **111** are each configured as rectangular plate elements that are cast integrally with the cover and are located perpendicular to the lower face **105**. The rectangular faces of the plate elements are in parallel with the centre axis **114** of the cover and are located with a second mutual spacing, corresponding to 9-10 mm. The plate elements are located in such a manner that, when the cover is located on an infusion device, they will fit into recesses on the infusion device, eg the recesses indicated in FIG. 2 by **37** and **38**. Hereby a firm attachment of the cover to the infusion device is ensured, since—on the one hand—there is a span between the two rectangular plate elements and—on the other—a span between flange and plate elements.

[0032] Conveniently the plate elements can be provided with a recess: a partially circular recess facing towards the flange and corresponding to the upper free edge, whereby a nail-shaped cavity is provided and being shown in the drawing with a concave face **113** that extends into the side faces at a concave delimiting edge **112**. It is the object of this recess to enable the cover to remain in place when the two parts of the infusion device, viz the cannula housing and the connection hub, are separated and wherein the infusion device remains in position on the cannula housing.

[0033] Furthermore, in this exemplary embodiment the attachment means **106** also comprise the two partially cylindrical elements **110** that are located with their centre axis perpendicular to the lower face **105** and located at a first mutual distance in such a manner that they fit into the openings and channels on the infusion device **27** and **28** that are shown in FIG. 2. The height of these partially cylindrical attachment means is typically in an order of magnitude of 1 mm. The height of the rectangular plate elements is typically 3.5 mm, whereas the length of the latter is comprised within the range 5-6 mm.

[0034] FIG. 7 shows a further exemplary embodiment of a cover **101** and wherein the difference over those described in FIGS. 5 and 6 resides in the shape of the attachment means and also the geometrical shape of the upper plate part **103**. In this case the upper plate element **103** is shaped to be circular and, likewise, the flange is not provided with a recess **116**. The rectangular face elements are provided on the same location relative to the infusion device as in FIGS. 5-6, but they do not comprise the concave delimiting edge **112**, but constitute a true rectangular plate. Further attachment means are in this case located on the flange, the inner face **109** of the flange being provided with two blocks **117**,

whose upper and lower delimiting faces are essentially in parallel with the lower face **105** of the upper plate portion **103**. These blocks are able to engage either underneath the lower edge of the infusion device or in suitable recesses on the side faces of the infusion device as such.

[0035] FIG. 8 shows a third exemplary embodiment of a cover according to the invention and wherein the difference between this and the teachings of FIGS. 5-6 is firstly that the attachment means **106** have plate elements **11** that do not in this case either comprise a concave delimiting edge **112**. These attachment means are thus true rectangular plates. Furthermore the flange **108** comprises essentially two wall portions **118** that extend perpendicular from the flange and has the same material thickness as the flange as such. This edge, which more or less corresponds to the delimiting edge of the flange—in such a manner, however, that the wall is interrupted—wherein the circular recess **116** is provided, can like the one shown in FIG. 7, engage either in convenient recesses on the infusion device or underneath this lower face. Furthermore the geometrical shape of the upper plate element is not completely circular; recesses having been provided that enable the fingers to more easily seize around the cover.

[0036] FIG. 9 is essentially identical to the one shown in FIG. 8, but wherein the perpendicular **118** extending from the flange **108** is not provided.

[0037] Conveniently the cover is made in an injection moulding process and wherein suitable materials are M-ABS and PC-ABS.

[0038] FIG. 10 shows a cover essentially like the one shown in FIGS. 5-6 located on an infusion device corresponding to an infusion device as taught in FIGS. 1-4. Thus the cover is shown to cover any recesses and cut-outs present in the upper face of the infusion device, and wherein the flange **108** engages downwards around the rear side face of the infusion device and corresponding to the rearmost face of the cannula housing and with a circular recess **116** that ensures free access of the hose from the infusion device. When the infusion device is thus to be used, its recesses **7** and **8** are seized and wherein the fingers are pressed towards each other on each their side. By this process the cannula housing and the connection hub are separated from each other. Due to the shape of the cover and the engagement of the attachment means in relation to the infusion device, it remains in place on the cannula housing, while the connection hub is separated off. Subsequently the infusion device can be used as is also taught in eg U.S. Pat. No. 5,522,803.

[0039] The cover is not intended for use merely in connection with such infusion device, of course it may also lend itself to other geometries, wherein the essential aspect is thus

that the lower face of the cover has attachment means that engage with elements on the upper face of the infusion device, typically by male/female engagement functionality, wherein the male part is located on the lower face of the cover and wherein the female part are the recesses and other cut-outs that are typically present on the upper face of an infusion device. Whether the upper face of the infusion device is curved or concave, flat or triangular is of lesser relevance, the cover being essentially manufactured with a plate element which is congruent with the face and thus covers the same completely or partially.

1. A cover (**101**) for being located on an infusion device, said cover (**101**) comprising an upper plate element (**103**) with an upper face (**104**) and a lower face (**105**) oriented towards the upper face of the infusion device, characterised in that the lower face (**105**) of the plate element (**103**) comprises attachment means (**106**), said means cooperating with elements on the infusion device.

2. A cover according to claim 1, characterised in that the cover (**101**) further comprises a flange (**108**) that forms a first angle in relation to the upper plate (**103**) and is connected thereto.

3. A cover according to claim 2, characterised in that the face of the flange (**108**) facing towards the outer side faces of the infusion device is essentially congruent therewith.

4. A cover according to claims 2-3, characterised in that the expanse of the upper plate element (**101**) is smaller than the expanse of the upper face of the infusion device, and that the flange (**108**) extends partially around the side faces of the infusion device.

5. A cover according to any one of the preceding claims, characterised in that the attachment means (**106**) are male parts and that the elements on the infusion device are provided by recesses.

6. A cover according to any one of the preceding claims, characterised in that the attachment means (**106**) comprise at least two protruding partially cylindrical elements located (**110**) at a first mutual distance.

7. A cover according to any one of the preceding claims, characterised in that the attachment means (**106**) comprise at least two protruding plate elements (**111**) located at a second mutual distance.

8. A cover according to claim 7, characterised in that the protruding plate elements (**111**) are essentially rectangular plate-shaped and axis parallel with the centre axis of the infusion device.

9. A cover according to claim 7 or 8, characterised in that the protruding plate elements (**111**) comprise a concave delimiting edge (**112**) and concave side face (**113**).

* * * * *