(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 420 219 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
04.06.2014 Bulletin 2014/23

(21) Application number: **11250656.3**

(22) Date of filing: **12.07.2011**

(51) Int Cl.:
A61J 1/14 *(2006.01)* ***A61J 1/10*** *(2006.01)*
B65D 51/00 *(2006.01)*

(54) **An administration port**

Entnahmeport

Port d'administration

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **19.08.2010 GB 201013899**

(43) Date of publication of application:
22.02.2012 Bulletin 2012/08

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Description

[0001] This invention relates to an administration port for a medical fluid container, a port assembly including such an administration port, and a method of assembling an administration port.

[0002] Medical fluids, such as fluids used for intravenous (IV) therapy, are stored in medical fluid containers. One type of container is a flexible bag formed from multilayer plastic sheeting. The flexible bags often include a rigid port assembly which has a medication port and an administration port. The medication port allows the addition of medication to fluid within the bag, while the administration port allows removal of fluid from the bag, e.g. during IV therapy.

[0003] Each of the medication and administration ports includes a seal formation, typically integrally formed within the corresponding port, to isolate the port from the medical fluid until access is desired.

[0004] To remove fluid from the bag a medical operative inserts an IV spike into the administration port. The spike punctures the seal formation to allow fluid to flow from the bag via a fluid conduit within the spike.

[0005] Some administration ports additionally include a self-sealing membrane which can be penetrated by an IV spike to allow dispensing of fluid, but which seals the administration port on removal of the spike to inhibit unintentional dispensing or leaking of fluid from the bag.

[0006] An example of an existing administration port configured in this way is disclosed in WO2006/042579.

[0007] However, such administration ports require a user to apply an additional insertion force to an IV spike in order to penetrate the self-sealing membrane. In addition, insertion of the IV spike often damages the membrane, thereby degrading its self-sealing performance and leading to unintentional dispensing or leaking of fluid from the associated bag.

[0008] There is, therefore, a need for an improved administration port which allows a user to easily insert an IV spike and has a reduced tendency to leak following removal of the spike.

[0009] According to a first aspect of the invention there is provided an administration port, for a medical fluid container, comprising a hollow port body receiving an insert member having an engagement portion defined by a cavity and a sealing portion defined by a self-sealing membrane extending across one end of the cavity, the self-sealing membrane including a penetration zone and respective upstream and downstream faces, the administration port being characterised in that the upstream face includes first and second recess formations each of which extends around the penetration zone.

[0010] The provision of first and second recess formations in the upstream face of the self-sealing membrane reduces the volume of material in the corresponding region of the membrane. As a consequence less of the membrane has to be deformed to allow insertion of an IV spike, and so the insertion force a user must apply is reduced.

[0011] Reducing the required insertion force also reduces the risk of the penetration zone becoming torn or otherwise damaged, and so helps to maintain the sealing integrity of the self-sealing membrane.

[0012] Having each recess formation extend around the penetration zone separates each recess formation from the penetration zone, thereby maintaining the configuration of the penetration zone, and so further allowing the membrane to maintain its self-sealing functionality.

[0013] In addition, the provision of discrete engagement and sealing portions allows the insert member to separate the retention and sealing functions, and so accommodate dimensional and structural variations between one IV spike and another without adversely affecting the sealing performance of the sealing portion.

[0014] Optionally at least one recess formation defines an annular recess formation.

[0015] Such a configuration helps to ensure that the reduction in membrane material is evenly distributed with respect to the inserted IV spike, and so the reduction in IV spike insertion force is also similarly evenly distributed.

[0016] Preferably at least one annular recess formation is centred about the penetration zone. This allows the or each annular recess formation and the penetration zone to work together to facilitate IV spike insertion by helping to provide a uniformly reduced insertion force.

[0017] In a preferred embodiment of the invention the self-sealing membrane includes first and second concentric annular recess formations, the first concentric annular recess formation defining an inner recess formation and the second concentric annular recess formation defining an outer recess formation.

[0018] Such an arrangement provides a desired reduction in required IV spike insertion force while maintaining self-sealing integrity.

[0019] The outer recess formation may have a larger cross-sectional shape than the inner recess formation.

[0020] The provision of an outer recess formation having a larger cross-sectional shape than the inner recess formation allows the outer recess formation additionally to act as a hinge. This permits pivoting of membrane material lying inside of the outer recess formation in an upstream direction to further reduce the required IV spike insertion force, and so further facilitate ready IV spike insertion.

[0021] In a preferred embodiment of the invention the penetration zone includes at least one slit formed therein. The provision of one or more slits aids a user in alligning an IV spike with the penetration zone.

[0022] Optionally the cavity defines a cylindrical cavity having a wall extending substantially perpendicular to the self-sealing membrane.

[0023] The provision of a cylindrical cavity having a wall extending substantially perpendicular to the self-sealing membrane enables the whole of the cavity wall to engage with, and hence retain, the body of an IV spike, and so maximise the effectiveness of the engagement

portion.

[0024] In a preferred embodiment of the invention the sealing portion lies upstream of the engagement portion.

[0025] The provision of such an arrangement helps to isolate the medical fluid from the engagement portion and so reduces the likelihood of the medical fluid acting on the engagement portion to dislodge an IV spike.

[0026] Conveniently the internal cross-sectional profile of the hollow port body corresponds in shape to the external cross-sectional profile of at least one portion of the insert member.

[0027] This allows the insert member to mate with the port body to inhibit movement of the insert member relative to the port body while providing a fluid-tight seal between the port body and the insert member.

[0028] The corresponding external cross-sectional profile of the insert member may extend over the engagement portion and the sealing portion. Such an arrangement maximises the size of the mating region between the port body and the insert member, and so improves the effectiveness of the mating therebetween.

[0029] In another preferred embodiment of the invention the external profile of the insert member is larger than the internal profile of the port body. Having an insert member with a larger external profile than the internal profile of the port body generates an interference fit between these elements, and so provides the desired inhibition of relative movement and a fluid-tight seal without the need for extensive secondary processing.

[0030] Preferably the external surface of the insert member is or includes a heat-activated adhesive. The inclusion of a heat-activated adhesive allows for heat-activated mating of the insert member and the port body to prevent relative movement and provide a fluid-tight seal. Heat-activating the mating allows, e.g. for the ready insertion of the insert member into the port body during assembly of the administration port, and ready securing of the insert member within the port body once correctly positioned.

[0031] Optionally the insert member includes an external sheath of heat-activated adhesive. Such an arrangement provides the external surface of the insert member with an adhesive in a manner that is readily manufacturable in a controllable manner, e.g. by bi-injection moulding.

[0032] According to a second aspect of the invention there is provided a port assembly, for a medical fluid container, comprising a medication port to allow the addition of medication to the medical fluid, the port assembly being characterised by the inclusion of an administration port as described hereinabove. The port assembly shares the advantages of the various:features of the medication port mentioned above.

[0033] According to a third aspect of the invention there is provided a method of assembling an administration port for a medical fluid container, the administration port including a hollow port body, the method comprising the characterising step of:

inserting into the hollow port body an insert member having an engagement portion defined by a cavity and a sealing portion defined by a self-sealing membrane extending across one end of the cavity, the self-sealing membrane including a penetration zone and respective upstream and downstream faces, the upstream face including first and second recess formations each of which extends around the penetration zone.

Inserting such an insert member into the port body allows ready insertion of an IV spike into the administration port while maintaining self-sealing performance following removal of the IV spike.

[0034] Optionally the method of assembling an administration port further includes the steps of:

heat sealing a downstream end of the port body to hermetically seal the port body; and
heating the administration port to bond the insert member with the port body.

[0035] Heating the administration port to bond the insert member with the port body allows for the ready insertion of the insert member during assembly of the administration port, and ready securing of the insert member within the port body once correctly positioned, e.g. during steam sterilization of the administration port following assembly.

[0036] There now follows a brief description of preferred embodiments of the invention, by way of non-limiting examples, with reference to the accompanying figures in which:

Figure 1 shows a cross-sectional view of an administration port according to a first embodiment of the invention in a hermitically sealed configuration;
Figure 2 shows a cross-sectional view of the administration port shown in Figure 1 in a ready-for-use configuration with an intravenous spike partially inserted therein;
Figure 3 shows an isometric view from below of an insert member; and
Figure 4 shows a cross-sectional view of the insert member shown in Figure 3.

[0037] An administration port according to a first embodiment of the invention is designated generally by the reference numeral 10.

[0038] The administration port 10 shown in the figures is part of a rigid port assembly 12 that additionally includes a medication port 14 via which medication can be added to medical fluid held in a bag (not shown) in which the port assembly 12 is located.

[0039] The administration port 10 is integrally formed with the medication port 14 in a single, unitary port assembly 12. In other embodiments of the invention (not

shown) the administration port 10 may be separate from the medication port 14, or the port assembly 12 may omit a medication port 14.

[0040] The administration port 10 includes a hollow port body 16 that extends lengthwise between an upstream end 18 and a downstream end 20. The downstream end 20 is hermetically sealed by a cap 22 that is removable by rupturing a frangible connection 24 between the downstream end 20 and the cap 22.

[0041] The administration port 10 also includes a first integrally formed seal formation 26 to isolate the upstream end 18 of the port body 16 from the medical fluid until access is desired.

[0042] The medication port 14 includes a similar, second integrally formed seal formation 28.

[0043] The hollow port body 16 receives an insert member 30 that has an engagement portion 32 and a sealing portion 34.

[0044] The engagement portion 32 is defined by a cavity 36, and the sealing portion 34 is defined by a self-sealing membrane 38 that extends across one end 40 of the cavity 36.

[0045] In the embodiment shown the sealing portion 34 lies upstream of the engagement portion 32.

[0046] The self-sealing membrane 38 includes a penetration zone 41 and respective upstream and downstream faces 44, 46. The penetration zone 41 includes a slit 42 formed therein to assist a user in aligning an IV spike 60 with the penetration zone 41. In other embodiments of the invention (not shown) the penetration zone 41 omits a slit and the self-sealing membrane 38 is formed from a material which is sufficiently soft to allow direct insertion of an IV spike 60 there through. In still further embodiments of the invention (not shown) the membrane 38 may include a plurality of slits.

[0047] The upstream face 44 includes first and second concentric annular recess formations 48, 50, each of which is centred about the penetration zone 41 and associated slit 42. Other embodiments of the invention (not shown) may include one or more recess formations having a different shape and a different configuration relative to one another and to the penetration zone 41.

[0048] Any of the aforementioned recess formations may not extend completely around the penetration zone 41, or may be constituted from a series of discrete recess formation portions which together define the recess formation as a whole.

[0049] In the embodiment shown, the first concentric annular recess formation 48 defines an inner recess formation 52 while the second concentric annular recess formation 50 defines an outer recess formation 54.

[0050] The inner recess formation 52 has a symmetrical cross-sectional shape which helps to uniformly reduce the insertion force required to insert an IV spike through the membrane 38.

[0051] The outer recess formation 54 has a larger cross-sectional shape than the inner recess formation 52. Such an arrangement facilitates the hinge functionality of the outer recess formation 54.

[0052] In addition, the outer recess formation 54 has an asymmetrical cross-sectional shape, and in particular has a larger inboard volume. This helps to further facilitate the hinge functionality of the outer recess formation 54.

[0053] The cavity 36 defines a cylindrical cavity 56 which has a wall 58 that extends substantially perpendicular to the membrane 38. In the embodiment shown the diameter of the cylindrical cavity 36 is approximately 6.0mm. The depth d_c of the cavity 36 in the lengthwise direction L is approximately 2.5mm while the depth d_m of the self-sealing membrane 38 in the lengthwise direction L is approximately 3.0mm.

[0054] The internal cross-sectional profile of the port body 16 corresponds in shape to the external cross-sectional profile of the whole of the insert member 30, i.e. the insert member 30 has a uniform external cross-sectional profile, and a uniform cylindrical cross-sectional profile in particular.

[0055] In other embodiments of the invention (not shown) only one or other of the engagement portion 32 and the sealing portion 34 has an external cross-sectional profile that corresponds in shape to the internal cross-sectional profile of the port body 16.

[0056] The external profile of the insert member 30 is larger than the internal profile of the port body 16, and in particular the insert member 30 has an external diameter of approximately 8.5mm while the port body 16 has an internal diameter of approximately 8mm. In other embodiments of the invention (not shown) the extent to which the insert member 30 has a larger diameter than the internal diameter of the port body 16 may differ from the aforementioned ratio.

[0057] The insert member 30 may be formed from a thermo plastic elastomer (TPE) such as DRYFLEX ® which is available from Elasto AB, or THERMOLAST ® that is available from Kraiburg TPE GmbH. Such elastomers are sufficiently soft to allow direct penetration of an IV spike 60 through the self-sealing membrane 38.

[0058] The administration port 10 may be assembled by inserting the insert member 30 into the hollow port body 16 with the interference fit allowing an assembly operative to position the insert member 30 within the port body 16 as desired.

[0059] Once the downstream end 20 has been hermetically sealed the administration port 10 can be heated, e.g. during steam sterilization, to bond the insert member 30 within the port body 16.

[0060] In use, a medical operative removes, e.g. snaps off, the cap 22 from the administrative port 10 to allow access to the port body 16.

[0061] The operative then inserts an IV spike 60 into the port body 16 via the downstream end 20 thereof, as shown in Figure 2. The slit 42 in the self-sealing membrane 38 aids the operative in aligning the body 62 of the IV spike 60 with the penetration zone 41.

[0062] The inner recess formation 52 reduces the ex-

tent to which the membrane 38 must deform to accommodate the IV spike 60 and so reduces the insertion force required.

[0063] The outer recess formation 54 provides a further reduction in the required deformation of the membrane 38 to accommodate the IV spike 60.

[0064] The outer recess formation 54 also acts like a hinge to allow pivoting of the membrane material lying inside of the outer recess formation 54 into the port body 16.

[0065] Accordingly the outer recess formation 54 provides a further reduction in the insertion force required to insert the IV spike 60 into the administration port 10.

[0066] The reductions in required insertion force provided by the inner and outer recess formations 52, 54 reduces the risk of the slit 42 becoming torn or the membrane 38 becoming damaged.

[0067] Further insertion of the IV spike 60 into the port body 16 by the operative causes the spike 60 to rupture and penetrate the first seal formation 26 to allow medical fluid to leave the bag (not shown) via the spike 60.

[0068] The spike body 62 lies within the cylindrical cavity 56 of the engagement portion 32. The wall 58 of the cylindrical cavity 56 deforms to accommodate any dimensional or structural deviation of the spike body 62 while maintaining a gripping engagement with the spike body 62.

[0069] Accordingly the engagement portion 32 retains the spike body 62 and forms a fluid-tight seal between the port body 16 and the spike body 62.

[0070] To remove the IV spike 60 from the administration port 10 the operative overcomes the gripping engagement provided by the engagement portion 32 to withdraw the spike body 62 from within the insert member 30. As the spike body 62 is withdrawn from the insert member 30 the self-sealing membrane 38 adopts its original, pre-penetration, configuration (as shown in Figure 2) to create a fluid-tight seal within the port body 16 and so inhibit leaking or further discharge of fluid from the bag.

[0071] The insert member 30 may include an external sheath (not shown) of heat-activated adhesive. For example, a modified insert member may be formed from a TPE such as thermoplastic silicone vulcanizate (TPSiV) while the external sheath may be formed from a hot melt adhesive such as ethylene vinyl acetate (EVA). Such an insert member and the external sheath may be formed by bi-injection molding these two constituent materials.

[0072] An administration port 10 including the modified insert member may be assembled in the same manner as set out above in connection with the insert member 30. Heating the administration port 10 activates the adhesive to bond the modified insert member within the port body 16.

[0073] Such an administration port 10 also functions in the same manner as described above in connection with the first insert member 30.

Claims

1. An administration port (10), for a medical fluid container, comprising a hollow port body (16) receiving an insert member (30) having an engagement portion (32) defined by a cavity (36) and a sealing portion (34) defined by a self-sealing membrane (38) extending across one end of the cavity (36), the self-sealing membrane (38) including a penetration zone (41) and respective upstream and downstream faces (44, 46), the administration port (10) being **characterised in that** the upstream face (44) includes first and second recess formations (48, 50), each of which extends around the penetration zone (41).

2. An administration port (10) according to Claim 1 wherein at least one recess formation (48, 50) defines an annular recess formation (48, 50).

3. An administration port (10) according to Claim 1 or Claim 2 wherein at least one annular recess formation (48, 50) is centred about the penetration zone (41).

4. An administration port (10) according to any preceding claim including a self-sealing membrane (38) having first and second concentric annular recess formations (48, 50), the first concentric annular recess formation (48) defining an inner recess formation (52) and the second concentric annular recess formation (50) defining an outer recess formation (54).

5. An administration port (10) according to Claim 4 wherein the outer recess formation (54) has a larger cross-sectional shape than the inner recess formation (52).

6. An administration port (10) according to any preceding claim wherein the penetration zone (41) includes at least one slit (42) formed therein.

7. An administration port (10) according to any preceding claim wherein the cavity (36) defines a cylindrical cavity (56) having a wall (58) extending substantially perpendicular to the self-sealing membrane (38).

8. An administration port (10) according to any preceding claim wherein the sealing portion (34) lies upstream of the engagement portion (32).

9. An administration port (10) according to any preceding claim wherein the internal cross-sectional profile of the hollow port body (16) corresponds in shape to the external cross-sectional profile of at least one portion of the insert member (30).

10. An administration port (10) according to Claim 9

wherein the corresponding external cross-sectional profile of the insert member (30) extends over the engagement portion (32) and the sealing portion (34).

11. An administration port (10) according to Claim 9 or Claim 10 wherein the external profile of the insert member (30) is larger than the internal profile of the port body (16).

12. An administration port (10) according to Claim 9 or Claim 10 wherein the external surface of the insert member (30) is or includes a heat-activated adhesive.

13. An administration port (10) according to Claim 12 wherein the insert member (30) includes an external sheath of heat-activated adhesive.

14. A port assembly (12), for a medical fluid container, comprising a medication port (14) to allow the addition of medication to the medical fluid, the port assembly being **characterised by** the inclusion of an administration port (10) according to any of Claims 1 to 13.

15. A method of assembling an administration port (10) for a medical fluid container, the administration port (10) including a hollow port body (16), the method comprising the characterising step of:

inserting into the hollow port body (16) an insert member (30) having an engagement portion (32) defined by a cavity (36) and a sealing portion (34) defined by a self-sealing membrane (38) extending across one end of the cavity (36), the self-sealing membrane (38) including a penetration zone (41) and respective upstream and downstream faces (44, 46), the upstream face (44) including first and second recess formations (48, 50), each of which extends around the penetration zone (41).

16. A method of assembling an administration port (10) according to Claim 15 further including the steps of:

heat sealing a downstream end of the port body (16) to hermetically seal the port body (16); and heating the administration port (10) to bond the insert member (30) with the port body (16).

Patentansprüche

1. Verabreichungsport (10) für einen Behälter mit medizinischer Flüssigkeit, umfassend einen hohlen Portkörper (16), der ein Einsatzglied (30) aufnimmt bzw. empfängt, das einen Eingriffsabschnitt (32), der durch einen Hohlraum (36) definiert ist, und einen Dichtungsabschnitt (34) aufweist, der durch eine selbstdichtende Membran (38) definiert ist, die sich über ein Ende des Hohlraums (36) erstreckt, wobei die selbstdichtende Membran (38) eine Penetrationszone (41) und jeweilige stromaufwärtige und stromabwärtige Flächen (44, 46) enthält, wobei der Verabreichungsport (10) **dadurch gekennzeichnet, dass** die stromaufwärtige Fläche (44) erste und zweite Aussparungs- bzw. Vertiefungsformationen (48, 50) enthält, von denen sich jede um die Penetrationszone (41) herum erstreckt.

2. Verabreichungsport (10) nach Anspruch 1, wobei zumindest eine Aussparungsformation (48, 50) eine ringförmige Aussparungsformation (48, 50) definiert.

3. Verabreichungsport (10) nach Anspruch 1 oder Anspruch 2, wobei zumindest eine ringförmige Aussparungsformation (48, 50) um die Penetrationszone (41) herum zentriert ist.

4. Verabreichungsport (10) nach einem der vorhergehenden Ansprüche, enthaltend eine selbstdichtende Membran (38), die erste und zweite konzentrische ringförmige Aussparungs- bzw. Vertiefungsformationen (48, 50) aufweist, wobei die erste konzentrische ringförmige Aussparungsformation (48) eine innere Aussparungs- bzw. Vertiefungsformation (52) definiert und die zweite konzentrische ringförmige Aussparungsformation (50) eine äußere Aussparungs- bzw. Vertiefungsformation (54) definiert.

5. Verabreichungsport (10) nach Anspruch 4, wobei die äußere Aussparungsformation (54) eine größere Querschnittsform als die innere Aussparungsformation (52) aufweist.

6. Verabreichungsport (10) nach einem der vorhergehenden Ansprüche, wobei die Penetrationszone (41) zumindest einen Schlitz (42) enthält, der in dieser gebildet ist.

7. Verabreichungsport (10) nach einem der vorhergehenden Ansprüche, wobei der Hohlraum (36) einen zylindrischen Hohlraum (56) mit einer Wand (58) definiert, die sich im Wesentlichen senkrecht zu der selbstdichtenden Membran (38) erstreckt.

8. Verabreichungsport (10) nach einem der vorhergehenden Ansprüche, wobei der Dichtungsabschnitt (34) stromaufwärts des Eingriffsabschnitts (32) liegt.

9. Verabreichungsport (10) nach einem der vorhergehenden Ansprüche, wobei das Innenquerschnittsprofil des hohlen Portkörpers (16) in seiner Form dem Außenquerschnittsprofil zumindest eines Ab-

schnitts des Einsatzglieds (30) entspricht.

10. Verabreichungsport (10) nach Anspruch 9, wobei sich das entsprechende Außenquerschnittsprofil des Einsatzglieds (30) über den Eingriffsabschnitt (32) und den Dichtungsabschnitt (34) erstreckt.

11. Verabreichungsport (10) nach Anspruch 9 oder Anspruch 10, wobei das Außenprofil des Einsatzglieds (30) größer ist als das Innenprofil des Portkörpers (16).

12. Verabreichungsport (10) nach Anspruch 9 oder Anspruch 10, wobei die Außenfläche bzw. -oberfläche des Einsatzglieds (30) ein wärmeaktivierbarer Klebstoff ist oder diesen enthält.

13. Verabreichungsport (10) nach Anspruch 12, wobei das Einsatzglied (30) einen Außenmantel bzw. -hülle aus wärmeaktivierbarem Klebstoff enthält.

14. Portanordnung (12) für einen Behälter mit medizinischer Flüssigkeit, umfassend einen Medikationsport (14), der die Zugabe von Medikament zu der medizinischen Flüssigkeit erlaubt, wobei die Portanordnung durch das Enthalten eines Verabreichungsports (10) nach einem der Ansprüche 1 bis 13 gekennzeichnet ist.

15. Verfahren zum Montieren bzw. Zusammenbauen eines Verabreichungsports (10) für einen Behälter mit medizinischer Flüssigkeit, wobei der Verabreichungsport (10) einen hohlen Portkörper (16) enthält, wobei das Verfahren den kennzeichnenden Schritt umfasst:

> Einsetzen, in den hohlen Portkörper (16), eines Einsatzglieds (30), das einen Eingriffsabschnitt (32), der durch einen Hohlraum (36) definiert ist, und einen Dichtungsabschnitt (34) aufweist, der durch eine selbstdichtende Membran (38) definiert ist, die sich über ein Ende des Hohlraums (36) erstreckt, wobei die selbstdichtende Membran (38) eine Penetrationszone (41) und jeweilige stromaufwärtige und stromabwärtige Flächen (44, 46) enthält, wobei die stromaufwärtige Fläche (44) erste und zweite Aussparungs- bzw. Vertiefungsformationen (48, 50) enthält, von denen sich jede um die Penetrationszone (41) herum erstreckt.

16. Verfahren zum Montieren eines Verabreichungsports (10) nach Anspruch 15, ferner enthaltend die Schritte:

> Heißsiegeln eines stromabwärtigen Endes des Portkörpers (16), um den Portkörper (16) hermetisch abzudichten; und
>
> Erwärmen des Verabreichungsports (10), um das Einsatzglied (30) mit dem Portkörper (16) zu verbinden.

Revendications

1. Orifice d'administration (10) pour un conteneur de fluide médical, comprenant un corps d'orifice creux (16) recevant un élément formant insert (30) comportant une partie de couplage (32) définie par une cavité (36) et une partie d'étanchéité (34) définie par une membrane auto-étanche (38) s'étendant à travers une première extrémité de la cavité (36), la membrane auto-étanche (38) comportant une zone de pénétration (41) et les faces amont et aval (44, 46) respectives, l'orifice d'administration (10) étant **caractérisé en ce que** la face amont (44) comporte des première et deuxième empreintes creuses (48, 50), chacune d'elles s'étend autour de la zone de pénétration (41).

2. Orifice d'administration (10) selon la revendication 1, dans lequel au moins une empreinte creuse (48, 50) définit une empreinte creuse annulaire (48, 50).

3. Orifice d'administration (10) selon la revendication 1 ou 2, dans lequel au moins une empreinte creuse annulaire (48, 50) est centrée autour de la zone de pénétration (41).

4. Orifice d'administration (10) selon l'une quelconque des revendications précédentes, comprenant une membrane auto-étanche (38) comportant des première et deuxième empreintes creuses annulaires concentriques (48, 50), la première empreinte creuse annulaire concentrique (48) définissant une empreinte creuse interne (52) et la deuxième empreinte creuse annulaire concentrique (50) définissant une empreinte creuse externe (54).

5. Orifice d'administration (10) selon la revendication 4, dans lequel l'empreinte creuse externe (54) présente une forme en section transversale plus grande que celle de l'empreinte creuse interne (52).

6. Orifice d'administration (10) selon l'une quelconque des revendications précédentes, dans lequel au moins une fente (42) est formée à l'intérieur de la zone de pénétration (41).

7. Orifice d'administration (10) selon l'une quelconque des revendications précédentes, dans lequel la cavité (36) définit une cavité cylindrique (56) comportant une paroi (58) s'étendant sensiblement perpendiculairement à la membrane auto-étanche (38).

8. Orifice d'administration (10) selon l'une quelconque

des revendications précédentes, dans lequel la partie d'étanchéité (34) se trouve en amont de la partie de couplage (32).

9. Orifice d'administration (10) selon l'une quelconque des revendications précédentes, dans lequel le profil de section transversale interne du corps d'orifice creux (16) correspond dans sa forme au profil de section transversale externe d'au moins une partie de l'élément formant insert (30).

10. Orifice d'administration (10) selon la revendication 9, dans lequel le profil de section transversale externe correspondant de l'élément formant insert (30) s'étend sur la partie de couplage (32) et la partie d'étanchéité (34).

11. Orifice d'administration (10) selon la revendication 9 ou 10, dans lequel le profil externe de l'élément formant insert (30) est plus grand que le profil interne du corps d'orifice (16).

12. Orifice d'administration (10) selon la revendication 9 ou 10, dans lequel la surface externe de l'élément formant insert (30) est ou comporte un adhésif activé à chaud.

13. Orifice d'administration (10) selon la revendication 12, dans lequel l'élément formant insert (30) comporte une gaine externe d'adhésif activé à chaud.

14. Ensemble d'orifice (12), pour un conteneur de fluide médical, comprenant un orifice de médicament (14) destiné à permettre l'ajout de médicament au fluide médical, l'ensemble d'orifice étant **caractérisé par** l'introduction d'un orifice d'administration (10) selon l'une quelconque des revendications 1 à 13.

15. Procédé d'assemblage d'un orifice d'administration (10) pour un conteneur de fluide médical, l'orifice d'administration (10) comportant un corps d'orifice creux (16), le procédé comprenant l'étape caractérisante de :

insertion, dans le corps d'orifice creux (16), d'un élément formant insert (30) comportant une partie de couplage (32) définie par une cavité (36) et une partie d'étanchéité (34) définie par une membrane auto-étanche (38) s'étendant à travers une première extrémité de la cavité (36), la membrane auto-étanche (38) comportant une zone de pénétration (41) et des faces amont et aval (44, 46) respectives, la face amont (44) comportant des première et deuxième empreintes creuses (48, 50), chacune d'elles s'étend autour de la zone de pénétration (41).

16. Procédé d'assemblage d'un orifice d'administration (10) selon la revendication 15, comportant en outre les étapes de :

scellement à chaud d'une extrémité aval du corps d'orifice (16) afin de sceller hermétiquement le corps d'orifice (16) ; et
chauffage de l'orifice d'administration (10) afin de solidariser l'élément formant insert (30) avec le corps d'orifice (16).

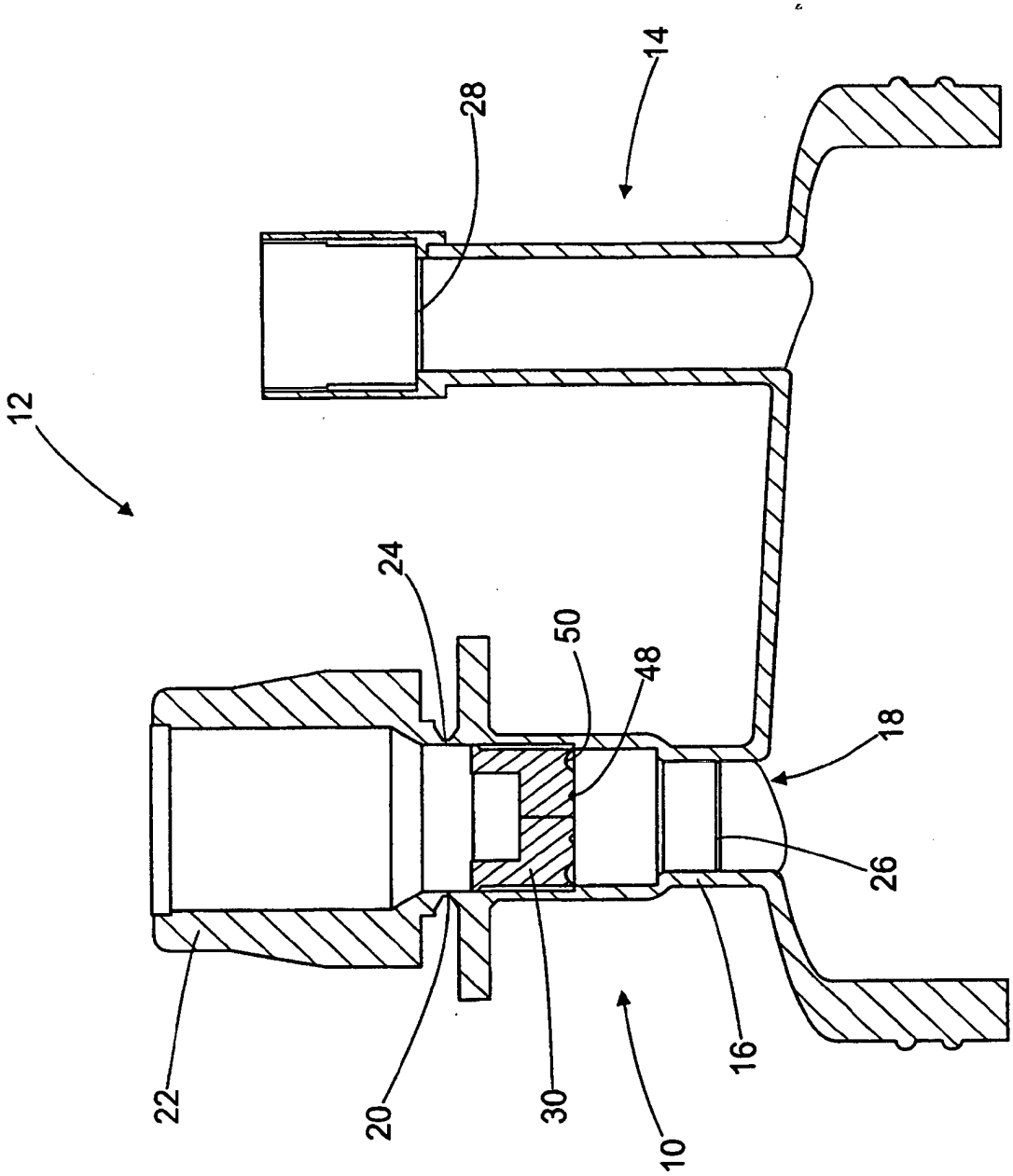

Fig. 1

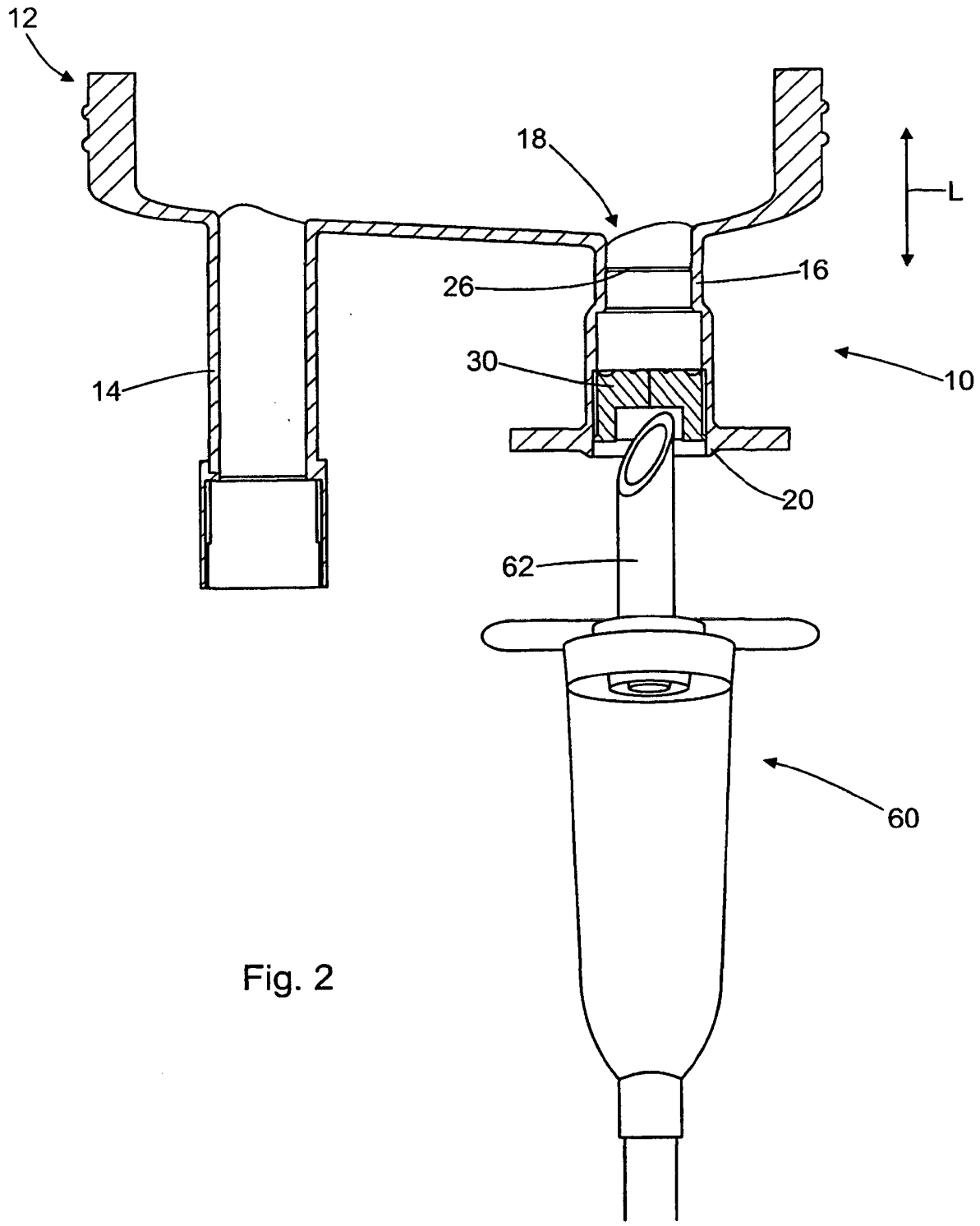

Fig. 2

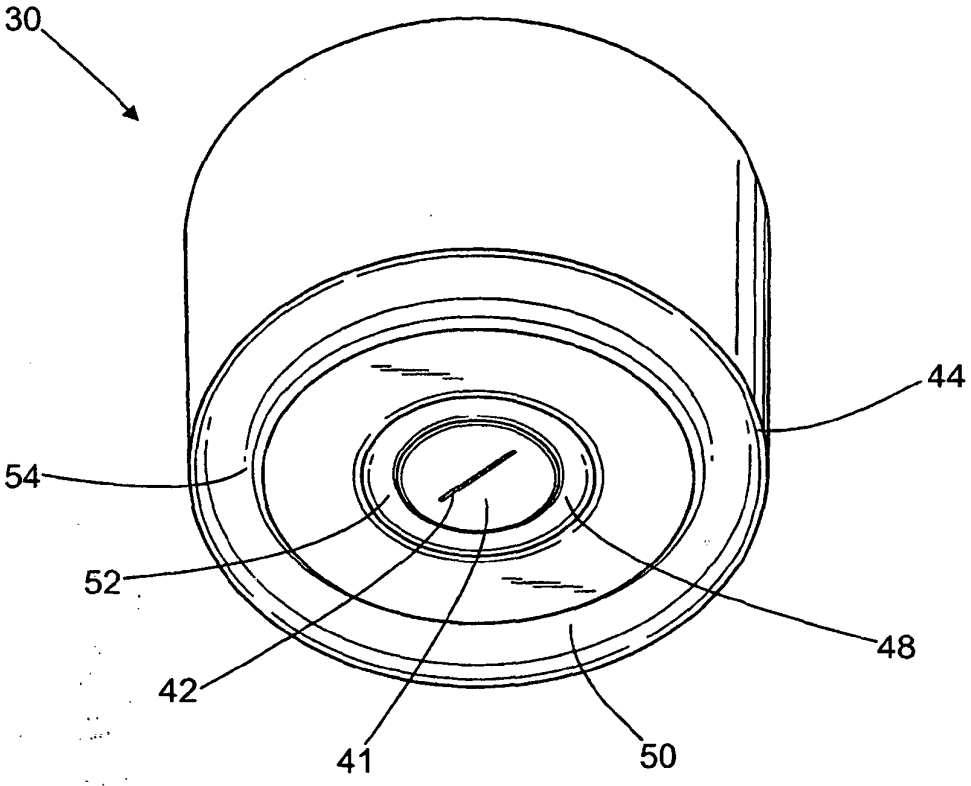
30
44
54
52
48
42
41
50

Fig. 3

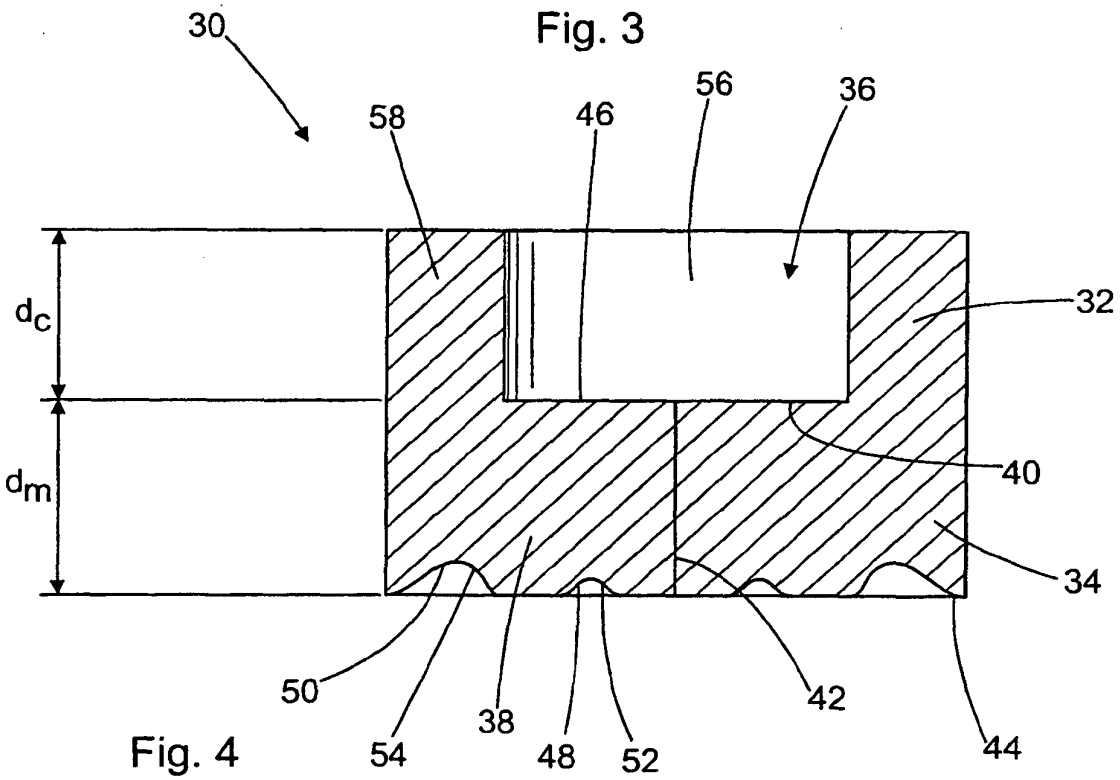
30
58
46
56
36
32
d_c
d_m
40
34
50
54
38
48
52
42
44

Fig. 4

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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