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(54) **Szerkezet gyógyászati felhasználású tartályok feltöltésére, amiknek van egy átlyukasztható záró membránja**

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(54) **DEVICE FOR THE FILLING OF CONTAINERS FOR MEDICAL USE HAVING A CLOSING MEMBRANE WHICH CAN BE PERFORATED**

VORRICHTUNG ZUM FÜLLEN VON BEHÄLTERN ZUR MEDIZINISCHEN VERWENDUNG MIT EINER PERFORIERBAREN VERSCHLUSSMEMBRAN

DISPOSITIF POUR LE REMPLISSAGE DE CONTENANTS DESTINÉS À UN USAGE MÉDICAL DOTÉS D'UNE MEMBRANE DE FERMETURE POUVANT ÊTRE PERFORÉE

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(56) References cited:
EP-A1- 1 323 403
WO-A1-2004/041148
DE-U1-202009 011 019

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Description

Technical Field

[0001] The present invention relates to a device for the filling of containers for medical use having a closing membrane which can be perforated, particularly of the type suitable for containing a radioactive pharmaceutical product.

Background Art

[0002] It is known that pharmaceutical products of radioactive type or the like are characterized by a very fast deterioration time, i.e., they lose their therapeutic properties within a time period of a few hours.

[0003] For this reason, it is absolutely indispensable that these be "consumed" a few moments after their preparation.

[0004] It therefore follows that their preparation plays a role of crucial importance, because it must occur in a very short space of time and in conditions such as to prevent any type of contamination of the pharmaceutical product.

[0005] For this reason, to date two known methods exist for the preparation of this type of pharmaceutical products, i.e., for the preparation of the relative single-dose containers.

[0006] The first type envisages setting up a sterile environment using adequate appliances which, conversely, are very costly and therefore require high investment costs.

[0007] The second type, which forms the subject of the present invention, instead concerns the use of consumable devices which are suitable for defining a closed circuit inside which the pharmaceutical product is introduced.

[0008] More in particular, these known devices are applicable to a glass container (also known by the name of Vial) closed at the top by a membrane which can be perforated and comprise an element for feeding the pharmaceutical product, which is fitted to the container and which is in turn connected to a series of pipings suitable for conveying the pharmaceutical product, introduced inside them by means of a syringe, towards the glass container.

[0009] The above element for feeding comprises two needles, suitable for perforating the membrane for introducing the pharmaceutical product inside the container and for allowing the air to come out of same respectively.

[0010] To perforate the membrane, an operator applies a pressure on the bottom of the container, so as to perform a relative movement of the membrane itself with respect to the needles.

[0011] This type of known devices also has drawbacks however.

[0012] Such devices, in fact, are not at all practical to use because it is hard for the operator to apply the force required to perforate the membrane because the only available thrust surface is the bottom of the container, the upper portion being occupied by the needles. This problem is even more serious if we consider that the perforation of the membrane is generally activated maintaining the device itself inside a flexible pack, in order to protect its sterility.

[0013] Another drawback consists in the fact that they do not allow a correct perforation of the membrane, with the consequent risk of accidental leaks occurring of the pharmaceutical product from the container.

[0014] This is due to the fact that the needles are arranged tilted the one with respect to the other to permit positioning a Luer-lock type connection for connecting to the above-mentioned pipings and an air filter, which have transversal overall dimensions considerably larger than those of the needles themselves. This implies the fact that the direction of approach of the needles to the membrane does not correspond to their longitudinal extension, and the holes thus obtained therefore have an oval conformation and do not therefore ensure a correct seal. Yet another drawback of these devices of known type consists in the risk that the connections of the needles to the pharmaceutical product conveyance pipes accidentally become detached, thus resulting in the undesired loss of the pharmaceutical product itself, as well as possible contamination of the medical staff.

[0015] Other devices of known type for filling containers for medical use are known from DE202009011019, EP1323403 and WO2004041148.

Description of the Invention

[0016] The main object of the present invention is to provide a device for the filling of containers for medical use having a closing membrane that is much easier to use compared to devices of known type and which, at the same time, are easy and practical to remove from the relative container.

[0017] In particular, the present invention proposes to provide a device that can be operated by an operator in a simple way without any particular effort including inside the relative flexible pack used for maintaining its sterility.

[0018] Another object of the present invention is to perforate the membrane of the relative container in such a way as to prevent undesired leaks of the pharmaceutical product contained inside it from occurring.

[0019] Yet another object of the present invention is to considerably reduce the risk of the piping connections suitable for conveying the pharmaceutical product towards the device being accidentally removed.

[0020] Another object of the present invention is to provide a device for the filling of containers for medical use having a closing membrane which can be perforated, which allows to overcome the mentioned drawbacks of the state of the art within the ambit of a simple and effective to use as well as low cost solution. The above-expounded objects are achieved by the present device

for the filling of containers for medical use having a closing membrane which can be perforated, particularly of the type suitable for containing radioactive pharmaceutical products, according to the claim 1.

Brief Description of the Drawings

[0021] Other characteristics and advantages of the present invention will become more evident from the description of a preferred, but not sole, embodiment of a device for the filling of containers for medical use having a closing membrane which can be perforated, illustrated purely as an example but not limited to the annexed drawings in which:

Figure 1 is an exploded view of a device according to the invention in a first embodiment;
Figure 2 is a front axonometric view of the device of figure 1 with the second portion of the element for the feeding of the pharmaceutical product in idle position;
Figure 3 is a rear axonometric view of the device of figure 2;
Figure 4 is a longitudinal section view of the device of figure 2;
Figure 5 is a front axonometric view of the device of figure 1 with the second portion of the element for the feeding of the pharmaceutical product in work position;
Figure 6 is a rear axonometric view of the device of figure 5;
Figure 7 is a longitudinal section view of the device of figure 5;
Figure 8 is a top plan view of a kit according to the invention.

Embodiments of the Invention

[0022] With particular reference to such figures, globally indicated by reference number 1 is a device for the filling of containers C for medical use having a closing membrane M which can be perforated, particularly of the type suitable for containing radioactive pharmaceutical products.

[0023] The device 1 and the container C together define an apparatus 30 for preparing radioactive pharmaceutical products or the like.

[0024] The device 1 comprises an element for feeding 2 a pharmaceutical product which can be fitted to a container C and having at least a pair of needles 3, 4 suitable for perforating the membrane M of the container itself.

[0025] More in detail, the element for feeding 2 comprises a first needle 3 suitable for conveying the pharmaceutical product inside the container C and a second needle 4 suitable for allowing the air to come out of the container itself.

[0026] By the word "needle" used here is meant any element suitable for perforating the membrane M.

[0027] The element for feeding 2 comprises a first portion 5 associable with the container C and at least a second portion 6, supporting the needles 3, 4, associated mobile with the first portion 5.

[0028] Suitably, the first portion 5 is hollow on the inside and has a supporting wall 5a intended to rest against the upper edge of the container C and a side wall 5b which extends substantially perpendicular from the supporting wall 5a.

[0029] More in detail, in the embodiment shown in the illustrations, the supporting wall 5a has a plurality of projections which directly contact the upper edge of the container C.

[0030] The supporting wall 5a is crossed by a hole 15 suitable for allowing the needles 3 and 4 to pass through.

[0031] The second portion 6 is mobile between an idle position, wherein it is raised with respect to the first portion 5 and the needles 3, 4 are moved away from the membrane M, and a work position, wherein the second portion 6 is close up to the first portion 5 with respect to the idle position and wherein the needles 3 and 4 perforate the membrane M.

[0032] Preferably, the second portion 6 is associated mobile in translation with respect to the first portion 5 along a direction of sliding indicated in the illustrations by the arrow 7.

[0033] More in detail, the first and the second portions 5 and 6 have a relative reference axis and the direction of sliding 7 substantially coincides with such axis.

[0034] In the embodiment shown in the illustrations, the first and the second portions 5 and 6 have a substantially circular section, i.e., they have relative side walls, identified in the illustrations by the reference numbers 5b and 6a, whose sections transversal to the axis have at least a stretch extending along a circumference. In other words, the side walls 5b and 6a have at least a cylindrical portion.

[0035] In the embodiment shown in the illustrations, the second portion 6 is fitted sliding over the first portion 5. More in particular, the second portion 6 comprises a housing seat 22 into which is inserted at least a part of the side wall 5b of the first portion 5. Such housing seat 22 is of the through type, has a curvilinear profile and faces, as can be seen in the illustrations 2 and 3, the upper face of the second portion 6. The side wall 5b of the first portion 5 has a breaking 23 delimiting two areas having heights different the one from the other, where only the higher area is inserted inside the housing seat 22. Suitably, the first portion 5 comprises a swelling 5c arranged at the base of the side wall 5b and suitable for being fitted over the container C.

[0036] It will appear evident to a technician in the sector that the conformations described here of the first and of the second portions 5 and 6 and the relative coupling procedures are given by way of example and that these can be changed without affecting the overall operation of the device 1, without prejudice to the fact that the second portion 6 must be coupled mobile to the first portion 5.

[0037] The second portion 6 defines a thrust surface 8 accessible from outside, which is substantially opposite and parallel to the bottom of the container C and which is meant to be pressed by an operator to move the second portion itself from the idle position to the work position. More in particular, the thrust surface 8 is defined on the wall delimiting at the top the second portion 6 and is substantially arranged orthogonal to the direction of sliding 7.

[0038] Advantageously, the needles 3 and 4 associated with the second portion 6 are arranged substantially (excepting machining tolerances) parallel to one another. More in particular, the needles 3 and 4 are arranged substantially parallel to the direction of sliding 7 of the second portion 6, in such a way that the direction of perforation of the membrane M corresponds to the direction of longitudinal extension of the needles 3 and 4 and that the holes defined on same are substantially circular.

[0039] In the embodiment shown in the illustrations, the needles 3 and 4 have relative exit openings tilted with respect to their longitudinal extension and diverging the one from the other proceeding from the element for feeding 2 towards the container C. This in order to avoid that, following the perforation of the membrane M, the needles 3 and 4 move reciprocally closer to one another.

[0040] In an alternative embodiment, the exit openings of the needles 3 and 4 are substantially tilted in the same direction.

[0041] The second portion 6 therefore comprises a first and a second housing seat 9 and 10, of the first and the second needles 3 and 4 respectively, which are arranged parallel to one another and communicating with a first duct 11, for the flow of the pharmaceutical product, and with a second duct 12, suitable for conveying the air towards the outside, respectively.

[0042] The first duct 11 is therefore associated with a tubular element 13 suitable for conveying the pharmaceutical product towards the first needle 3 and the second duct 12 is associated with a filtering element 14 suitable for preventing impurities entering from the outside.

[0043] In particular, in the embodiment shown in the illustrations, the tubular element 13 is suitable for being fitted over the protuberance 24 defined on the upper part of the second portion 6 and crossed by the first duct 11. It cannot however be ruled out that in an alternative embodiment, the tubular element 13 be inserted inside the first duct 11, the latter defining a relative housing seat for the tubular element itself.

[0044] The second duct 12 in turn defines a housing seat for the filtering element 14, which is therefore at least partially contained inside the second portion 6. Suitably, the tubular element 13 and the filtering element 14 are associated integral with the first and second ducts 11 and 12 respectively, e.g., by interposing adhesive means such as adhesives or the like.

[0045] Preferably, the first and the second ducts 11 and 12 are arranged diverging the one from the other towards the outside, meaning they move away from each other. More in particular, in the embodiment shown in the illustrations, the first and the second ducts 11 and 12 are arranged substantially orthogonal the one to the other and face in the proximity of the thrust surface 8 and onto the side wall 6a of the second portion 6, respectively.

[0046] Suitably, the breaking 23 defined on the side wall 5b is substantially aligned with the second duct 12, in such a way that the side wall itself does not obstruct it when the second portion 6 is moved to the work position.

[0047] According to the invention, the device 1 comprises removable fastening means 17 of the first portion 5 to the container C.

[0048] The fastening means 17 comprise at least a fastening element 18 of the elastically yielding type, defined on the first portion 5 and shaped so as to cooperate with the container C to lock the position of the first portion 5 with respect to this. The fastening element 18 is mobile between a fastening configuration, wherein it cooperates with the container C to lock the position of the first portion 5, and a release configuration, wherein it is moved away from the container itself to release the first portion 5.

[0049] The fastening element 18 therefore comprises at least an inner abutment surface 25 suitable for cooperating with the edge of the container C to lock the position of the first portion 5 with respect to the container itself.

[0050] Preferably, the first portion 5 comprises a plurality of through cuts 27 delimiting a plurality of elastically yielding fastening elements 18. The first portion 5 therefore clips into the container C, automatically moving to the fastening configuration, and can be removed from the container itself by applying a force on the first portion 5 in the direction of moving away from the container C. According to the invention, the device 1 also comprises identification means for identifying the position of the second portion 6 with respect to the first portion and which are suitable for temporarily making the first portion 5 integral with the second portion 6 in the idle position and in the work position.

[0051] More in detail, such identification means comprise a pair of openings 20a, 20b, of which a first opening 20a and a second opening 20b defined on the first portion 5 and arranged at a distance from one another along the direction- of sliding 7, and at least a protrusion 21, defined on the second portion 6. Suitably, the wall that supports the protrusion 2 is elastically yielding and the protrusion itself clips into the first opening 20a when the second portion 6 is in the idle position and clips into the second opening 20b when the second portion 6 is in work position. The insertion of the protrusion 21 in the first or in the second opening 20a, 20b thus permits identifying the reaching of the idle position and of the work position respectively by the second portion 6. The insertion of the protrusion 21 in the first and in the second opening 20a and 20b also permits making the first and the second portions 5 and 6 integral the one with the other. It is easy for the technician in the field to appreciate that the openings 20a and 20b and the protrusion 21 can be inverted, i.e., that the former can be defined on the second portion 6 and the latter can be defined on the first portion 5. Ac-

cording to the invention, the second portion 6 also comprises an abutment element 26 suitable for being intercepted by the operator by means of grip means to apply a force on the first portion 5 in away movement from the container C, so as to separate the element for feeding 2 from the container C. The abutment element 26 defines an abutment surface 26a arranged facing a reference surface 28 defined by the first portion 5, where the abutment surface 26a is spaced away from the reference surface 28 with the second portion 6 in work position.

[0052] The abutment surface 26a and the reference surface 28 therefore define a housing area 29 placed in between them for inserting the aforementioned grip means.

[0053] More in particular, the abutment surface 26a extends transversally to the axis of the second portion 6.

[0054] In the embodiment in the illustrations, the abutment element 26 extends radially from the side wall 6a towards the outside.

[0055] The abutment surface 26a and the reference surface 28 are both arranged transversal to the direction of sliding 7.

[0056] In the embodiment shown in the illustrations, the abutment element 26 has a substantially annular shape and is defined in correspondence to the extremity of the second portion 6 turned towards the first portion 5.

[0057] The present invention also refers to a kit 50 for the preparation of medicinal products comprising at least an apparatus 30 according to what is described above, and therefore consisting of a device 1 associated with a container C, at least a syringe 51 containing the pharmaceutical product to be introduced into the container itself, valve means 52 suitable for hydraulically connecting the syringe 51 to the device 1 and at least a support pack 53. The valve means 52 also comprise the above-mentioned tubular element 13.

[0058] The pack 53 has at least a seat 54 for housing the device 1 and at least a tray 55 for containing at least the syringe 51. In the embodiment shown in the illustrations, the pack 53 comprises a plurality of seats 54.

[0059] The pack 53 is shaped in such a way that the second portion 6, in its idle position, protrudes from the relative seat 54 and that the thrust surface 8 is spaced away from the wall 55a delimiting the tray 55 and turned towards the seat 54. The purpose of this is to allow the operator to easily intervene on the thrust surface 8 and thus move the second portion 6 to the work position. Advantageously, the seat 54 has at least a pair of stop surfaces 56 facing one another and suitable for cooperating with relative counter stop surfaces defined by the device 1 and, more in particular, by the first portions 5.

[0060] Suitably, the kit 50 also comprises at least a flexible sealed bag (not shown in the illustrations), preferably two, containing the pack 53, the apparatus 30, the syringe 51 and the valve means 52.

[0061] The operation of the present invention is as follows.

[0062] As already said above, the apparatus 30 consisting of the assembly made up of the device 1 and the container C is initially associated with the pack 53 in turn fitted inside one or more flexible bags.

[0063] In this configuration, the first portion 5 is associated with the container C by means of the fastening means 17 and the second portion 6 is arranged in the idle position.

[0064] To be able to introduce the pharmaceutical product inside the container C, the membrane M must be perforated and, consequently, the second portion 6 must be moved from the idle position to the work position.

[0065] To do this, the operator intervenes on the apparatus 30 contacting the bottom of the container C and the thrust surface 8 and pressing the one towards the other in a direction of reciprocal approach. This causes the sliding of the second portion 6 with respect to the first portion 5 and, consequently, the perforation of the membrane M by the needles 3 and 4.

[0066] The reaching of the work position by the second portion 6 is identified by the clip in of the protrusion 21 inside the second opening 20b defined in the first portion 5.

[0067] With the second portion 6 in the work position the filling of the container C with the relative pharmaceutical product can therefore start.

[0068] More in detail, the pharmaceutical product is injected by means of the syringe 51 and reaches the first duct 11 passing through the valve means 52. The pharmaceutical product thus injected therefore enters the inside of the container C passing through the first needle 3.

[0069] At the same time, during the filling of the container C with the relative pharmaceutical product, the air initially contained in this comes out towards the outside passing in succession through the second needle 4, the second duct 12 and the filtering element 14.

[0070] Once the filling of the container C has been completed, the device 1 must be removed from same to allow using the pharmaceutical product.

[0071] To remove the device 1, the fastening elements 18 must be released from the container C, moving them from the fastening configuration to the release configuration.

[0072] The movement of the fastening elements 18 is perfonned, in the described embodiment, by applying a traction force in correspondence to the abutment element 26 defined on the second portion 6, in such a way as to release the relative abutment surfaces 25 from the edge of the container C. Such traction force is applied by inserting grip means in the housing area 29 placed in between the abutment surface 26a and the reference surface 28 and moving same in a direction opposite to the direction of sliding 7, so as to contact the abutment surface 26a.

[0073] The fastening elements 18 thus disengage from the container C, thereby permitting the removal of the device 1 from it.

[0074] It has in fact been ascertained how the described invention achieves the proposed objects and in

particular the fact is underlined that the device fonning the subject of the present invention provides ease of use and reliable operation. In particular, the device forming the subject of the present invention is easy to operate by an operator by effect of the reciprocal sliding of the first and of the second portions and, at the same time, is easy to remove thanks to the presence of the housing area which permits inserting the grip means.

[0075] Furthermore, the device according to the invention permits the perfect positioning of the needles suitable for perforating the membrane of the relative container and, therefore, permits considerably reducing the risk of subsequent leaks.

[0076] Not last, the device forming the subject of the present invention permits avoiding the use of removable connections to connect the pharmaceutical product conveyor pipings, consequently reducing the risk of leaks occurring due to the accidental detachment of same.

Claims

1. Device (1) for the filling of containers (C) for medical use having a closing membrane (M) which can be perforated, particularly of the type suitable for containing radioactive pharmaceutical products, comprising

   - an element for feeding (2) a pharmaceutical product which can be fitted to a container (C) and having at least a pair of needles (3, 4) suitable for perforating the membrane (M) of the container itself, of which a first needle (3) suitable for conveying the pharmaceutical product inside the container (C) and a second needle (4) suitable for allowing the air to come out of said container (C), where said element for feeding (2) comprises a first portion (5) connectable to said container (C) and at least a second portion (6), supporting said needles (3, 4) and associated mobile with said first portion (5) between an idle position, wherein it is raised with respect to said first portion (5) and said needles (3, 4) are moved away from said membrane (M), and a work position, wherein said second portion (6) is close up to said first portion (5) with respect to the idle position and wherein said needles (3, 4) perforate said membrane (M);
   - removable fastening means (17) of said first portion (5) to said container (C);

   characterized by the fact that it comprises identification means (20a, 20b, 21) for identifying the reaching of the idle position and of the work position respectively by said second portion (6) with respect to said first portion (5), said identification means being suitable for making said first portion (5) fixed with respect to said second portion (6) in a removable way and by the fact that said second portion (6) has at least an abutment element (26) defining an abutment surface (26a) arranged facing a reference surface (28) defined by said first portion (5), said abutment surface (26a) being spaced away from said reference surface (28) with said second portion (6) in work position to define a housing area (29) placed in between them for inserting the grip means suitable for removing said fastening means (17) to separate said element for feeding (2) from the container (C).

2. Device according to claim 1, **characterized by** the fact that said second portion (6) has a reference axis and that said abutment surface (26a) extends transversally to said reference axis.

3. Device according to claim 1 or 2, **characterized by** the fact that said second portion (6) has a side wall (6a) having a substantially cylindrical shape and that said abutment element (26) protrudes radially from said side wall (6a) towards the outside.

4. Device according to one or more of the preceding claims, **characterized by** the fact that said abutment element (26) has a substantially annular shape.

5. Device according to one or more of the preceding claims, **characterized by** the fact that said fastening means (17) comprise at least an elastically yielding fastening element (18), defined on said first portion (5) and shaped so as to cooperate with said container (C) to lock the position of the first portion itself with respect to said container (C).

6. Device according to one or more of the preceding claims, **characterized by** the fact that said second portion (6) is associated mobile in translation with respect to said first portion (5) along at least one direction of sliding (7).

7. Device according to one or more of the preceding claims, **characterized by** the fact that said second portion (6) defines at least a thrust surface (8) accessible from outside, which is arranged opposite to the bottom of said container (C) and transversal to said direction of sliding (7), said thrust surface (8) being suitable for being pressed by an operator to move said second portion (6) from said idle position to said work position.

8. Device according to one or more of the preceding claims, **characterized by** the fact that said needles (3, 4) are arranged parallel to one another.

9. Device according to one or more of the preceding claims, **characterized by** the fact that said direction of sliding (7) is substantially parallel to the longitudinal extension of said needles (3, 4).

10. Device according to one or more of the preceding claims, **characterized by** the fact that said needles (3, 4) have a relative exit opening tilted with respect to their longitudinal extension, said exit openings diverging the one from the other proceeding from said element for feeding (2) towards said container (C).

11. Device according to one or more of the claims from 1 to 9, **characterized by** the fact that said needles (3, 4) have a relative exit opening tilted with respect to their longitudinal extension, said exit openings being tilted substantially in the same direction.

12. Device according to one or more of the preceding claims, **characterized by** the fact that said second portion (6) comprises a first and a second housing seats (9, 10), of said first and second needles (3, 4) respectively, which are arranged parallel to one another and communicating with a first duct and a second duct (11, 12) respectively communicating with the outside.

13. Device according to claim 12, **characterized by** the fact that said first and second ducts (11, 12) are arranged diverging the one from the other towards the outside.

14. Device according to one or more of the preceding claims, **characterized by** the fact that it comprises at least a tubular element (13) associated integral with said first duct (11) and/or at least a filtering element (14) associated integral with said second duct (12).

15. Kit (50) for the preparation of medicinal products, **characterized by** the fact that it comprises at least a syringe (51) containing a pharmaceutical product to prepare, at least a device (1) according to one or more of the preceding claims associated in a removable way with a container (C) to fill, valve means (52) suitable for connecting said syringe (51) to said device (1), at least a pack (53) having at least a seat (54) for housing said container (C) and at least a tray (55) for containing at least said syringe (51), said second portion (6) protruding from said seat (54) in its idle position, in which said thrust surface (8) is spaced away from the wall (55a) delimiting said tray (55) and turned towards the seat itself.

Patentansprüche

1. Vorrichtung (1) für die Befüllung von Behältern (C) zum medizinischen Gebrauch, die eine Verschluss-Membran (M) aufweisen, welche perforiert werden kann, insbesondere von der Art, die zur Aufnahme von radioaktiven pharmazeutischen Produkten geeignet ist, umfassend:

- ein Element zum Zuführen (2) eines pharmazeutischen Produkts, welches an einen Behälter (C) angebracht werden kann und mindestens ein Paar von Nadeln (3, 4) aufweist, welche zur Perforation der Membran (M) des Behälters selbst geeignet sind, von denen eine erste Nadel (3) geeignet ist, um das pharmazeutische Produkt in den Behälter (C) zu befördern und eine zweite Nadel (4) geeignet ist, um die Luft aus dem Behälter (C) entweichen zu lassen, wobei das Element zum Zuführen (2) einen ersten Abschnitt (5) aufweist, der mit dem Behälter (C) verbunden werden kann, und mindestens einem zweiten Abschnitt (6), der die Nadeln (3, 4) trägt und beweglich mit dem ersten Abschnitt (5) verbunden ist, zwischen einer Ruheposition, in welcher der Abschnitt bezüglich des ersten Abschnitts (5) angehoben ist und die Nadeln (3, 4) von der Membran (M) weg bewegt sind, und einer Arbeitsposition, in welcher der zweite Abschnitt (6) gegenüber der Ruheposition nahe dem ersten Abschnitt (5) ist und wobei die Nadeln (3, 4) die Membran (M) perforieren;
- lösbare Mittel (17) zur Befestigung des ersten Abschnitts (5) an dem Behälter (C);

dadurch gekennzeichnet, dass sie Identifizierungsmittel (20a, 20b, 21) aufweist, zum Identifizieren des Erreichens der Ruheposition und der Arbeitsposition jeweils durch den zweiten Abschnitt (6) bezüglich des ersten Abschnittes (5), wobei die Identifizierungsmittel geeignet sind, um den ersten Abschnitt (5) bezüglich des zweiten Abschnitts (6) in lösbarer Art und Weise zu fixieren, und durch die Tatsache, dass der zweite Abschnitt (6) wenigstens ein Widerlagerelement (26) aufweist, welches eine Widerlagerfläche (26a) definiert, welche einer Referenzfläche (28) zugewandt ist, die durch den ersten Abschnitt (5) definiert wird, wobei die Widerlagerfläche (26a) in einem Abstand zu der Referenzfläche (28) angeordnet ist, wobei sich der zweite Abschnitt (6) in der Arbeitsposition befindet, um einen Gehäusebereich (29) zu definieren, der zwischen ihnen angeordnet ist, um das Greifmittel einzubringen, das zum Lösen der Mittel (17) zur Befestigung geeignet ist, um das Bauteil zum Zuführen (2) von dem Behälter (C) zu trennen.

2. Vorrichtung nach Anspruch 1, **gekennzeichnet durch** die Tatsache, dass der zweite Abschnitt (6) eine Referenzachse aufweist und sich die Widerlagerfläche (26a) transversal zu der Referenzachse erstreckt.

3. Vorrichtung nach Anspruch 1 oder 2, **gekennzeichnet durch** die Tatsache, dass der zweite Abschnitt (6) eine Seitenwand (6a) aufweist, welche eine im Wesentlichen zylindrische Form aufweist, und dass

das Widerlagerelement (26) radial von der Seitenwand (6a) nach außen hin hervorragt.

4. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass das Widerlagerelement (26) eine im Wesentlichen ringförmige Form aufweist.

5. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass die Mittel (17) zur Befestigung mindestens ein elastisch nachgebendes Befestigungselement (18) aufweisen, welches auf dem ersten Abschnitt (5) definiert ist und derart geformt ist, dass es mit dem Behälter (C) zusammenwirkt, so dass die Position des ersten Abschnitts selbst bezüglich des Behälters (C) arretiert wird.

6. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass der zweite Abschnitt (6) translatorisch beweglich bezüglich des ersten Abschnitts (5) entlang wenigstens einer Gleitrichtung (7) angeschlossen ist.

7. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass der zweite Abschnitt (6) wenigstens eine Schuboberfläche (8) aufweist, welche von außen zugänglich ist, die gegenüber dem Boden des Behälters (C) und transversal zur Gleitrichtung (7) angeordnet ist, wobei die Schuboberfläche (8) vom einem Anwender gedrückt werden kann, um den zweiten Abschnitt (6) von der Ruheposition in die Arbeitsposition zu bewegen.

8. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass die Nadeln (3, 4) parallel zueinander angeordnet sind.

9. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass die Gleitrichtung (7) im Wesentlichen parallel zu der longitudinalen Ausdehnung der Nadeln (3, 4) verläuft.

10. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass die Nadeln (3, 4) eine relativ zu ihrer longitudinalen Ausdehnung geneigte Ausgangsöffnung haben, wobei die Ausgangsöffnungen vom Element zum Zuführen(2) in Richtung des Behälters (C) verlaufend voneinander weg divergieren.

11. Vorrichtung nach einem oder mehreren der Ansprüche 1 bis 9, **gekennzeichnet durch** die Tatsache, dass die Nadeln (3, 4) jeweils eine bezüglich zu ihrer longitudinalen Ausdehnung geneigte Ausgangsöffnung haben, wobei die Ausgangsöffnungen im Wesentlichen in derselben Richtung geneigt sind.

12. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass der zweite Abschnitt (6) einen ersten und einen zweiten Gehäusesitz (9, 10) für jeweils eine der ersten und zweiten Nadeln (3, 4) aufweist, welche parallel zueinander angeordnet sind und mit einer ersten Leitung und einer zweiten Leitung (11, 12) verbunden sind, welche jeweils mit der Außenseite verbunden sind.

13. Vorrichtung nach Anspruch 12, **gekennzeichnet durch** die Tatsache, dass die ersten und zweiten Leitungen (11, 12) derart angeordnet sind, dass sie nach außen hin voneinander weg divergieren.

14. Vorrichtung nach einem oder mehreren der vorangegangenen Ansprüche, **gekennzeichnet durch** die Tatsache, dass sie wenigstens ein röhrenförmiges Element (13) aufweist, welches integral mit der ersten Leitung (11) verbunden ist und/oder wenigstens ein Filterelement (14), das integral mit der zweiten Leitung (12) verbunden ist.

15. Kit (50) zur Herstellung von medizinischen Produkten, **gekennzeichnet durch** die Tatsache, dass es wenigstens eine Spritze (51) umfasst, welche ein herzustellendes pharmazeutisches Produkt enthält, und wenigstens eine Vorrichtung (1) nach einem oder mehreren der vorangegangenen Ansprüche, welche lösbar mit dem zu füllenden Behälter (C) verbunden ist, ein Ventilmittel (52), das zur Verbindung der Spritze (51) mit der Vorrichtung (1) geeignet ist, wenigstens eine Packung (53), die wenigstens einen Sitz (54) für das Gehäuse des Behälters (C) aufweist, und wenigstens einen Einsatz (55) zur Aufnahme wenigstens der Spritze (51) umfasst, wobei der zweite Abschnitt (6) in seiner Ruheposition von dem Sitz(54) hervorragt, in welcher die Schuboberfläche (8) in einem Abstand von der Wand (55a) angeordnet ist, um den Einsatz (55) zu begrenzen, und er selbst zum Sitz hin gedreht ist.

Revendications

1. Dispositif (1) pour le remplissage de contenants (C) destinés à un usage médical dotés d'une membrane de fermeture (M) pouvant être perforée, notamment du type apte à contenir des produits pharmaceutiques radioactifs, comprenant :

   - un élément pour l'alimentation (2) d'un produit pharmaceutique qui peut être adapté sur un contenant (C) et possédant au moins une paire

d'aiguilles (3, 4) aptes à perforer la membrane (M) du contenant lui-même, dont une première aiguille (3) apte à acheminer le produit pharmaceutique vers l'intérieur du contenant (C) et une seconde aiguille (4) apte à permettre à l'air de sortir dudit contenant (C), dans lequel ledit élément pour l'alimentation (2) comprend une première portion (5) pouvant être adaptée sur ledit contenant (C) et au moins une seconde portion (6), supportant lesdites aiguilles (3, 4) et associée de façon mobile à ladite première portion (5) entre une position de repos, dans laquelle elle est surélevée par rapport à ladite première portion (5) et lesdites aiguilles (3, 4) sont éloignées de ladite membrane (M), et une position de travail, dans laquelle ladite seconde portion (6) est rapprochée de ladite première portion (5) par rapport à la position de repos et dans laquelle lesdites aiguilles (3, 4) perforent ladite membrane (M) ;
- des moyens de fixation amovibles (17) de ladite première portion (5) audit contenant (C) ;

caractérisé en ce qu'il comprend des moyens d'identification (20a, 20b, 21) pour identifier l'atteinte de la position de repos et de la position de travail respectivement par ladite seconde portion (6) par rapport à ladite première portion (5), lesdits moyens d'identification étant aptes à rendre ladite première portion (5) fixe par rapport à ladite seconde portion (6) de manière amovible et **en ce que** ladite seconde portion (6) possède au moins un élément de butée (26) définissant une surface de butée (26a) agencée en regard d'une surface de référence (28) définie par ladite première portion (5), ladite surface de butée (26a) étant espacée de ladite surface de référence (28) avec ladite seconde portion (6) dans la position de travail pour définir une zone de logement (29) placée entre elles pour l'insertion de moyens de saisie aptes à enlever lesdits moyens de fixation (17) pour séparer ledit élément pour l'alimentation (2) du conteneur (C).

2. Dispositif selon la revendication 1, **caractérisé en ce que** ladite seconde portion (6) a un axe de référence et **en ce que** ladite surface de butée (26a) s'étend transversalement audit axe de référence.

3. Dispositif selon la revendication 1 ou 2, **caractérisé en ce que** ladite seconde portion (6) a une paroi latérale (6a) ayant une forme sensiblement cylindrique et **en ce que** ledit élément de butée (26) fait saillie radialement depuis ladite paroi latérale (6a) vers l'extérieur.

4. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** ledit élément de butée (26) présente une forme sensiblement annulaire.

5. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** lesdits moyens de fixation (17) comprennent au moins un élément de fixation à fléchissement élastique (18), défini sur ladite première portion (5) et conformé de manière à coopérer avec ledit contenant (C) pour verrouiller la position de la première portion elle-même par rapport audit contenant (C).

6. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** ladite seconde portion (6) est associée mobile en translation par rapport à ladite première portion (5) selon au moins une direction de coulissement (7).

7. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** ladite seconde portion (6) définit au moins une surface de poussée (8) accessible de l'extérieur, qui est agencée à l'opposé du fond dudit contenant (C) et transversale à ladite direction de coulissement (7), ladite surface de poussée (8) étant apte à être pressée par un opérateur pour déplacer ladite seconde portion (6) de ladite position de repos à ladite position de travail.

8. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** lesdites aiguilles (3, 4) sont agencées l'une parallèle à l'autre.

9. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** ladite direction de coulissement (7) est sensiblement parallèle à l'extension longitudinale desdites aiguilles (3, 4).

10. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** lesdites aiguilles (3, 4) possèdent une ouverture de sortie relative inclinée par rapport à leur extension longitudinale, lesdites ouvertures de sortie divergeant l'une de l'autre en allant dudit élément pour l'alimentation (2) vers ledit contenant (C).

11. Dispositif selon l'une ou plusieurs des revendications de 1 à 9, **caractérisé en ce que** lesdites aiguilles (3, 4) possèdent une ouverture de sortie relative inclinée par rapport à leur extension longitudinale, lesdites ouvertures de sortie étant inclinées sensiblement dans la même direction.

12. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce que** ladite seconde portion (6) comprend un premier et un second sièges de logement (9, 10), desdites première et seconde aiguilles (3, 4) respectivement, qui sont agen-

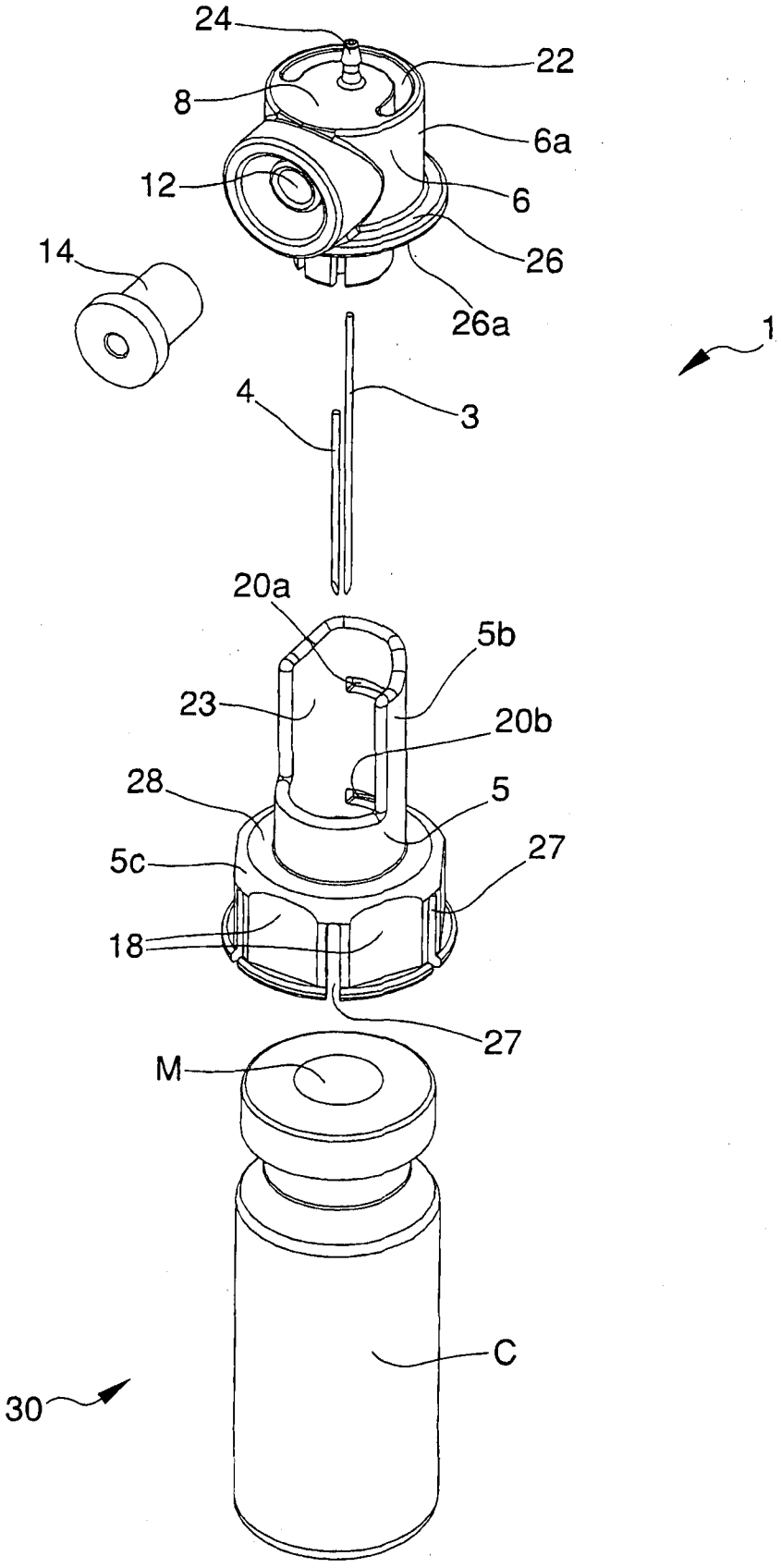
cés l'un parallèle à l'autre et en communication avec un premier conduit et un second conduit (11, 12) communiquant respectivement avec l'extérieur.

13. Dispositif selon la revendication 12, **caractérisé en ce que** lesdits premier et second conduits (11, 12) sont agencés divergeant l'un de l'autre vers l'extérieur.

14. Dispositif selon l'une ou plusieurs des revendications précédentes, **caractérisé en ce qu'**il comprend au moins un élément tubulaire (13) associé solidaire dudit premier conduit (11) et/ou au moins un élément filtrant (14) associé solidaire dudit second conduit (12).

15. Kit (50) pour la préparation de produits médicinaux, **caractérisé en ce qu'**il comprend au moins une seringue (51) contenant un produit pharmaceutique à préparer, au moins un dispositif (1) selon l'une ou plusieurs des revendications précédentes associé de manière amovible à un contenant (C) à remplir, des moyens de valve (52) aptes à relier ladite seringue (51) audit dispositif (1), au moins un étui (53) possédant au moins un siège (54) destiné à loger ledit contenant (C) et au moins un bac (55) destiné à contenir au moins ladite seringue (51), ladite seconde portion (6) faisant saillie dudit siège (54) dans sa position de repos, dans laquelle ladite surface de poussée (8) est maintenue éloignée de la paroi (55a) délimitant ledit bac (55) et orientée vers le siège lui-même.

Fig. 1



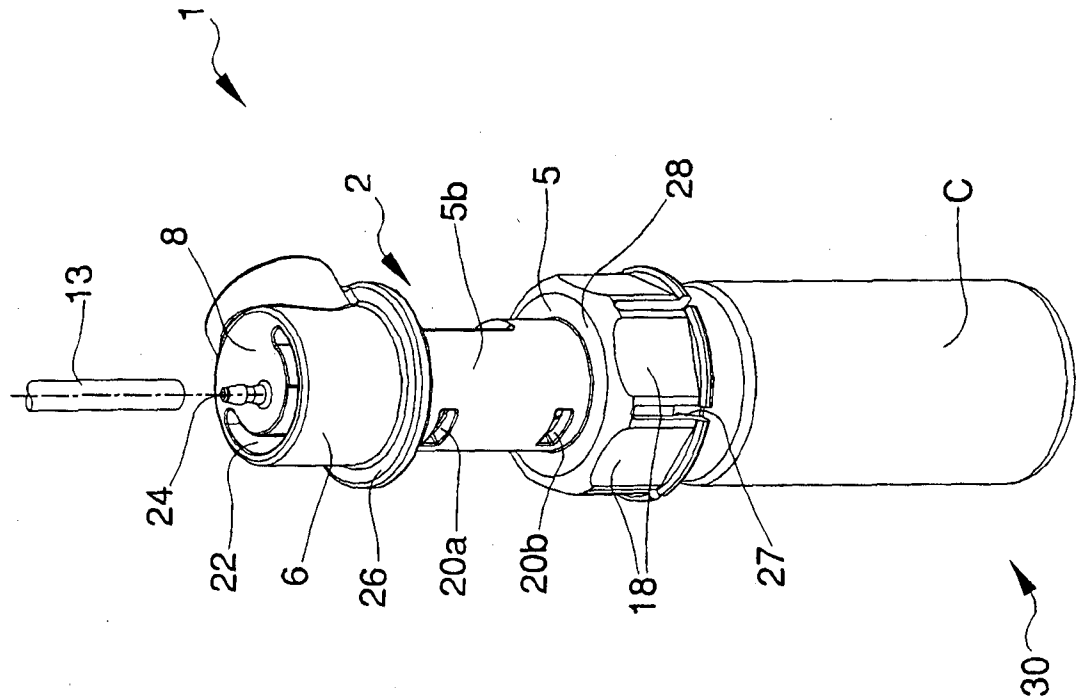

1
2
5b
5
28
C
8
13
24
22
6
26
20a
20b
18
27
30

Fig. 3

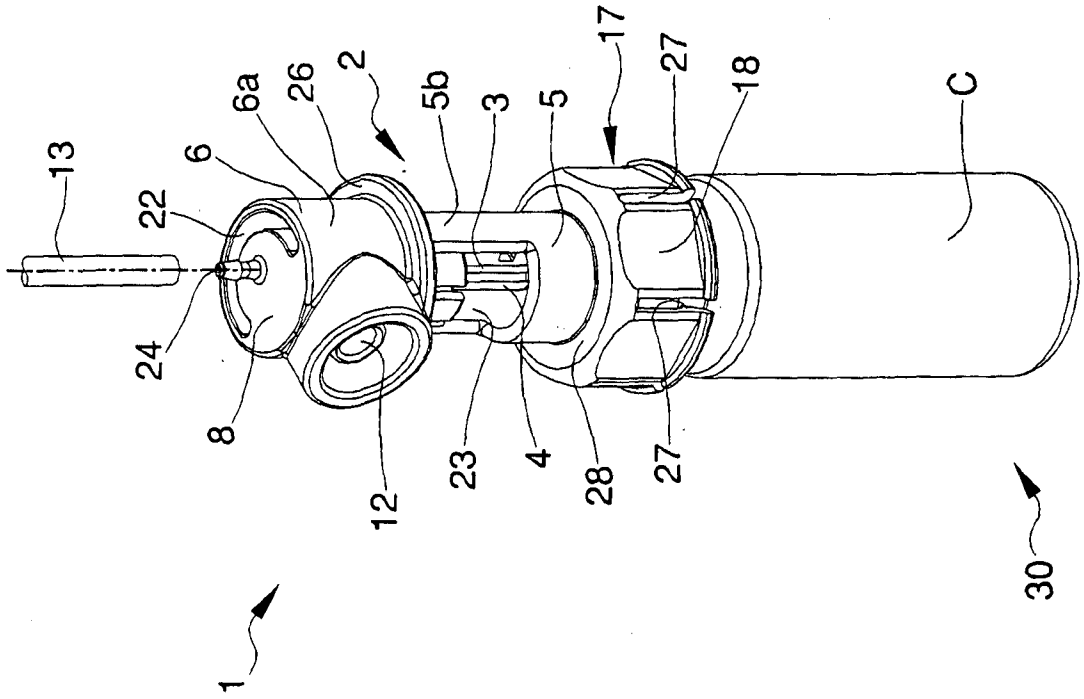

17
27
18
2
6a
26
5b
3
5
C
13
6
22
24
8
12
23
4
28
27
30
1

Fig. 2

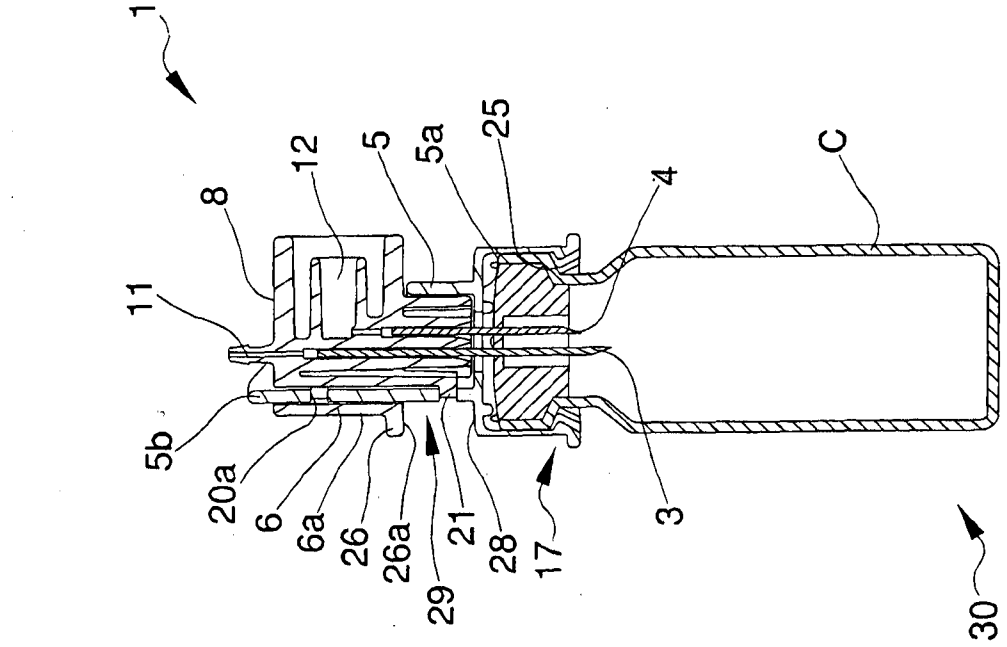

1
12
5
5a
25
8
4
C
11
5b
20a
6
6a
26
26a
29
21
28
17
3
30

Fig. 7

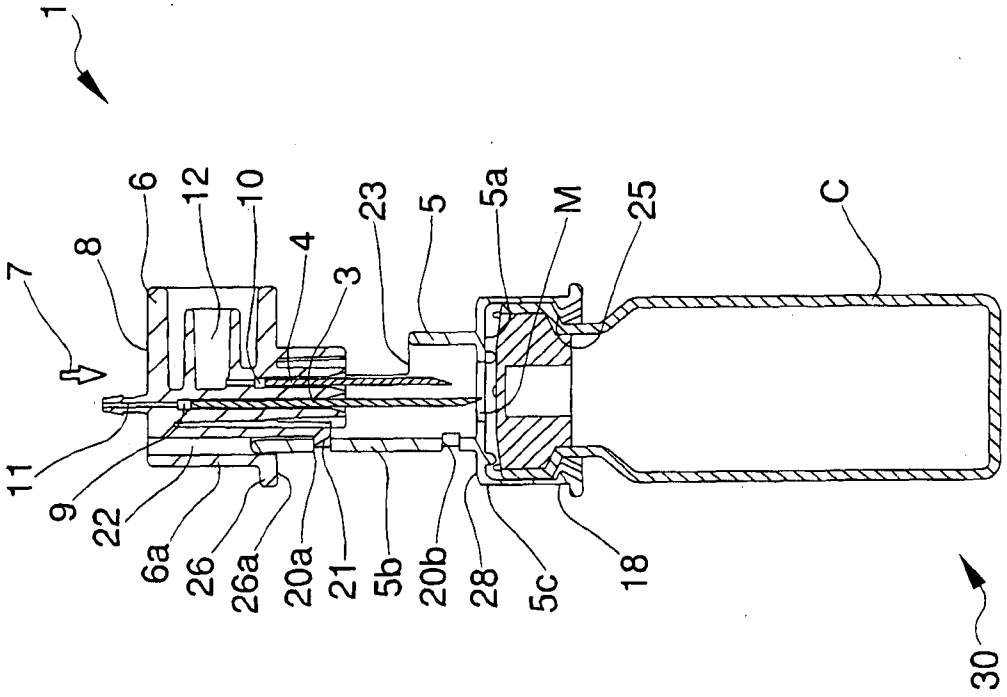

1
6
12
10
23
5
5a
M
25
C
7
8
4
3
11
9
22
6a
26
26a
20a
21
5b
20b
28
5c
18
30

Fig. 4

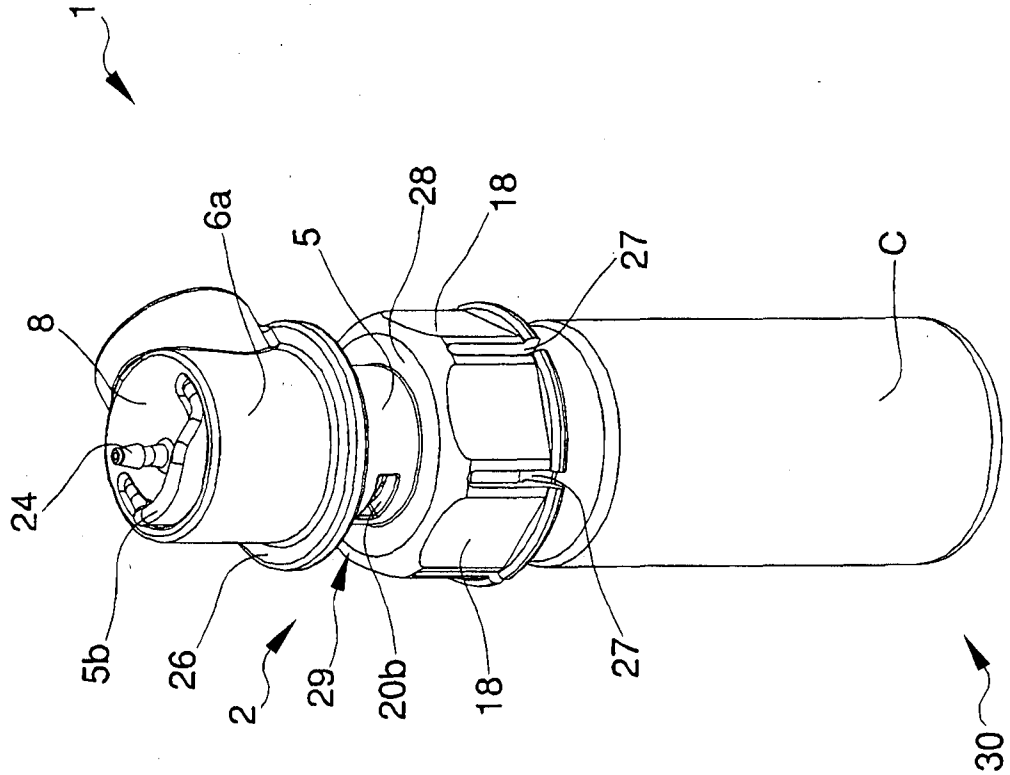

1
6a
5
28
18
27
C
8
24
5b
26
2
29
20b
18
27
30

Fig. 6

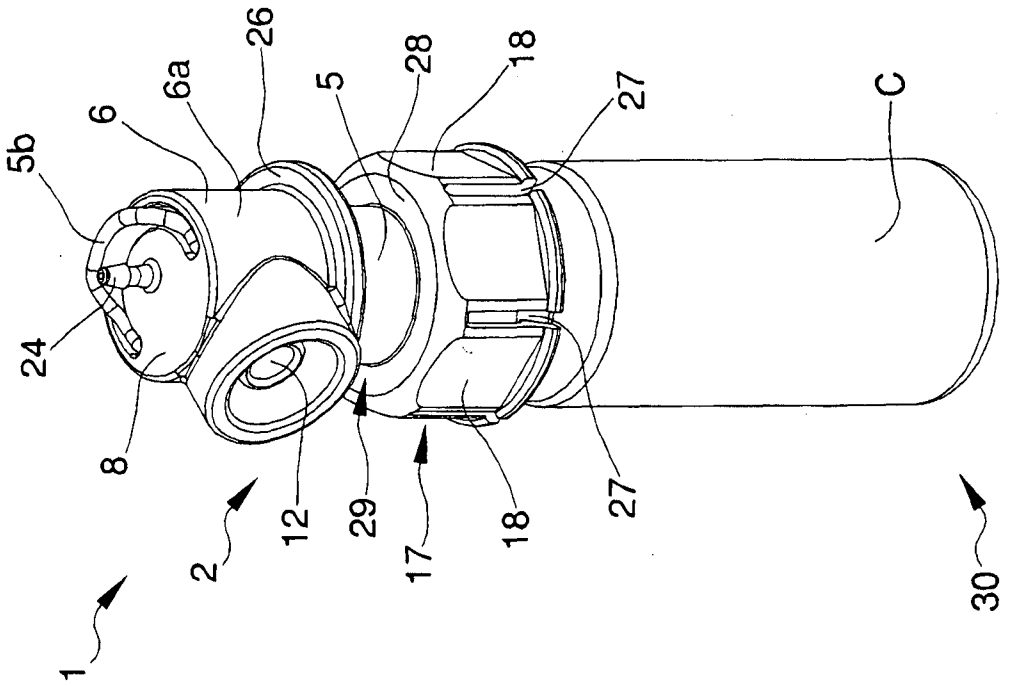

26
6a
6
5b
5
28
18
27
C
24
8
2
12
29
17
18
27
30
1

Fig. 5

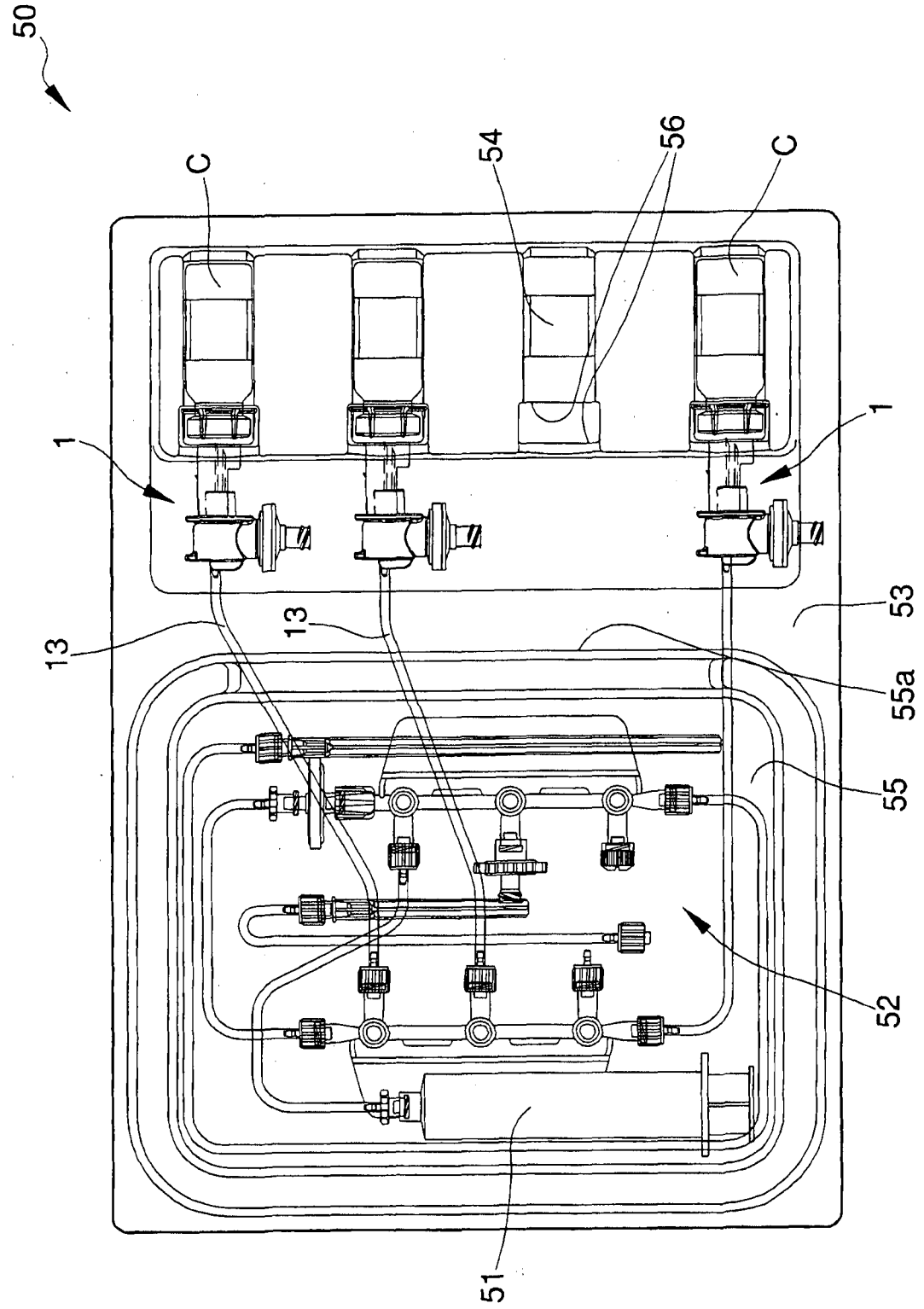


Fig. 8

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- DE 202009011019 **[0015]**
- EP 1323403 A **[0015]**
- WO 2004041148 A **[0015]**

SZERKEZET GYÓGYÁSZATI FELHASZNÁLÁSÚ TARTÁLYOK FELTÖLTÉSÉRE, AMIKNEK VAN EGY ÁTLYUKASZTHATÓ ZÁRÓ MEMBRÁNJA

SZABADALMI IGÉNYPONTOK

1. Szerkezet (1) gyógyászati felhasználású tartályok (C) feltöltésére, amiknek van egy átlyukasztható záró membránja (M), és amik különösen alkalmasak radioaktív gyógyászati termékek tárolására, és amik tartalmaznak

   - egy elemet a gyógyászati termék betöltésére (2), ami illeszkedik a tartályhoz (C), és ami el van látva legalább egy pár, a tartály membránjának (M) átlyukasztására alkalmas tűvel (3, 4), ahol az első tű (3) alkalmas a gyógyászati termék betöltésére a tartályba (C), a második tű (4) pedig alkalmas a levegő kivezetésére a tartályból (C), ahol a töltő elem (2) tartalmaz egy olyan első részt (5), ami csatlakoztatható a tartályhoz (C), és legalább egy olyan második részt (6), ami a tűket (3, 4) tartja, és két helyzet között mozgathatóan csatlakozik az első részhez (5), ahol az egyik, tétlen helyzetben felemelkedik az első részhez (5) képest, és a tűk (3, 4) eltávolodnak a membrántól (M), a másik, munkahelyzetben pedig a második rész (6) rázár az első részre (5) a tétlen helyzethez képest, és ahol a tűk (3, 4) átszúrják a membránt (M);
   - egy eltávolítható rögzítőelemet (17), ami az első részt (5) a tartályra (C) szorítja,

   azzal jellemezve, hogy azonosító eszközöket (20a, 20b, 21) tartalmaz a második rész (6) első részhez (5) viszonyított tétlen helyzetének és munkahelyzetének azonosítására és elérésére, és az azonosító eszközök alkalmasak az első résznek (5) a második részhez (6) képest oldhatóan történő rögzítésére, és hogy a második rész (6) legalább egy ütköző elemet (26) tartalmaz, ami meghatároz egy ütköző felületet (26a), ami egy, az első rész (5) által meghatározott referencia felület (28) felé néz, ahol az ütköző felület (26a) távközzel van elrendezve a referencia felülethez (28) képest, amikor a második rész (6) munkahelyzetben van, és meghatároz egy befogadó tartományt (29) közöttük, ahova be lehet illeszteni egy fogót, ami alkalmas arra, hogy leválassza és eltávolítsa a rögzítőelemet (17), hogy tölteni (2) lehessen a tartályt (C).
2. Az 1. igénypont szerinti szerkezet, **azzal jellemezve**, hogy a második rész (6) egy referencia tengelyt tartalmaz, és az ütköző felület (26a) erre a referencia tengelyre keresztirányú.
3. Az 1. vagy 2. igénypont szerinti szerkezet, **azzal jellemezve**, hogy a második résznek (6) van egy oldalfala (6a), ami lényegében hengeres alakú, és az ütköző elem (26) sugárirányban nyúlik ki ebből az oldalfalból (6a).
4. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy az ütköző elem (26) lényegében gyűrű alakú.
5. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a rögzítőelem (17) tartalmaz legalább egy rugalmasan nyúló rögzítő eszközt (18) az első részen (5), és úgy van kialakítva, hogy együttműködjék a tartállyal (C) annak érdekében, hogy reteszelje az első rész helyzetét a tartályhoz (C) képest.

6. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a második rész (6) elcsúsztathatóan kapcsolódik az első részhez (5) képest legalább egy csúszási irányban (7).
7. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a második rész (6) meghatároz legalább egy, kívülről hozzáférhető nyomófelületet (8), ami a tartály (C) fenekével szemben, és a csúszási irányra (7) keresztirányban van elrendezve, ahol a nyomófelület (8) alkalmas arra, hogy a felhasználó lenyomja és ezzel a második részt (6) kimozdítsa tétlen helyzetből munkahelyzetbe.
8. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a tűk (3, 4) egymással párhuzamosan vannak elrendezve.
9. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a csúszási irány (7) lényegében párhuzamos a tűk (3, 4) hosszirányú kiterjedésével.
10. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a tűk (3, 4) kivezető nyílásai hosszirányukkal szöget zárnak be, és egymáshoz képest széttartóak a töltő elemtől (2) a tartály (C) felé haladva.
11. Az 1 - 9. igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a tűk (3, 4) kivezető nyílásai hosszirányukkal szöget zárnak be, és lényegében azonos irányba dőlnek.
12. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy a második rész (6) tartalmaz egy első és egy második befogadó üléket (9, 10) az első és második tű számára (3, 4), amik párhuzamosak egymással és összeköttetésben vannak egy első vezetékkel és egy második vezetékkel (11, 12), amik a külső térrel vannak összeköttetésben.
13. A 12. igénypont szerinti szerkezet, **azzal jellemezve**, hogy az első vezeték és a második vezeték (11, 12) egymástól széttartóan vannak elrendezve a külső tér felé.
14. Az előző igénypontok bármelyike szerinti szerkezet, **azzal jellemezve**, hogy tartalmaz legalább egy hengeres elemet (13), ami össze van építve az első vezetékkel (11) és/vagy legalább egy szűrő elemet (14), ami össze van építve a második vezetékkel (12).
15. Készlet (50) gyógyszer termékek előállítására, **azzal jellemezve**, hogy tartalmaz legalább egy fecskendőt (51), ami tartalmaz egy előállítandó gyógyászati terméket, legalább egy, az előző igénypontok bármelyike szerinti szerkezetet (1) elmozdíthatóan összeállítva egy feltöltendő tartállyal (C), szelepeket (52), amik alkalmasak arra, hogy összekössék a fecskendőt (51) a szerkezettel (1), legalább egy csomagot (53), amiben van legalább egy ülék (54) a tartály (C) befogadására és legalább egy tálca (55), amin van legalább egy fecskendő (51), ahol a második rész (6) tétlen helyzetben kinyúlik az ülékből (54), ahol a nyomófelület (8) távközzel van elrendezve a tálcát (55) határoló falhoz (55a) képest, és az ülék felé van fordítva.