



(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
07.10.2020 Bulletin 2020/41

(51) Int Cl.:
A61J 1/20 (2006.01)

(21) Application number: **19166447.3**

(22) Date of filing: **01.04.2019**

(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
Designated Extension States:
BA ME
Designated Validation States:
KH MA MD TN

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(54) **VIAL ADAPTOR WITH AIR RESISTOR**

(57) A vial adaptor (110) may comprise a body portion (120). The body portion includes a vial connection port (122), a syringe connection port (124), an access passageway (126) between the vial connection port and the syringe connection port, and a regulation passageway (128). The vial adaptor may further comprise an expandable and/or contractible chamber (140) comprising one or more membranes impermeable to gas and/or liquid, the regulation passageway being between the vial connection port and the chamber, and a housing (150) casing the chamber. The chamber may comprise a two-way air resistor (146) arranged on the one or more membranes. Such a vial adaptor constitutes an improved vial adaptor.

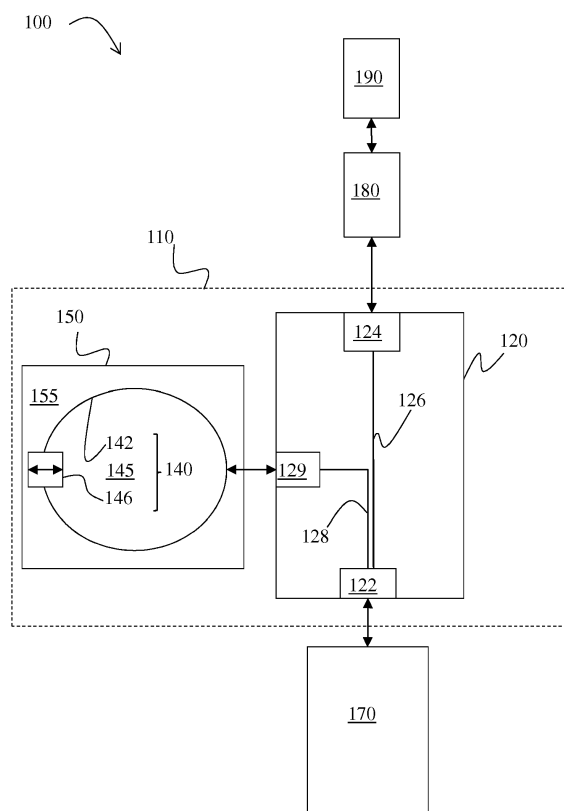


FIG. 1

Description

TECHNICAL FIELD

[0001] The disclosure relates to the field of devices and methods used for handling recipients in a medical context, and more particularly to vial adaptors.

BACKGROUND

[0002] A vial adaptor is a device configured for being connected to a vial, for example that contains a medical substance. A syringe may be connected to the vial adaptor, for example via a syringe adaptor. The assembly may be operated to establish fluid communication between the syringe and the vial, for example to allow transfer of liquid from the vial to the syringe.

[0003] Some known vial adaptors comprise an expandable and/or contractible chamber comprising at least one membrane impermeable to gas and/or liquid. These known vial adaptors are configured for fluid communication between the vial and the chamber. When fluid is communicated between the syringe and the vial, the vial adaptor may accordingly communicate fluid between the vial and the chamber. Such fluid communication between the vial and the chamber may at least reduce (i.e. prevent or reduce) fluid communication between the vial and ambient air (i.e. air of the working environment, which may be cleaned and/or sterilized). For example, when fluid is communicated from the syringe to the vial (e.g. during reconstitution), gas contained in the vial may accordingly be transferred to the chamber so as to regulate pressure inside the vial, with at least reduced gas communication between the vial and ambient air.

[0004] Within this context, there is a need to provide an improved vial adaptor.

SUMMARY

[0005] It is therefore provided a vial adaptor comprising a body portion. The body portion includes a vial connection port, a syringe connection port, an access passageway between the vial connection port and the syringe connection port, and a regulation passageway. The vial adaptor also comprises an expandable and/or contractible chamber. The chamber comprises one or more membranes impermeable to gas and/or liquid. The regulation passageway is between the vial connection port and the chamber. The chamber further comprises a two-way air resistor arranged on the one or more membranes. The vial adaptor also comprises a housing casing the chamber.

[0006] In examples, the vial adaptor may present any one or any combination of the following features:

- the two-way air resistor comprises a rubber element and a slit formed in the rubber element, the slit connecting an interior of the chamber and an exterior of

the chamber;

- the two-way air resistor has a rest state in which the slit is airtightly closed;
- the two-way air resistor further comprises a frame maintaining the rubber element in an airtight manner;
- the frame is welded to one or more membranes;
- the chamber is configured for expanding inside the housing until the two-way air resistor is pressed against a stopping portion of the housing, the slit being prevented from being opened when the two-way air resistor is pressed against the stopping portion;
- the housing comprises an aperture for fluid communication between an interior of the housing and an exterior of the housing;
- the vial adaptor further comprises a filter arranged between the regulation passageway and the chamber;
- the chamber is welded to an inside wall of the housing;
- the housing comprises a bowl coupled to the body portion and a cover, the chamber being welded to an inside wall of the bowl, the stopping portion being arranged on an inside wall of the cover;
- the housing presents a generally spherical shape; and/or
- the vial connection port defines a vial connection axis, the vial adaptor being configured for the housing to protrude in a direction transverse to the vial connection axis.

[0007] It is further provided a kit comprising a piece of information indicating a vial capacity, the chamber being inflated with no gas or with a volume of gas lower than k_1 times the vial capacity. k_1 is equal to 1, to 0.5, or to 0.2..

[0008] In examples, the kit may present any one or any combination of the following features:

- the housing presents a volume lower than k_2 times the vial capacity, k_2 being equal to 2, to 1.5, or to 1.2; and/or
- the sealed package comprises plastic material;
- the piece of information is an inscription, for example comprising text; and/or
- the piece of information is visible, provided on (i.e. carried by) a part of the sealed package, and/or (e.g. also) provided on (i.e. carried by) a part of the vial adaptor.

[0009] The kit may further comprise a syringe adaptor and/or a syringe. The syringe adaptor may be configured to cooperate with the vial adaptor. The syringe adaptor may for example be configured to be connected to the vial adaptor. The syringe may enable fluid mixing.

[0010] The syringe adaptor and/or the syringe may be arranged in any manner within the kit, optionally contained within the sealed package which contains the vial adaptor or alternatively within another sealed package.

In case the kit comprises both a syringe adaptor and a syringe, the syringe adaptor may be arranged contained within the sealed package comprising the vial adaptor or alternatively another sealed package, and the syringe may be arranged contained within the sealed package comprising the vial adaptor or alternatively another sealed package. In case the syringe adaptor and the syringe are both arranged outside the sealed package which contains the vial adaptor, the syringe adaptor and the syringe may be arranged contained within a common other sealed package, or alternatively within different other sealed packages.

[0011] It is further provided a method of using the vial adaptor or the kit. The method comprises providing at least the vial adaptor or the kit, a vial with content in fluid form or in solid form, and a syringe. The method also comprises connecting the vial adaptor to the vial and to the syringe, and then reconstituting and/or extracting a solution in the vial.

[0012] In case the vial adaptor is provided contained within a sealed package, the method may comprise opening the sealed package to provide the vial adaptor, and then directly performing the connecting. By "directly", it is hereby meant that at or after the opening and before the connecting, the chamber is not expanded and/or contracted, and rather stays at substantially constant volume. In other words, the vial adaptor is not operated in a way that modifies volume of the chamber before the connecting to the vial. In examples of the case where the chamber is provided substantially deflated within the sealed package or inflated with a volume of gas lower than a vial capacity, the vial may be provided with a solution already in fluid form before the connecting, and the method may optionally comprise, after the connecting, directly extracting the solution in the vial. By "directly", it is hereby meant that at or after the connecting and before the extracting, the chamber is not expanded, and rather stays substantially deflated or at constant volume. In other words, the vial adaptor is not operated in a way that modifies volume of the chamber before the extracting of the solution.

[0013] It is further provided a method of manufacturing the vial adaptor or the kit. The method comprises providing at least the body portion and the chamber, and assembling the body portion to the chamber such that the regulation passageway is configured for establishing fluid communication between the vial connection port and the chamber. The method then comprises assembling the housing, for example thereby obtaining the vial adaptor. The method may further comprise providing a package, arranging the assembled vial adaptor inside the package, and sealing the package, for example thereby obtaining the kit. The method may optionally comprise deflating the chamber before the assembling of the housing, such that the chamber is substantially deflated or inflated with a volume of gas lower than a vial capacity.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Non-limiting examples will now be described in reference to the accompanying drawings, where:

- FIG. 1 illustrates schematically an example of an assembly comprising the vial adaptor;
- FIGs. 2-3 illustrate examples of the vial adaptor.

DETAILED DESCRIPTION

[0015] FIG. 1 illustrates schematically an assembly 100 comprising a vial adaptor 110.

[0016] The vial adaptor 110 comprises a body portion 120. The body portion 120 includes a vial connection port 122, a syringe connection port 124, an access passageway 126, and a regulation passageway 128. The access passageway 126 is between the vial connection port 122 and the syringe connection port 124. This means that the access passageway 126 is configured for establishing or enabling fluid communication between the vial connection port 122 and the syringe connection port 124, or in other words for providing a fluid path between the vial connection port 122 and the syringe connection port 124. The access passageway 126 may form the fluid path, or a conduit in which a component forming the fluid path may be inserted (such as a hollow needle of a syringe adaptor 180). The vial adaptor 110 also comprises an expandable and/or contractible chamber 140 comprising one or more membranes 142 impermeable to gas and/or liquid. The regulation passageway 128 is between the vial connection port 122 and the chamber 140. This means that the regulation passageway 128 is configured for establishing or enabling fluid communication between the vial connection port 122 and the chamber 140, or in other words for providing a fluid path between the vial connection port 122 and the chamber 140. The vial adaptor 110 also comprises a housing 150 which cases the chamber 140.

[0017] The chamber further comprises a two-way air resistor 146 arranged on the one or more membranes 142. The two-way air resistor 146 is arranged between an interior 145 of the chamber 140 and an exterior 155 of the chamber. The interior 145 is an inside space of the chamber 140 configured for receiving gas. The exterior 155 is an inside space of the housing 150 configured for being occupied by the chamber 140. The one or more membranes 142 form with the two-way air resistor 146 a physical separation between the interior 145 and the exterior 155. The two-way air resistor 146 is an element configured to resist to air or gas passage between the interior 145 and the exterior 155 in both ways. By "both ways", it is meant both from the interior 145 to the exterior 155, and from the exterior 155 to the interior 145. By "resist", it is meant that the two-way air resistor 146 comprises a path for air or gas passage between the exterior 155 and the interior 145 in both ways, but that the path remains airtightly closed (i.e. air or gas passage between

the interior 145 and the exterior 155 is prevented along said path) unless the air or gas forces passage, the two-way air resistor 146 being configured for enabling such forcing of passage in both ways. By "forcing passage", it is meant that the chamber 140 is in a state such that the pressure differential between the interior 145 and the exterior 155 exerts a force that unseals the path, such that air or gas is enabled to pass between the exterior 155 and the interior 145. In particular, both when the two-way air resistor 146 is in a rest state (i.e. the chamber is not being inflated or deflated, e.g. such that no pressure differential is created - between the interior 145 and the exterior 155 - that solicits the two-way air resistor 146) and when alternatively the chamber 140 is being inflated (respectively deflated) and is physically free to expand (respectively be contracted), the two-way air resistor 146 prevents (at least substantially) air or gas passage from the interior 145 to the exterior 155 (respectively from the exterior 155 to the interior 145). But when the chamber 140 is being inflated (respectively deflated) and is physically prevented from expanding (respectively being contracted) and nothing obstructs the path of the two-way air resistor 146, the two-way air resistor 146 allows air or gas passage from the interior 145 to the exterior 155 (respectively from the exterior 155 to the interior 145).

[0018] This provides an improved vial adaptor.

[0019] Notably, the vial connection port 122 allows connection of the vial adaptor 110 to a vial 170, and the syringe connection port 124 allows connection of a syringe 190 to the vial adaptor 110. The access passageway 126 allows fluid communication between the syringe 190 and the vial 170. The vial adaptor 110 thereby forms an intermediate component between the syringe 190 and the vial 170 which allows avoiding direct access to the vial 170 with a manually-handled syringe having a protuberant needle. The vial adaptor 110 thereby at least reduces pricking risks. Also, once connected to the vial 170, the vial adaptor 110 may be left in place.

[0020] The regulation passageway 128 is configured to provide a fluid path thereby allowing establishing fluid communication between the vial 170 (via the vial connection port 122) and the chamber 140, when the vial 170 is connected to the vial connection port 122 (as represented on FIG. 1). During fluid withdrawal from the vial 170 or fluid insertion into the vial 170 (e.g. during powder drug reconstitution) and/or at time of piercing a septum of the vial 170, fluid communication (in particular gaseous exchange) can therefore occur between the vial 170 and the chamber 140. In fact, fluid withdrawal or insertion or said septum piercing may impact pressure inside the vial 170 (i.e. tending to increase or decrease said pressure). Therefore, establishment of fluid communication between the vial 170 and the chamber 140 allows regulating pressure inside the vial 170 by compensating such impact. This is performed with no or marginal fluid communication between the vial 170 and ambient air, unlike vial adaptors having no such chamber. The vial adaptor 110 thereby increases safety of use, by at least reducing aer-

osoling and/or leaking into ambient air of the content of the vial 170 and/or syringe 190, and/or contamination by ambient air of said content of the vial 170 and/or syringe 190.

[0021] Moreover, the vial adaptor 110 comprises a housing 150 which cases the chamber 140 and thereby offers a protection to the chamber 140. Such protection at least reduces risks of damage of the chamber 140 (such as piercing and/or explosion) and/or consequences thereof (such as aerosoling and/or leaking into ambient air of the content of the chamber 140 and/or contamination by ambient air of the content of the vial 170 and/or syringe 190 via contamination of the content of the chamber 140). The housing 150 thereby yet increases safety of use.

[0022] Furthermore, the two-way air resistor 146 resists to air passage between the exterior 155 and the interior 145, such that the two-way air resistor 146 forms with the one or more membranes 142 a usually airtight (i.e. impermeable to gas and/or liquid) enclosure that allows the chamber 140 to expand by being inflated, when there is space available for that inside the housing, and thereby perform correctly its function of regulating pressure and increasing safety of use. Yet, air may be enabled to force its passage along the path of the two-way air resistor 146. This holds true in particular when the chamber 140 is fully deflated and thus physically prevented from being contracted/shrunk anymore. In such a state of the chamber 140, air is enabled to pass through the two-way air resistor 146 from the exterior 155 to the interior 145 if the pressure in the interior 145 is reduced. Thus, in such a fully deflated state of the chamber 140, the vial adaptor 110 is still configured if needed to extract liquid from the vial 170 even if the chamber 140 contains no air to perform the regulation. Indeed, upon the extraction, air will force passage through the two-way air resistor 146 from the exterior 155 to the interior 145 and pass through the regulation passageway 128 so as to regulate the pressure inside the vial 170.

[0023] As a result, the vial adaptor 110 may in examples be provided (e.g. in a sealed package of a kit) in a state where the chamber 140 is substantially deflated or inflated with a volume of gas (e.g. sterilized air) lower than a vial capacity, and yet be readily usable with a vial 170 having its content in liquid form (in other words, not calling for a reconstitution that would allow expanding the chamber 140 before the extraction). The vial capacity is a predetermined value representing a maximal volume of solution present in the vial with which the vial adaptor 110 is intended to be used. The vial capacity may correspond to any standard provided for vials used in the medical industry (e.g. higher than 1 mL, 10 mL or 20 mL and/or lower than 500 mL, 200 mL or 100 mL, e.g. between 1 mL and 200 mL e.g. equal to 50 mL). The vial adaptor 110 and/or the package may in examples comprise a piece of information (e.g. an inscription, for example comprising text) indicating such vial capacity. In particular, the chamber 140 may be inflated with (substantially) no

gas or with a volume of gas strictly lower than k_1 times the capacity of the vial 170, k_1 being equal to 1, to 0.5, or to 0.2.

[0024] As a further result, since in such examples the chamber 140 is substantially deflated or inflated with a relatively low volume of gas and thus occupies relatively little space, the vial adaptor 110 may in options of such examples be provided (e.g. in the sealed package) with a housing 150 which is relatively compact. For example, the vial adaptor 110 may be provided (e.g. in the sealed package) with a housing 150 which presents an (at least initial) volume (i.e. volume of the inside space available for expansion of the chamber) corresponding to the vial capacity (i.e. just a little higher than the vial capacity), for example strictly lower than k_2 times the vial capacity, k_2 being equal to 2, to 1.5, or to 1.2. By "initial", it is meant the volume as the vial adaptor 110 is provided before use, for example the volume as the vial adaptor 110 stands inside the sealed package. This allows optimizing space, by making the vial adaptor 110 relatively little cumbersome. The vial adaptor 110 thus allows an increase in safety of use at a relatively low cost in terms of space or cumbersomeness. Such space optimization is particularly useful for an optimized storage and/or transportation of the housing 150 and/or vial adaptor 110, for example in a batch thereof. This compactness of the housing 150 also makes the vial adaptor 110 relatively easy to operate to a user, since for example the vial adaptor 110 may be relatively easy to manipulate when compact.

[0025] In examples of such options, the housing 150 may be configured to provide an (at least maximal) volume higher than or equal to k_3 times the vial capacity, k_3 being equal to 2, 1.5 or to 1. This allows the chamber 140 to start from a state where the chamber 140 is deflated or inflated with a volume of gas lower than k_1 times the capacity of the vial 170, and to expand freely inside the housing until full reconstitution inside the vial 170 of a volume of solution equal to the vial capacity, with substantially no leak of gas/fluid (in particular even through the two-way air resistor 146) and thus in a safe manner if such a reconstitution is needed.

[0026] For such a purpose, the housing 150 may be expandable such that its volume can be adapted to the volume of the chamber 140. In such a case, the vial adaptor 110 may optionally be provided (e.g. in the sealed package) with a housing 150 which presents a particularly low initial volume and is thus particularly compact. For example, the vial adaptor 110 may be provided (e.g. in the sealed package) with a housing 150 which presents an (at least initial) volume strictly lower than k_4 times the vial capacity, with k_4 being equal to 1, to 0.75, or to 0.6. For example, the housing 150 may be configured to expand so as to multiply its volume, e.g. by a factor higher than or equal to 1, 1.5, or 2. In particular, the housing 150 may be configured to double its volume. This allows further optimizing space, for example by contracting (i.e. compacting) the housing 150 and thereby compacting the vial adaptor 110 when needed. The volume variability

of the housing 150 also makes the vial adaptor 110 relatively easy to operate to a user, since for example the vial adaptor 110 may be relatively easy to manipulate when compacted.

[0027] Alternatively for such a purpose, the housing 150 may be un-expandable or of invariable volume (i.e. configured to be used at constant and fixed volume), but with an initial volume already adapted to the maximal volume contemplated for the chamber 140. In other words, the housing is made of one rigid or semi-rigid integrally formed part or of several parts each rigid or semi-rigid, integrally formed, and fixed/unmovable one relative to any other during use of the vial adaptor 110. A constant-volume housing 150 is particularly simple to manufacture. The housing 150 may for example present a constant volume higher than or equal to k_3 times the vial capacity, k_3 being equal to 1.2 or to 1, but yet strictly lower than k_2 times the vial capacity, k_2 being equal to 2, to 1.5, or to 1.2.

[0028] The two-way air resistor 146 thus allows compactness of the vial adaptor 110. In addition, the two-way air resistor 146 may be easy to manufacture and cheap.

[0029] For example, the two-way air resistor 146 may comprise a rubber element and a slit formed in the rubber element. The slit may connect the interior 145 of the chamber 140 and the exterior 155 of the chamber 140. In other words, the slit may enable gas communication between the chamber 140 and the inside space of the housing 150 around the chamber 140, when the slit is open or deflected (i.e. forming a gap which presents a positive width, that is, a non-zero width). The slit may for example link two opposite external faces of the rubber element, one face in contact with the interior 145 and the other face in contact with the exterior 155. Also, the slit may form two internal opposite faces of the rubber element, said internal opposite faces being in contact one with another when the slit is closed, that is with no gap between them due to the compression exerted by the rubber material, but on the contrary separated when the slit is opened, that is with a positive gap between them. Opening/deflecting of the slit may occur when air forces its passage through the two-way air resistor 146.

[0030] The two-way air resistor 146 may have a rest state in which the slit is airtightly closed. In other words, when the two-way air resistor 146 is in such a rest state, thanks to compression exerted by the rubber material, the slit is undeflected (i.e. no gap) and prevents/blocks passage/leakage of gas or liquid between the interior 145 of the chamber 140 and the exterior 155 of the chamber 140. In particular, the rubber element may be configured for the two-way air resistor 146 to be in such a rest state when the chamber 140 is not being inflated or deflated, or when the chamber 140 is being inflated or deflated while having space available for the chamber 140 to freely expand or be contracted, in other words while the chamber 140 does not occupy the whole inside space of the housing 150 or is not yet fully deflated. In such a case, the pressure differential between the interior 145 and the

exterior 155 exerts a force low enough for the slit to remain sealed, that is, lower than the compression force of the rubber element that maintains the slit airtightly closed. However, when the chamber 140 is being inflated or deflated but has no more space available for expanding or to be contracted, the pressure differential may exert a force which opens the slit and thereby forces passage of gas through the slit between the interior 145 of the chamber 140 and the exterior 155 of the chamber 140. This allows passage of air in the chamber 140 and then in the vial when necessary, for example during extraction at a point where the chamber 140 is fully shrunk and contains no air for performing the regulation inside the vial 170, such that air needs to be taken from the exterior 155.

[0031] Such a two-way air resistor 146 is particularly easy and cheap to manufacture. It is also particularly robust, as it does not involve a complex mechanism. In examples, the rubber element may be integrally formed (i.e. forming a unitary piece). The rubber element may be made of a resilient elastomeric material, such as silicone rubber and/or butyl rubber.

[0032] The two-way air resistor 146 may comprise a frame maintaining the rubber element in an airtight manner. In other words, the rubber element may be provided with a surrounding frame, the connection between the rubber element and the surrounding element being airtight such that the chamber 140 remains generally impermeable. Such a frame may be made of rigid or semi-rigid material, for example rigid plastic material. The frame may be molded, for example injection-molded. This facilitates the manufacturing and also the connection to the chamber membrane(s) 142. Notably, the frame may be simply welded to one or more membranes 142 of the chamber 140.

[0033] The body portion 120 of the vial adaptor may comprise or consist of an assembly of several integrally formed components or of a single integrally formed component which define(s) the general shape of the body portion 120, and/or one or more additional components integrated to said integrally formed component(s). The integrally formed component(s) may be made of rigid and/or semi-rigid material, for example plastic. The integrally formed component(s) may be molded, for example injection-molded.

[0034] The syringe connection port 124 is a structure of the body portion adapted for connection of a syringe 190 (such as a luer fitted syringe) so as to allow fluid communication between the syringe 190 and the vial 170 via the access passageway 126 upon operation of the syringe 190. The connection of the syringe 190 to the syringe connection port 124 may be performed in an at least substantially airtight manner, such that there is no or only little leak to the outside and/or no or only little contamination from the outside when fluid communicates between the syringe 190 and the vial 170. The syringe connection port 124 may be configured for an indirect connection and/or a direct connection. In an indirect con-

nection case (represented on FIG. 1), the syringe 190 is connected to the vial adaptor 110 via an intermediate component mounted on the vial adaptor 110, such as a syringe adaptor 180. In a direct connection case (not represented), the syringe 190 directly accesses the vial adaptor 110 with no intermediate component. The same syringe connection port 124 may be configured for both the direct type of connection and the indirect type of connection.

[0035] The syringe connection port 124 may for example comprise an opening formed on the body portion 120 and defining an upper extremity of the access passageway 126 (relative to the vial 170 considered supported on a horizontal plane). The body portion 120 may integrate a septum which seals said upper extremity of the access passageway 126. The body portion 120 may comprise a casing which maintains firmly the septum so as to close airtightly said upper extremity of the access passageway 126. The septum may for example comprise an elastomeric material. The elastomeric material may be configured for deforming when punctured by a hollow needle of the syringe adaptor 180 or of the syringe in such a way that the hollow needle can pierce through the septum and the elastomeric material forms an at least substantially airtight seal around the needle. The elastomeric material may be resilient i.e. further configured for deforming back to its initial shape when the hollow needle is withdrawn, so as to again at least substantially seal the upper extremity of the access passageway 126. The elastomeric material may for example comprise rubber, such as silicone rubber and/or butyl rubber. Alternatively or additionally, the body portion 120 may comprise a detachable cap which may be mounted on the syringe connection port 124 so as to close the upper extremity of the access passageway 126. The detachable cap may in examples seal the upper extremity of the access passageway 126. The detachable cap may be detached upon need to connect a syringe 190 to the syringe connection port 124. The detachable cap may be fully removable or alternatively stay maintained to the syringe connection port 124 after detaching, for example via a hinge connecting the detachable cap to the vial adaptor 110.

[0036] In examples, the opening defining the upper extremity of the access passageway 126 may be formed at the tip of a tubular member of the body portion 120. The interior of the tubular member may thereby constitute part of the access passageway 126. In examples, the tubular member may optionally be of a generally cylindrical shape. The syringe connection port 124 may be configured for releasably connecting to a syringe adaptor 180. The syringe adaptor 180 may comprise a syringe adaptor body generally shaped as a sleeve. The syringe connection port 124 may for example be configured for said tubular member to be inserted in said sleeve. For example, said tubular member may be slid inside the sleeve via an open end of said sleeve. The syringe adaptor 180 may comprise a hollow needle extending inside the sleeve from a base element closing the other end of

the sleeve. The nozzle of a syringe 190 may be mounted on a syringe mounting port of the syringe adaptor 180 in fluid communication with the hollow needle. The syringe mounting port may be formed on a side of the base element opposite to a side from which the needle extends. The syringe mounting port may be configured for the direct mounting of a nozzle of the syringe 190. The nozzle of the syringe 190 may be of a non-needle type, for example of a luer type, and/or formed in a non-metallic material, for example in plastic. The syringe adaptor 180 may thus allow using components which do not present any protuberant metallic needle.

[0037] In such examples, the syringe adaptor 180 may optionally further comprise a cork arranged in the sleeve so as to enclose a space inside the sleeve that comprises the hollow needle. The cork may isolate the needle. The cork may close the needle aperture (so that a user cannot push the syringe plunger when the syringe adaptor 180 is not connected). The cork may in examples be a (e.g. single and/or massive) septum. The cork may in examples comprise two septa enclosing a volume of air (the aperture of the needle in the rest position is at a location within the cork - in particular in the middle "air" portion). Other examples of a cork may include a distal disk septum and a sleeve septum which closes the needle aperture or distal disk septum only. Such cork improves safety of use.

[0038] The cork may comprise a septum. The septum of the syringe adaptor may present any feature or combination of features of any example of the septum of the vial adaptor 110. The cork may be mobile and configured to slide inside the sleeve upon the tubular member of the vial adaptor being itself slid inside the sleeve. The tubular member may reach the cork and impart sliding to the cork, such that the hollow needle of the syringe adaptor 180 comes out of the enclosed space through the septum of the syringe adaptor 180, said hollow needle then further piercing the septum of the vial adaptor 110 as the cork and the tubular member continue to be slid inside the sleeve. The tip of the hollow needle may initially be planted inside the septum before the syringe adaptor 180 is mounted on the vial adaptor 110. The tip of the hollow needle may alternatively initially be arranged inside the enclosed space. This at least reduces contamination risks of said tip of the hollow needle. The syringe adaptor 180 may further comprise a spring element configured for the cork to slide in the sleeve back to its initial position when the syringe adaptor 180 is dismounted from the vial adaptor 110. The spring element may be a compressible spring linking the cork and the base element, thereby biasing the cork distally.

[0039] In examples, the syringe connection port 124 (e.g. the tubular member) may optionally comprise a structure configured for the mounting of the syringe adaptor 180 thereon to be performed via attachment, for example via snapping. Such structure may comprise recess(es) - or respectively clamp(s) - configured for co-operating with corresponding clamp(s) - or respectively

recess(es) - of the syringe adaptor 180. The syringe adaptor 180 may comprise handles configured to control said clamp(s) or recess(es) of the syringe adaptor so as to perform unsnapping, e.g. manually.

[0040] The vial connection port 122 is a structure of the body portion adapted for connection to the vial 170. Upon connection to the vial, fluid communication between the vial 170 and the syringe 190 via the access passageway 126 and between the vial 170 and the chamber 140 via the regulation passageway 128 may be enabled. The connection of the vial connection port 122 to the vial 170 may be performed in an at least substantially airtight manner, such that there is no or only little leak to the outside and/or no or only little contamination from the outside when fluid communicates between the vial 170 and the syringe 190 and/or between the vial 170 and the chamber 140.

[0041] The vial connection port 122 may be configured for connection of the vial adaptor 110 to any one or more types of vial. A vial is a recipient or bottle containing or configured for containing any type of medical substance. The vial adaptor 110 may be configured for use with any one or more types of vial, for example with vials containing drugs used in chemotherapies, such as vials containing an anticancer medication. The materials and processes used for manufacturing the vial adaptor 110 may thereby be appropriate for such use. The vial 170 may be provided with the substance contained in fluid form (e.g. as a liquid), or in a soluble solid form (e.g. as a powder). A vial may comprise a vial neck configured for mounting a vial connection port of a vial adaptor thereon, and a container portion configured for containing the substance.

[0042] The vial neck may as known comprise a cap mounted on a container neck arranged at one extremity of the container portion. The container neck may be integrally formed with the container portion. The container neck and/or the container portion may be made of a rigid or semi-rigid material, for example glass or plastic. The container portion may present a tubular shape. The container neck and/or the vial neck may present a tubular shape. The container neck may comprise an opening sealed with the cap. The cap may integrate a septum. The cap may for example comprise a casing. The casing may comprise a skirt portion configured for mounting and airtightly attaching the cap on the container neck and a substantially plane portion defining the top of the cap and presenting an aperture filled by the septum. The casing may maintain firmly the septum so as to close airtightly the aperture. The aperture and correspondingly the septum may present a generally disk shape and/or be located at the center of the top of the cap. The casing may be made of a rigid or semi-rigid material, for example metal (such as aluminum) or plastic. The skirt portion may present a shape complementary to the container neck, for example a tubular shape. The skirt portion may comprise a thread configured for screwing the cap on a corresponding thread of the container neck. Alternatively,

the skirt portion may be configured for crimping the container neck airtightly. The container neck may for example comprise a circumferential bead forming a peripheral protuberance and the skirt portion may be metallic (e.g. in aluminum) and crimped on the bead. The cap may further comprise a removable cover configured for protecting the septum and detachable before use of the vial.

[0043] The vial connection port 122 may be configured for a direct connection and/or an indirect connection. In the direct connection case (represented on FIG. 1), the vial connection port 122 may be mounted directly on the vial 170. This simplifies the assembly. In the indirect connection case (not represented), the connection may be performed for example via an intermediate element mounted on the vial 170, such as a vial converter. This allows using the same vial adaptor 110 for connection to different types of vials. The vial converter may be mounted on the vial neck. A vial converter may notably allow using the same vial adaptor for different vial neck diameters, including diameters out of the range of a direct mounting of the vial connection port. A same vial connection port may be configured for both the direct type of connection and the indirect type of connection.

[0044] The vial connection port 122 may define a vial connection axis. The mounting of the vial adaptor 110 on a vial neck or on a vial converter may include a relative translational movement between the vial adaptor 110 and the vial neck along said vial connection axis. The vial connection axis may be an axis along which the vial neck extends during the mounting, for example a central longitudinal and straight axis of the vial neck.

[0045] In examples, the vial connection port 122 may optionally comprise a structure configured for the mounting on the vial 170 or vial converter to be performed via attachment, for example via snapping. Such attachment structure may comprise clamp(s) and/or recess(es) configured for cooperating with corresponding structure of the vial or vial converter, for example the vial neck. The attachment and/or snapping may be performed by pressing the attachment structure of the vial adaptor 110 onto the corresponding structure of the vial 170 or vial converter along the vial connection axis.

[0046] The vial connection port 122 may for example comprise a docking structure formed by the body portion 120 of the vial adaptor 110. The vial connection axis may be the central axis of the docking structure. The docking structure may present a shape adapted to the vial neck or vial converter, such that the vial neck or vial converter may be inserted inside the docking structure along the central axis of the docking structure, for example press-fitted inside the docking structure. The vial connection port 122 may comprise one or more peripheral walls extending in a direction at least substantially parallel to the central axis of the docking structure and bounding the docking structure. The one or more peripheral walls may be configured for accommodating the vial neck or vial converter, for example as a skirt. The one or more peripheral walls may be configured for being fitted to the

vial neck or vial converter. This allows the docking structure to encase the vial neck or vial converter and thus provides an easy and stable mounting of the vial adaptor. The docking structure may present a generally prism (e.g. cylindrical) shape. The vial connection port 122 may in examples comprise a single peripheral wall delimiting the docking structure and presenting a rim delimiting entry of the docking structure. In alternative examples, the vial connection port 122 may comprise several peripheral walls forming legs delimiting the docking structure.

[0047] The docking structure may present a diameter (i.e. largest dimension in a plane perpendicular to the central axis of the docking structure) higher than the diameter of the vial neck or vial converter. The diameter of the docking structure may for example be higher than the diameter of the cap of the vial 170. The docking structure may be further shaped for the vial neck to be radially stable when inserted inside the docking structure. The docking structure may correspond to any standard provided for vials used in the medical industry.

[0048] The vial connection port 122 may comprise a system for retaining the vial 170 after connection to the vial, for example after insertion of the vial neck or vial converter inside the docking structure. The vial adaptor 110 may be configured for connection of the vial connection port 122 to the vial 170 by pushing the vial adaptor 110 onto the vial neck or vial converter such that the vial neck or vial converter is pressed and snapped inside the docking structure. One or more peripheral walls of the docking structure may for example comprise clamps extending inwardly toward the central axis of the docking structure. The diameter of the portion of the docking structure bounded by the clamps may be smaller than the diameter of the cap of the vial 170 or top part of the vial converter. The one or more peripheral walls of the docking structure may present at least slight elasticity. The clamps may be configured for abutting the bottom edge of the skirt portion of the cap of the vial 170 or top part of the vial converter after snapping, thereby acting as a system for retaining the vial 170.

[0049] The vial connection port 122 may comprise a piercing member having a tip configured for piercing the septum of the vial 170 when the vial connection port 122 is mounted on the vial neck. The septum of the vial may for example comprise an elastomeric material. The elastomeric material may be configured for deforming when punctured by the piercing member in such a way that the piercing member can pierce through the septum and the elastomeric material forms an at least substantially airtight seal around the piercing member. The elastomeric material may for example comprise rubber, such as silicone rubber and/or butyl rubber. The piercing member may have a length configured for the tip of the piercing member to go beyond the septum and be inside the vial when the vial connection port 122 is mounted on the vial neck or vial converter.

[0050] When the vial connection port 122 comprises a docking structure for insertion of the vial neck or vial con-

verter inside the docking structure, the piercing member may for example extend in the docking structure in a direction parallel to the central axis of the docking structure, for example from the bottom face of the docking structure and toward the vial 170. The piercing member may for example extend substantially from the center of the bottom face of the docking structure and/or substantially along the central axis of the docking structure.

[0051] The piercing member may comprise or consist of one or more spikes. The spike(s) may comprise a pointed tip. The spike(s) may be rigid or semi-rigid. The spike(s) may be integrally formed and/or in the same material as the body portion of the vial, for example in plastic. The piercing member may alternatively or additionally comprise one or more needles. The needle(s) may be metallic. The needle(s) may be integrated to the body portion 120 of the vial adaptor 110. In examples, the piercing member may comprise one or more (e.g. plastic) spikes (each) embedding (i.e. coating) one or more (e.g. metallic) needle(s). In other examples, the piercing member may comprise or consist of one or more uncoated needles. A needle may be relatively easy to manufacture, for example relative to a thin hollow spike.

[0052] Alternatively or additionally to such piercing member, the vial connection port 122 may comprise one or more orifices configured for passage of a separate piercing component, such as a hollow needle. The one or more orifices may in examples be formed on a surface of the vial connection port 122 facing the vial 170, e.g. on the bottom face of the docking structure of the vial connection port 122, and/or aside the piercing member if any.

[0053] The access passageway 126 is a conduct structure enabling connection between the vial connection port 122 and the syringe connection port 124 so as to allow fluid communication between the vial 170 and the syringe 190. The regulation passageway 128 is a conduct structure connected to the vial connection port 122 and allowing establishment of fluid communication between the vial 170 and the chamber 140. The regulation passageway 128 may for example connect airtightly the vial connection port 122 to at least one opening 129 formed on the body portion 120, said opening 129 defining a respective upper extremity 129 of the regulation passageway 128 (relative to the vial 170 considered supported on a horizontal plane). The vial adaptor 110 may be configured for establishment of fluid communication between said opening 129 and the chamber 140. The access passageway 126 and the regulation passageway 128 may be disconnected, i.e. without any fluid communication therebetween. The access passageway 126 and/or the regulation passageway 128 may each consist of one or more linear conducts (i.e. without any manifold), for example straight conducts.

[0054] In case the vial connection port 122 comprises a piercing member configured to pierce the vial septum, the piercing member may integrate an extremity portion of the access passageway 126 and/or an extremity por-

tion of the regulation passageway 128. Each such passageway (126 and/or 128) extremity portion may form a respective opening on the tip of the piercing member so as to allow fluid communication between the passageway and the vial when the piercing member has pierced the septum of the vial. The tip of the piercing member and thereby the openings may indeed be inside the vial at that time. In examples, the vial connection port 122 may in examples comprise a piercing member which integrates only an extremity of the regulation passageway 128. In particular configurations of such examples, the access passageway 126 may form a conduct between the syringe connection port 124 and an aforementioned orifice configured for passage of a separate piercing component. In such configurations, the vial adaptor 110 may be configured for insertion of a hollow needle (e.g. of the syringe adaptor 180) inside the access passageway 126, the hollow needle coming out of said orifice so as to pierce the vial septum and access content of the vial 170.

[0055] In examples, the piercing member may comprise a single spike integrally formed so as to comprise several lumens forming the respective portions of the access passageway and of the regulation passageway (and in examples only these two lumens). In other examples, the piercing member may comprise several spikes, one spike being integrally formed so as to comprise a lumen forming the extremity portion of the access passageway (and in examples only this one lumen), and another distinct spike being integrally formed so as to comprise a lumen forming the extremity portion of the regulation passageway. In other examples, the piercing member may comprise one or more spikes integrally formed so as to each embed one or more hollow needles, the inside of the hollow needles forming the passageway extremity portions. In yet other examples, the piercing member may consist of several uncoated hollow needles. In other examples, the piercing member may consist of a needle integrated in the vial adaptor 110 and protruding out of the body portion 120 into the skirt of the vial connection port 122. The access passageway 126 may comprise an orifice within the vial adaptor body portion 120. Said lumen may be configured to guide a needle being removably insertable through the vial adaptor 110 from the syringe adaptor 180.

[0056] In examples, the body portion 120 may comprise or consist of an extremity section forming the vial connection port 122, another extremity section forming the syringe connection port 124, and a central section between the two extremity sections. The body portion 120 may present an elongate shape and its sections may extend along a (e.g. straight) central axis of the body portion 120. The vial connection axis may be the central axis of the body portion 120. One or more (e.g. all) sections of the body portion may present a generally prism (e.g. cylindrical) outer shape. Such examples of the body portion 120 are relatively simple to manufacture and relatively compact.

[0057] In such examples, the vial connection port 122

may comprise a docking structure as earlier-described. The central axis of the docking structure may be the central axis of the body portion 120. The vial connection port 122 may further comprise a piercing member as earlier-described, such as an integrally formed spike comprising several lumens or embedding several hollow metallic needles. The piercing member may extend at least substantially parallel to and/or along the central axis of the docking structure. The syringe connection port 122 may comprise an opening as earlier-described. The opening may be formed on the tip of a tubular member of the body portion 120 as earlier-described. The central axis of the opening and/or of the tubular member may be the central axis of the body portion 120. The access passageway 126 may be at least substantially straight. The access passageway 126 may extend at least substantially along the central axis of the body portion 120, for example between the opening of the syringe connection port 124 and the tip of the piercing member. In the case of a docking structure and an opening, the docking structure and the opening may be oriented in opposite directions of the central axis of the body portion. The body portion 120 thereby allows mounting the vial adaptor 110 on a vial neck or vial converter by plugging the vial neck or vial converter inside the docking structure along the central axis of the body portion 120, and (e.g. then) mounting the syringe adaptor 180 on the syringe connection port 124 along the same central axis of the body portion 120. The syringe adaptor 180 may be mounted on the syringe connection port 124 after or before the syringe adaptor 180 is assembled to a syringe 190.

[0058] The regulation passageway 128 may extend from the vial connection port 122 to one or more openings 129 formed on the body portion 120 and each defining an upper extremity 129 of the regulation passageway 128 (relative to the vial 170 considered supported on a horizontal plane). Each opening 129 defining an extremity of the regulation passageway 128 may be formed on a wall of the body portion 120, for example on a (e.g. peripheral) wall of the central section. A first axial portion of the regulation passageway 128 may for example extend from the tip of the piercing member at least substantially along the central axis of the body portion 120 (and thus for example parallel to and/or aside a first portion of the access passageway 126). The regulation passageway 128 may further present one or more second radial portions in the central section each extending toward a (e.g. peripheral) wall of the central section. The access passageway 126 may further comprise a second portion extending longitudinally in the central section to the syringe connection port 124). The regulation passageway 128 may for example present only one such second portion. The first portion and/or the second portion(s) of the regulation passageway 128 may be at least substantially linear. The second portion(s) of the regulation passageway 128 may form an angle with the first portion of the regulation passageway 126, for example an at least substantially right angle. Such examples of the body portion

120 are relatively simple to manufacture and stable in use.

[0059] In such examples, the central section of the body portion 120 and/or the syringe connection port 124 section may present a diameter substantially equal or lower than the diameter of the vial connection port 122 section. This allows keeping the body portion 120 compact. Notably, the vial connection port 122 section may present a diameter equal or higher than a minimal value required by the docking structure. The syringe connection port 124 section may present a diameter of the order of the diameter of the central section. This allows inserting the body portion via the syringe connection port 124 section inside a hollow portion of a coupling portion such as a sleeve portion, for example by press-fitting and/or snapping. The "diameter" of a section may refer to the length of the largest segment of said section contained in a plane perpendicular to the central axis of the body portion 120. The body portion 120 may thus generally present a shape which becomes more and more slender from the vial connection port 122 toward the syringe connection port 124.

[0060] In examples, the body portion 120, the syringe adaptor 180, the syringe 190, and/or the vial 170 may optionally present any other feature or combination of features discussed in WO 2005/041846 A2 which is incorporated herein by reference in this respect, in particular with reference to the description of the syringe adaptor and vial adaptor on pages 20 to 24.

[0061] The chamber 140 is configured to be in fluid communication with the vial via the regulation passageway 128, for example through operation of the syringe 190. The chamber 140 thereby defines an inside space available for containing gas and/or liquid and for exchanging such gas and/or liquid with the vial 170. The chamber 140 may thereby be configured for the exchange to operate regulation of pressure inside the vial 170 (e.g. equalization with ambient pressure) when adding and/or removing gas and/or liquid to and/or from the vial 170 via the access passageway 126, or when piercing a septum of the vial 170.

[0062] The chamber 140 comprises one or more membranes impermeable to gas and/or liquid. The chamber 140 is thus capable of holding gas and/or liquid with at least substantially no leakage to the outside and/or no contamination from the outside, for example at least temporarily (e.g. for a minimal period of time). The minimal period of time may be higher than 7 days after manufacturing and seal-packaging the vial adaptor, for example 28 days. After the vial adaptor 110 is removed from a sealed package, the minimal period of time may be shorter. The assembly of the syringe 190, the vial adaptor 110, and the vial 170 (and optionally the syringe adaptor 180 and/or vial converter) may form a closed fluid circulation system, i.e. with no or marginal fluid exchange with ambient air.

[0063] The chamber 140 is expandable and contractible i.e. it has variable volume. The chamber volume is

the volume of the inside space of the chamber 140. The chamber is in other words configured for expanding and/or contracting (i.e. shrinking) to operate regulation of pressure inside the vial, for example upon the chamber 140 being inflated and/or deflated. Thus, the chamber 140 is configured for containing a variable volume of gas and/or liquid to operate said regulation, and for accordingly occupying more or less space depending on said volume of gas and/or liquid that the chamber 140 contains. The space occupied by a physical object may be understood as the volume of the convex hull or of a concave hull of all 3D positions occupied by said physical object. The convex hull is the smallest convex set of 3D positions that comprises said all 3D positions occupied by said physical object. The concave hull may correspond to a predetermined concave hull determination scheme applied to said all 3D positions occupied by said physical object.

[0064] The housing 150 is a structure of the vial adaptor 110 casing the chamber 140. The housing 150 is distinct and separate from the chamber 140. The housing 150 thereby defines an inside space available for being occupied by the chamber 140. The housing volume is the volume of said inside space. In examples, substantially all the inside space of the housing 150 is available for being occupied by the chamber 140. The housing 150 may comprise or consist of one or more portions made of rigid and/or semi-rigid material. The housing 150 may for example comprise or consist of one or more components made of plastic, for example molded or injection-molded. The housing 150 and the body portion 120 of the vial adaptor 110 may be separate components which are assembled. Alternatively, the housing 150 may form at least a portion of the body portion 120 and/or the body portion 120 may form at least a portion of the housing 150.

[0065] The housing 150 shells the chamber 140 during chamber volume variation. This means that during regular use of the vial adaptor, whichever the volume of the chamber (at least below a predetermined threshold), the housing 150 envelopes the chamber 140. By "enveloping", "shelling" or "casing", it may in examples be meant that the chamber is inside the housing. The housing 150 thereby offers a protection barrier to the chamber 140.

[0066] The housing 150 may comprise one or more apertures through which the inside space of the housing 150 and thus the chamber 140 is visible from the outside, at least at some point. The housing 150 may for example form an (e.g. expandable/contractible) cage or basket enveloping the chamber 140. The one or more apertures may simplify sterilization of vial adaptor 110. In examples, the one or more apertures may be apparent in one or more states including the expanded state and/or excluding at least the contracted state.

[0067] Alternatively, the housing 150 may comprise no such aperture and thereby always cover the chamber 140. It is hereby meant that the inside space of the housing 150 and thus the chamber 140 is substantially never visible from the outside through an aperture. This pro-

vides a particularly high level of protection to the chamber 140, since no portion of the chamber 140 is ever accessible from the outside (at least directly or straightforwardly).

[0068] One or more components of the housing 150 may be made at least partly of a transparent material, for example a transparent plastic. This allows viewing the interior of the housing 150 during use of the vial adaptor 110, even in cases where the housing fully or substantially covers the chamber 140.

[0069] The housing 150 may comprise or consist of one or more housing units, each housing unit presenting a connected inside space. Each housing unit may be of constant or variable volume and envelope a respective part of the chamber of variable volume. Volume variation of the housing unit(s) and respectively of the chamber part(s) may correspond to area variation of the outer surface of the housing unit(s) and respectively of the chamber part(s). Namely, when a housing unit and respectively a chamber unit is expanded (respectively contracted), the area of the outer surface of the housing unit and respectively of the chamber part correspondingly increases (respectively decreases).

[0070] The housing 150 and/or the chamber 140 may each comprise one or more moving portions (e.g. relative to the body portion), the movement of which corresponding to volume variation of the housing 150 and/or the chamber 140. The one or more moving portions of the housing 150 may notably form a moving boundary between the inside space of the housing 150 and ambient air, with no other structure and/or vent compartment between the inside space of the housing 150 and ambient air.

[0071] The chamber 140 may in examples be configured for imparting expansion to the housing 150 (and thereby to the vial adaptor 110). In other words, upon the chamber 140 expanding, for example upon the chamber 140 being inflated, the chamber may occupy substantially all the inside space of the housing 150. The chamber 140 may comprise, upon the chamber expanding, one or more moving portions (e.g. relative to the body portion 120 and/or e.g. membranes such as sheets) which enter into contact each with a respective moving portion of the housing 150 (e.g. relative to the body portion 120 and/or e.g. walls of the housing 150), and upon the chamber 140 continuing to expand, each moving portion of the chamber 140 may press said moving portion the housing 150 outwardly. In examples, the whole chamber 140 moves when it expands. The housing 150 may be configured for expanding and for making the vial adaptor 110 occupy more space upon such pressing. This means that the housing 150 does not present a resistance forbidding such chamber-imparted expansion. This increases ergonomics of use of the vial adaptor, since the vial adaptor 110 may be provided and connected to a vial in a compacted state, and then automatically expand upon use, without any manual intervention. Alternatively or additionally, the housing 150 may be manually expandable.

[0072] Examples of use of the vial adaptor 110 are now discussed.

[0073] Use of the vial adaptor 110 may comprise initially providing the vial adaptor 110 and a vial 170, and then connecting the vial adaptor 110 to the vial 170 (optionally via a vial converter) in order to later operate a syringe 190 and extract (i.e. draw) content from the vial 170 into the syringe 190 for administration to a patient, for example via perfusion and/or injection. The syringe 190 may be provided and connected to the vial adaptor 110 any time before its operation, optionally via a syringe adaptor 180. At least at some point before the extraction, the vial 170 may be filled with fluid content (e.g. liquid). The vial 170 may be substantially fully filled with such fluid content. The vial 170 may present a capacity higher than 1 mL, 10 mL or 20 mL and/or lower than 500 mL, 200 mL or 100 mL. The capacity may for example correspond to any standard provided for vials used in the medical industry, and for example be between 1 mL and 200 mL, e.g. equal to 50 mL. The extraction may be performed at a single time or alternatively at several times, depending on the medical application. The vial adaptor 110 may be kept connected to the vial 170 during the whole extraction process. In other words, the vial adaptor 110 may stay connected to the vial 170 until the whole content of the vial 170 is extracted. This facilitates user operations.

[0074] The following discusses examples of how the vial adaptor 110 and the vial 170 are initially provided, before connection of the vial adaptor 110 to the vial 170.

[0075] The vial adaptor 110 may always be prepared for a vial 170 having content in fluid form, for example as a liquid. The content of the vial 170 is in such a case ready for extraction. The vial adaptor 110 may for example be initially provided with a positive volume of gas contained in the chamber 140, for example the maximal volume of gas allowed by the initially provided state of the housing 150. In other words, the vial adaptor 110 may be provided with the chamber 140 not shrunk, at least not completely. The gas initially contained in the chamber 140 may be cleaned and/or sterilized gas, for example cleaned and/or sterilized air. Alternatively, the vial adaptor 110 may be provided with the chamber 140 completely or partially shrunk as mentioned above, and the two-way air resistor 146 still allows passage of air for extraction.

[0076] The vial adaptor 110 may alternatively or additionally be initially provided prepared for a vial 170 having content in soluble solid form, for example as a powder. The content of the vial 170 may in such a case require reconstitution before being used. In other words, the content of the vial 170 may be in a state where addition to the vial 170 of liquid with a syringe 190 is needed in order to reconstitute a solution ready for use in the vial 170. The housing 150 may be expandable and the vial adaptor 110 may for example initially be provided with the housing 150 in a state different from the expanded state, for example in the contracted state. Upon the reconstitution, the housing 150 and the vial adaptor 110 may expand

as the chamber 140 expands due to the reconstitution. The chamber 140 being expanded after reconstitution, the content of the chamber 140 then allows performing pressure regulation when later extracting reconstituted content from the vial 170, such that the vial adaptor 110 may be left connected to the vial 170 after the reconstitution and used for such later extraction. Alternatively, the vial adaptor 110 may be provided with the chamber 140 completely or partially shrunk as mentioned above, and even if the housing 150 is compact but not expandable the chamber 140 may freely expand.

[0077] In examples, the vial adaptor 110 may be initially provided prepared for being used both with vials initially provided with content in fluid form and with vials initially provided with content in soluble solid form.

[0078] The vial adaptor 110 may be initially provided in a package, for example a sealed package. The vial adaptor 110 and any gas contained in the chamber 140 or in the package may be cleaned and/or sterilized before packaging. The vial adaptor 110 may in such a case be removed from the package and connected to a vial 170 for any of the above use examples.

[0079] A cleaned gas is a gas that has been filtered by a filter to remove particles and/or viable micro-organisms to such an extent that the gas is classified to be aseptic and accepted by the relevant authority and/or any standards. The degree of purity can be expressed in the largest particles allowed to pass the filter for a given flow rate of gas. In examples no or very few particles having a size exceeding 5 μm are allowed to be present in the cleaned gas. However, the allowed particle size is determined by the requirements in the current application. Some drug treatments require that substantially all particles having a size exceeding 0.15 μm are removed from the gas by the particulate air filter. As an example, a filter with the mesh size 0.2 μm can be used to remove substantially all particles and micro organisms of that size or larger. A sterilized gas is a gas that has been subjected to a sterilization method to remove viable micro-organisms. The sterilization method may be a standard method known in the art. For example, current regulations in Europe for medical devices to be designated "STERILE" may be found in standards "ETO: ISO 11135:2014" and "ETO/ECH : ISO 10993-7 :2008". Other regulations may exist in other countries. The sterilization can be ethylene oxide sterilization, sterilization by irradiation, or (moist) heat sterilization or any other accepted method. The European standard requirements imply that the theoretical probability of there being a viable micro-organism present on/in the sterilized device shall be equal to or less than 1×10^{-6} . In the case a gas is sterilized, it is not always necessary to clean the gas according to the cleaning process as described above, although such cleaning and the sterilization can be combined. However, other methods can be used to remove particles from the gas if required or the sterilization process itself may be sufficient to bring the gas into a state where the gas is to be considered as both cleaned and sterilized.

[0080] Different examples of the vial adaptor are now discussed.

[0081] The chamber 140 may comprise at least one flexible and/or elastic portion. Such a portion may be made of flexible and/or elastic material delimiting the chamber volume. The chamber 140 may form an inflatable/deflatable balloon and/or comprise a foldable bladder or diaphragm delimiting an inflatable/deflatable volume. In such cases, the presence of the housing 150 is particularly relevant, since the chamber 140 is relatively fragile in such examples.

[0082] By "flexible" material it is hereby meant a material that can be deformed so as to be folded. The chamber 140 may thus comprise at least one foldable portion, which is folded notably when the housing 150 is in the compacted state. The foldable portion may be made of a foldable material. Contrary to a rigid or semi-rigid material, a flexible material may form a surface which may be significantly folded (i.e. not only slightly), for example at least above 10° or 45°. By "elastic" material it is hereby meant a material that can be deformed by application of a force and that tends to return to its original shape when application of the force stops. The flexible and/or elastic portion of the chamber 140 may thus be deformed as the chamber 140 expands or contracts in accordance with chamber volume variation.

[0083] The flexible and/or elastic portion may comprise at least one sheet. The sheet may comprise a single material layer or a laminate of several material layers. A sheet is relatively easy to manufacture. A sheet may notably be vacuum-formed. In other words, a sheet may be given a 3D surface shape by providing a - e.g. plastic - planar sheet and vacuum forming the sheet with an adequate mold (e.g. including placing the planar sheet above the mold in a vacuum former, heating the planar sheet, and/or pumping air), and then optionally performing one or more perforations on the sheet.

[0084] Furthermore, the chamber 140 may be welded on one or more other components of the vial adaptor, for example on an inside wall of the housing 150 or on the body portion 120, so as to be in gas communication with the opening 129. The chamber 140 may thus be not integrally formed with the other components, but assembled thereto afterwards. The welding ensures airtightness. In case the chamber 140 comprises a sheet, such welding may be performed relatively easily at an edge of the sheet. The welding of an edge of a sheet to another object may be performed via an intermediary component, such as a stiffening component (e.g. a stiffening ring used for a circular edge of a sheet). The use of a sheet thereby yet facilitates the manufacturing of the vial adaptor 110.

[0085] The flexible and/or elastic portion may in particular comprise or consist of two sheets welded together. The sheets may be welded at respective edges. This allows predefining an expansion direction to the chamber 140 and avoids flipping operations in cases of one single sheet. In examples, the two sheets may each have a generally annulus shape (i.e. a two-dimensional manifold

shape topologically equivalent to an annulus). Such annulus shapes are particularly easy to manufacture. The two sheets may also be sized such that they may be superposed with their respective external edges one on the other. This way, the two sheets may be welded at their respective external edges. The free internal edges of the two sheets may then be welded on one or more other parts of the vial adaptor 110. The edges of the annulus shapes may be peripheral and/or present ring shapes. The welding of each such ring shapes may be performed via a stiffening ring. The space between the two sheets then constitutes the inside space of the chamber 140. Such a manufacturing is relatively easy to perform.

[0086] The chamber 140 may be generally configured to unfold, unroll, expand, contract, inflate, deflate, compress, and/or decompress. The chamber membrane(s) 142 may comprise any one of a wide variety of flexible and/or expandable materials. In examples, the chamber membrane(s) 142 may comprise polyester, polyethylene, polypropylene, saran, latex rubber, polyisoprene, silicone rubber, vinyl, polyurethane, or other materials. In examples, the chamber membrane(s) 142 may comprise a material having a metal component to further inhibit fluid (including gas or air) leakage through the material of the bag, e.g., metalized biaxially-oriented polyethylene terephthalate (also known as PET and available under the trade name Mylar®). In examples, the chamber membrane(s) 142 may comprise a laminate. For example, the chamber membrane(s) 142 can be constructed of a layer of 0.36 Mil (7.8#) metalized (e.g., aluminum) PET film and a layer of 0.65 Mil (9.4#) linear low-density polyethylene. In examples, the chamber membrane(s) 142 may comprise a material capable of forming a substantially airtight seal with any material it is welded on. In examples, the chamber membrane(s) 142 may be transparent or substantially transparent. In other examples, the chamber membrane(s) 142 may be opaque. In examples, the chamber membrane(s) 142 may comprise a material that is generally impervious to liquid and air. In examples, the chamber membrane(s) 142 may comprise a material that is inert with respect to the intended contents of the vial 170. For example, the chamber membrane(s) 142 may comprise a material that does not react with certain drugs used in chemotherapy. In examples, the chamber membrane(s) 142 may comprise latex-free silicone having a durometer that is between about 10 and about 40. In examples, the chamber membrane(s) 142 may comprise a coating. In examples, the chamber membrane(s) 142 may comprise a coating that reduces the porosity of the chamber. In examples, the coating may be evaporated aluminum or gold. In examples, the coating includes a water soluble plastic configured to form a barrier to inhibit passage of gases thereacross. In examples, the coating may be applied to the outside of the chamber. In other examples, the coating may be applied to the inside of the chamber membrane(s) 142. In examples, the coating may be applied to the inside and the

outside of the chamber membrane(s) 142. In examples, the coating is a polyolefin.

[0087] The housing 150 may comprise at least two portions configured for being connected one to another. This allows a simple manufacturing. In examples, the housing 150 may comprise or consist of a cover and a bowl. The housing 150 may thus present a compact shape. In particular, the housing may optionally present a generally spherical shape. In further options, the cover and/or the bowl may each present a generally semi-spherical shape. The bowl may be located between the cover and the body portion 120 after connection of the vial adaptor 110 to a vial 170. The assembly may thus present a compact shape.

[0088] In examples, the cover may be fixed and the bowl may be mobile relative to the body portion 120 and/or to the vial 170, for example configured to slide relative to the bowl. The housing 150 may notably be as in any example described in patent application No. PCT/IL2018/051202, which is incorporated herein by reference in this respect. In alternative examples, the cover and the bowl may be configured for being fixed relative to the body portion 120 and thus one relative to the other, optionally assembled by snapping or press-fitting. Such steps allow a simple manufacturing.

[0089] Examples of cooperation between the body portion 120 and the housing 150 and/or chamber 140 are now discussed.

[0090] The body portion 120 may be assembled in the vial adaptor 110 via press-fitting and/or snapping. In case of a hollow portion of a coupling portion such as a sleeve portion, the body portion 120 may be press-fitted and/or snapped inside the hollow portion, or alternatively press-fitted and/or snapped to another component and then inserted inside the hollow portion, for example again via press-fitting and/or snapping said other component. The body portion 120 and the housing 150 may thus be separate components (i.e. not integrally formed).

[0091] The vial adaptor 110 may comprise a coupling portion separate from a central section of the body portion 120. The coupling portion is a structure of the vial adaptor 110 (for example of the housing 150) which allows assembly of the body portion 120 in the vial adaptor 110. The vial adaptor 110 may comprise an opening formed on the central section and defining an upper extremity 129 of the regulation passageway 128 (relative to the vial 170 considered supported on a horizontal plane). The coupling portion may in such a case include a regulation port, and the vial adaptor 110 is configured for establishing fluid communication between the regulation port and the upper regulation passageway opening 129 and between the regulation port and the chamber 140 by providing respective fluid paths. The coupling portion may in examples be fully separate from the body portion 120. In alternative examples, the coupling portion may be integrally formed with a portion of the body portion 120 (not including the central section).

[0092] The coupling portion constitutes an intermedi-

ate portion between the regulation passageway 128 and the chamber 140. The coupling portion may notably be separate from at least a part of the body portion which may wholly integrate the access passageway 126 and the regulation passageway 128. Such a part is relatively complex to manufacture, due to the passageways requiring to be formed with special care. Such manufacturing may thus be rather dedicated to such a part and not involve any coupling consideration.

[0093] The coupling portion may comprise or consist of a single integrally formed component or of several integrally formed components made of rigid and/or semi-rigid material. The coupling portion may for example comprise or consist of one or more components made of plastic, for example molded or injection-molded. The regulation port may be formed on a wall of the coupling portion made in such materials. The regulation port may in examples consist of one or more apertures of a diameter inferior to 5 mm.

[0094] In examples, the coupling portion may form a passage and the central section of the body portion may be inserted and/or fitted in the passage, for example via press-fitting and/or snapping. The central section may in examples be press-fitted and/or snapped into any one or more components of the coupling portion which form the passage. The coupling portion may notably include a sleeve portion which forms the passage (inside the sleeve) and the central section of the body portion 120 may be inserted internal said sleeve portion. The vial connection port 122 and the syringe connection port 124 may be arranged at opposite ends of the sleeve portion. The body portion 120 may be elongated and inserted inside the sleeve portion via the syringe connection port 122 as earlier-mentioned, for example until press-fitting and/or snapping such that the central section of the body portion 120 is maintained inside the sleeve portion. The central section may in examples be press-fitted and/or snapped into the sleeve portion. Such insertion may occur during manufacturing after the sleeve portion is formed. The central section of the body portion 120 may be surrounded by the sleeve portion after the assembly. The sleeve portion and the body portion 120 may in examples be of a general prism (e.g. cylindrical) shape.

[0095] The regulation port of the coupling portion and the upper regulation passageway opening 129 of the regulation passageway 128 may in examples face each other. In cases where the coupling portion comprises a sleeve portion and the body portion is elongated and inserted inside the sleeve portion, the chamber 140 may be peripheral to said sleeve portion and thus to the body portion 120. The regulation port may be formed on an internal wall of the sleeve portion in cooperation with a peripheral wall of the body portion 120, for example a peripheral wall of the central section of the body portion 120. The upper regulation passageway opening 129 may be formed on said peripheral wall and/or facing the regulation port.

[0096] The chamber 140 may be welded at a zone of

the vial adaptor 110 as in any example described in patent application No. PCT/IL2018/051202, which is incorporated herein by reference in this respect. Alternatively, the chamber 140 may be welded on an inside wall of the housing 150 or on the body portion 120 in a way such that the chamber 140 is in gas communication with the opening 129 and/or the regulation port. Welding the chamber 140 on an inside wall of the housing 150 is particularly easy to perform.

[0097] The vial adaptor 110 may in examples comprise one or more filters arranged between the regulation passageway 128 and the chamber 140. One or more filters may be located anywhere between the regulation passageway 128 and the chamber 140, for example at the upper regulation passageway opening 129, at the regulation port, and/or at another port formed on the housing and in fluid communication with the chamber. A filter may be arranged against any such opening or port, for example on the chamber side. The filter may allow cleaning air communicated between the chamber 140 and the regulation passageway 128 and/or at least reducing passage of liquid.

[0098] In examples, the filter may be chemically or mechanically held in position, e.g., by adhesive or a snap ring, or welded. Certain examples of the vial adaptor 110 include a plurality of filters. In some examples, the filter is a hydrophobic membrane, which is generally configured to allow gases to pass therethrough, but to inhibit or prevent passage of liquids therethrough. In some examples, gases (e.g., sterilized air) are able to pass through the filter so as to move between the vial and the bag, but liquid from the vial is blocked by the filter. Examples of the adaptor with the filter can therefore reduce the likelihood of liquid spilling from the vial even if the vial adaptor is detached. In examples, the filter can remove particles and/or contaminants from the gas that passes through the filter. For example, in examples, the filter may be configured to remove nearly all or about 99.9% of airborne particles 0.3 micrometers in diameter. In some examples, the filter may be configured to remove microbes. In examples, the filter comprises nylon, polypropylene, polyvinylidene fluoride, polytetrafluoroethylene, or other plastics. In some examples, the filter includes activated carbon, e.g., activated charcoal. In certain configurations, the filter comprises a mat of regularly or randomly arranged fibers, e.g., fiberglass. In some arrangements, the filter comprises Gortex® material or Teflon® material.

[0099] The upper regulation passageway opening 129 may be formed on a wall of the body portion 120, for example a peripheral wall of the central section of the body portion 120. The vial adaptor 110 may comprise a sealing member arranged against said wall and providing airtightness of the fluid communication between the regulation port of the coupling portion and the upper regulation passageway opening 129. The wall of the body portion 120 and the coupling portion are formed on separate components or formed by separate components.

The body portion 120 may for example comprise or consist of one or more components all separate from the coupling portion 120. In such a case, the body portion 120 and the coupling portion may be assembled such that fluid communication between the regulation port of the coupling portion and the upper regulation passageway opening 129 is airtight. The sealing member provides a simple way of doing that in terms of manufacturing, notably compared to welding operations such as welding the walls of the body portion and of the coupling portion to create a sealed passage between them, such welding being particularly complex in such difficultly accessible zone. The sealing member may comprise or consist of one or more integrally formed components separate from the rest of the assembly and/or assembled to the rest of the assembly without any mechanical connection and/or without any welding.

[0100] The wall on which the regulation passageway opening 129 is formed may cooperate with the coupling portion, and for example present a shape complementary to the coupling portion (e.g. the central section being fitted internal a sleeve portion of the coupling portion). The sealing member may in such a case be arranged against the wall and against the coupling portion. In case the coupling portion comprises a sleeve portion and the body portion 120 is elongated and inserted (e.g. fitted) inside the sleeve portion, the sealing member may be sandwiched by the peripheral wall of the body portion 120 and the internal face of the sleeve portion, or alternatively sandwiched by the peripheral wall of the body portion 120, an edge of the sleeve portion and one or more other components.

[0101] The sealing member may comprise elastic material, such as an elastomeric material (e.g. rubber). The sealing member may in such examples be pressed against and by the peripheral wall of the body portion and one or more components of the vial adaptor. Such pressing ensures airtightness. The sealing member may be configured for creating an airtight interstitial space between the body portion 120 and the coupling portion in fluid communication with the opening 129 and the regulation port, the interstitial space being delimited airtightly by walls of components and pressed elastic material. The pressing thereby ensures airtightness of the interstitial space and thus allows the regulation passageway opening 129 and the regulation port to be in airtight fluid communication.

[0102] The sealing member may comprise one or more rings. When the section of the body portion comprising the regulation passageway opening 129 is of a generally cylindrical shape, said section of the body portion may be inserted easily in such ring(s) with an airtight fitting. The sealing member may comprise or consist of a rubber ring or of one or more O-rings for example a pair of O-rings, which may or may not be over-molded. The body portion may correspondingly comprise one or more grooves, for example grooves configured to lodging O-rings. In case the regulation passageway opening 129

faces the regulation port, the sealing member may comprise O-rings arranged on both sides of the regulation passageway opening 129. In case the sealing member comprises a rubber ring, said rubber ring may be arranged around the regulation passageway opening 129 and comprise recesses and/or passages configured to direct fluid from the regulation passageway opening 129 to the regulation port in cooperation with the components the rubber ring is pressed against.

[0103] The vial adaptor 110 may comprise a duct member arranged between the regulation passageway opening 129 and the regulation port. The duct member may comprise at least a portion the diameter of which is smaller than the diameter of the regulation passageway opening 129 and/or of the regulation port. The duct member may thereby form a tool to reduce said diameter(s) of the regulation passageway opening and thus reduce fluid flow. This is performed at a relatively low cost in terms of manufacturing. The manufacturing of a relatively large regulation passageway opening and/or regulation port then reduced by the duct member may indeed be simpler than the initial manufacturing of relatively small regulation passageway opening 129 and/or regulation port.

[0104] The duct member may in particular be arranged against and/or plugged inside the regulation passageway opening 129 and reduce the diameter of said regulation passageway opening 129. This allows decreasing the flow in the interstitial space and thereby reduces risks of failure of the sealing member and leaks.

[0105] In examples, the duct member may be integrally formed with the sealing member. The sealing member and the duct member may thus form a single piece. In particular, the sealing member may comprise a pair of over-molded O-rings, the over-molding connecting the two O-rings and also forming the duct member between the O-rings. This simplifies the assembly of the vial adaptor 110, as the over-molded O-rings may be assembled to the body portion 120 in one single operation. In case of a rubber ring, passages in the rubber ring may act as such a duct member.

[0106] The vial adaptor 110 may further comprise a regulation compartment between the regulation passageway 128 and the chamber. The regulation compartment constitutes an intermediary room between the regulation passageway 128 and the chamber 140 where gas may circulate. This may increase uniformity of inflation/deflation of the chamber. The regulation compartment may be formed peripherally to the body portion. The regulation compartment may present a volume higher than the volume of the regulation passageway 128. The regulation compartment may be formed between the regulation port and the chamber 140, for example by the coupling portion and/or the housing 150. The regulation compartment may for example present a toroid shape and/or surround the sleeve portion. The regulation compartment may in examples be formed between the chamber 140 and the sleeve portion, for example between the sleeve portion and the internal wall of the telescopic sec-

tion of the cover. The regulation compartment may in alternative examples be formed inside the cover.

[0107] The wall, the coupling portion, the cooperation therebetween, the sealing member, and/or the duct member may be as in any example described in in patent application No. PCT/IL2018/051202, which is incorporated herein by reference.

[0108] Examples of the vial adaptor are now discussed with reference to FIGs. 2-3, which both illustrate a vial adaptor oriented vertically for use with a vial supported on a horizontal plane.

[0109] FIG. 2 shows schematically a vial adaptor 200 mounted on a vial 270.

[0110] Vial adaptor 200 comprises a body portion 220 which includes a vial connection port 222, a syringe connection port 224, an access passageway 226 between vial connection port 222 and syringe connection port 224, and a regulation passageway 228 between vial connection port 222 and an interior 245 of a chamber 240. Body portion 220 presents a shape which becomes more and more slender from vial connection port 222 toward syringe connection port 224. This provides compactness to vial adaptor 100.

[0111] Vial connection port 222 comprises a docking structure for mounting vial adaptor 100 on the neck of a vial 270, by insertion of the neck of vial 270 inside the docking structure. Vial connection port 222 comprises one or more peripheral walls 234 extending in a vertical direction and forming the docking structure as a skirt for accommodating the neck of vial 270. Vial connection port 222 also comprises a support portion 238 abutting on the top surface of the neck of vial 270 for providing stability to the assembly. Vial connection port 222 further comprises a spike 236 which comprises a pointed tip for piercing a septum of vial 270 when the vial connection port 222 is mounted on the vial neck. Spike 236 may be straight and/or vertical.

[0112] Access passageway 226 comprises a first section 226a partly formed inside spike 236 and having an extremity at the pointed tip so as to be inside vial 270, and a second section 226b connecting the first section 226a to syringe connection port 224. First section 226a and/or second section 226b may be straight and/or vertical. The first section 226a may present a relatively small diameter, limited by the size of spike 236, and the second section 226b may present a larger diameter.

[0113] Regulation passageway 228 comprises a first section 228a partly formed inside spike 236 and having an extremity at the pointed tip so as to be inside vial 270, and a second section 228b connecting the first section 228a to an opening formed a peripheral wall of a central section 232 of body portion 220. First section 228a and/or second section 228b may be straight. First section 228a may be vertical and/or second section 228b may be horizontal, optionally with first section 228a and second section 228b forming a right angle one relative another.

[0114] Sections 226a, 226b, 228a, 228b each form a conduct enabling fluid communication from one extremity

to another.

[0115] Vial adaptor 200 further comprises an expandable and/or contractible chamber 240, and a housing 250 casing chamber 240. Housing 250 protects chamber 240 and increases safety of use of the vial adaptor 200.

[0116] In the example of the figure, housing 250 presents a generally spherical shape which protrudes in a direction substantially transverse a vial connection axis defined by vial connection port 223, which is here the vertical direction. This provides compactness to vial adaptor 200 while allowing an easy manufacturing. In alternative examples, the housing may present other shapes and/or be arranged in other manners.

[0117] In the example of the figure, housing 250 comprises a bowl 251 coupled to body portion 220 and a cover 252 assembled to bowl 251, for example by snapping or press-fitting. Housing 250 may be of fixed size (i.e. non-expandable). This allows a particularly simple manufacturing. In alternative examples, the housing may be formed in different manners, for example expandable.

[0118] Chamber 240 may be welded to an inside wall of housing 250, in particular to an inside wall of bowl 251. This allows an easy assembling, by initially welding chamber 240 to bowl 251 and coupling bowl 251 to body portion 220, and then coupling cover 252 to bowl 251 so as to case chamber 240.

[0119] Chamber 240 comprises one or more membranes 242 impermeable to gas and/or liquid, and thereby forming a barrier between an interior 245 and an exterior 255, so as to regulate pressure inside vial 270 via regulation passageway 228. During such regulation, chamber 240 is expanded or contracted/shrunk and thus occupies a variable space inside housing 250.

[0120] Housing 250 may comprise an aperture 254 for fluid communication between an interior 255 of housing 250 and an exterior of housing 250. This facilitates expansion/contraction of chamber 240. This also allows coupling cover 252 to bowl 251 airtightly, so as to restrict fluid communication between the interior 255 of housing 250 and the exterior of housing 250 to passage via the aperture 254.

[0121] Chamber 240 further comprises a two-way air resistor 246 arranged on the one or more membranes 242. Two-way air resistor 246 resists to passage of air from the inside 245 of chamber 240 to the outside 255 of chamber 240, when chamber 240 is expanded and has free space inside housing 250 for such expansion (such as in the situation illustrated on the figure). Such expansion is needed for example for reconstitution of a liquid inside vial 270. Yet, two-way air resistor 246 allows passage of air from the outside 255 of chamber 240 to the inside 245 of chamber 240, when chamber 240 is fully shrunk or almost fully shrunk (such as in the situation illustrated on the figure). Such passage of air is needed for example for extraction of a liquid inside vial 270.

[0122] Thus, the two-way air resistor 246 allows vial adaptor 200 to be configured for being used both directly for reconstitution or directly for extraction, even in the

situation illustrated on the figure where chamber 240 is already fully shrunk or almost fully shrunk. As a result, the housing 250 can be kept small and the vial adaptor 200 can be made compact. In other words, even in the situation illustrated on the figure where chamber 240 is already fully shrunk or almost fully shrunk, vial adaptor 200 is ready for use in two different situations: either reconstitution or direct extraction.

[0123] Vial adaptor 200 may further comprise a filter 235 arranged between the regulation passageway 228 and the chamber 240. Filter 235 may be arranged against the peripheral wall of central section 232 of body portion 220, on the passage of air or gas between the interior 245 of chamber 240 and the inside of regulation passageway 228. Since vial adaptor 200 may be used for extracting fluid inside vial 270 when chamber 240 is already fully shrunk or almost fully shrunk, air may pass from the outside 255 of chamber 240 to the inside of vial 270 to perform regulation. Filter 235 allows in such a case to reduce contamination risk of the content of vial 270 by such outside air.

[0124] FIG. 3 shows another vial adaptor 300.

[0125] Vial adaptor 300 comprises a body portion 320 which is inserted, for example by press-fitting or snapping, in a hollow sleeve portion 362 of a coupling portion 360. Coupling portion 360 couples a bowl 351 of a housing 350 to body portion 320. Bowl 351 comprises a regulation port 364 facing the opening of regulation passageway 328 of body portion 320. Regulation port 364 allows passage of fluid (i.e. air/gas) between regulation passageway 328 and an inside 345 of an expandable and/or contractible chamber, through filter 335. The chamber, fully expanded and not distinctly visible on the figure, is cased by housing 350, after cover 352 is coupled to bowl 351.

[0126] The chamber comprises a two-way air resistor 346 which comprises a rubber element 347 and a slit 348 formed in rubber element 347. The two-way air resistor 346 further comprises a frame 349 maintaining rubber element 347 in an airtight manner. Frame 349 may be welded to one or more membranes of the chamber.

[0127] The slit connects the interior 345 of the chamber and an exterior of the chamber, thereby allowing air to force its passage from the outside of the chamber to the interior 345 when needed (e.g. when the chamber is fully shrunk) by deflecting rubber element 347 and opening slit 348. On the other hand, when the two-way air resistor 346 is in a rest state, slit 348 is airtightly closed, thereby preventing contamination of the vial by the content of the outside environment or contamination of the outside environment by the content of the vial.

[0128] The chamber is configured for expanding inside the housing 350 until the two-way air resistor 346 is pressed against a stopping portion 356 of the housing 350. In such a circumstance, the slit 348 is prevented from being opened. In other words, when the two-way air resistor 346 and in particular its rubber element 347 is pressed against the stopping portion 356 due to the

chamber undergoing expansion, the slit 348 cannot be deflected such that air cannot pass from the interior 345 of the chamber to the outside. This increases safety of use.

[0129] The two-way air resistor 346 is positioned on the chamber membrane(s) and the stopping portion 356 is positioned on the housing 350 in a manner that when the chamber is expanded, the two-way air resistor 346 is naturally pressed against the stopping portion 356.

[0130] In examples, the stopping portion 356 comprises one or more protrusions 357 formed an inside wall of the housing 350, in particular on an inside wall of the cover 352, which cooperate with the slit 348. The protrusions create a small air trap that allow airtightness, even at the time the two-way air resistor 346 encounters the stopping portion 356.

[0131] The housing 350 comprises an aperture 354 for air communication between an interior of the housing 350 and an exterior of the housing 350. This facilitates expansion and shrinkage of the chamber. In the example of the figure, aperture 354 is located apart from the stopping portion 356.

[0132] A vial adaptor and examples thereof have been described. It will however be appreciated that variations may be contemplated by the skilled person. For example, the vial adaptor may in a variation be provided with no housing casing the chamber. Such a variation vial adaptor may comprise a body portion including a vial connection port, a syringe connection port, an access passageway between the vial connection port and the syringe connection port, and a regulation passageway. The variation vial adaptor may further comprise an expandable and/or contractible chamber comprising one or more membranes impermeable to gas and/or liquid, the regulation passageway being between the vial connection port and the chamber. And the chamber may further comprise a two-way air resistor arranged on the one or more membranes. Any element of the variation vial adaptor, such as the two-way air resistor, may be as described above, except that the variation vial adaptor comprises no housing casing the chamber. The variation vial adaptor may comprise, instead of the housing casing the chamber, either nothing or another type of protection such as rigid or semi-rigid skirt.

Claims

1. A vial adaptor (100, 200, 300) comprising:

- a body portion (120, 220, 320) including:

- a vial connection port (122, 222),
- a syringe connection port (124, 224),
- an access passageway (126, 226) between the vial connection port and the syringe connection port, and
- a regulation passageway (128, 228,

328);

- an expandable and/or contractible chamber (140, 240), comprising one or more membranes (142, 242) impermeable to gas and/or liquid, the regulation passageway being between the vial connection port and the chamber, the chamber further comprising a two-way air resistor (146, 246, 346) arranged on the one or more membranes (142, 242); and
- a housing (150, 250, 350) casing the chamber.

2. The vial adaptor of claim 1, wherein the two-way air resistor comprises a rubber element (347) and a slit (348) formed in the rubber element, the slit connecting an interior (145, 245, 345) of the chamber and an exterior (155, 255) of the chamber.
3. The vial adaptor of claim 2, wherein the two-way air resistor has a rest state in which the slit is airtightly closed.
4. The vial adaptor of claim 2 or 3, wherein the two-way air resistor further comprises a frame (349) maintaining the rubber element in an airtight manner.
5. The vial adaptor of claim 4, wherein the frame is welded to one or more membranes.
6. The vial adaptor of any one of claims 1 to 5, wherein the chamber is configured for expanding inside the housing until the two-way air resistor is pressed against a stopping portion (356) of the housing (350), the slit being prevented from being opened when the two-way air resistor is pressed against the stopping portion.
7. The vial adaptor of claim 6, wherein the housing comprises an aperture (254, 354) for fluid communication between an interior of the housing and an exterior of the housing.
8. The vial adaptor of any one of claims 1 to 7, wherein the vial adaptor further comprises a filter (235, 335) arranged between the regulation passageway and the chamber.
9. The vial adaptor of any one of claims 1 to 8, wherein the chamber is welded to an inside wall of the housing.
10. The vial adaptor of claim 9, wherein the housing comprises a bowl (251, 351) coupled to the body portion and a cover (252, 352), the chamber being welded to an inside wall of the bowl, the stopping portion being arranged on an inside wall of the cover.
11. The vial adaptor of any one of claims 1 to 10, wherein

the housing presents a generally spherical shape.

12. The vial adaptor of any one of claims 1 to 11, wherein the vial connection port defines a vial connection axis, the vial adaptor being configured for the housing to protrude in a direction transverse to the vial connection axis. 5
13. A kit comprising a sealed package which contains a vial adaptor according to any one of claims 1 to 12, the chamber being optionally substantially deflated or inflated with a volume of gas lower than a vial capacity. 10
14. The kit of claim 13, further comprising a piece of information indicating a vial capacity, the chamber being inflated with no gas or with a volume of gas lower than k_1 times the vial capacity, k_1 being equal to 1, to 0.5, or to 0.2. 15
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15. The kit of claim 14, wherein the housing presents a volume lower than k_2 times the vial capacity, k_2 being equal to 2, to 1.5, or to 1.2. 25

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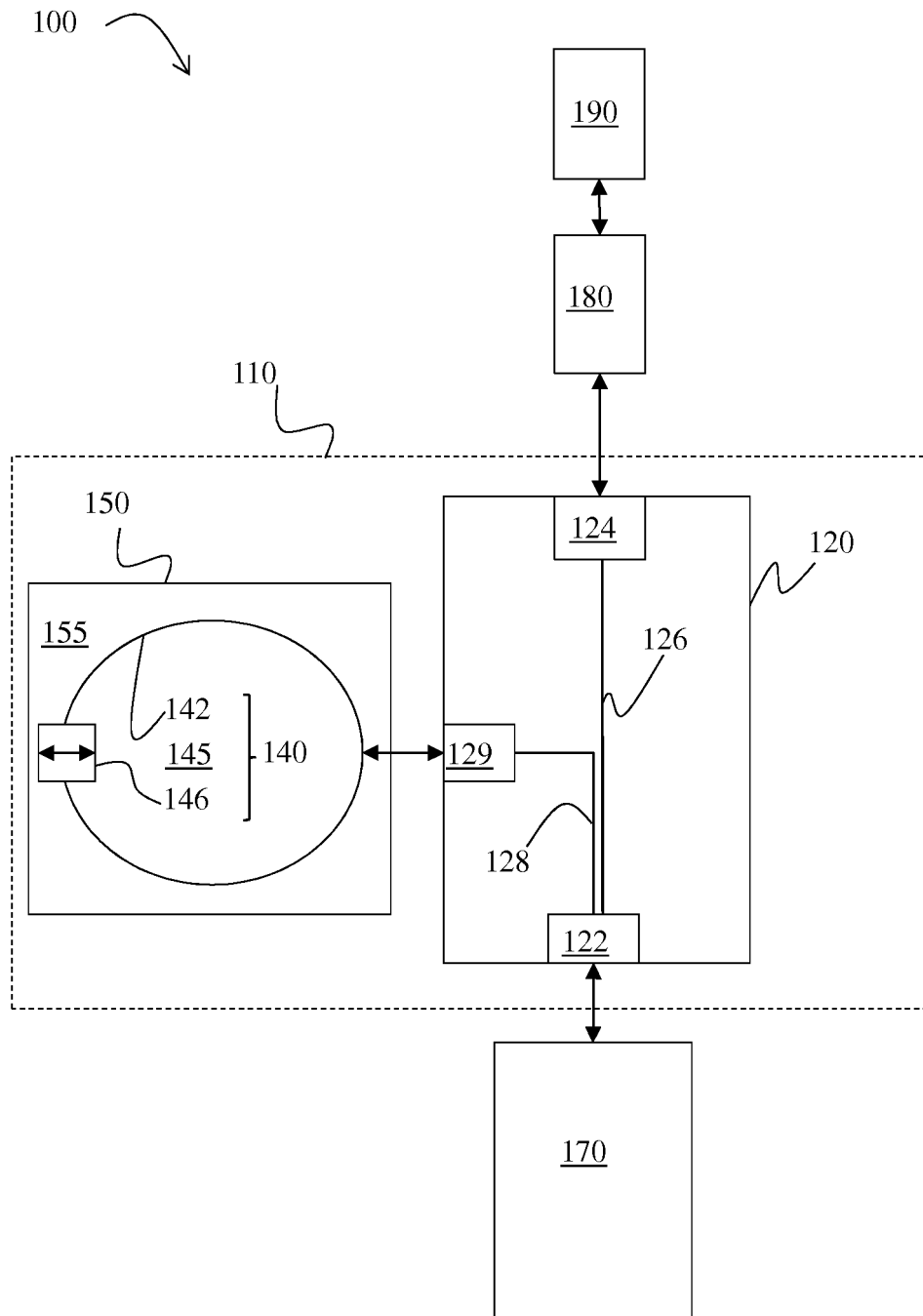


FIG. 1

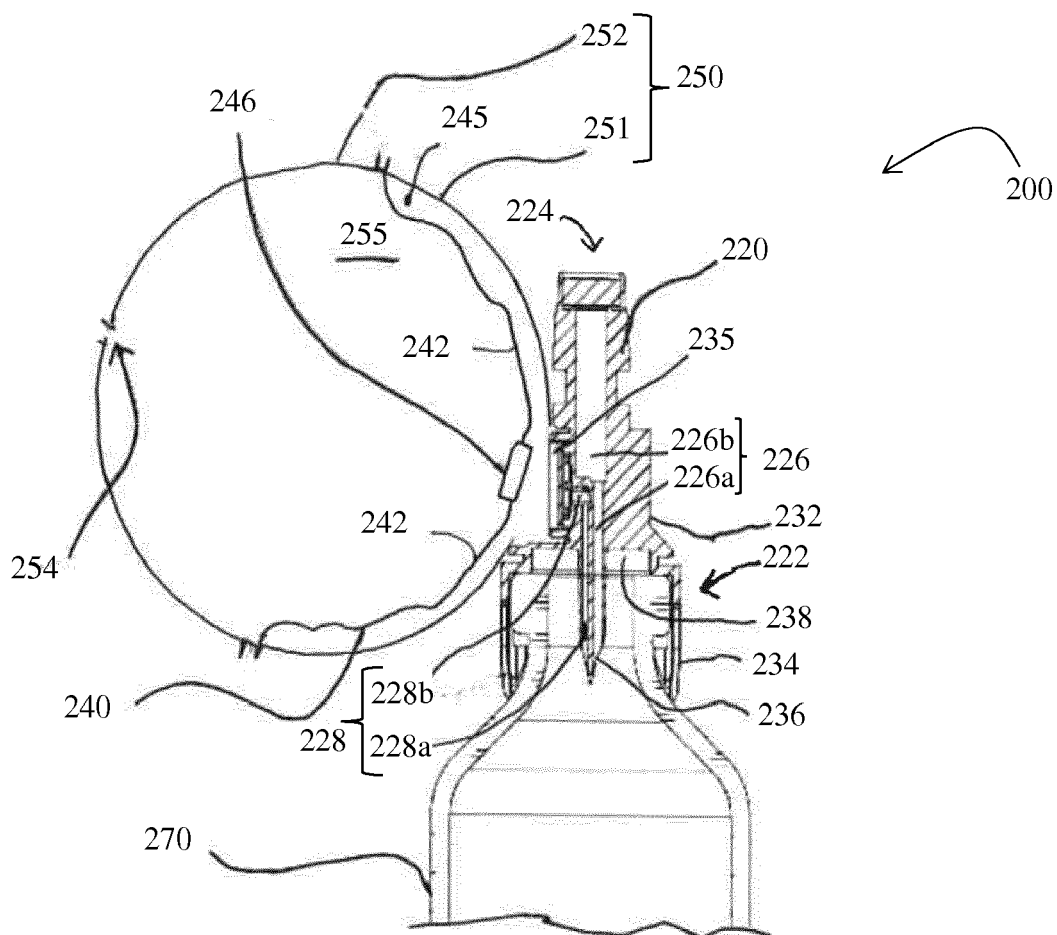


FIG. 2

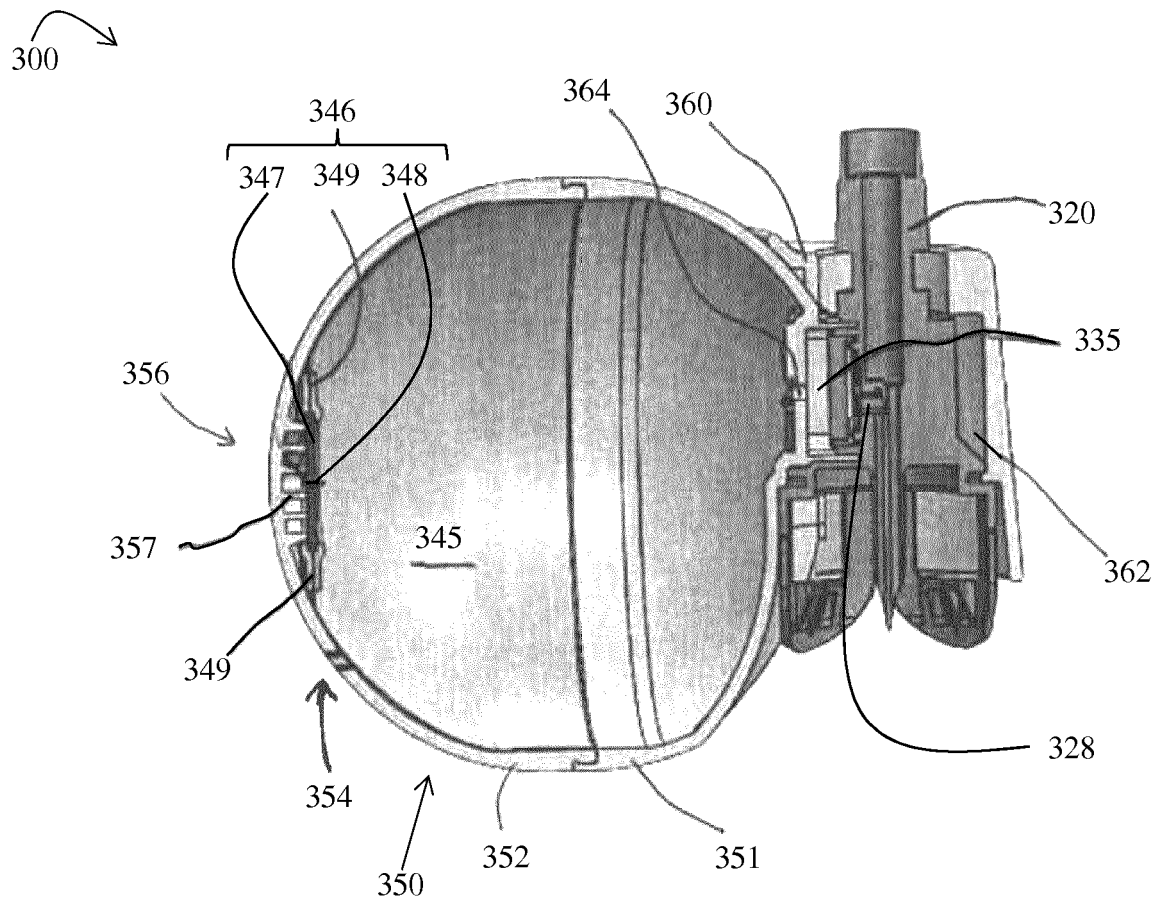


FIG. 3



EUROPEAN SEARCH REPORT

 Application Number
 EP 19 16 6447

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DOCUMENTS CONSIDERED TO BE RELEVANT			
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A	US 8 029 747 B2 (CARMEL PHARMA AB [SE]) 4 October 2011 (2011-10-04) * figures 1-3 * * column 3, line 39 - column 4, line 54 * -----	1-15	INV. A61J1/20
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			TECHNICAL FIELDS SEARCHED (IPC)
			A61J
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 4 September 2019	Examiner Koszewski, Adam
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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**ANNEX TO THE EUROPEAN SEARCH REPORT
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EP 19 16 6447

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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04-09-2019

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