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(54) **Title:** A MEDICAL CONTAINER FOR STORING A LIQUID DRUG

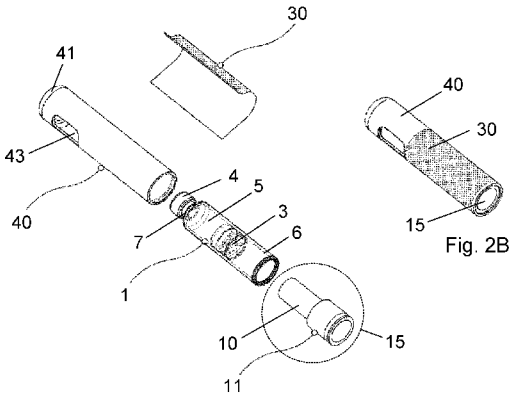


Fig. 2A

Fig. 2B

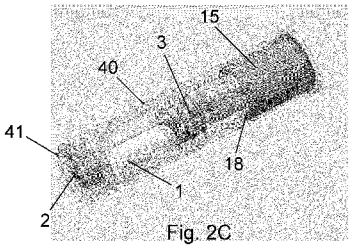


Fig. 2C

(57) **Abstract:** The invention relates to a medical container for storing a liquid drug. The medical container comprises a glass cartridge which is distally sealed by a pierceable septum and proximally sealed by a movable plunger which together defines a compartment containing the liquid drug. The medical container is further provided with means preventing the movable plunger inside the cartridge from movement in the proximal direction.

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A Medical Container for Storing a Liquid Drug

THE TECHNICAL FIELD OF THE INVENTION:

The invention relates to a medical container for storing a liquid drug and especially a medical container of the type from which a user can draw a liquid drug using an ordinary injection needle and syringe. The medical container preferably stores one single dose of the liquid drug.

DESCRIPTION OF RELATED ART:

Cartridges for liquid drugs made from glass has been known for many years. Glass is the preferred material for such medical cartridges as glass is inert to many pharmaceutical liquids. Such cartridges usually have a pierceable septum at the distal end which can be penetrated by a needle cannula. The proximal end of the glass cartridge is usually closed by a movable plunger such that the area inside the cartridge located between the septum and the movable plunger makes up a compartment containing the liquid drug. When a needle cannula is penetrated through the septum and the movable plunger is moved in the distal direction the volume of the compartment decreases as the liquid drug is pressed out through the lumen of the needle cannula.

Glass cartridges are generally used in connection with the many different injection pen system available on the market today. Usually, a cartridge is loaded into the injection pen either by the user himself or by the manufacturer of the injection pen. The injection pen being durable or pre-filled is provided with a mechanism which is able to force the plunger in the distal direction in suitable and controlled increments to thereby expel the liquid drug in precise doses.

An example of a glass cartridge containing a liquid is disclosed in US 2005/0075602. The cartridge is used in a reconstitution process and is attachable to a syringe device. The liquid inside the cartridge is sucked out from the cartridge and into a second container by a vacuum stored in the second container when the septum is pierced by

a double ended needle cannula. In one embodiment a finger-rest can be attached to the distal glass end of the cartridge. This finger-rest can serve to block the piston of the cartridge rearwards to prevent the piston from being extracted from the cartridge.

An alternative way to inject liquid drug is to use an ordinary syringe in combination with an injection needle. The user thus draws the liquid drug to be injected from a vial and into the syringe by moving the plunger rod and the plunger of the syringe in the proximal direction. A vial is typically a glass container with a compartment having a fixed and permanent volume and where the distal end is provided with a pierceable septum through which the user penetrates the needle cannula and draws the liquid drug into the syringe. In order to draw the liquid drug from the vial, the user first needs to blow air into the vial to create an over-pressure inside the vial. Only after having created such over-pressure inside the vial will it be possible to draw liquid drug from the vial. The air is typically blown into the cartridge from the syringe once the needle cannula has penetrated through the septum.

Vials for liquid drugs are highly standardized and usually contains a relatively high volume of liquid drug. A volume of 10 ml seems to be the standard. Further, vials often contain a larger volume of air which can impact drug stability. It would henceforth be desirable if cartridges could be used as vials. This is especially desirable for very specialized liquid drugs. For some specialized drugs the time between each injection can be relatively long e.g. one week, one month or even longer. For such liquid drugs it would be desirable if the drug was delivered to the user with only one shot per container and with as little air as possible, however, for such use standardized vials are not particular suitable.

Hence it would be desirable if a cartridge could be used as a vial. However, a drawback would be that a user which habitually uses a vial could accidentally blow air into the cartridge which would course the plunger to move in the proximal direction. This is undesirable as the plunger would move into a non-sterile part of the cartridge or even pop out of the cartridge.

DESCRIPTION OF THE INVENTION:

It is henceforth an object of the present invention to provide a solution which makes it possible to use a cartridge as a vial such that a user can draw the liquid drug from the cartridge using a standard syringe.

When using a cartridge as a vial it would hence be possible to fill only one single dose of the liquid drug into a cartridge as the movable piston or plunger inside the cartridge can be positioned to accommodate any filling level. Further, it would be possible to fill a cartridge with liquid drug with less air ending up in the cartridge due to the variable volume created by the movable plunger.

In one example, the liquid drug contained in the glass cartridge does not contain any preservatives which often are preferred for single dose injectors. Consequently, when the volume in the cartridge is reduced to only accommodate one single dose, the patient safety is improved as the user does not have the option to use potentially contaminated drug to perform a second dose.

The invention is defined in claim 1. Advantageous embodiments are further defined in the dependent claims.

Accordingly, in one aspect of the present invention, a prefilled single use medical container is provided which comprises a glass cartridge being distally sealed by a pierceable septum and proximal sealed by a movable plunger defining a compartment containing the liquid drug. The volume of liquid drug stored in the compartment is preferably sufficient for only one single shot or one dose.

The medical container is hence for single use and is discarded after one use only. The single shot or dose stored in the medical container is prefilled into the medical container by the manufacturer of the medical container.

The compartment of the glass cartridge has a longitudinal section transforming into a distal neck section and the movable plunger inside the compartment is axially movable within the longitudinal section of the compartment and the longitudinal section has an inner diameter and an outer diameter.

According to the invention, the longitudinal section of the glass cartridge is proximally provided with a spacer element made from one or more elements and having a distal stop surface. The spacer element is preferably entirely surrounded by the glass cartridge and fixated relatively to the cartridge to prevent the plunger from movement in the proximal direction when the movable plunger abuts the stop surface.

The prefilled volume in the glass cartridge and the position of the stop surface of the spacer element is made such that the movable plunger abuts i.e. is in physical contact with the stop surface of the spacer element when the medical container is delivered to the end user. Thus, it is not possible for the user to move the plunger in the proximal direction as only movement of the plunger in the distal direction is allowed for.

The spacer element can thus be any physical element which can be located inside the cartridge and secured relatively to the glass cartridge such that movement of the plunger in the proximal direction is prevented. The spacer element thus only allows distal movement of the plunger further into the sterile area of the cartridge thereby keeping the plunger away from the non-sterile area of the glass cartridge. When extracting the liquid drug into the syringe it is thus not necessary to blow air into the glass cartridge prior to drawing liquid drug from the glass cartridge as the plunger is able to move in the distal direction.

When the spacer element is physically located inside the parameters of the glass cartridge, no elements need to be provided outside the glass cartridge and a very slim and functional solution is thus provided.

A multitude of different spacer elements for preventing the plunger from movement in the proximal direction can be envisaged. In one example the spacer element is a separate spacer element inserted into the glass cartridge to abut the movable plunger and secured to prevent proximal movement of the movable plunger. Alternatively, the spacer element can be formed from any number of separate elements which together forms the spacer element. In one example the spacer element is secured to the cartridge by a tape or the like adhered to the cartridge such that the spacer element and the tape together prevents proximal movement of the plunger.

In a further example the spacer element is a liquid substance which can be poured into the non-sterile area of the cartridge and hardened to thereby prevent proximal movement of the movable plunger. When the liquid substances harden it adheres to the inside surface of the glass cartridge, however, proximal movement of the harden spacer can be prevented by securing the harden spacer using tape or the like as described above. In one example, the liquid substance is a suitable silicone material. The liquid substance could fill the entire space proximally to the plunger or just a minor area as long as the hardened substance prevents the movable plunger from movement in the proximal direction. In order to make sure the movable plunger is not adhered to the liquid substance a small disc e.g. made from a suitable polymer can be located between the movable plunger and the liquid substance.

A major benefit of using the above cartridge as a vial is that the position of the plunger can be any random position and preferably a position such that only one single dose is available in the cartridge. The position of the plunger is determined by the length of the spacer element. By optimizing the length of the cartridge and the length of the spacer element, the medical container can be produced from a minimum of materials to exactly accommodate the dose volume wanted.

In a second embodiment the medical container comprises a polymeric housing or shell which partly or fully surrounds the glass cartridge. Seen in a cross-sectional view, the polymer housing surrounds the cartridge on the full outer circular surface or less meaning that the polymer housing does not necessarily cover the full 360° of the

glass cartridge but could cover the cartridge on less than 360°. The polymer housing could e.g. be provided with an opening or a window allowing the user to inspect the liquid drug inside the cartridge. Further, the polymer housing need not cover the cartridge in the full lengthwise direction. The cartridge could thus be longer than the polymer housing. Any combination of covering the cartridge in the cross-sectional direction or the lengthwise direction can be envisaged.

The polymeric housing is preferably injection moulded in a mould using a suitable polymer and the cartridge is thereafter inserted into the polymer housing. Alternatively, the polymer housing is moulded directly onto the cartridge. In both examples, the polymer housing protects the vulnerable glass cartridge from breakage should the user drop the medical container onto a hard surface like a furniture surface or a floor.

The polymeric housing of the medical container defines a distal end and a proximal end. The cartridge is preferably inserted between the distal end and the proximal end. The distal end preferably has an opening with a diameter smaller than the outer diameter of the glass cartridge and through which opening a needle cannula can be inserted into the glass cartridge.

The glass cartridge is preferably secured within the polymeric housing such that the pierceable septum is positioned in the close proximity of the distal opening in the polymeric housing making the pierceable septum reachable for a needle cannula.

The spacer element inside the polymer housing is in one example held in place by a closing element which is connected to the polymeric housing such that the spacer element is secured between the movable plunger in the glass cartridge and the closing element. In one example, the closing element is click-fitted to the polymer housing however many other ways of securing the closing element to the polymer housing can be envisaged. In one example the closing element is glued or welded to the polymer housing.

Both the spacer element and the closing element are preferable also produced from a suitable polymer. Both the spacer element and the closing element are preferably produced by injection moulding. The spacer element preferably has a length to exactly fill out the longitudinal distance of the glass cartridge being proximal to the plunger. In one example, the spacer element can be a soft element or comprise at least a soft area such that a little force is applied onto the plunger when the spacer element is secured inside the cartridge by the closing element. Such softer area is also better suitable for absorbing tolerances in the parts making up the medical container. The softer area can e.g. be moulded as a part of the spacer element using a 2K moulding technic. In a further example the soft area can be a separate soft part which is thus to be understood as a part of the spacer element.

It has shown that connecting elements to a glass surface of a cartridge as e.g. described in US 2005/0075602 is rather difficult especially as a glass cartridge has no natural physical fixation points. Usually, glass cartridges are greased on the inside with a silicone oil to make the plunger slide better inside the cartridge. This so-called siliconization usually takes place during manufacture and/or filling of the cartridge. However, the presence of silicone oils in the production and on the glass cartridge makes it difficult to glue objects to the cartridge. One solution could hence be to encapsulate the glass cartridge inside a polymer shell and secure the spacer element relatively to the polymer shell, such that the process of gluing can be eliminated. From a manufacturing viewpoint this solution is to be preferred as it avoids the use of glue and is very simple to use in large scale production. Once the polymeric shell and the closing element has been moulded in the correct physical dimension to accommodate the volume of liquid drug wanted in the glass cartridge (defined by the position of the plunger inside the cartridge) they just need to be assembled around the cartridge to thereby form a single medical container.

To further add to the simplicity, the spacer element and the closing element can be formed as one unitary stopper element. This unitary stopper element thus abuts the plunger at its distal end and is oppositely irreversible secured to the polymer housing e.g. by a click-fit or an alternative lock. As for the spacer element, such unitary stop-

per element is injection moulded from a suitable polymer and can also have a soft area as explained.

The unitary stopper element can also be provided with a flange or the like supporting the proximal end of the glass cartridge.

In a further example, the polymeric housing is provided with radial bearings for supporting the glass cartridge. In such example, the polymer housing can be shaped as a traditional vial, and the radial bearings on the inner surface can abut and hold the cartridge in the center of the polymer housing. In this example, the medical container has the appearance of a traditional vial and it works as a traditional vial. The user can insert the needle cannula through the distal opening of the polymer housing and through the septum of the cartridge. Once the needle cannula is inserted into the cartridge, the user can draw the liquid drug from the medical container either by blowing air into the cartridge or not.

The polymeric housing is in one example provided with a radial end surface securing the cartridge in the distal direction. Alternatively, the polymer housing is provided with a support surface being substantially parallel to the centre axis of the glass cartridge and secures the cartridge by supporting the shoulders of the cartridge.

In order to provide a medical container which can be placed on a surface such as a table or the like, the closing element or the stopper element is provided with a relatively large support surface being substantially perpendicular to the centre axis of the glass cartridge. By having such “Elephant foot” shaped bottom, the medical container can be placed on a table or the like without tilting when the user inserts the needle cannula through the distal opening and into the cartridge.

When lying on a table, the medical container can be prevented from rolling on the table surface by having an area with a non-circular cross section. This non-circular area can be provided in the polymer housing and/or in the closing element or the stopper element.

To prevent dirt and dust from entering the medical container, the medical container is provided with a removable cap which in one example covers the distal opening of the polymer housing.

DEFINITIONS:

An **"injection pen"** or **"Pen for Injection"** is typically an injection apparatus having an oblong or elongated shape somewhat like a pen for writing. Although such pens usually have a tubular cross-section, they could easily have a different cross-section such as triangular, rectangular or square or any variation around these or other geometries.

A **"Syringe"** usually also has an oblong or elongated shape. Syringes usually comprises a barrel into which the liquid drug is sucked by rearwards movement of a plunger rod connected to a plunger movable within the barrel. During expelling, the plunger rod and the plunger are moved in the opposite direction and into the barrel such that the liquid drug in the barrel is pressed out through a needle cannula connected to the barrel.

The term **"Needle Cannula"** is used to describe the actual conduit performing the penetration of the skin during injection. A needle cannula is usually made from a metallic material such as e.g. stainless steel and preferably connected to a hub made from a suitable material e.g. a polymer. A needle cannula could however also be made from a polymeric material or a glass material. The needle cannula mounted in the hub and referred to as the injection needle or the needle assembly can either be exchangeable or permanently attached to the injection device. A special needle assembly is the so-called **"Pen Needle"** wherein a part of the needle cannula extend in the proximal direction from the hub such that this proximal part can penetrate into the cartridge once the pen needle is attached to the injection device.

As used herein, the term **"Liquid drug"** is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle cannula in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs could include pharmaceuticals such as peptides, proteins (e.g. insulin, insulin analogues and C-peptide), and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form.

"Cartridge" is the term used to describe the primary container actually containing the liquid drug. Cartridges are usually made from glass e.g. borosilicate glass which is highly inert to most liquids but could alternatively be moulded from any suitable polymer. A cartridge or ampoule is preferably sealed at one end by a pierceable membrane referred to as the **"septum"** which can be pierced e.g. by the non-patient end of a needle cannula. Such septum is usually self-sealing which means that the opening created during penetration seals automatically by the inherent resiliency after the needle cannula has been removed from the septum. The opposite end of the cartridge is typically closed by a movable **"plunger or piston"** made from a rubber composition or a suitable polymer. The space between the pierceable membrane and the movable plunger forms the compartment holding the liquid drug. The plunger or piston can be slidable moved inside the compartment of the cartridge, preferably in the distal direction, to thereby decrease the volume of the compartment of the cartridge and to press the liquid drug out through a needle cannula pierced through the septum.

Since a cartridge usually has a narrower distal neck portion into which the plunger cannot be moved not all of the liquid drug contained inside the cartridge can actually be expelled. The term **"initial quantum"** or **"substantially used"** therefore refers to the injectable content contained in the cartridge and thus not necessarily to the entire content.

The term **"permanently connected"** or **"irreversible secured"** as used herein is intended to mean that the parts is permanently secured to each other and requires

the use of tools or the like in order to be separated and should the parts be separated there would be a permanently damage to at least one of the parts thus rendering the assembly unable to operate according to the intentions.

All references, including publications, patent applications, and patents, cited herein are incorporated by reference in their entirety and to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

All headings and sub-headings are used herein for convenience only and should not be constructed as limiting the invention in any way.

The use of any and all examples, or exemplary language (e.g. such as) provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

The citation and incorporation of patent documents herein is done for convenience only and does not reflect any view of the validity, patentability, and/or enforceability of such patent documents.

This invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law.

BRIEF DESCRIPTION OF THE DRAWINGS:

The invention will be explained more fully below in connection with a preferred embodiment and with reference to the drawings in which:

Figure 1A-B-C show an exploded view of a first embodiment of the invention.

Figure 2A show an exploded view of a second embodiment of the invention in which the medical container comprises an outer polymeric housing.

Figure 2B-C show perspective views of the medical container according to the second embodiment.

Figure 3A-B show exploded views of the second embodiment of the invention with an alternative stopper element.

Figure 4A-B show cut-through views of medical containers according to the second embodiment shaped as traditional vials.

Figure 5 show an alternative entry opening of the polymeric housing of the second embodiment of the invention.

Figure 6A-B show different examples of a cover for the medical container according to the invention.

Figure 7 show examples of different cross sections of the polymeric housing or the unitary stopper element of the second embodiment of the invention.

The figures are schematic and simplified for clarity, and they just show details, which are essential to the understanding of the invention, while other details are intentionally left out. Throughout the examples, the same reference numerals are used for identical or corresponding parts.

DETAILED DESCRIPTION OF EMBODIMENT:

When in the following terms as “upper” and “lower”, “right” and “left”, “horizontal” and “vertical”, “clockwise” and “counter-clockwise” or similar relative expressions are used, these only refer to the appended figures and not necessarily to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as their relative dimensions are intended to serve illustrative purposes only.

In that context it may be convenient to define that the term “distal end” in the appended figures is meant to refer to the end of the medical container to be pierced by the needle cannula, whereas the term “proximal end” is meant to refer to the opposite end usually carrying the movable plunger as depicted in figure 1A. Distal and proximal is meant to be along an axial orientation extending along the longitudinal axis (X) of the medical container as also shown in figure 1A.

First embodiment:

Figure 1A-B-C discloses a glass cartridge 1 which distally is sealed with a pieceable septum 2 and distally closed with a movable plunger 3. In figure 1A, the movable plunger 3 is shown in perspective with its outer contour being visible. The space 5 inside the cartridge 1 which axially is defined between the proximal surface of the septum 2 and the distal surface of the movable plunger 3 is filled with the liquid drug.

The cartridge 1 comprises a longitudinal section 6 in which the movable plunger 3 is movable. Distally this longitudinal section 6 terminates into a neck portion 7 against which the septum 2 is sealed. The interior of this neck portion 7 has a smaller diameter than the longitudinal section 6 as best seen in figure 1A with the result that the movable plunger 3 cannot be moved into this neck portion 7. The cartridge 1 has its largest inner diameter (d) and its largest outer diameter (D) at the longitudinal section 6.

During the filling process, the inside of the cartridge 1 is sterilized. Usually both the filling and the sterilization occurs from the distal end of the cartridge 1. Once the cartridge 1 is filled with the wanted quantum of liquid drug, the septum 2 is sealed to the distal end of the neck section 7 of the cartridge 1 by a metal band 4 (a so-called crimp cap) which is preferably rolled onto the glass cartridge 1 and bended around the neck section 7 of the cartridge 1.

The part of the cartridge 1 being proximal to the movable plunger 3 is hence not sterile as it is exposed to the surroundings. In order to prevent the movable plunger 3 from moving in the proximal direction and into the not-sterile part of the cartridge 1, a spacer element 10 is positioned inside the cartridge 1 and secured to the cartridge 1. In the embodiment disclosed in figure 1A-B-C, the spacer element 10 is secured by a tape 20 adhering to the outer surface of the cartridge 1 however many alternative ways of securing the spacer element 10 exist. In one alternative example, the spacer element 10 can be glued directly to the cartridge 1.

The tape 20 is preferably a polymeric tape which is adhered to the outer surface cartridge 1 using a suitable glue.

The spacer element 10 can in one example be slightly resilient at least at the distal end such that it applies a minor bias onto the movable plunger 3 in the distal direction.

Once the spacer element 10 has been inserted into the proximal end of the cartridge 1 and secured to the cartridge 1 e.g. as disclosed in figure 1B, a label 30 can be adhered to the cartridge 1. The label 30 further secures the tape 20 to the cartridge 1.

The cartridge 1 with the spacer element 10 inserted and attached is in this first embodiment referred to as the medical container.

In one example of the spacer element 10, a liquid substance can be poured into the proximal opening of the cartridge 1 and hardened such that the substance makes up a plug-like structure or spacer element preventing the movable plunger 3 from moving in the proximal direction. In one example a silicone material can be used. However, any material which can be poured into the cartridge 1 in a liquid form and thereafter be hardened to form a plug-like structure and attach to the cartridge 1 such that it prevent the movable plunger 3 from moving proximally would be usable.

The spacer element 10 is preferably located in the longitudinal section 6 of the cartridge 1 and is provided with a distal surface 12 such that the movement of the movable plunger 3 in the proximal direction is limited by the physical position of the distal surface 12 of the spacer element 10.

Second embodiment:

A second embodiment is disclosed in **figure 2A-C**. In this embodiment, the cartridge 1 is inserted into a polymer housing or shell 40 which is moulded from a suitable polymer. In the specific example, the polymer shell 40 has the same geometrical shape as the cartridge 1 but it can have any shape wanted. Alternatively, the polymer shell 40 can be moulded around the cartridge 1. The essence is that the cartridge 1 is contained inside the polymer shell 40 hence physically protecting the vulnerable glass making up the cartridge 1.

Distally the polymer shell 40 is provided with an end surface 41 having an opening 42 as also seen in **figure 4A-B** such that a needle cannula 50 can be penetrated through the septum 2 of the cartridge 1 while the cartridge 1 is maintained inside the polymeric shell 40. Near the distal end of the polymer shell 10, a window 43 is provided such that a user can inspect the content of the cartridge 1 inside the polymeric shell 40.

Proximally, a spacer element 10 is inserted into the cartridge 1. This spacer element 10 can in one example be a separate element which fits into the longitudinal section 6 of the cartridge 1 and is held in place by a closing element 11 which is connected to the polymeric shell 40 by a click-fit or the like.

In a different example of the second embodiment, the spacer element 10 and the closing element 11 can be moulded as one unitary stopper element 15 as e.g. indicated with a punctured circle in figure 2. This unitary stopper element 15 can be attached to the polymeric shell 40 in a multitude of different ways. It can be welded to the polymer shell 40, it can be glued, it can be click-fitted as shown in the figures 4A-B or connected in any alternative way.

The polymer housing or shell 40 with the cartridge 1 and the unitary stopper element 15 connected or alternatively the spacer element 10 and the closing element 11 connected is in this second embodiment referred to as the medical container and is depicted in figure 2B and in figure 2C.

In figure 2C, the polymeric shell 40 is depicted as transparent but it can have any wanted colour.

The polymer shell 40 and the total length of the unitary stopper element 15 are preferably correlated such that the movable plunger 3 inside the cartridge 1 is prevented from movement in the proximal direction once the unitary stopper element 15 has been connected to the polymeric shell 40. If a small force is wanted to be executed onto the movable plunger 3, a part of the unitary stopper element 15 can be made resilient e.g. in a 2K moulding process such that e.g. the distal end of the stopper element 15 is made from a softer material.

As in the first embodiment, a label 30 is adhered to the polymeric shell 40 as disclosed in figure 2B. Such label 30 preferably carries information regarding the liquid drug inside the cartridge 1.

Figure 2C discloses the medical container just as the unitary stopper element 15 is clicked into engagement with the polymer shell 40. Once the unitary stopper element 15 is fully connected to the polymer shell 40, the distal end of the unitary stopper element 15 will abut the movable plunger 3 inside the cartridge 1. The unitary stopper element 15 is in this example provided with a recess 18 which supports the proximal end of the cartridge 1.

As disclosed in **figure 3A-B**, the stopper element 15 can at the proximal end terminate into a bottom surface 16 which in the disclosed embodiment is significantly larger that the remaining part of the stopper element 15. This “elephant foot” shape makes the medical container more stable when standing on a surface such as a table

or the like. The user can then position the medical container on a table surface while inserting the needle cannula 50 through the opening 42 in the polymer shell 40 and through the distal septum 2 of the cartridge 1 inside the polymer shell 10.

An alternative medical container is disclosed in figure 4A. In this example of the second embodiment, the outer diameter of the polymer shell 40 is significantly larger than the outer diameter (D) of the cartridge 1 and the inner surface of the polymer shell 40 is provided with a number of inwardly pointing ribs 45. Distally the end surface 41 of the polymer shell 40 prevents the cartridge 1 from movement in the distal direction such that the cartridge 1 is embedded between the distal end surface 41 of the polymer shell 40 and the unitary stopper element 15 (or alternatively the spacer element 10 secured by the closing element 11).

As also seen in figure 4A, the unitary stopper element 15 is provided with click arms 17 which connects to the polymer shell 40. Further, the distal end of the unitary stopper element 15 abut the movable plunger 3 which is henceforth prevented from travelling further in the proximal direction.

As an alternative to having inwardly pointing ribs 45, the polymeric shell 40 can be moulded with an internal support surface 46 which supports the neck section 7 of the cartridge 1 and surrounds the opening 42 as disclosed in figure 4B. This support surface 46 is further provided with an inner neck 47 such that the cartridge 1 is held axially in place between the inner neck 47 and the unitary stopper element 15.

Figure 5 discloses an alternative example of the distal end surface 41 of the polymer shell 40. In this example, the distal end surface 41 is distally provided with a concave area 44 which surrounds the opening 42 and helps to guide the needle cannula 50 into the septum 2 of the cartridge 1.

Preferably, the opening 42 at the distal end is covered by a removable cover 60 when the medical container is delivered to the user. In one example disclosed in **figure 6A**, the removable cover 60 is attached to the cartridge 1 by having a plurality of

flexible arms 61 engage the metal band 4 of the cartridge 1. In a different example disclosed in **figure 6B**, the flexible arms 61 engage around the polymer shell 40.

In order to prevent the medical container from rolling when laying on a surface, either the polymer shell 40 and/or the stopper element 15 can be provided with a non-circular cross section as disclosed in **figure 7**.

Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these but may be embodied in other ways within the subject matter defined in the following claims.

CLAIMS:

1. A medical container for one single dose of a liquid drug comprising:

A glass cartridge (1) having a centre axis (X) and being distally sealed by a pierceable septum (2) and proximally sealed by a movable plunger (3) defining a compartment (5) containing the liquid drug,

Wherein the compartment (5) of the glass cartridge (1) has a longitudinal section (6) transforming into a distal neck section (7) and wherein the movable plunger (3) is axially movable within the longitudinal section (6) of the compartment (5) and which longitudinal section (6) has an inner diameter (d) and an outer diameter (D),

and wherein the longitudinal section (6) of the glass cartridge (1) proximally is provided with a spacer element (10) having a distal stop surface (12) and which spacer element (10) is fixated relatively to the glass cartridge (1) to prevent the plunger (3) from movement in the proximal direction when the movable plunger (3) abuts the stop surface (12).

2. A medical container according to claim 1, wherein a polymeric housing (40) surrounds the glass cartridge (1).

3. A medical container according to claim 2, wherein the polymeric housing (40) defines a distal end and a proximal end and wherein the distal end has a distal end surface (41) provided with a distal opening (42).

4. A medical container according to claim 3, wherein the distal opening (42) has a diameter smaller than the outer dimeter (D) of the glass cartridge (1)

5. A medical container according to claim 3 or 4, wherein the glass cartridge (1) is secured within the polymeric housing (40) such that the pierceable septum (2) is po-

sitioned in the proximity of the distal opening (42) in the polymeric housing (40) making the pierceable septum (2) reachable for a needle cannula (50).

6. A medical container according to any of the claims 2 to 5, wherein the proximal end of the polymeric housing (40) is provided with a closing element (11) connected to the polymeric housing (40) such that the spacer element (10) is prevented from proximal movement when abutting the closing element (11).

7. A medical container according to claim 6, wherein the spacer element (10) and the closing element (11) together makes up one unitary stopper element (15).

8. A medical container according to any of the 7, wherein the unitary stopper element (15) is secured to the polymeric housing (40).

9. A medical container according to any of the claims 2 to 8, wherein the polymeric housing (40) is provided with radial bearings (45) for supporting the glass cartridge (1).

10. A medical container according to any of the claims 2 to 9, wherein the polymeric housing (40) is provided with a support surface (46) being substantially parallel to the centre axis (X) of the glass cartridge (1).

11. A medical container according to any of the claims 8 to 10, wherein the unitary stopper element (15) is provided with a bottom surface (16) being substantially perpendicular to the centre axis (X) of the glass cartridge (1).

12. A medical container according to any of the claims 8 to 11, wherein the polymeric housing (40) or the unitary stopper element (15) at least in one axial position has a non-circular cross section.

13. A medical container according to any of the previous claims, wherein the medical container distally is provided with a removable cap (60).

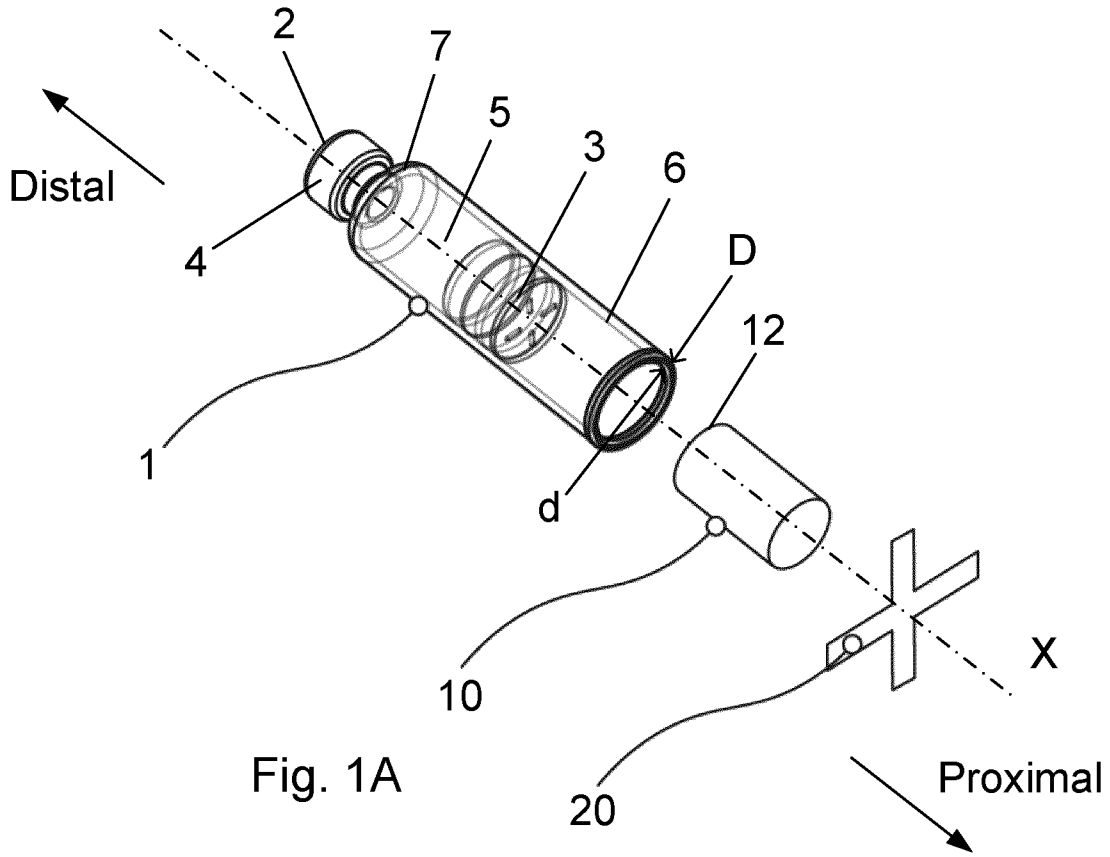


Fig. 1A

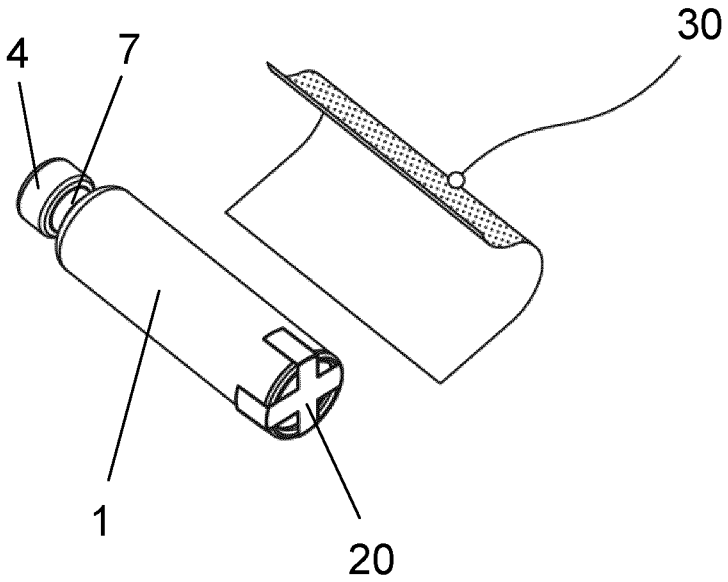


Fig. 1B

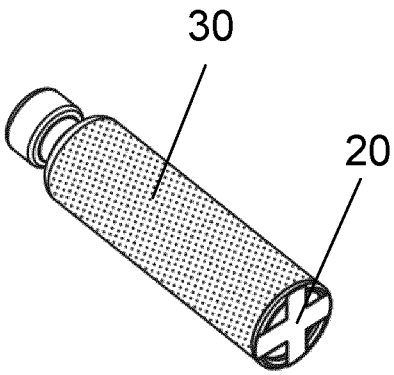


Fig. 1C

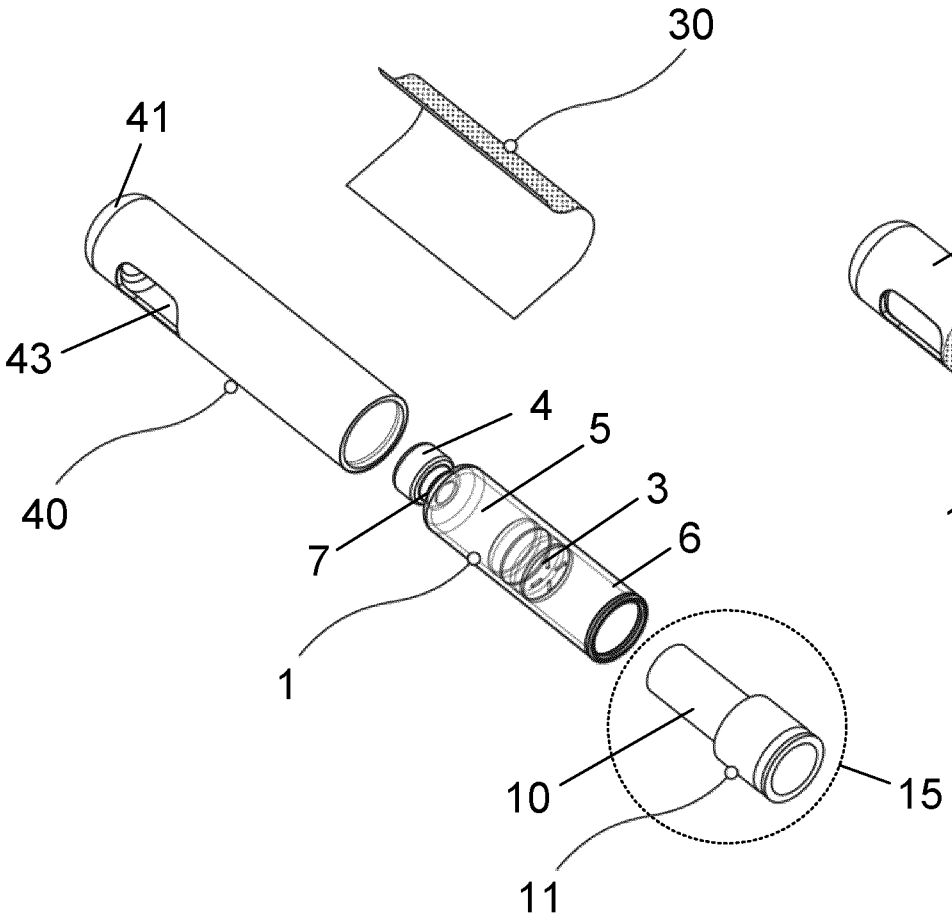


Fig. 2A

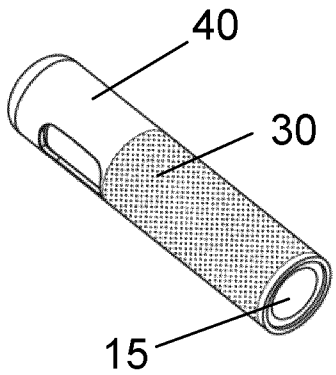


Fig. 2B

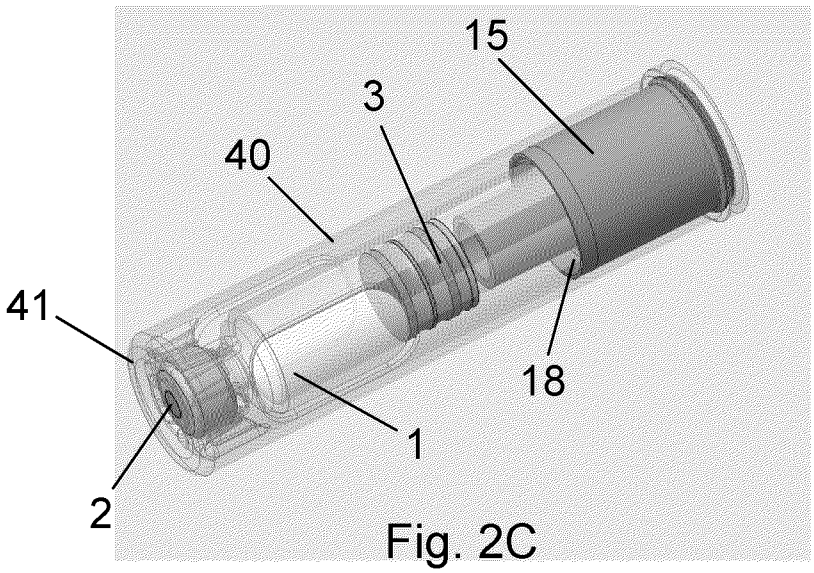


Fig. 2C

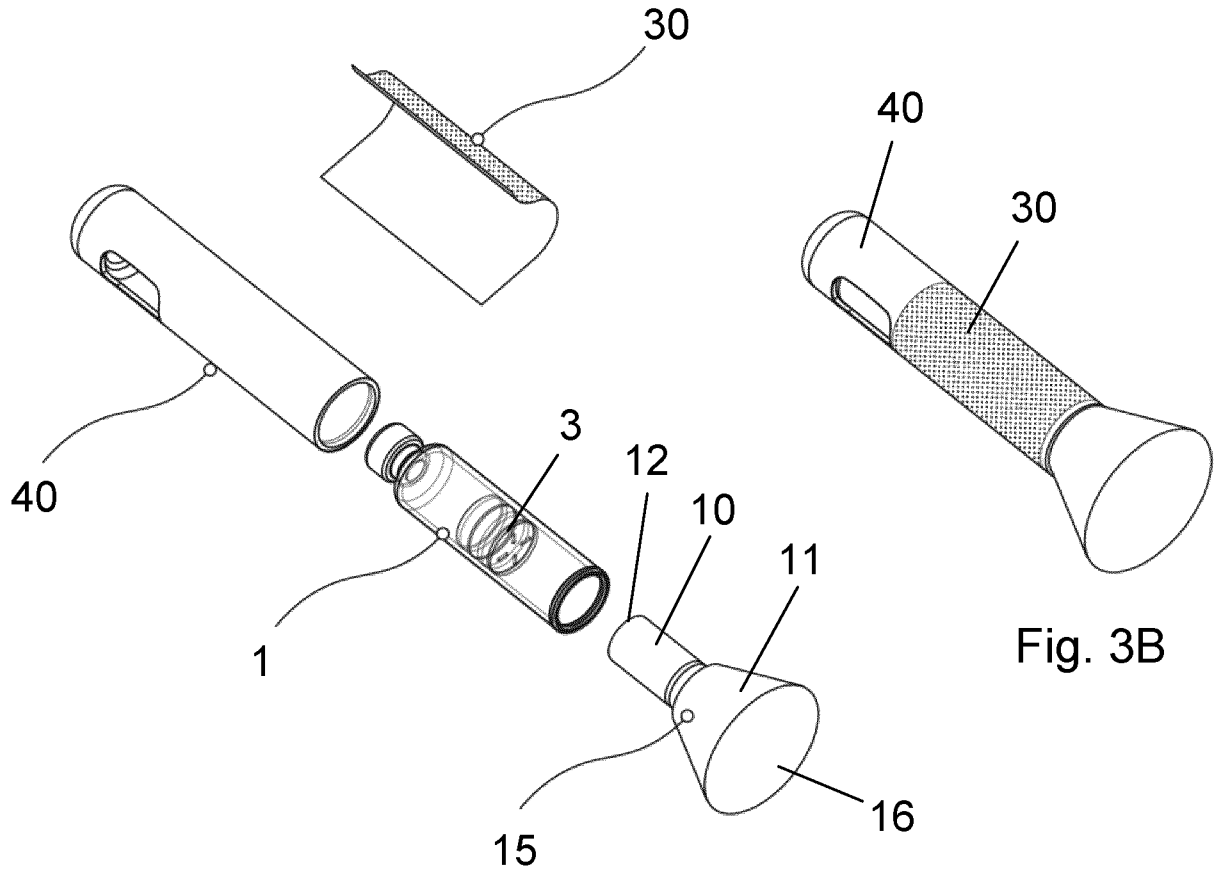


Fig. 3A

Fig. 3B

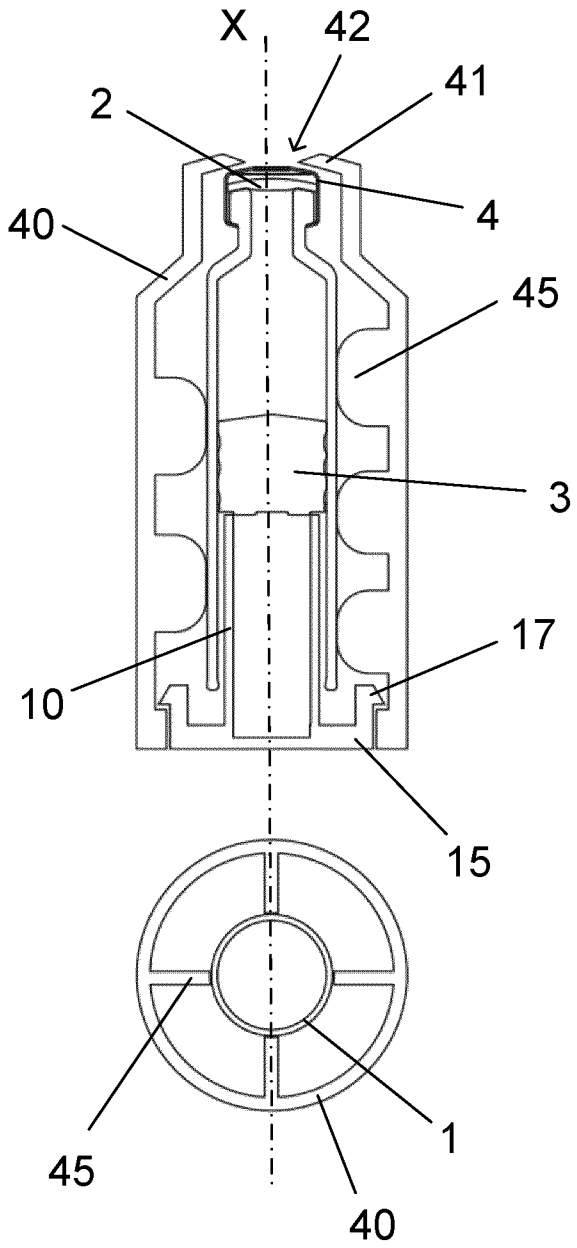


Fig. 4A

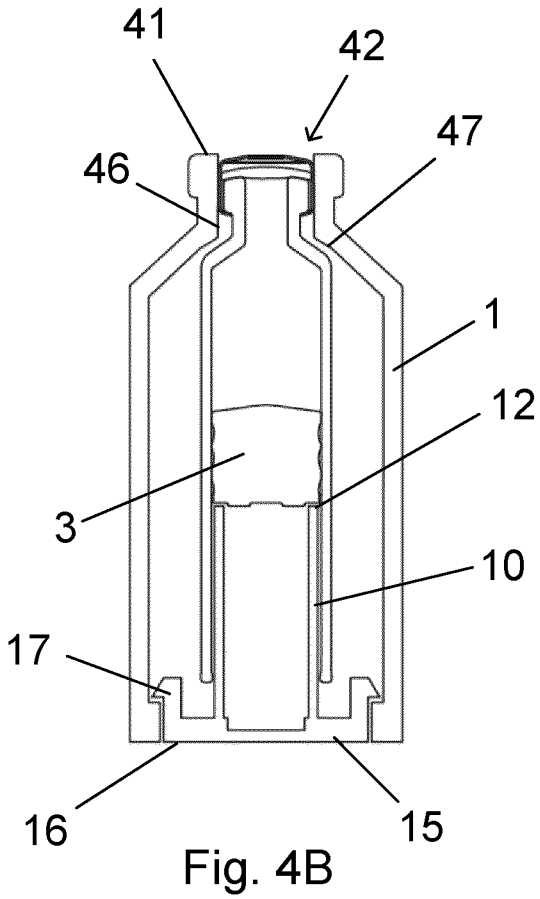
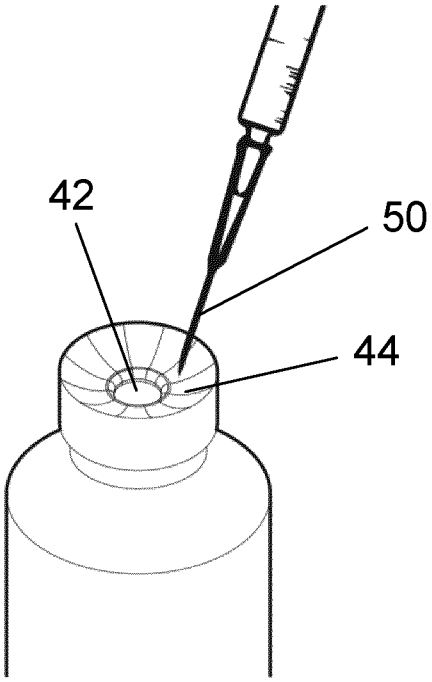


Fig. 4B



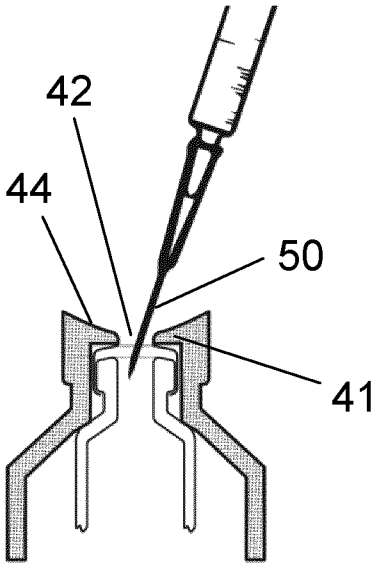


Fig. 5

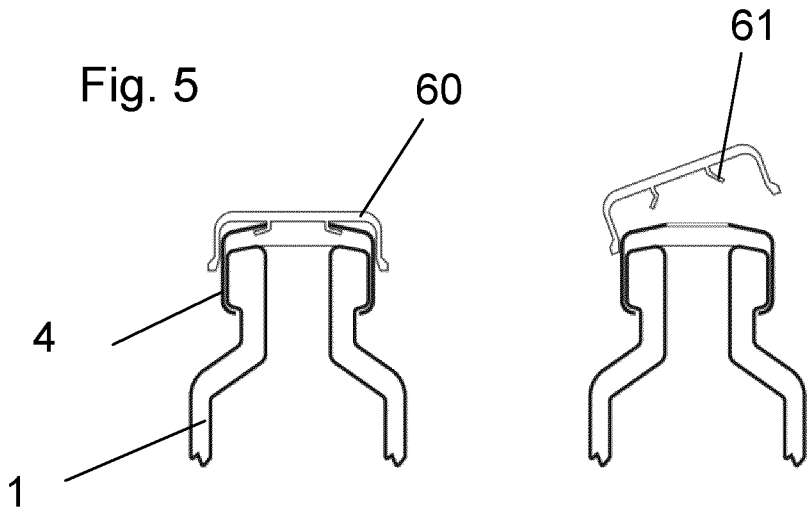


Fig. 6A

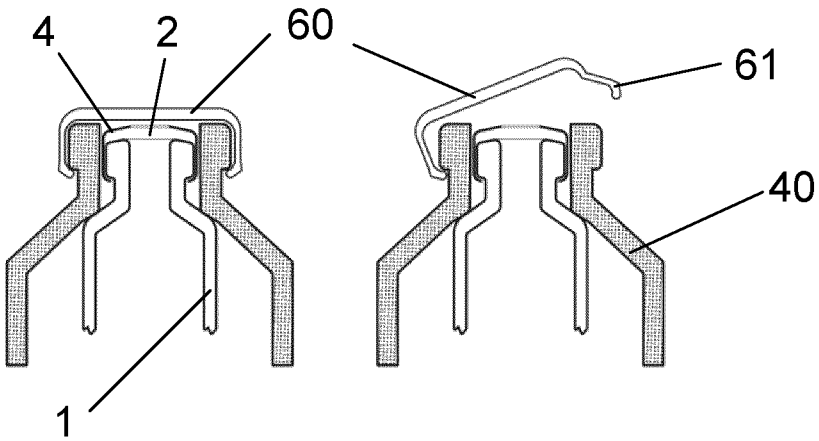


Fig. 6B

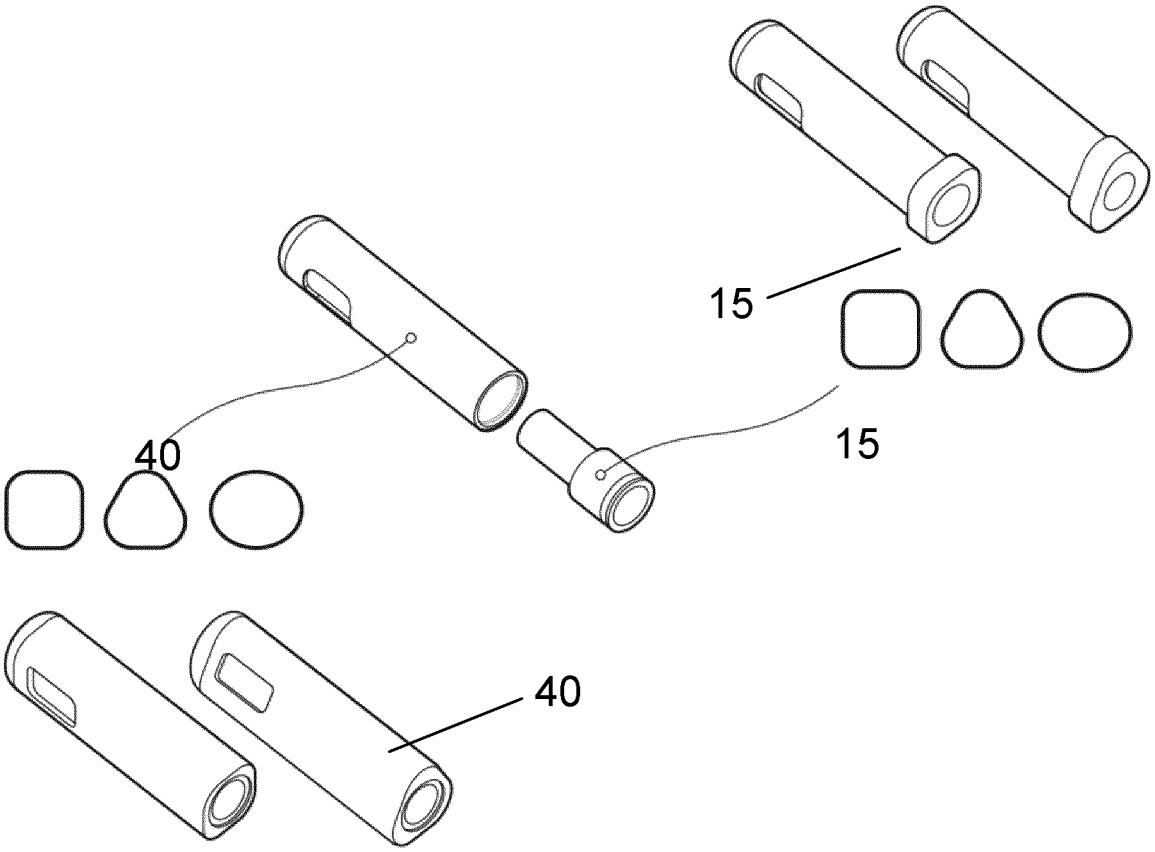


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2021/078311

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/28 A61J1/06 A61J1/14 A61J1/16
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	WO 2012/115022 A1 (MITSUI CHEMICALS INC [JP]; ASADA NORIAKI [JP] ET AL.) 30 August 2012 (2012-08-30) figure 4 and the respective parts of the description (see the enclosed translation).	1-13
X	EP 1 825 878 A1 (VEENSTRA INSTR B V [NL]; CYCLOTRON VRIJE UNIVERSITEIT B [NL]) 29 August 2007 (2007-08-29) figures 2a, 2b paragraph [0029]	1-11,13

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 November 2021	22/11/2021

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Petersheim, Markus

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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