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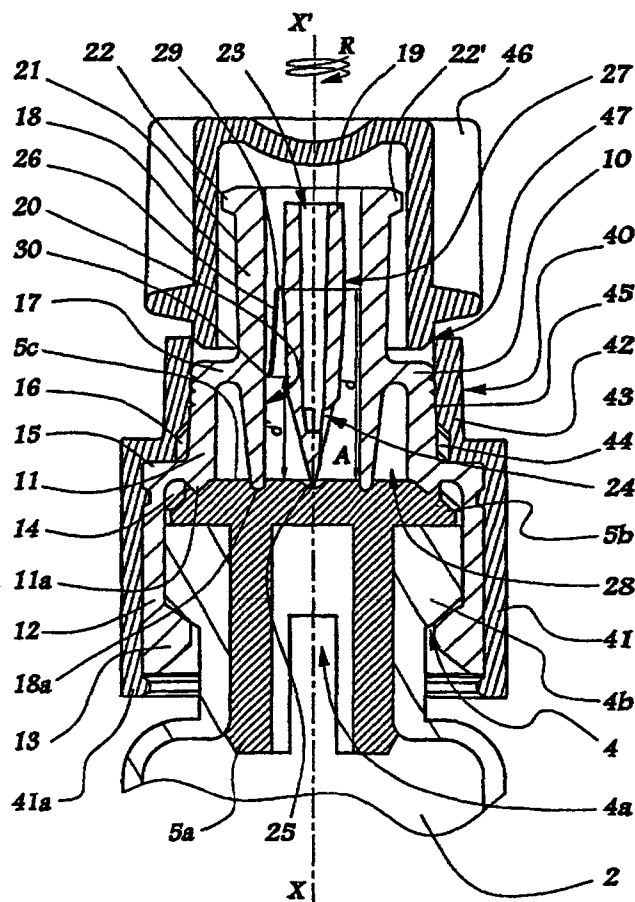
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(57) Abstract: The invention concerns a device comprising a cap (10) to be mounted on a container (2) and comprising a sleeve (18) forming an internal bore (A) and a piston (19) capable of sliding inside said bore (A), between a first released position relative to the stopper (5) and a second position, called transfer position, wherein a hollow needle (19) borne by or forming the piston passes through the stopper (5). The piston (19) and the cap (10) are formed in one single piece and connected by at least an elastic tab (26) capable of being deformed, essentially along a direction parallel to a central axis (X-X') of the bore (A) to accompany the movement of the piston between said first and second positions.

(57) Abrégé: Ce dispositif comprend une embase (10), apte à être montée sur un récipient (2) et comportant un manchon (18) formant un alésage interne (A), et un piston (19) apte à coulisser dans cet alésage (A), entre une première position délogée par rapport au bouchon (5) et une seconde position, dite de transfert, dans laquelle une aiguille creuse (19) portée par ou constituant ledit piston traverse le bouchon (5). Le piston (19) et l'embase (10) sont formés d'une seule pièce et reliés par au moins une languette (26) élastique apte à se déformer, essentiellement selon une direction parallèle à un axe central (X-X') de l'alésage (A), pour accompagner le mouvement du piston entre les première et seconde positions précitées.

## READY-TO-USE CONNECTING DEVICE

The present invention relates to a device for connection between a closed recipient and a container. The invention also relates to a ready-to-use assembly comprising, *inter alia*, a closed recipient and a connection device of the afore-mentioned type.

In the medicament-packaging domain, it is known to store a component of a pharmaceutical preparation, such as for example its active ingredient, in a recipient closed by a stopper made of relatively non-rigid material, for example of elastomer. A liquid can be introduced in this recipient after perforation of the stopper in order to dissolve the component contained in the recipient or place it in suspension, in order to obtain a preparation, in particular a medicament or a vaccine, in liquid form ready to be administered to the patient.

Documents WO-A-97/10156, WO-A-98/37854 and US-A-5 925 029 disclose connection devices, each comprising a base adapted to cap the neck of a recipient and extending in a flange or sleeve forming an inner bore, while a piston is mounted to slide in this bore. The piston is provided to be pushed towards a position of transfer in which a hollow needle borne by this piston traverses the stopper of the recipient. These devices must incorporate means for maintaining the piston in each of its two positions, i.e. in its position separate from the stopper and in the position of transfer. In addition, other means must be provided in order to guide the piston in translation, avoiding rotation thereof as much as possible, as such rotation is detrimental to an efficient boring of the stopper. In particular, any rotation of the needle during boring might lead to the formation of slivers in the stopper. These guiding means render the pieces constituting the known devices complex, which increases

their cost accordingly, while different pieces manufactured individually must be designed and managed singly.

It is a particular object of the present invention to overcome these drawbacks by proposing a connection device in which the piston is efficiently guided in its movement of translation between the afore-mentioned positions, while the cost price of the assembly of the device may be substantially reduced with respect to that of the known devices.

To that end, the invention relates to a device for connection between a closed recipient and a container, this recipient comprising a neck whose opening is obturated by a stopper while the connection device comprises a base, adapted to be mounted on the recipient and comprising a sleeve forming an inner bore, and a piston adapted to slide in this bore, between a first position separate with respect to this stopper and a second, so-called transfer position, in which a hollow needle borne by or constituting the piston passes through this stopper. This device is characterized in that the piston and the base are formed in one piece and connected by at least one elastic tongue adapted to be deformed, essentially in a direction parallel to a central axis of the bore, in order to accompany the movement of the piston between the afore-mentioned positions.

Thanks to the invention, the base and the piston may be mounted in one operation, making it possible to optimize the range of manufacture of the device of the invention and to reduce the cost thereof. The elastic tongue or tongues determine the intensity of the effort that a user must apply in order to displace the piston and the needle between the first and the second position, such effort being able to be relatively little, which facilitates use thereof by the medical personnel. In particular, the piston is much easier to move than in the case of it being connected to the base by one or more breakable tabs which a considerable effort might be required to break. The tongue or tongues of the device of the invention, which are deformed essentially

in the direction of translation of the piston, are not deformed in a direction which would allow the piston to rotate. This is why these tongues also constitute means for guiding the piston in translation between these two positions, without rotation.

According to advantageous but non-compulsory aspects of the invention, the device  
5 incorporates one or more of the following characteristics:

- It comprises a plurality of elastic tongues distributed about the central axis of the bore, which makes it possible to distribute the guiding obtained thanks to the tongues.

- The tongue or tongues presents a width, measured in a direction substantially parallel to a radial surface of the bore, substantially greater than their thickness, measured in a  
10 direction substantially perpendicular to this surface. Thanks to this geometry of the tongues, they present a good stiffness in torsion, with the result that they efficiently oppose any rotation of the piston about the central axis of the bore. In particular, their width may be provided to be greater than five times their thickness. The tongue or tongues thus present a sufficient stiffness in torsion to guide the piston in translation in the bore, without noteworthy rotation.

15 In position of transfer, the tongue or tongues form two zones of abutment against an inner radial surface of the bore and against an outer radial surface of the piston.

- The base bears means for elastically clipping on the neck of the recipient, a ring for  
hooping these means in clipped position on this neck being provided around these means, this  
ring being formed in one piece with a cap for protecting the base, while a continuous  
20 breakable zone connects this ring and this cap. This breakable zone is advantageously formed by a water- and air-tight membrane, with the result that it efficiently protects the base against microbial pollution during storage of a recipient equipped with a device according to the invention. The expression "water- and air-tight" is understood to mean that the membrane is tight with respect to the pressures that

such a device usually withstands, in particular during storage thereof.

- The base comprises means for abutment on the outer surface of the stopper around the hollow needle, the diameter of these means being slightly larger than the diameter of this needle. These means thus make it possible to avoid the stopper bulging while it is being bored and, if necessary, to guide the needle during boring. In particular, these means may be provided to be constituted by a sleeve forming that part of the bore nearest to the stopper, the edge of this sleeve intended to be in abutment against the stopper having a profile allowing a superficial penetration of this edge in the outer surface of the stopper. A confined volume, of relatively small diameter, is thus created around the piston and inside the bore, this volume limiting the quantity of product that may be lost due to a leakage between the needle and the stopper, in particular in the case of the needle not being driven in the stopper in a direction strictly parallel to the central axis of the bore.

The invention also relates to an assembly ready for use, comprising a closed recipient containing a product, in particular a pharmaceutical preparation, this recipient being provided with a neck whose opening is obturated by a stopper, and a connection device as described hereinbefore mounted on the recipient. Such an assembly makes it possible to conserve a component of a medicament or a vaccine, in particular its active ingredient, sterile, and to prepare it when required by mixing with a liquid, while its piston is efficiently maintained in position and guided during a displacement.

The invention will be more readily understood and other advantages thereof will appear more clearly on reading the following description of a form of embodiment of a connection device in accordance with its principle, given solely by way of example and made with reference to the accompanying drawings, in which:

Figure 1 is an exploded side view of

a ready-to-use assembly according to the invention and of a syringe provided to cooperate with this assembly.

Figure 2 is an axial section of the device mounted on the assembly of Figure 1, in storage configuration.

5 Figure 3 is a view in perspective, with parts torn away, of the piece forming base of the device of Figure 2, and

Figure 4 is a section similar to Figure 2 while the device is in transfer configuration.

Referring now to the drawings, the device 1 according to the invention has a dual function: On the one hand, it guarantees the tamper-proof nature of a recipient 2, for example  
10 a glass flask containing a product (not shown) and previously closed or stopped. This product may be a powder intended to form a vaccine to be taken orally, or it may be question of any other type of pharmaceutical preparation, in particular of any type of medicament.

On the other hand, the device 1 ensures or establishes a tight connection between the interior of the recipient 2 and the interior of another container, such as a syringe 3 containing a  
15 liquid intended to dissolve the product contained in the recipient 2 or to place it in suspension. Instead of a syringe, the container 3 might be formed by a supple bag, another glass flask or any other container.

The flask 2 comprises a neck 4 of which the opening 4a is tightly obturated by a stopper 5 made of a relatively non-rigid material, for example elastomer, in particular rubber.  
20 According to a variant embodiment of the invention (not shown), a capsule may be disposed around the stopper 5 and an outer annular part 4b of the neck 4, this capsule being provided with a central opening through which it is possible to perforate the stopper 5. The stopper 5 comprises a substantially cylindrical central part 5a adapted for supple and tight fit inside the opening 4a, and a flattened part 5b shouldering on part 4b and possibly covered by the  
25 capsule.

The device 1 is essentially formed by two pieces

made by injection of plastics material, for example polyethylene and/or polypropylene, namely a base element, or base, 10, intended to be mounted around the elements 4 and 5, and an outer envelope 40.

The base 10 comprises a cylindrical part 11 provided to be centred on the axis X-X' of symmetry of the elements 2, 4 and 5. This part 11 comprises a lower edge 11a presenting, in cross-section, a pointed profile intended to penetrate superficially in the upper or exposed surface 5c of the stopper 5. Part 11 extends in a plurality of elastic tabs 12 each equipped with a beak 13 adapted to cooperate with the outer surface of the neck 4 so that the base 10 clips elastically on the neck.

At the join between the tabs 12 and the part 11, the base 10 is provided with teeth 14 forming device for blocking rotation of the base 10 with respect to the stopper 5 with which the teeth 14 are in engagement.

Opposite the teeth 14 with respect to the zone 15 of join between tabs 12 and part 11, the base 10 bears a second series of teeth 16.

Opposite the edge 11a, the part 11 extends in an annular band 17 for join with a sleeve 18 which forms an inner bore A for storage and displacement of a piston 19 constituted by a hollow needle. The inner radial surface 10 of the sleeve 18 is substantially cylindrical and centred on axis X-X' which is thus the central axis of the bore A, while its outer surface 21 is slightly truncated and it bears two doubly bevelled lugs 22 and 22' allowing it to cooperate with a system for fixing the syringe 3 of "LUER-LOCK" type by means of a nut 6 for mounting the syringe 3 on the base 10. The syringe 3 and nut 6 may be joined by clipping or by the fact that the nut 6 forms an integral part of the syringe 3.

The hollow needle 19 forms a central channel 23 and three openings 24, of which two appear in Figures 2 and 4, near its sharp point 25.

As is more particularly visible in Figure 3,



the sleeve 18 and the needle 19 are connected by three elastic tongues 26, with the result that elements 11 to 26 form a single piece constituting the base 10.

The tongues 26 have a width  $l$ , measured parallel to the surface 20 or to the outer radial surface 27 of the needle 19, largely greater than their thickness  $e$  which is measured  
5 perpendicularly to the surfaces 20 and 27. In this way, the tongues 26 may be deformed in a direction parallel to axis X-X' but present a relatively high stiffness in rotation about axis X-X'. In practice, the width  $l$  is at least five times larger than the thickness  $e$ .

The edge 18a of the sleeve 18 which is opposite the flange 2 presents, like edge 11a, a pointed profile enabling it to penetrate superficially in the surface 5c of the stopper 5, a  
10 hollow volume 28 being defined between that part of the sleeve 18 nearest the stopper 5 and the cylindrical part 11.

The envelope 40 is also in one piece and comprises a ring 41 serving as hoop for the tabs 12 when the beaks 13 are in place under part 4b of the neck 4. Ring 41 is bordered by an inner flange 41a for locking under the beaks 13. This ring 41 extends in a second ring 42 of  
15 slightly smaller diameter which surrounds more specifically part 11 of the base 10. At the level of the zone 43 of join between the rings 41 and 42 and on its inner surface, the envelope 40 presents teeth 44 provided to cooperate with the teeth 16 of the base 10 in order to allow immobilization of the envelope 40 with respect to base 10 in rotation.

On its inner radial surface, the ring 42 bears three ribs 45, centred on axis X-X' and  
20 perpendicular thereto, intended to create a tight assembly, without the interposition of a seal, between the base 10 and the envelope 40. The assembly between base 10 and envelope 40 is tight as long as the ring 42 bears at least one rib of the type such as ribs 45. The exact number of ribs, which may be less or more than three, depends on the choice of design.

A cap 46 forms an integral part of envelope 40 and is connected to an upper edge of the ring 42 by a continuous breakable zone 47 of small thickness. The thickness of the zone 47 may be included between 0.5 and 1 tenth of a millimeter.

In the configuration of Figures 2 and 3, the device 1 is mounted on a recipient 2 during a relatively long period, during storage of the product contained in the recipient 2. When the syringe 3 is to be connected to the recipient 2, the cap 46 is removed by exerting thereon a movement of rotation R which has the effect of tearing the zone 47 since elements 10 to 45 are immobilized in rotation about neck 4.

It is then possible to introduce the end 3a of the syringe 3 inside the sleeve 18 by using the nut 6 to force the end 3a to advance in the sleeve 18. It is also possible to push the syringe 3 in the direction of the recipient 2, particularly when the syringe is not equipped with a nut of the type such as nut 6, in order to transmit a movement of translation to the needle 19. An effort of thrust is thus created on the needle 19, represented by arrow F in Figure 4, with the result that the needle perforates the stopper 5, which makes it possible to place in communication the internal volume of the recipient 2 and a channel 3b of the end 3a, through the channel 23 and the openings 24.

In this configuration, the tongues 26 have been deformed with respect to their configuration of Figures 2 and 3.

In the configuration of Figures 2 and 3, each tongue 26 has an end 29 fast with the piston 19 spaced by a distance  $\underline{d}$  with respect to surface 5c, while its end 30 fast with the surface 20 is spaced by a distance  $\underline{d}'$  with respect to the same surface 5c. Distance  $\underline{d}$  is greater than distance  $\underline{d}'$  of the configuration of Figures 2 and 3. On the contrary, in the configuration of Figure 4, distance  $\underline{d}$  is shorter than distance  $\underline{d}'$  which remains constant. In other words, the end 29 of each tongue 26 is advanced towards the stopper 5 during

the translation of the needle or piston 19 corresponding to the perforation of the stopper 5.

In the configuration of Figure 4, the tongues 26 form two zones of abutment 31 and 32 respectively against the surfaces 27 and 20, with the result that the advance of the needle 19 in the direction of the internal volume of the recipient 2 is blocked in this configuration. In this way, the tongues 26 can stop the displacement of the needle 19 during perforation of the stopper 5.

During perforation of the stopper 5, the edge 18a of the sleeve 18 is permanently in firm abutment against the stopper 5, which makes it possible to avoid any effect of bulging of the stopper due to a creeping of the material constituting it. In addition, the superficial penetration of the edge 18a in the surface 5c guarantees a seal between the volume 50, defined inside the sleeve 18 around the needle 19 and between the stopper 5 and the end 3a of the syringe 3, and the volume 28. The dead volume 50 constitutes the volume in which part of the liquid coming from the recipient 2 due to a leakage between the needle 19 and the stopper 5, might flow. In this way, the maximum loss of active liquid is confined to this volume 50 which may be relatively small due to the very slight difference of diameter between surfaces 20 and 27.

The elasticity of the tongues 26 may be chosen so that their configuration shown in Figure 4 is a stable configuration, in that the needle 19 does not tend to rise in the direction of the opening of the sleeve 18 equipped with the flange 22, including after removal of the end 3a.

## C L A I M S

1. Device for connection between a closed recipient and a container, said closed recipient comprising a neck whose opening is obturated by a stopper, said connection device comprising:

5 - a base, adapted to be mounted on the recipient and comprising a sleeve forming an inner bore, and

- a piston adapted to slide in said bore, between a first position separate with respect to said stopper and a second, so-called transfer position, in which a hollow needle borne by or constituting the piston passes through said stopper,

10 characterized in that said piston and said base are formed in one piece and connected by at least one elastic tongue adapted to be deformed, essentially in a direction parallel to a central axis of said bore, in order to accompany the movement of said piston between the said first and second positions.

2. Device according to Claim 1, characterized in that it comprises a plurality of elastic  
15 tongues distributed about said central axis

3. Device according to one of the preceding Claims, characterized in that said tongue or tongues have a width, measured in a direction substantially parallel to a radial surface of said bore, substantially larger than their thickness, measured in a direction  
substantially perpendicular to said surface.

20 4. Device according to Claim 3, characterized in that said width is five times larger than said thickness

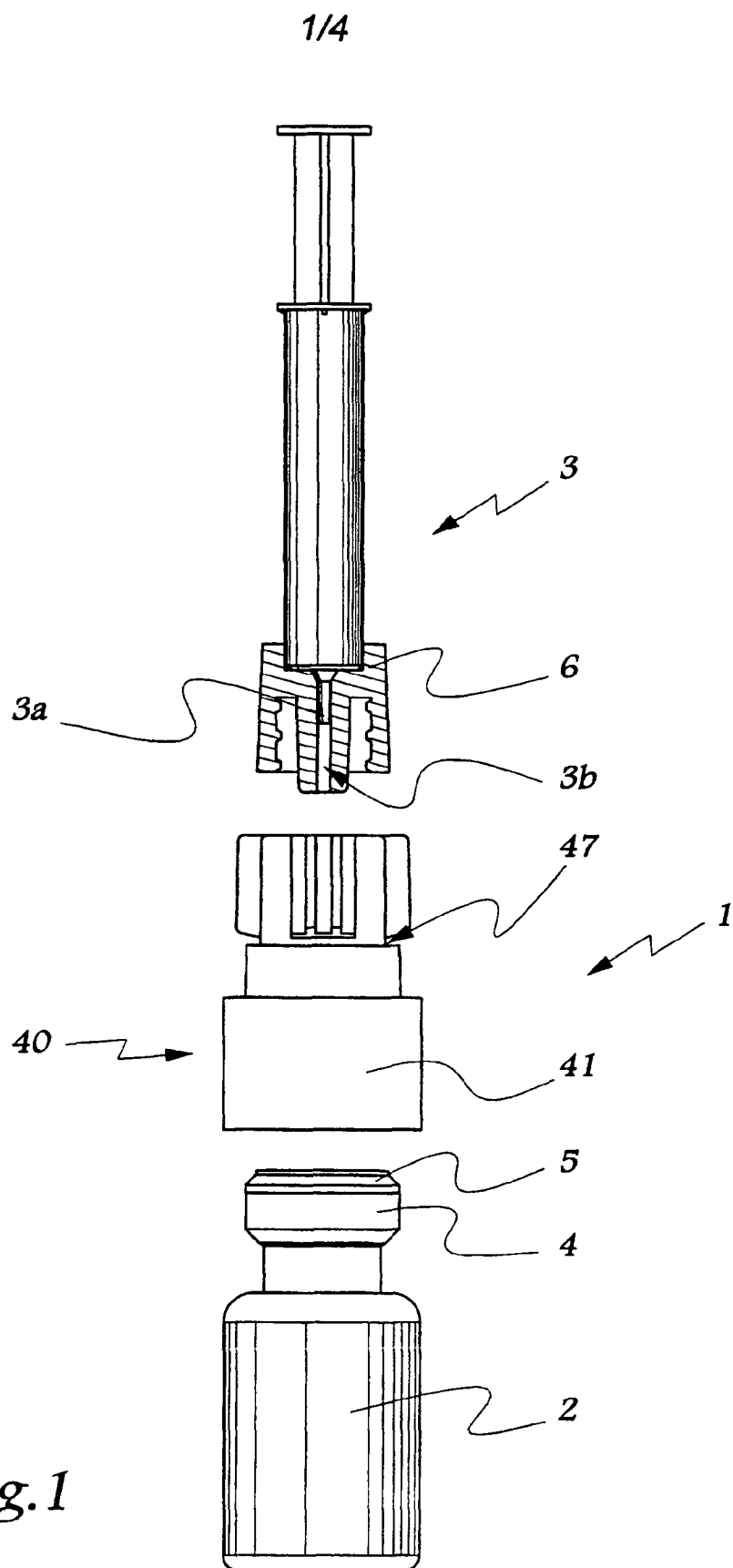
5. Device according to one of the preceding Claims, characterized in that, in transfer position, said tongue or tongues form two zones of abutment against an inner radial surface of said bore and against an outer radial surface of said piston

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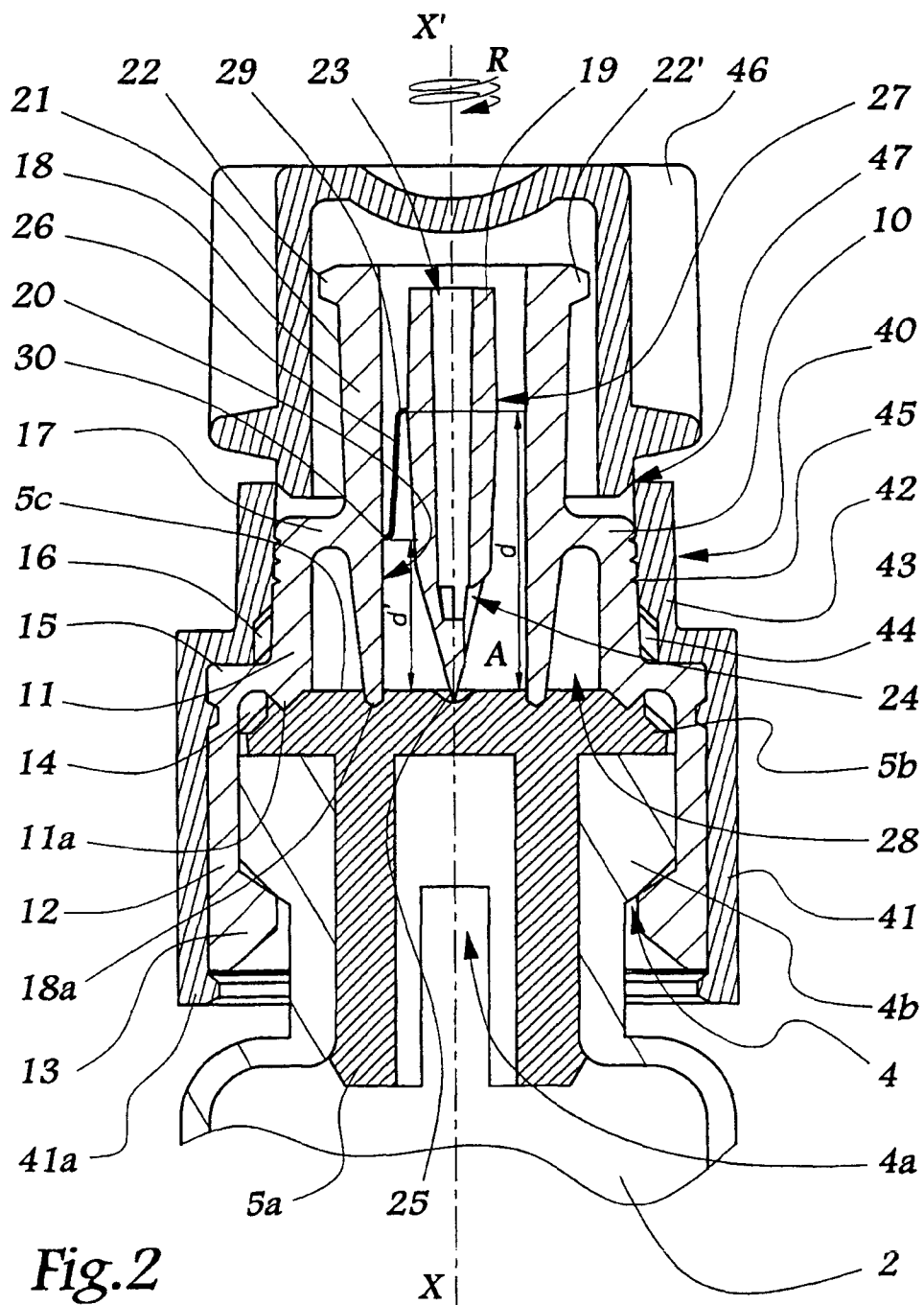
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6. Device according to one of the preceding Claims, characterized in that said base bears means for elastically clipping on said neck, a ring for hooping said means in clipped position on said neck being provided around said means, said ring being formed in one piece with a cap for protecting said base, a continuous breakable zone connecting said ring and said cap.
7. Device according to Claim 6, characterized in that said breakable zone is formed by a water- and air-tight membrane.
8. Device according to one of the preceding Claims, characterized in that said base comprises means for abutment on the outer surface of said stopper around said hollow needle, the diameter of said means being slightly greater than the diameter of said needle.
9. The device of Claim 8, characterized in that said abutment means are constituted by that part of said sleeve nearest said stopper, the edge of said sleeve intended to be in abutment against said stopper having a profile allowing a superficial penetration of said edge in said surface of said stopper.
10. Ready-to-use assembly comprising a closed recipient containing a product, particularly a pharmaceutical preparation, said recipient being provided with a neck whose opening is obturated by a stopper and a connection device, according to one of the preceding Claims, mounted on said recipient.
11. A device for connection between a closed recipient and a container substantially as herein described and as illustrated in Figures 1 to 4.
12. A ready to use assembly substantially as herein described and as illustrated in Figures 1 to 4.

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*Fig. 1*

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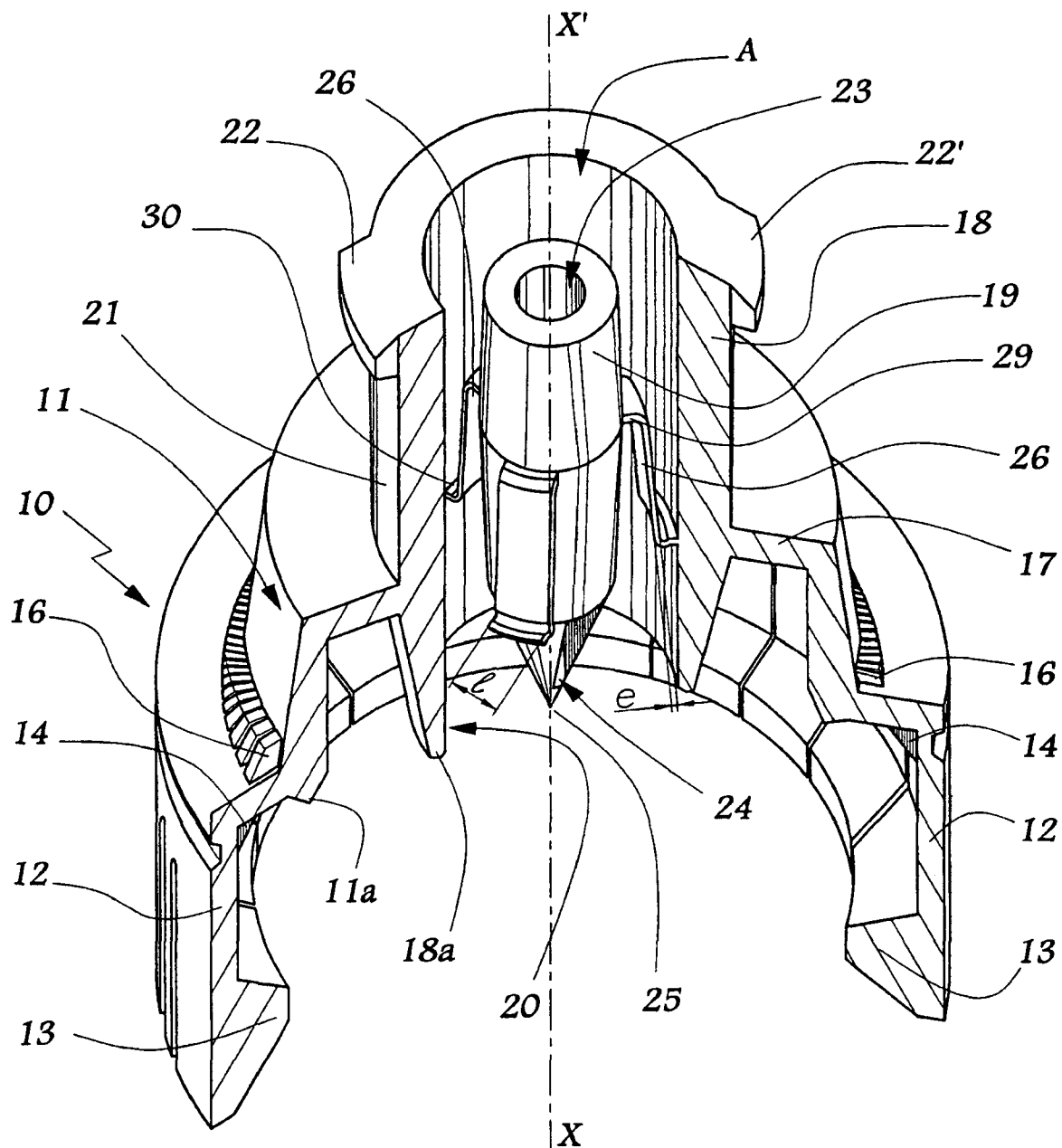


Fig. 3



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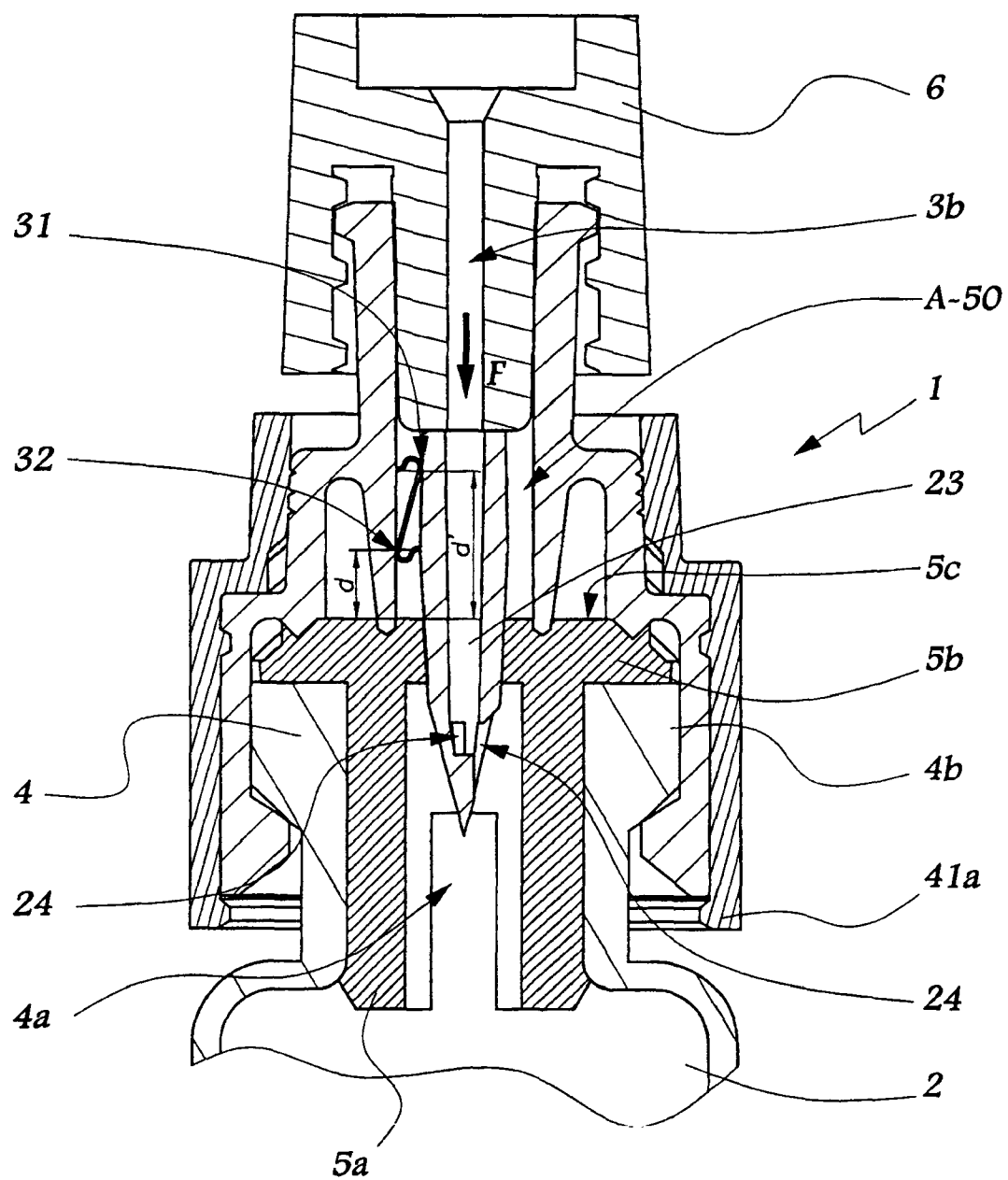


Fig. 4