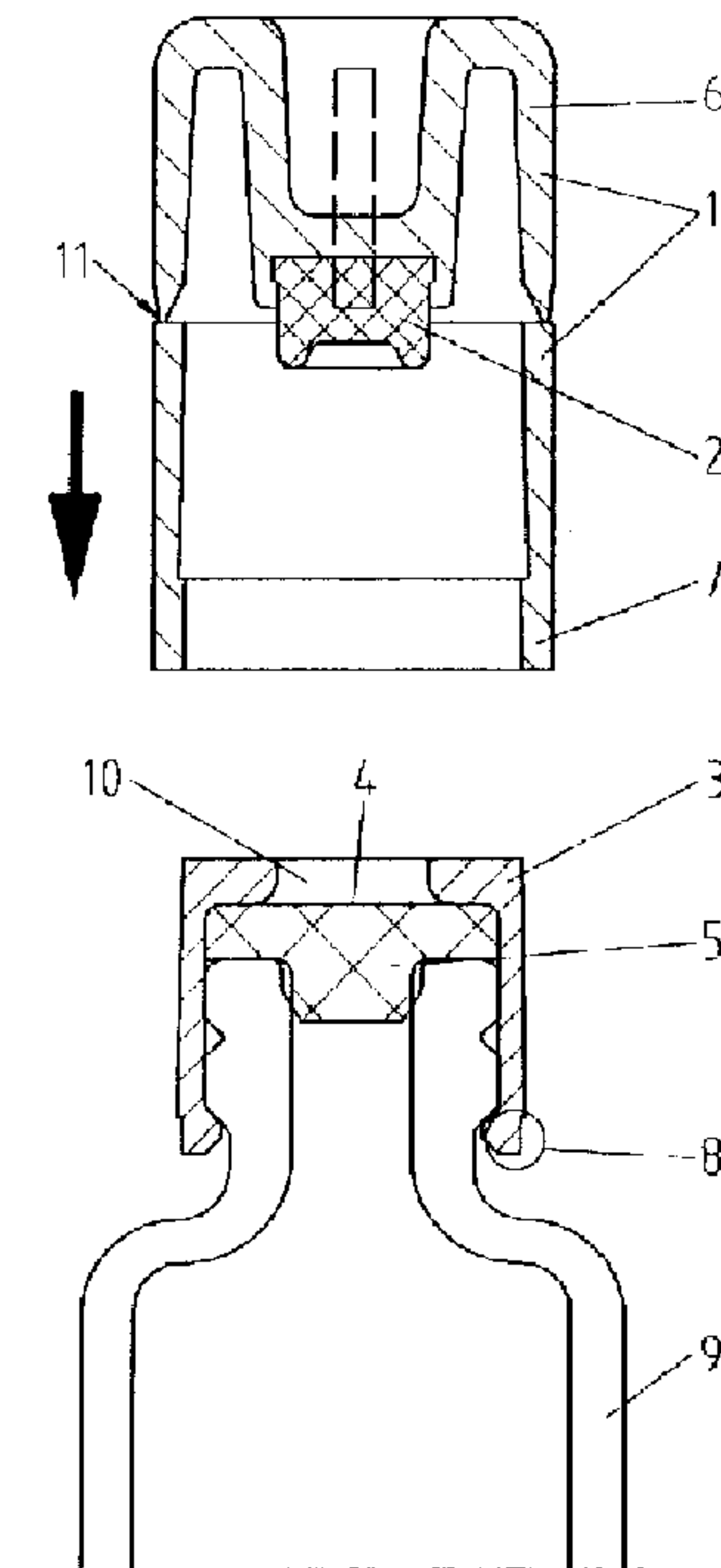




(22) Date de dépôt/Filing Date: 1998/11/19
 (41) Mise à la disp. pub./Open to Public Insp.: 1999/05/19
 (45) Date de délivrance/Issue Date: 2003/10/28
 (30) Priorité/Priority: 1997/11/19 (197 51 219.4-35) DE

(51) Cl.Int.⁶/Int.Cl.⁶ A61M 5/31
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(54) Titre : DISPOSITIF D'ETANCHEITE POUR SERINGUES OU AMPOULES
 (54) Title: A SYRINGE OR AMPOULE SEALING DEVICE



(57) **Abrégé/Abstract:**

The more particularly pre-filled syringe or ampoule is intended for medical purposes and displays a syringe barrel and as required a syringe plunger that can be moved by means of a plunger actuating rod. On the end of the syringe barrel where the cannula is inserted, a cover piece is axially fitted so that it enclaspes the end of the syringe barrel in which the cannula is inserted. As well, a sealing element is provided, which is interposed between the face of the syringe barrel and the cover piece, and whose face on the one side abuts the syringe barrel, and on the other side the inner face of the cover piece. The cover piece is at the same time provided with a central recess for penetration by a cannula or needle, as well as with a security cap enclosing the cover piece, and which is conformably fitted onto the cover piece and held in the installed position on the cover piece. In the interior of the security cap is arranged an elastic sealing piece which projects into the central recess of the cover piece and which abuts the surface of the sealing element.

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15 abuts the surface of the sealing element.

A SYRINGE OR AMPOULE SEALING DEVICE

Technical Field

The subject of the invention is a syringe or ampoule, particularly those that are pre-filled with material for injection.

5 Background of the Invention

Most preferred syringes or ampoules known to art comprise a sealing element which can be punctured at a recess with a needle to remove or inject material. Care must be taken after the removal of a security cap to ensure that any impurities, such as dust or bacteria adhering to the sealing element in the vicinity of the recess are not
10 carried into the interior of the syringe or ampoule. This means that the surface of the sealing element must be cleaned, which is not only time-consuming, but is also awkward, since the surface to be cleaned lies in the base area of the recess. Moreover, it means that cleaning or sterilizing agents must always be kept ready for use.

Summary of the Invention

15 The invention provides a syringe or ampoule in such a way that the area of the sealing element provided for being pierced through by a cannula requires no (sterilizing) cleaning after the removal of the security cap, that is, before the syringe or ampoule is used.

The invention pertains to a device for maintaining a syringe or an ampoule in
20 sterile condition, wherein the syringe or ampoule comprises an open end for receiving a needle or cannula, the device comprising: a sealing element that has on one side a surface which, in use, abuts and seals the open end, and which has on an opposite side a substantially flat surface that is capable of being pierced by a needle or cannula; an annular cover piece that grasps the open end and holds the sealing element in place, the
25 cover piece forming a recess defining an insertion area for a needle or cannula on the substantially flat surface of the sealing element; an elastic sealing plug which projects into the recess and abuts the insertion area, thereby forming a sterile seal with the insertion area; and an at least partially removable security cap that envelopes at least

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part of the cover piece, and which envelopes entirely the sealing element and the sealing plug, thereby providing a sterile internal environment, wherein when the security cap, or a part of it, is removed, the insertion area is exposed.

Detailed Description of Preferred Embodiments

5 The syringe or ampoule according to the invention is configured such that within the security cap there is arranged an elastic sealing plug which projects into central recess of a cover piece and abuts the surface of a sealing element.

10 The advantage achieved by the invention essentially consists in that the sealing piece, after the security cap is applied, closes off the surface of the cover piece that is exposed by the recess in such a way that it is kept free from impurities. The security cap with elastic sealing plug is thus installed at the end of the production or

manufacturing process while still under sterile conditions, so that the exposed surface of the sealing element is sterile and is kept sterile by the sealing plug.

In a preferred embodiment of the invention the sealing plug is configured as an essentially cylindrical stopper which is inserted into a blind hole of the security cap and has on its face oriented towards the sealing element an annular lip running all
5 round its circumference. The stopper is at the same time made to fit the diameter of the recess. In this way the annular lip ensures particularly advantageous sealing characteristics.

It is further provided, according to the invention, that the sealing plug on its
10 face oriented towards the sealing element displays a radially projecting annular flange, which projects into an annular groove in the wall of the blind hole of the security cap. By this means, the secure retention of the sealing plug in the security cap is ensured.

In a first embodiment of the invention, which is preferably used with syringes, the security cap carries a security ring attached by means of a circumferentially annular
15 predetermined breakage zone and which is held in an engaged position on the cover piece by an annular shoulder. When the syringe is to be used the security cap can then be ripped away along the predetermined breakage zone, which ensures that the cover piece continues to be retained by the security ring. Incidentally, the security cap in this way forms a seal guaranteeing purity, from which the user can detect whether the
20 syringe has already been prepared for use or used, or whether it is still in an intact condition.

In a second embodiment of the invention, which would preferably be used for ampoules, in which the cover piece is formed from a crimped cap, the security cap is
25 enwrapped in shrink film. In this case, the shrink film acts as a seal guaranteeing purity and also incidentally acts to retain the security cap on the cover piece. In ampoules available on the market the external diameter dictated by the cover piece must not be increased if the syringes or ampoules are to be used in existing application systems, the security cap must be removed before injection. It goes without saying that the security cap can consequently not be fitted with a locking device that would
30 make it difficult to remove the security cap. In this way the security cap can be removed all at once, as soon as the shrink film is removed.

Brief Description of the Drawings

- Fig. 1: A syringe and above it a security cap, before the security cap is put in place;
- Fig. 2: The subject of the invention according to Fig. 1, but with security cap fitted in place;
- Fig. 3: The subject of the invention according to Fig. 2, but in this case made ready for application;
- Fig. 4: A representation corresponding to Fig. 1, but in this example of an ampoule;
- Fig. 5: The subject of the invention according to Fig. 4, in the condition corresponding to Fig. 2;
- Fig. 6: The subject of the invention according to Fig. 4, as made ready for application.

The syringe or ampoule represented in the drawings comprises a syringe barrel 9, in which a syringe plunger, that can be actuated by a plunger actuating rod, can, if required, be fitted (not shown). A cover piece 3 is axially fitted to the needle end of the syringe barrel 9 and grasps the bottleneck-shaped end of the syringe barrel 9. Between the face of the syringe barrel 9 and the cover piece 3 is interposed a sealing element 5, which abuts the face of the syringe barrel 9, on the one side, and the internal face of the cover piece 3, on the other side.

The cover piece 3 is provided with a central recess 10 which is provided for the penetration of the cover piece 3 by a cannula or needle.

Additionally, a security cap 1 is provided which is installed conformably to the cover piece 3 in such a way that it encloses cover piece 3 and is held in its installed position on the cover piece 3.

In the interior of the security cap 1 an elastic sealing plug 2 is arranged so that it projects into the central recess 10 of the cover piece 3 and abuts the surface of the sealing element 5 in the area designated as 4. The emplacement of the security cap 1 comes at the end of the production or manufacturing process while still under sterile

conditions, so that it is ensured that the area in sealing element 5 exposed by the recess 10 in cover piece 3 is sterile and has been kept sterile by the elastic sealing plug 2.

The sealing plug 2 is configured as an essentially cylindrical stopper, which is inserted into a blind hole in the security cap 1. On its face oriented towards the sealing element 5, the sealing plug 2 is provided with an annular lip 2.1, which runs all round the circumference of the sealing plug 2. The sealing plug 2 consequently displays in the region of the annular lip 2.1 a particularly high elasticity, as a result of which a high-quality seal is ensured.

On its face opposite sealing element 5, sealing plug 2 displays a radially projecting annular flange 2.2 which projects into an annular groove in the wall of the blind hole of security cap 1.

In a first embodiment of the invention according to Figs. 1 to 3, the security cap 1 carries a securing ring 7, which is provided with a predetermined annular circumferential breaking zone 11. This securing ring 7 is held in locked position on cover piece 3 by an annular shoulder 8. After the security cap 1 is put on, as shown in Figs. 1 and 2, the security cap 1 with the securing ring 7 cannot be removed. By this means it is ensured that the sealing plug 2 can no longer be unintentionally removed from the sealing element 5, so that any contamination of the surface 4 to be protected is prevented. At the same time this makes it possible to recognize that the syringe with its firmly emplaced security cap 1 is still in its original condition and thus can be unhesitatingly put to use. To do this, the part identified as 6 of the security cap 1 must be detached along the predetermined breaking zone 11, as represented in Fig. 3. In the process, the sealing plug 2 is lifted up off sealing element 5, thus exposing the sterile surface 4, so that it can be immediately and without further measures being taken be pierced through sealing element 5 with a cannula or needle.

Figs. 4 to 6 portray a second embodiment in which an ampoule has a cover piece 3 formed by a crimped cap, which is normally made of aluminium. In ampoules available on the market it must be ensured that when brought to use the external diameter as determined by the crimped cap does not have to be enlarged during application so that the ampoule can still be inserted into existing application systems. That is why in this embodiment, it is preferred that the security cap 1 have no

predetermined breaking point; rather, the security cap is enwrapped by a shrink film 12 that encloses the crimped cap all around its rim. This shrink film 12 also acts as a seal guaranteeing purity and thus makes it easy to verify that the ampoule is in its original condition.

- 5 After the removal of the shrink film 12 the security cap 1, which in this case has no locking device whatsoever, can be instantly removed from the crimped cap whereby the sealing plug 2 then exposes the insertion area 4 of the sealing element, which had up until that point been maintained in a sterile condition by the sealing plug 2.

What is claimed:

1. A device for maintaining a syringe or an ampoule in sterile condition, wherein the syringe or ampoule comprises an open end for receiving a needle or cannula, the device comprising:
 - 5 a sealing element that has on one side a surface which, in use, abuts and seals the open end, and which has on an opposite side a substantially flat surface that is capable of being pierced by a needle or cannula;
 - an annular cover piece that grasps the open end and holds the sealing element in place, the cover piece forming a recess defining an insertion area for a needle or
10 cannula on the substantially flat surface of the sealing element;
 - an elastic sealing plug which projects into the recess and abuts the insertion area, thereby forming a sterile seal with the insertion area; and
 - an at least partially removable security cap that envelopes at least part of the cover piece, and which envelopes entirely the sealing element and the sealing plug,
15 thereby providing a sterile internal environment, wherein when the security cap, or a part of it, is removed, the insertion area is exposed.
2. The device of claim 1, wherein the removable security cap is provided with an annular circumferential breaking zone dividing the security cap into a bottom portion and a top portion, the bottom portion being provided with means for locking
20 the bottom portion on the cover piece, the breaking zone allowing the top portion to be ripped off, thereby exposing the insertion area.
3. The device of claim 1 or 2, wherein the security cap is enveloped in shrink film.
4. The device of claim 1, wherein the security cap is entirely removable,
25 and wherein the security cap is enveloped in shrink film.

5. The device of any one of claims 1 to 4, wherein the sealing plug is an essentially cylindrical plug which abuts at a bottom end the insertion area, the plug being provided with an annular lip running around its circumference on the bottom end.

6. The device of any one of claims 1 to 5, wherein the sealing plug is
5 attached to the security cap.

7. The device of claim 6, wherein the sealing plug is attached to the security cap by means of an annular circumferential flange provided at a top end of the sealing plug, the flange engaging with an annular groove provided on the security cap.

8. The device of any one of claims 1 to 7, for use with an ampoule or a
10 syringe that is pre-filled with material for injection.

9. A syringe or ampoule for medical purposes, with a syringe barrel and a syringe plunger fitted inside the syringe barrel that can be moved by means of a plunger actuating rod, and with an axially located cover piece on a cannula-end of the syringe barrel that enclasps a cannula-side end of the syringe barrel, as well as with a
15 sealing element which is interposed between a face of the syringe barrel and the cover piece and one of whose faces abuts the face of the syringe barrel while the other abuts the inner face of the cover piece, and where the cover piece is provided with a central recess for the insertion of a cannula, as well as with a security cap enclosing the cover piece, and which is conformably applied to the cover piece and which when applied is
20 retained firmly on the cover piece, characterized in that there is fitted in the interior of the security cap an elastic sealing plug which projects into the central recess of the cover piece and abuts the surface of the sealing element.

10. A syringe or ampoule according to claim 9, characterized in that the sealing plug is configured as an essentially cylindrical stopper which is inserted into a
25 blind hole of the security cap and which shows on its face oriented towards the sealing element an annular lip running all around its circumference.

11. A syringe or ampoule according to claim 10, characterized in that the sealing plug shows on its face adjacent to the sealing element a radially projecting annular flange, which projects into an annular groove in the wall of the blind hole of the security cap.

5 12. A syringe or ampoule according to any one of claims 9 to 11, characterized in that the security cap carries a securing ring enclosed over a predetermined annular circumferential break zone and which is held in the engaged position by an annular shoulder on the cover piece.

10 13. A syringe or ampoule according to any one of claims 9 to 11, in which the cover piece is formed by a crimped cap, characterized in that the security cap is enwrapped by a shrink film.

14. A syringe or ampoule according to claim 9, wherein the syringe is a pre-filled syringe.

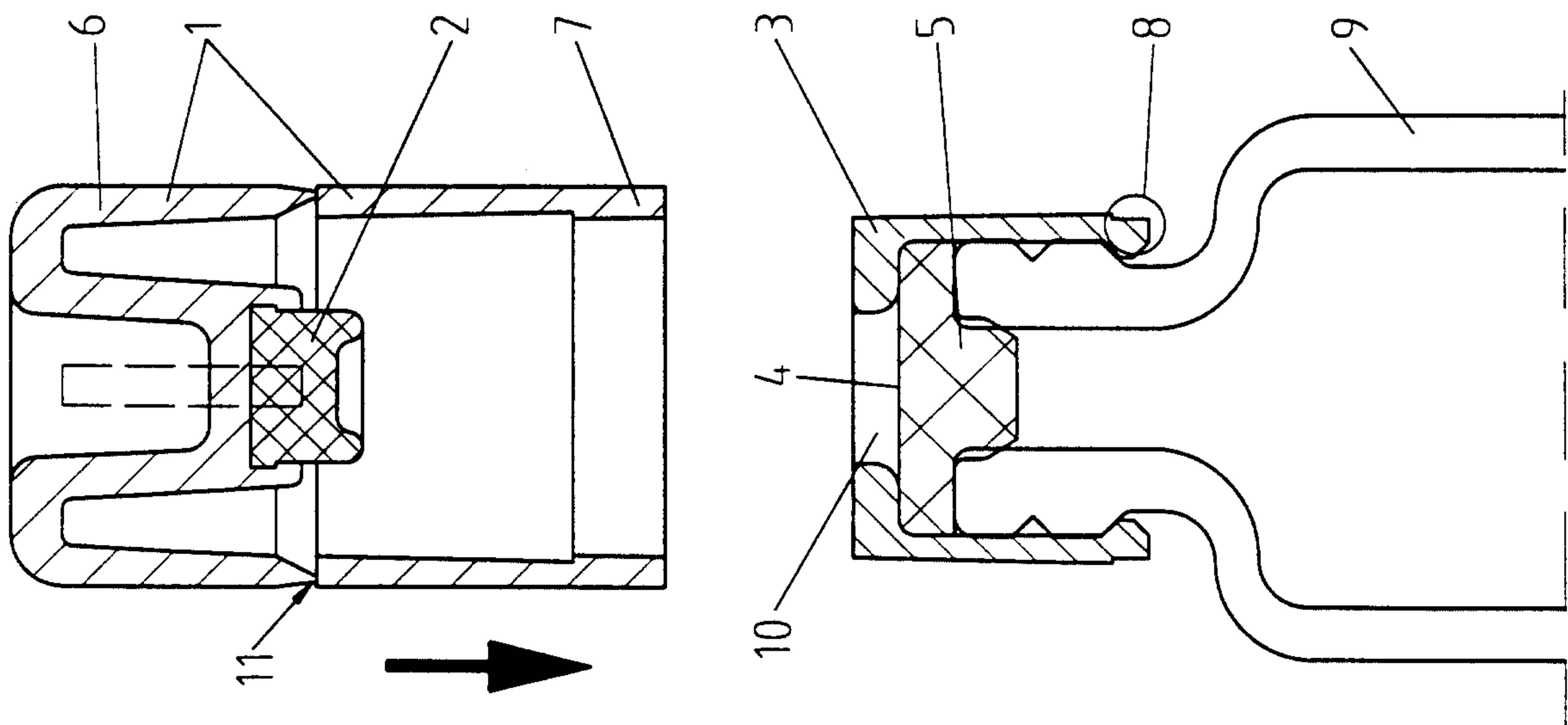


Fig. 1

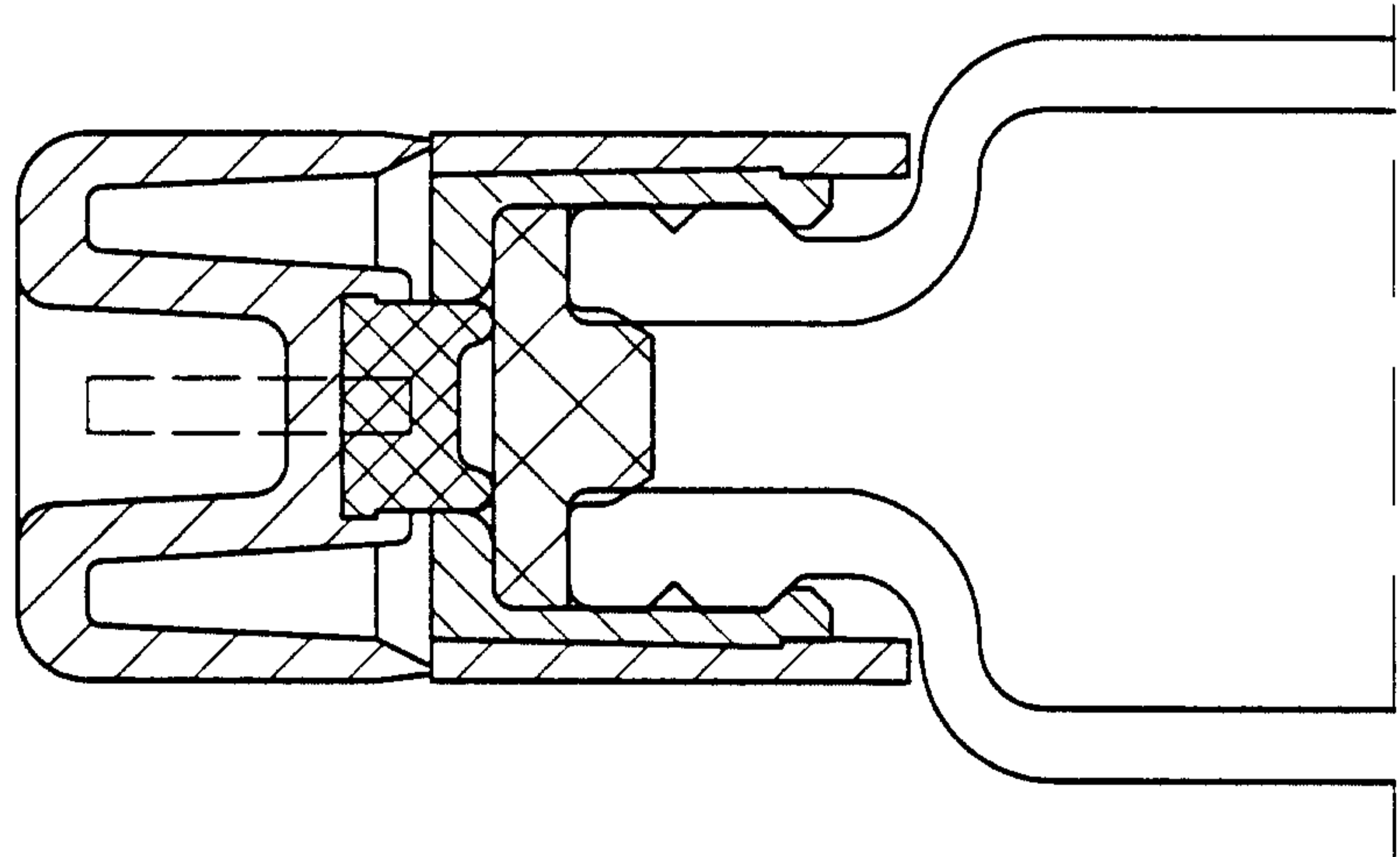


Fig. 2

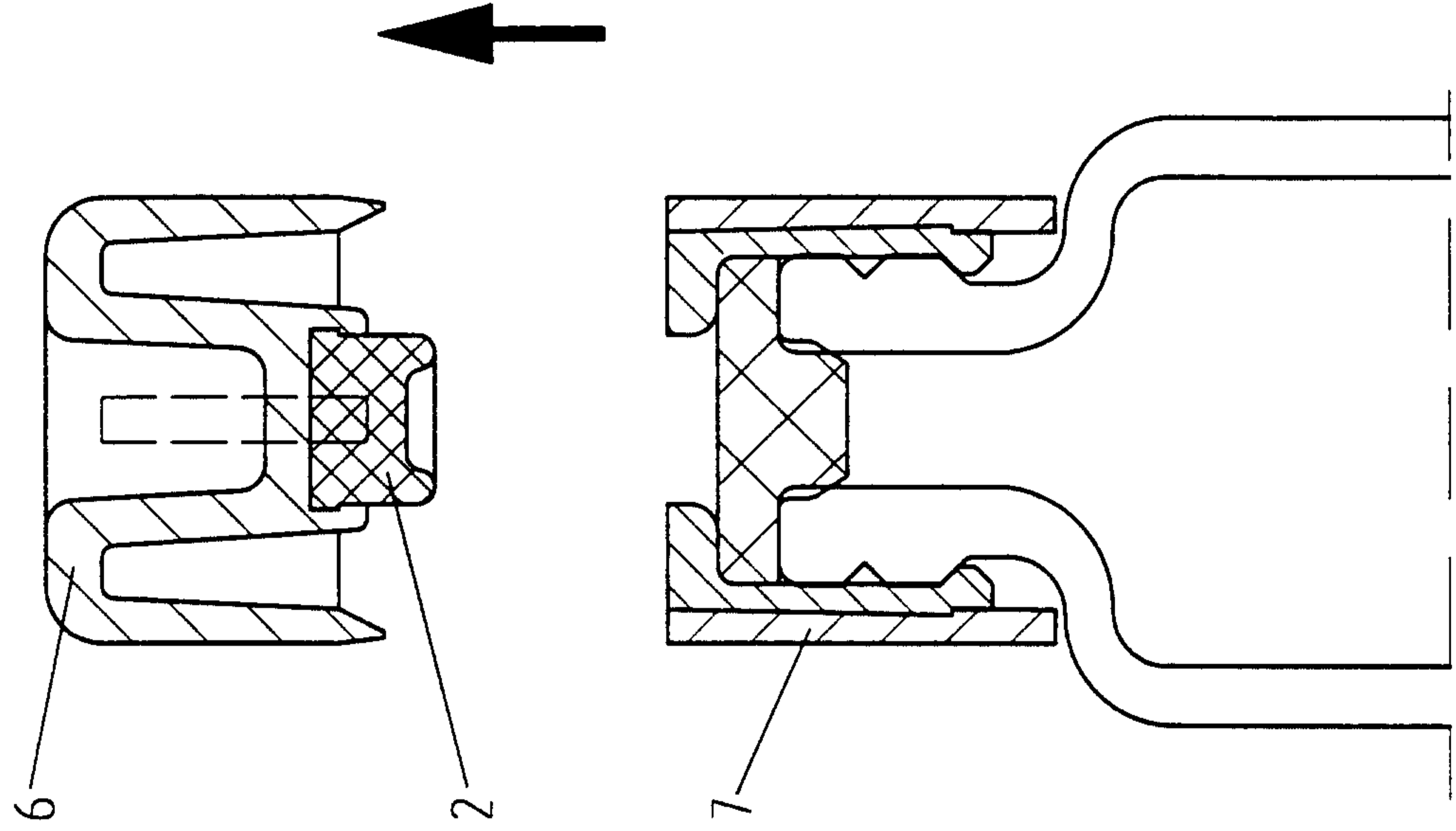


Fig. 3

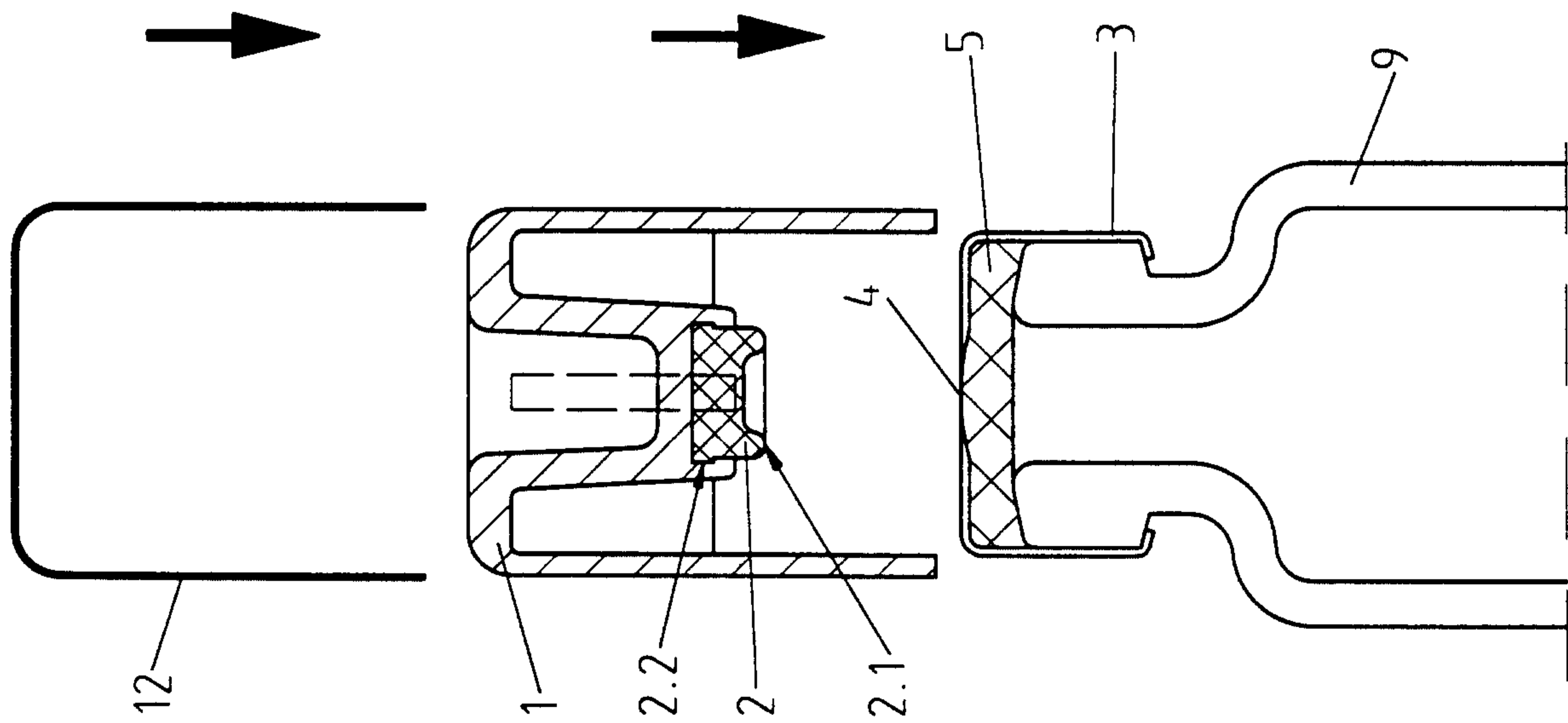


Fig. 4

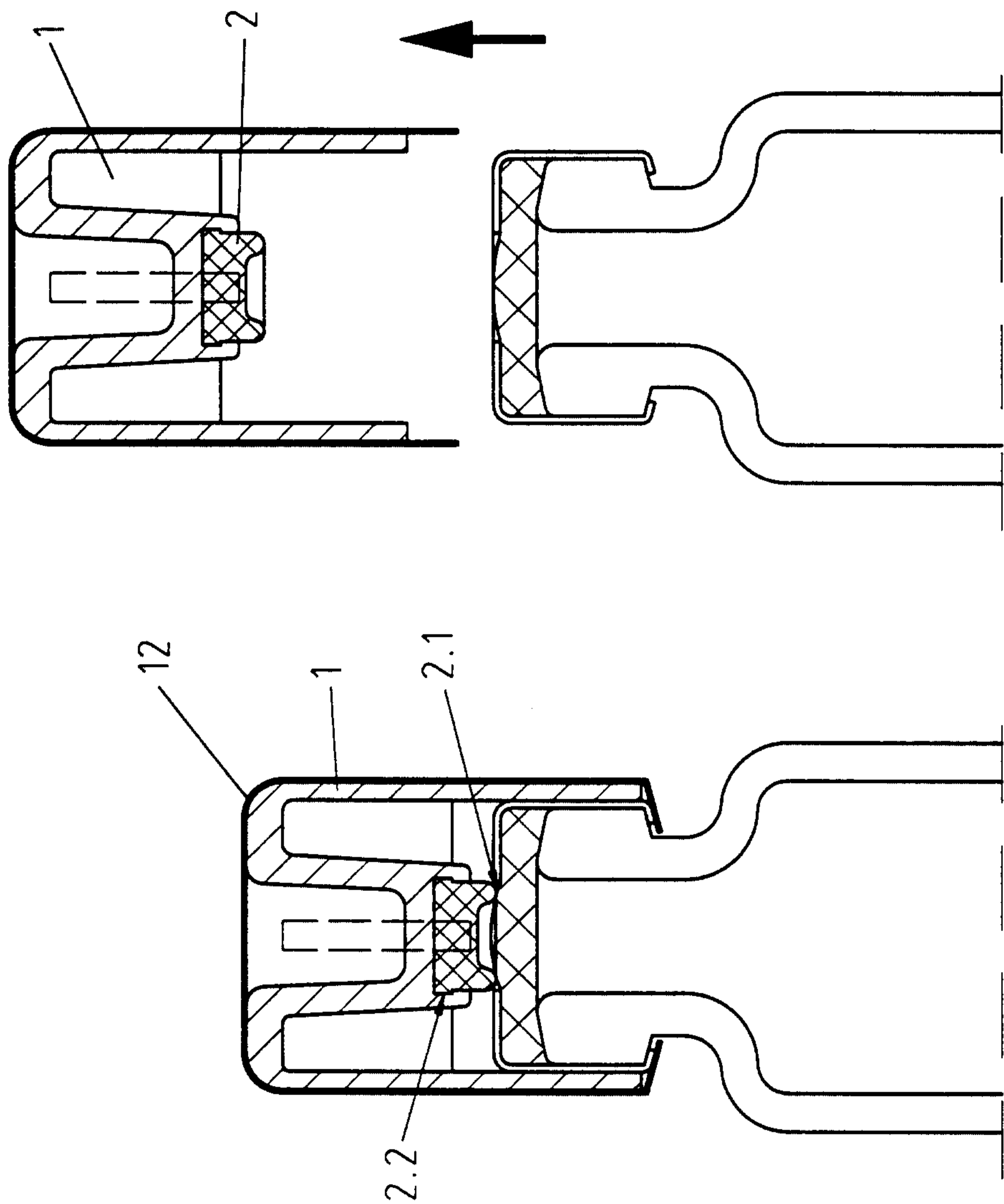


Fig. 5

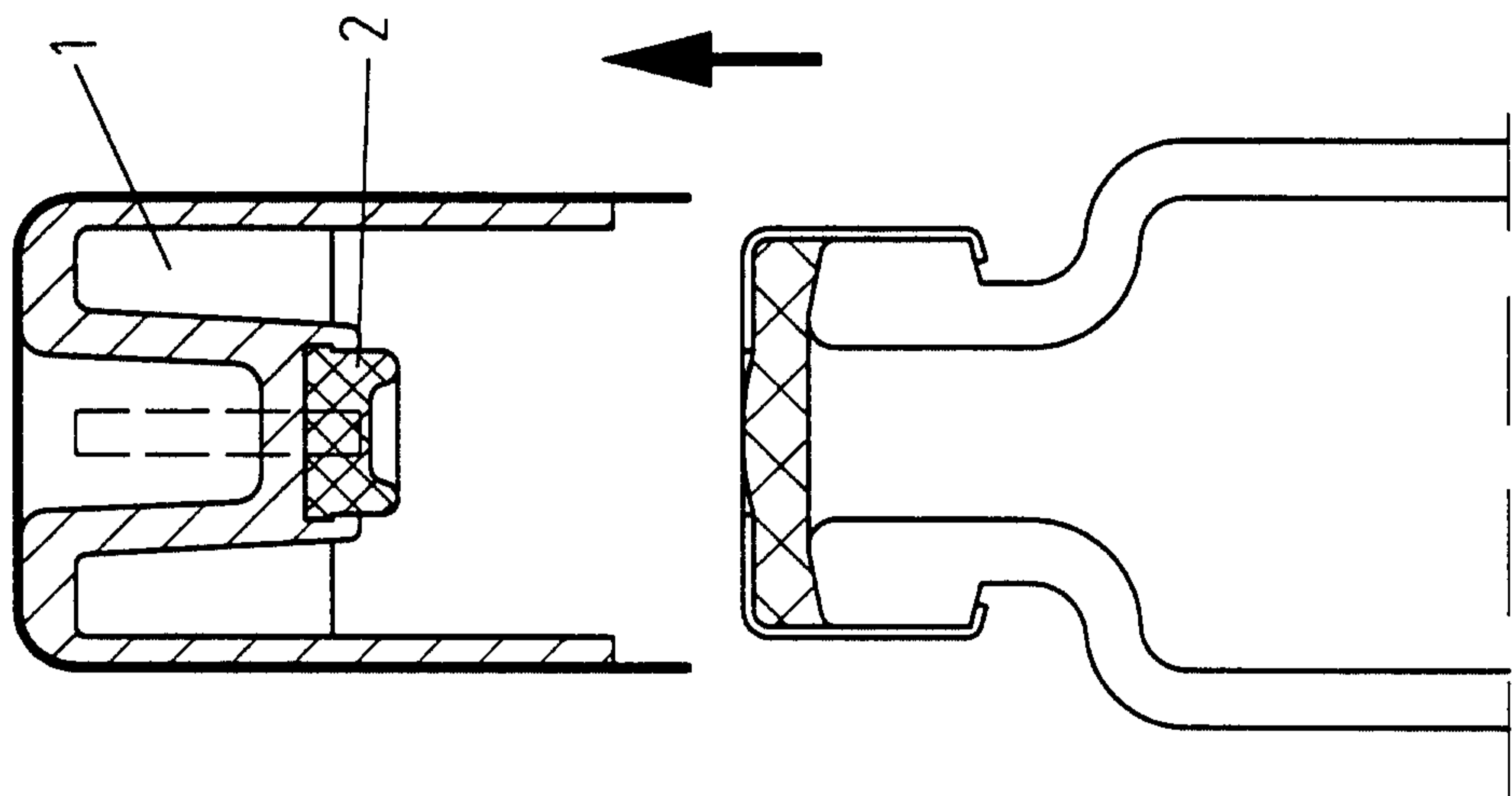


Fig. 6

