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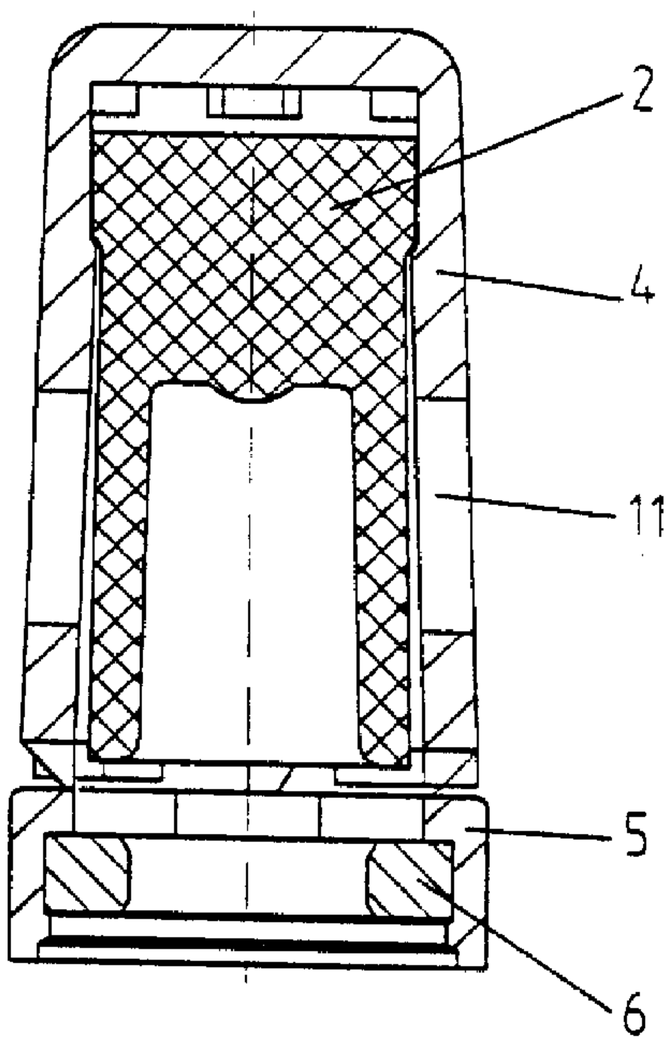
(54) **SERINGUE MEDICALE ET PROCEDURE D'ASSEMBLAGE**
(54) **MEDICAL SYRINGE AND ASSEMBLY PROCEDURE**



(57) The syringe is designed for medical use and has, attached to its cylindrical body (1), a needle-receiving device (3) in the shape of a Luer cone, for inserting a cannula. This needle receptacle (3) is sealed until use with a cap (2), such as a tip-cap. The sealing cap (2), together with the end of the needle receptacle (3), is enclosed by a detachable safety cap (4) secured by a safety ring (5). The sealing cap (2) is snapped and/or affixed firmly into the safety cap (4). The safety ring (5) is attached to the needle receptacle (3) by a holding ring (6), in such a way that the safety ring (5) surrounds and grips the holding ring (6) and the holding ring (6), when pushed into position over the needle receptacle (3), engages it securely.

Abstract

The syringe is designed for medical use and has, attached to its cylindrical body (1), a needle-receiving device (3) in the shape of a Luer cone, for inserting a cannula. This needle receptacle (3) is sealed until use with a cap (2), such as a tip-cap. The sealing cap (2), together with the end of the needle receptacle (3), is enclosed by a detachable safety cap (4) secured by a safety ring (5). The sealing cap (2) is snapped and/or affixed firmly into the safety cap (4). The safety ring (5) is attached to the needle receptacle (3) by a holding ring (6), in such a way that the safety ring (5) surrounds and grips the holding ring (6) and the holding ring (6), when pushed into position over the needle receptacle (3), engages it securely.

(Figure 2)

Medical Syringe and Assembly Procedure

Field of the Invention

The invention concerns a medical syringe with a safety cap, and a procedure for assembling such a syringe.

Background of the Invention

A syringe disclosed in DE 195 37 163, has proven good in practice. A drawback is that the individual sealing parts require special machines for handling them during manufacture, in particular for washing them, siliconizing them if necessary, and autoclaving them, before proceeding, under strict clean-room conditions, with further processing and automatic filling.

Summary of the Invention

The purpose of the invention is to improve this procedure, and in particular to optimize the sealing of the syringe, after washing or before filling.

The invention achieves this purpose, in terms of the device itself, by having the sealing cap snapped into and /or affixed in the safety cap, and having the safety ring attached firmly to the needle receptacle by a holding ring, so that the safety ring surrounds and grips the holding ring and the holding ring, and when pushed into position over the needle receptacle, engages it securely.

Detailed Description of the Invention

The advantage of the invention is essentially that the individual sealing parts can be pre-assembled in usable condition, without going through the usual production or assembly procedure, and the later process of sealing the syringe is reduced to one of simply applying the pre-assembled sealing device. Because the pre-assembled sealing parts go through the usual sterilization process and are thus sterile when the assembly process begins, this pre-assembly feature reduces handling of the parts and makes the procedure both safer and easier.

In a preferred embodiment of the invention, the interior surface of the safety cap is designed with two diametrically opposed, radially inward-facing ribs or fins, so that the sealing cap is firmly held within the safety cap.

It is also possible to design the inner surface of the safety cap with a shoulder ring that engages behind a projecting lip of the sealing cap.

The invention can be used to further advantage if the safety cap has at least one window in its circumference. This makes it possible to confirm visually that the safety cap is in place. In addition the interior ribs serve to distort the sealing cap into the window, so that the rim of the window exerts friction to hold the safety cap more securely.

In a preferred embodiment of the invention, the holding ring can be arranged in a circular groove of the safety ring.

It is also possible, however, for the safety ring to have a projecting lip on its inner surface that snaps behind the holding ring. The decisive point here is that the holding ring and the safety ring should make a sufficiently tight seal so that the two parts cannot be separated, inadvertently or otherwise, without leaving evidence.

The holding ring can have a collar facing the end of the needle receptacle and distanced from it by a gap, with the inner surface of the collar threaded as a Luer Lock connector for the cannula, so that the cannula can be screwed on, using the Luer Lock System.

The connection between the safety cap and the safety ring, removable when the syringe is used, is designed so that there is a gap between the safety cap and the safety ring, bridged in several places. Between any two bridges there is at least one spacer, attached either to the safety cap or the safety ring, with its free end lying against, or slightly distant from, the safety

ring or the safety cap. The connecting bridges should in this case be distributed evenly around the circumference.

It has also been shown to be advantageous if the connecting bridges taper towards the safety ring.

Finally, it is recommended that, to ensure that the sealing elements are reliably tight, the needle receptacle should have a circular groove, bulge or shoulder for the holding ring, although it is also possible in principle to cement the holding ring to the needle receptacle.

The purpose of the invention is further achieved through the procedure for assembling a syringe of the kind described, characterized in that, during pre-assembly of the sealing elements, the holding ring is first applied to an auxiliary cone, the sealing cap is then put in place, and finally the safety cap with the safety ring is installed, so that the safety ring engages the holding ring. This produces a completely pre-assembled sealing device, independent of the production process itself, that can be used as a unit in further processing after the required cleaning and sterilization stages.

It is also appropriate if the pre-assembly of the sealing components is itself conducted under aseptic conditions.

For further handling it is recommended that the pre-assembled sealing components be cleaned, wrapped in sterile packages and sterilized.

The sterilization process can be conducted on the assembled unit (post-treatment) or on its unassembled components (pre-treatment).

Finally, further processing can be arranged so that the sterile-packed sealing components, after sterilization, are air-locked through to the further production stage of sealing the syringe cylinders, under clean-room conditions, or the unsterilized parts can be assembled after washing, and then autoclaved with the empty, washed syringes.

The invention is further explained below, in the embodiment shown in the illustrations. These show:

Fig. 1 in drawings 1a) to 1c), the sealing elements before assembly, consisting of the safety cap with its safety ring, the sealing cap and the holding ring;

Fig. 2 the object according to Fig. 1, but in its assembled state;

Fig. 3 the cannula-receiving end of the syringe (the rest of which is merely indicated);

Fig. 4 an illustration, similar to Fig. 2, of a second embodiment;

Fig. 5 a side view of the object according to Fig. 4;

Fig. 6 a cross-sectional view of the object according to Fig. 4, along line VI-VII;

Figs. 7 and 8 an illustration, similar to Fig. 2, of the second embodiment according to Fig. 4.

The syringe (shown only schematically in the illustration) is intended for medical use, and can be essentially of any shape. It has a needle receptacle 3, attached to its cylinder 1, that is sealed until use of the syringe with a sealing cap 2, such as a tip cap. This needle receptacle 3 is shaped as a Luer cone, and is arranged to receive a cannula. The sealing cap 2, together with the end of the needle receptacle 3, is enclosed in a safety cap 4, that is secured to the needle receptacle 3 with a safety ring 5. The safety cap 4 is designed to be removed from the safety ring 5 when the syringe is to be used.

In the production process, the above-mentioned elements, which together make up a sealing device, are pre-treated, in particular washed and if necessary siliconized, in specially designed machines, and then, either after or before sterilization, and under clean-room conditions, subjected to further processing; or the fully-assembled sealing device can be

washed as a whole. Thereafter they are individually applied, in a filling machine or washing machine, following filling or cleaning of the syringe.

Under the cost-intensive clean-room conditions referred to, this requires several procedural steps until the sealing devices are fully assembled.

In order to improve this procedure, it is recommended to use a syringe where the sealing cap 2 is snapped and/or affixed in the safety cap 4, and the safety ring 5 is attached to the needle receptacle 3 by a holding ring 6. The safety ring surrounds and grips the holding ring 6, and when the holding ring 6 is pushed into position on the needle receptacle 3 it engages the needle receptacle 3.

This design makes it possible to pre-assemble the individual sealing components in usable condition, independent of the rest of the production or assembly process of the syringe itself. This means that the later process of sealing the syringe is reduced to the simple application of the pre-assembled sealing device to the needle receptacle 3.

Since the pre-assembled sealing devices also go through the usual cleaning process and can then be processed in sterile state, the process is safer and simpler, because, thanks to pre-assembly, the number of parts that must be handled to seal the syringe can be substantially reduced, in fact to one.

As shown in Fig. 6, there are two diametrically opposing, radially inward facing ribs or fins 7 on the inner surface of the safety cap 4, by means of which the sealing cap 2 is held securely in the safety cap 4. In addition, there are channels 8 provided beside the ribs 7, which allow fluid or steam to enter during cleaning and sterilization.

As shown in Figures 1 and 2 it is possible, however, to design a shoulder ring 9 on the inner side of the safety cap 4 that grips behind a projecting ring 10 of the sealing cap 2. This again allows the sealing cap 2 to be held securely in the safety cap 4.

As Figures 1, 2, 4 and 5 show, the safety cap 4 is arranged with two windows 11 in its circumference. This makes it possible to confirm visually that the sealing cap 2 is in place.

The windows 11 also serve to allow fluid or steam to enter during cleaning and sterilization.

The inward-facing ribs 7 serve to distort the sealing cap 2 towards the window 11, so that the rim of the window 11 helps further to secure the sealing cap 2 by friction.

In the embodiment shown in Figures 1 and 2 the holding ring 6 is arranged in a circular groove 12 in the safety ring 5.

In the embodiment shown in Figure 4 to 8, on the other hand, the safety ring 5 has a projecting lip 13 on its inner surface, which snaps behind the holding ring 6. The decisive point here, regardless of the specific design, is that the holding ring 6 and the safety ring 5 should make a sufficiently tight seal. This ensures that the two parts cannot be separated, inadvertently or not, or that if they are there will be evidence of this fact.
To make it possible for the cannula be screwed into place using the Luer Lock System, the holding ring 6, as shown in the further embodiment in Figures 4 to 6, can have a collar 14 facing the end of the needle receptacle 3 and distanced from it by a gap. The inner surface of the collar has a thread that forms a Luer Lock connector for the cannula.

The connection between the safety cap 4 and the safety ring 5, removable when the syringe is used, is designed (not shown in detail in the illustration) so that there is a circular gap between the safety cap 4 and the safety ring 5, and these are joined by bridges 15 at several points. Between any two bridges 15 there is a spacer 16, attached either to the safety cap 4 or the safety ring 5. The free end of the spacer 16 lies against, or slightly distant from, the safety ring 4 or the safety cap 5. In this way, the safety cap 4, together with the safety ring 5, as well as the sealing cap 2 pre-mounted within it and the holding ring 6, can be snapped onto the needle receptacle 3, without breaking or damaging the connection between the safety cap 4 and the safety ring 5. Moreover, the spacers prevent the safety cap from being pushed out over the contact point when it is applied.

The connecting bridges 15 are, in the usual manner, evenly spaced around the circumference and are tapered towards the safety ring 5.

To ensure that the holding ring 6 is securely fastened to the needle receptacle 3, the latter has a gripping element 17 in the form of a circular groove, bulge or shoulder against which the holding ring 6 engages.

With the syringe or the sealing device as described, the production process, especially for assembling the syringe, is significantly simplified and improved if, during pre-assembly of the sealing elements at the needle-receiving end of the syringe, the holding ring 6 is first applied to an auxiliary cone, the sealing cap 2 is then put in place, and finally the safety cap 4 with the safety ring 5 is installed. In this way the safety ring 5 engages the holding ring 6. This produces a completely pre-assembled sealing device, independent of the production process itself, that can be used as a single unit in further processing after the required cleaning and sterilization stages.

The pre-assembly of the sealing components can itself be conducted under aseptic conditions.

For further handling it is recommended that the pre-assembled sealing components be wrapped in suitable sterile packages and sterilized.

Further processing can be arranged so that, after sterilization, the sterile-packed sealing components are air-locked through to the further production stage, where the syringe cylinders are filled and sealed, under clean-room conditions.

Claims:

1. A syringe for medical use comprising a needle receptacle in the shape of a Luer cone, for inserting a cannula, which needle receptacle is sealed until use with a sealing cap whereby the sealing cap, together with the end of the needle receptacle, is enclosed by a safety cap detachably secured by a safety ring wherein:

the sealing cap is snapped and/or affixed firmly into the safety cap and the safety ring is attached to the needle receptacle by a holding ring, in such a way that the safety ring surrounds and grips the holding ring and the holding ring, when pushed into position over the needle receptacle, engages it securely.

2. A syringe according to Claim 1, wherein the interior surface of the safety cap is designed with two diametrically opposite, radially inward-facing ribs or fins.

3. A syringe according to Claim 1, wherein the inner surface of the safety cap is designed with a shoulder ring that engages behind a projecting lip of the sealing cap.

4. A syringe according to any one of Claims 1 to 3, wherein the safety cap has at least one window in its circumference.

5. A syringe according to any one of Claims 1 to 4, wherein the holding ring can be arranged in a circular groove of the safety ring.

6. A syringe according to any one of Claims 1 to 4, wherein the safety ring has a projecting lip on its inner surface that grips behind the holding ring.

7. A syringe according to any one of Claims 1 to 6, wherein the holding ring has a collar facing the end of the needle receptacle and distanced from it by a gap, with the inner surface of the collar threaded as a Luer Lock connector for the cannula.

8. A syringe according to any one of Claims 1 to 7, wherein there is a circular gap between the safety cap and the safety ring, and these are joined by bridges at several

points, whereby between any two bridges there is at least one spacer, attached either to the safety cap or the safety ring and the free end of the spacer lies against, or slightly distant from, the safety ring or the safety cap.

9. A syringe according to Claim 8, wherein the connecting bridges are evenly spaced around the circumstance.

10. A syringe according to Claim 8 or 9, wherein the connecting bridges taper toward the safety ring.

11. A syringe according to any one of Claims 1 to 10, wherein the needle receptacle has a gripping element in the form of a circular groove, bulge or shoulder for the holding ring.

12. A procedure for assembling a syringe according to Claims 1 to 11, wherein during pre-assembly of the sealing elements arranged at the cannula end, the holding ring is first applied to an auxiliary cone, the sealing cap is then put in place, and finally the safety cap with the safety ring is installed, so that the safety ring engages the holding ring.

13. A procedure according to Claim 12, wherein the pre-assembly of the sealing elements is done under aseptic conditions.

14. A procedure according to Claim 12 or 13, wherein the sealing elements are wrapped in suitable sterile packages and are sterilized.

15. A procedure according to Claims 12 to 14, wherein the sterile-packed sealing elements, after sterilization, are air-locked through to the further production stage of sealing the syringe cylinders, under clean-room conditions.

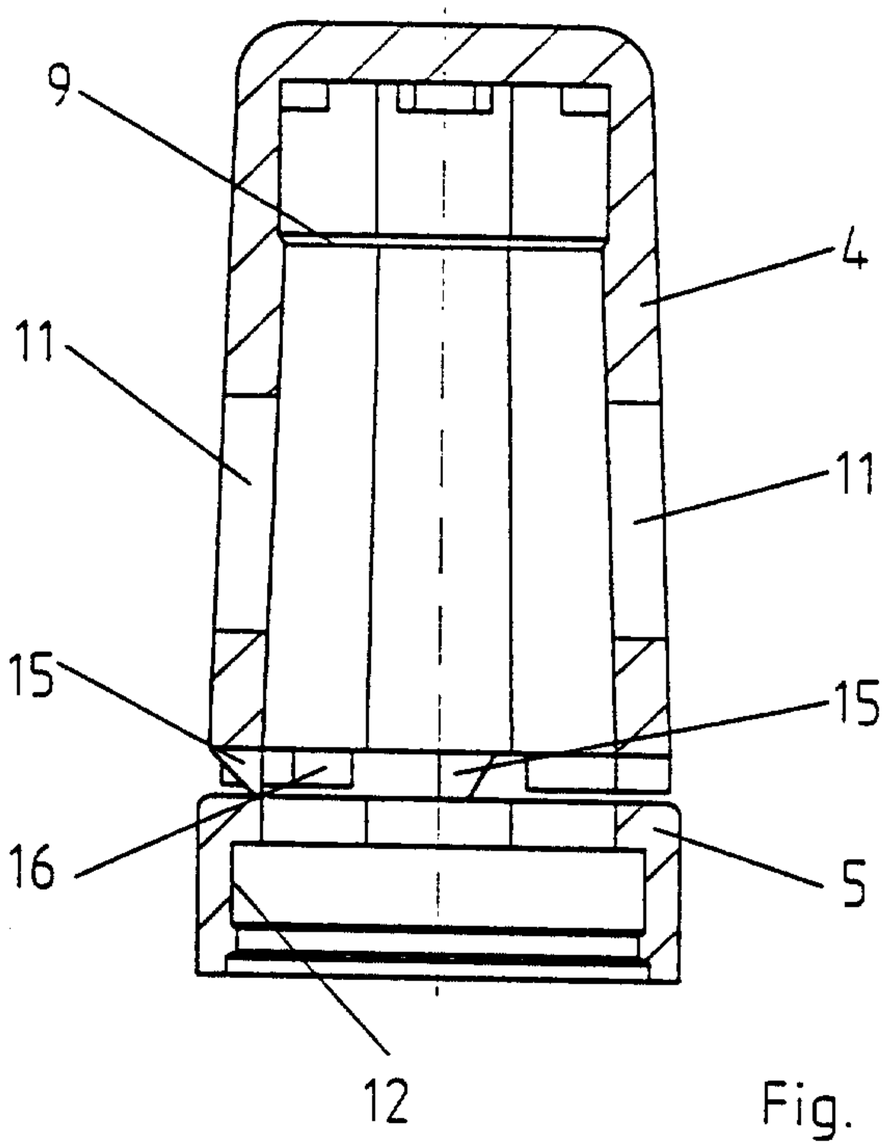


Fig. 1a

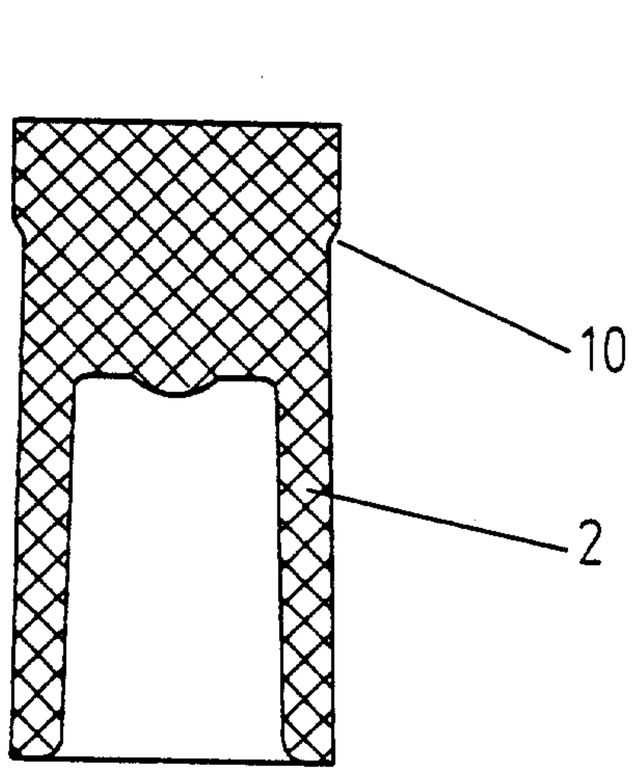


Fig. 1b

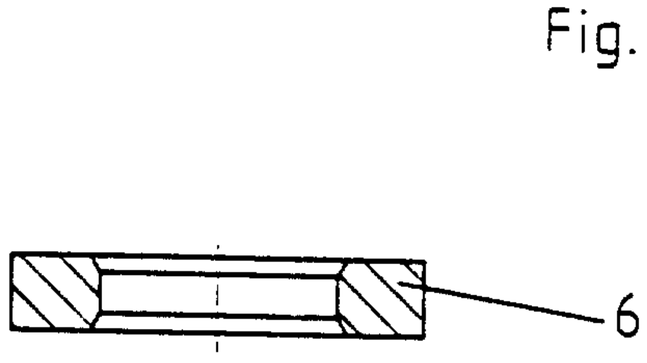


Fig. 1c

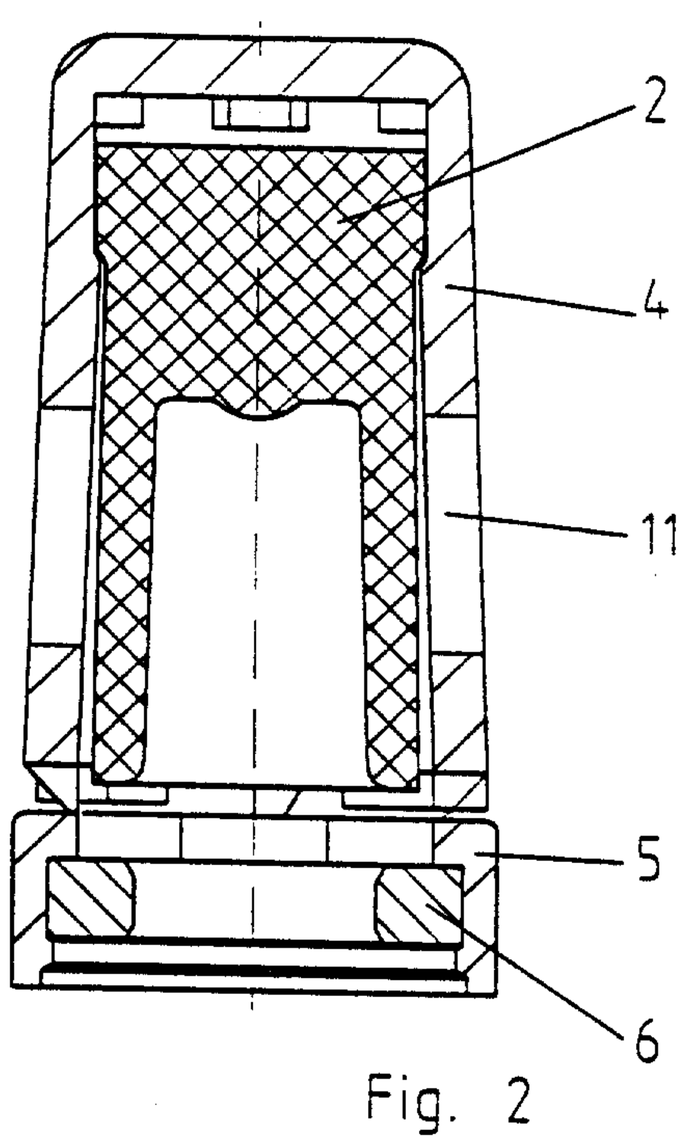


Fig. 2

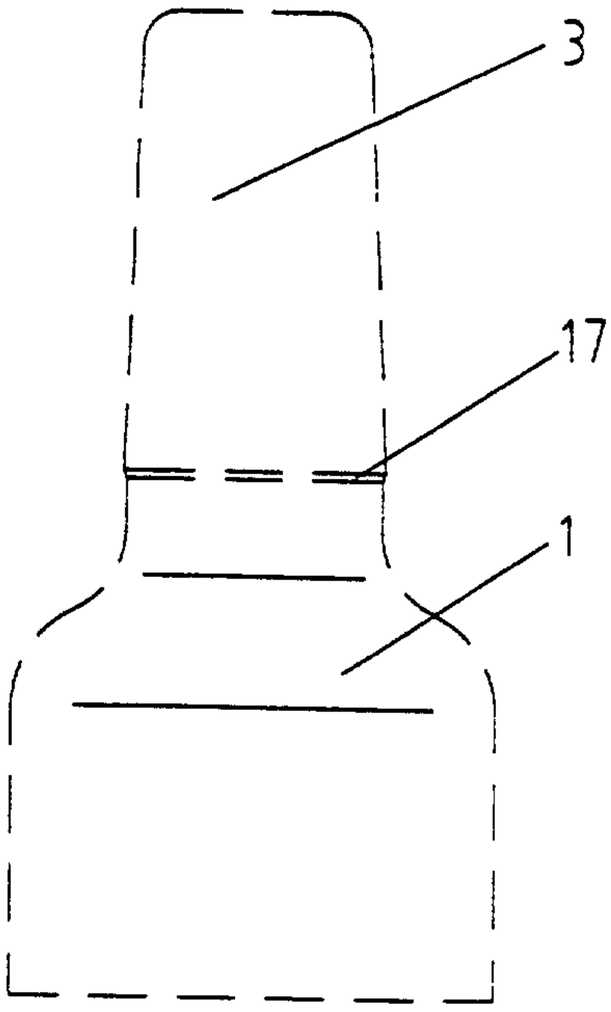


Fig. 3

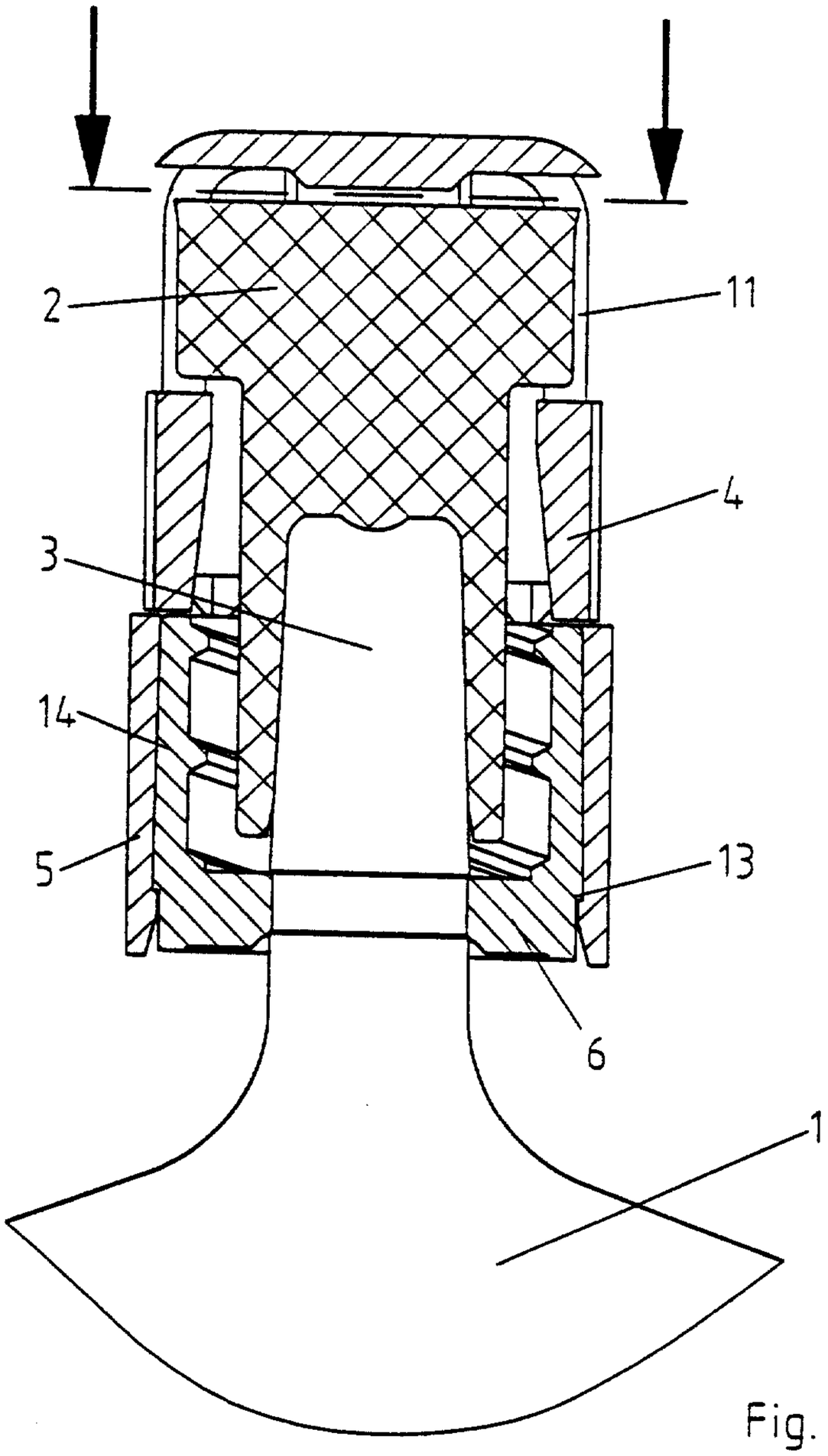


Fig. 4

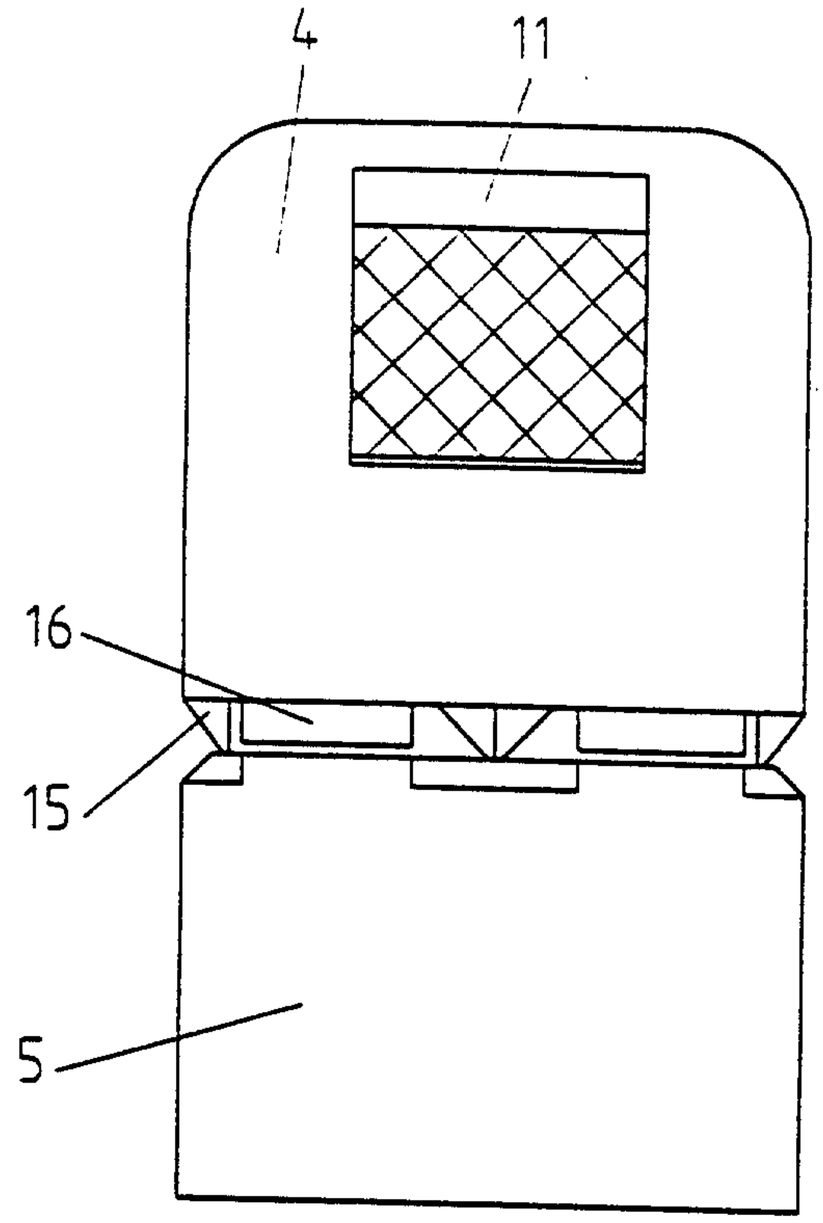


Fig. 5

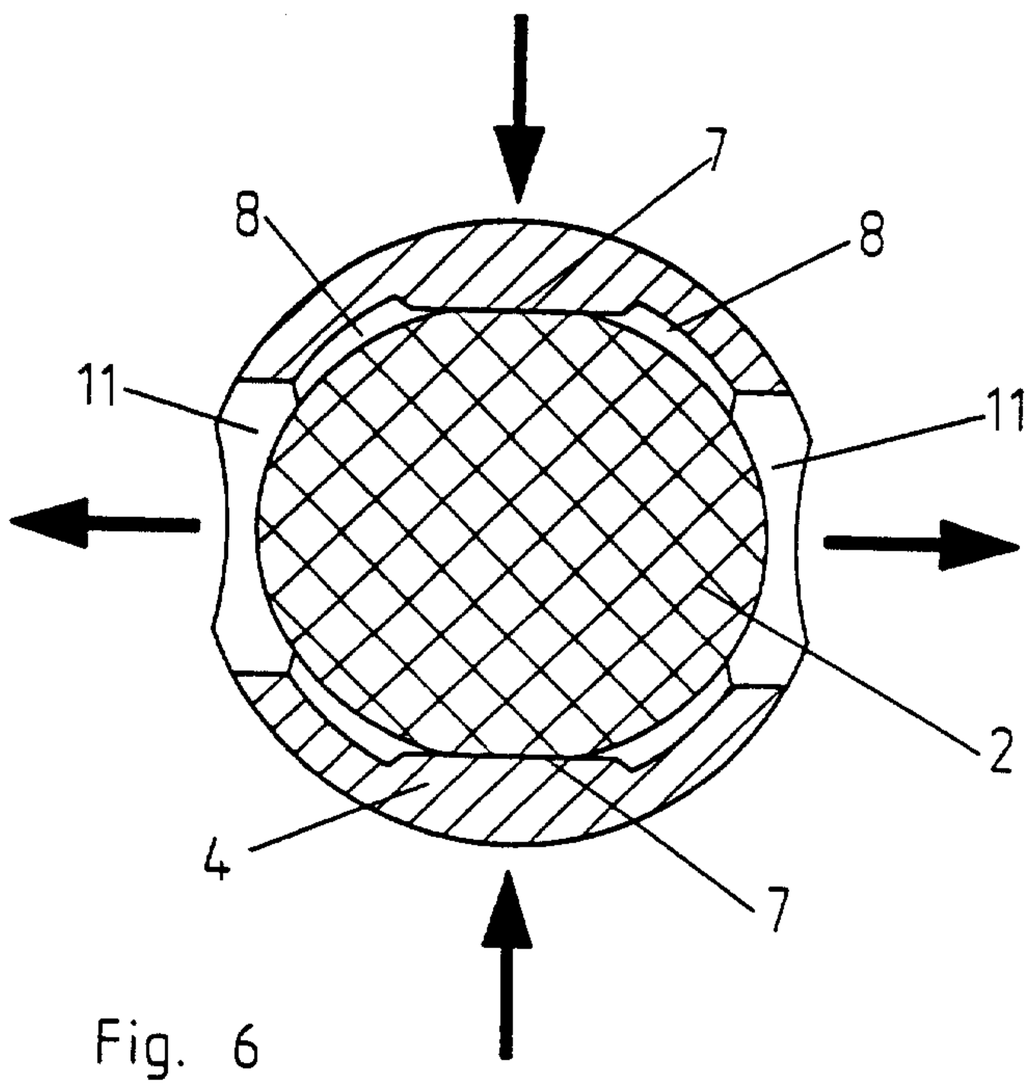


Fig. 6

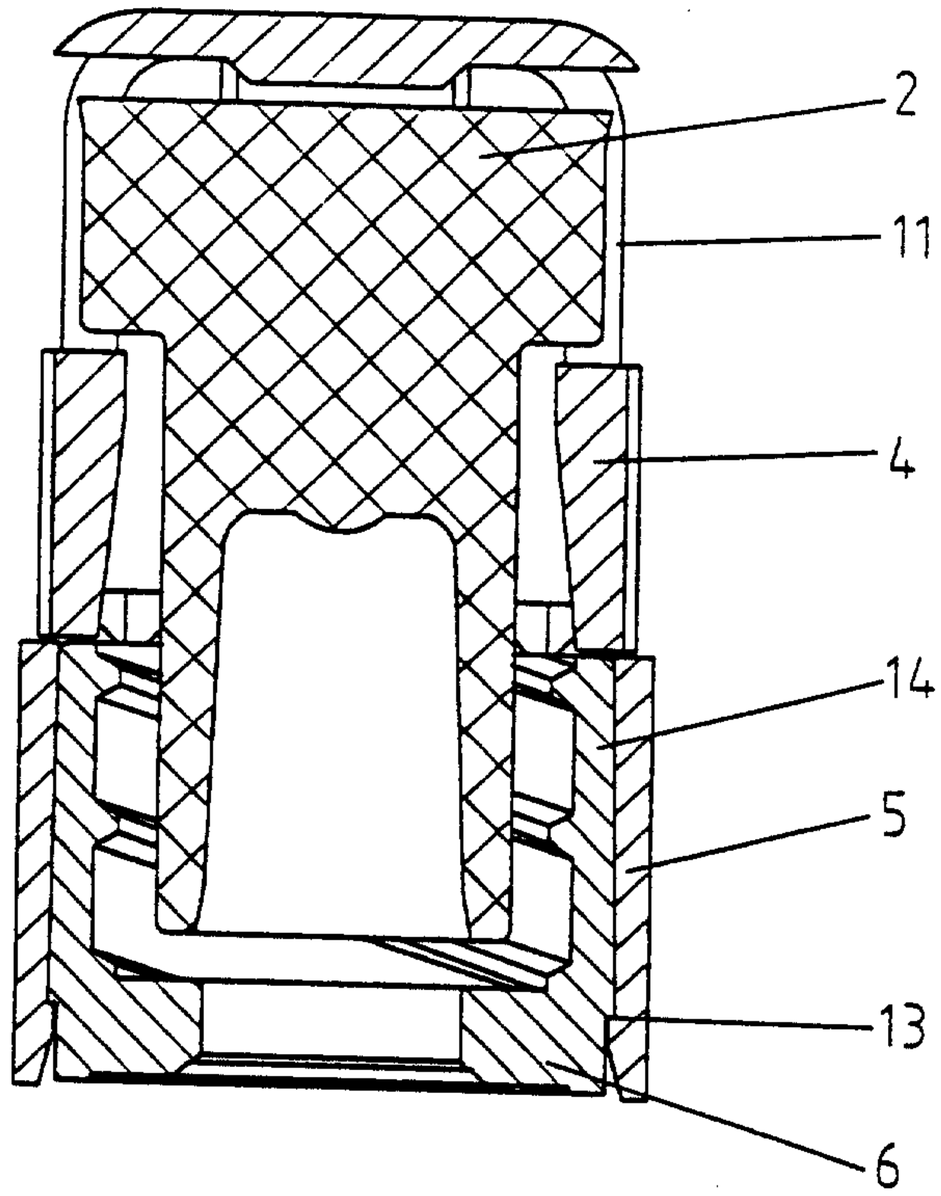


Fig. 7

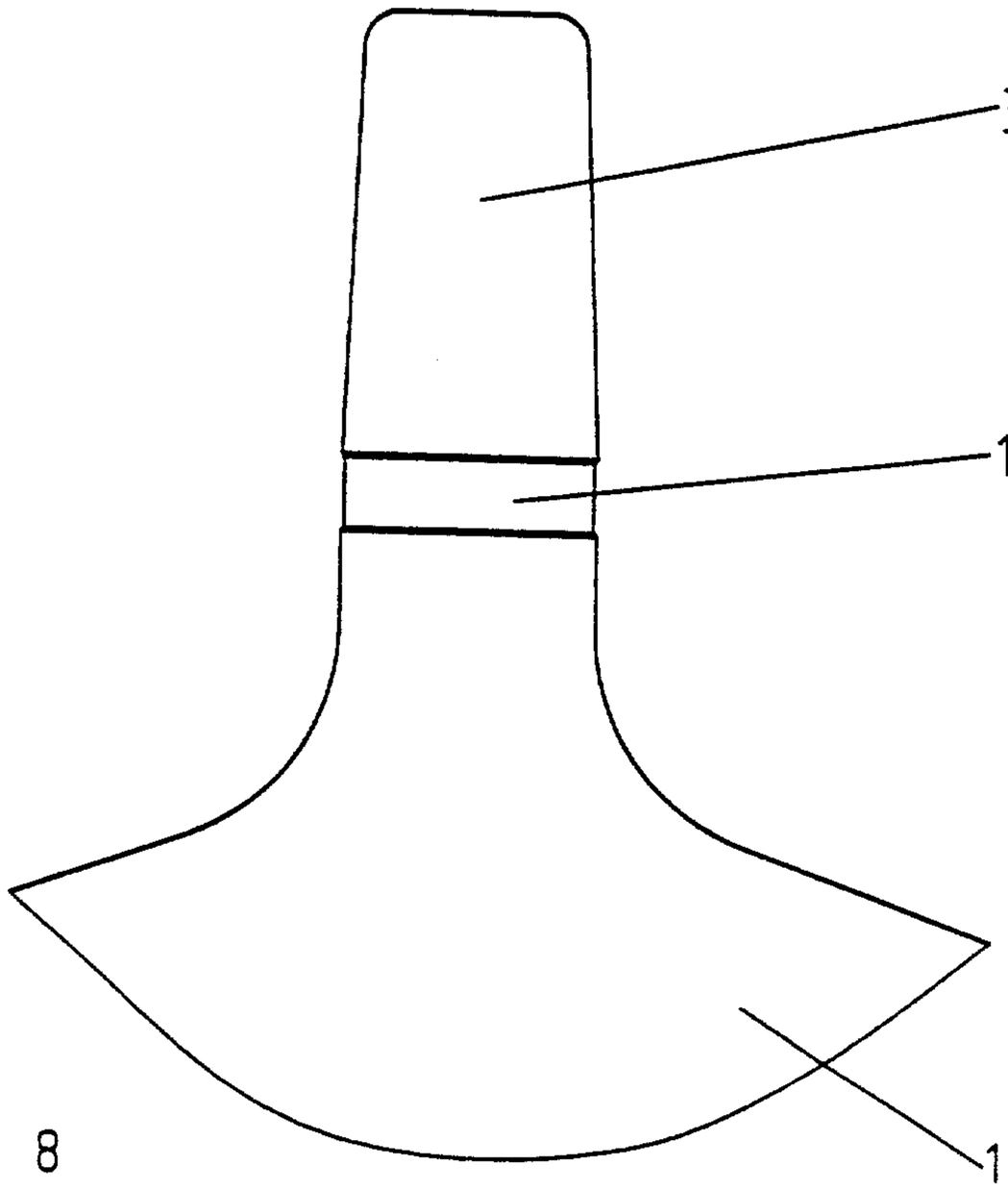
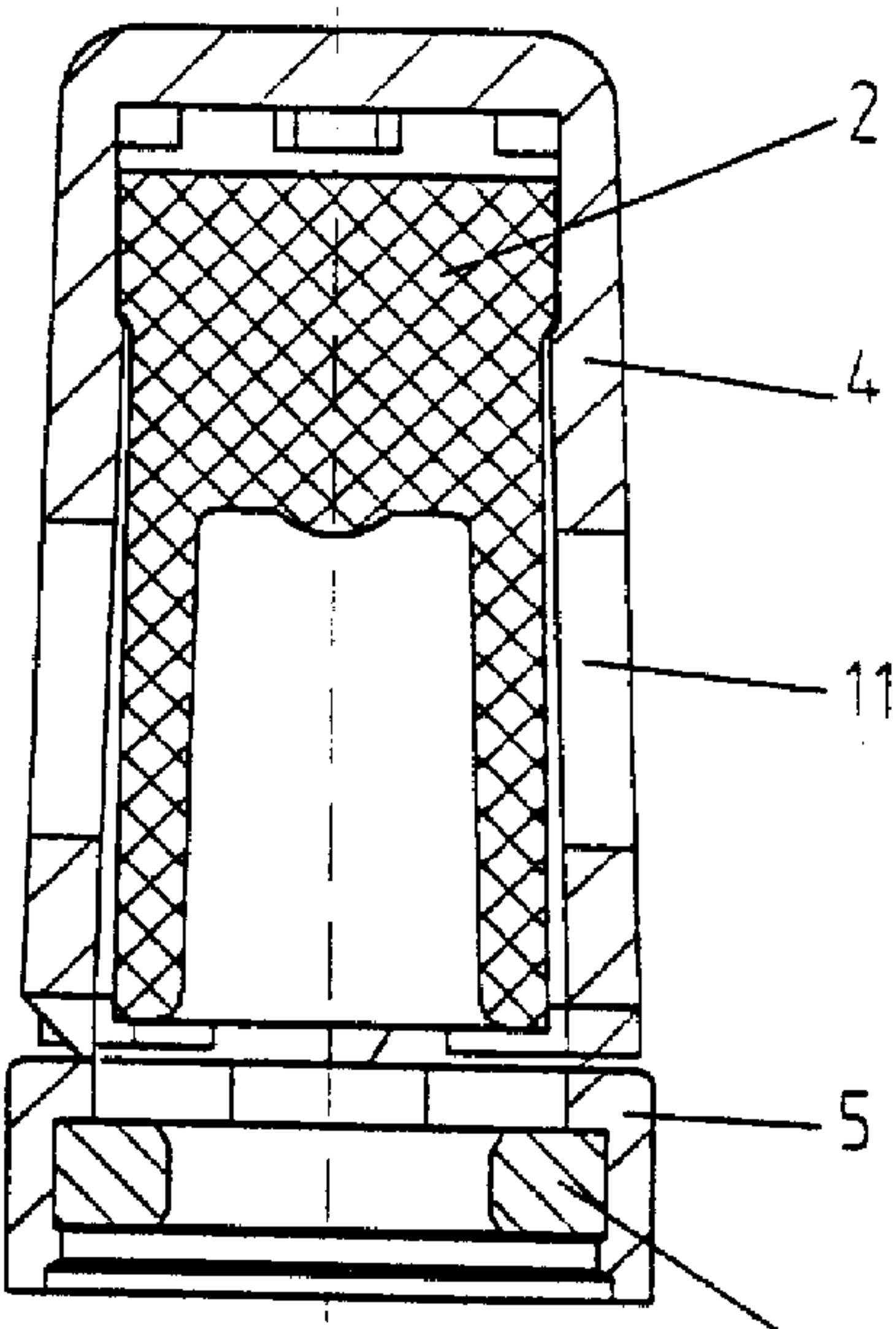


Fig. 8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