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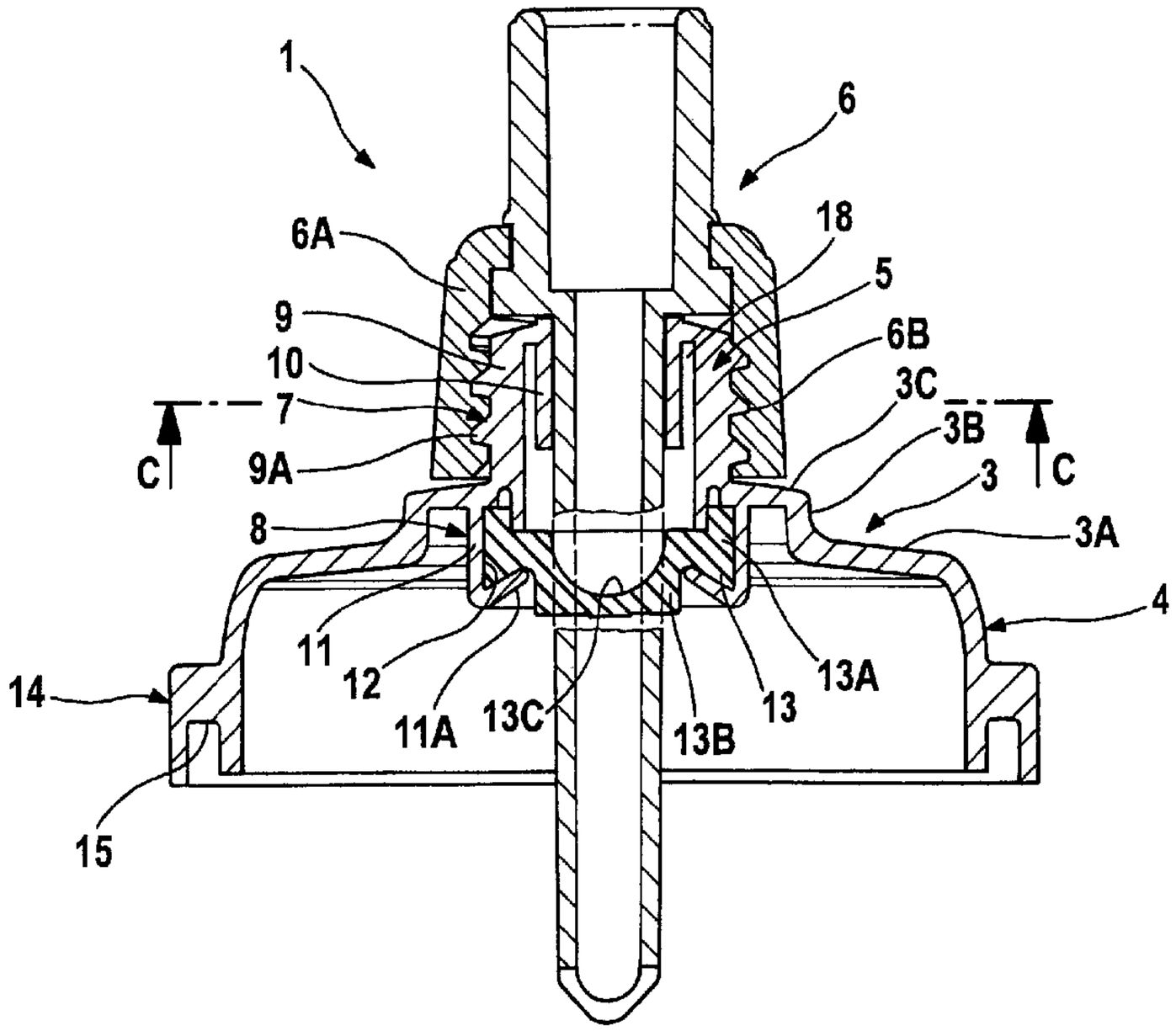
(54) Titre : COIFFE DE FERMETURE POUR RECIPIENT DESTINE A CONTENIR DES LIQUIDES, EN PARTICULIER UNE SOLUTION NUTRITIVE ENTERALE, ET RECIPIENT MUNI D'UNE TELLE COIFFE DE FERMETURE

(54) Title: CLOSURE CAP FOR A CONTAINER FOR RECEIVING LIQUIDS AND IN PARTICULAR AN ENTERAL NUTRIENT SOLUTION, AND CONTAINER HAVING SUCH A CLOSURE CAP



(57) Abrégé/Abstract:
The invention relates to a closure cap for a container for receiving fluids, particularly a container for receiving a fluid for the enteral nutrition, comprising a lid part (3) and an edge part (4). The lid part (3) is provided with a removal part (5) for removing a fluid,

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(57) Abrégé(suite)/Abstract(continued):
comprising a connecting part (7) for a spike of a hose line of a transfer device and a closure part (8) having a membrane that can be punctured for closing the recess (12) of the closure part. The removal part (5) comprises a receiving part (12) for receiving the spike, designed as a ring-shaped body tightly surrounding the spike and connected to the upper edge of the connecting part and extending to the inside into the edge part. The receiving part for the spike ensures that no enteral nutrient solution escapes from the closure cap when the spike is introduced in the removal part (5) of the closure cap.

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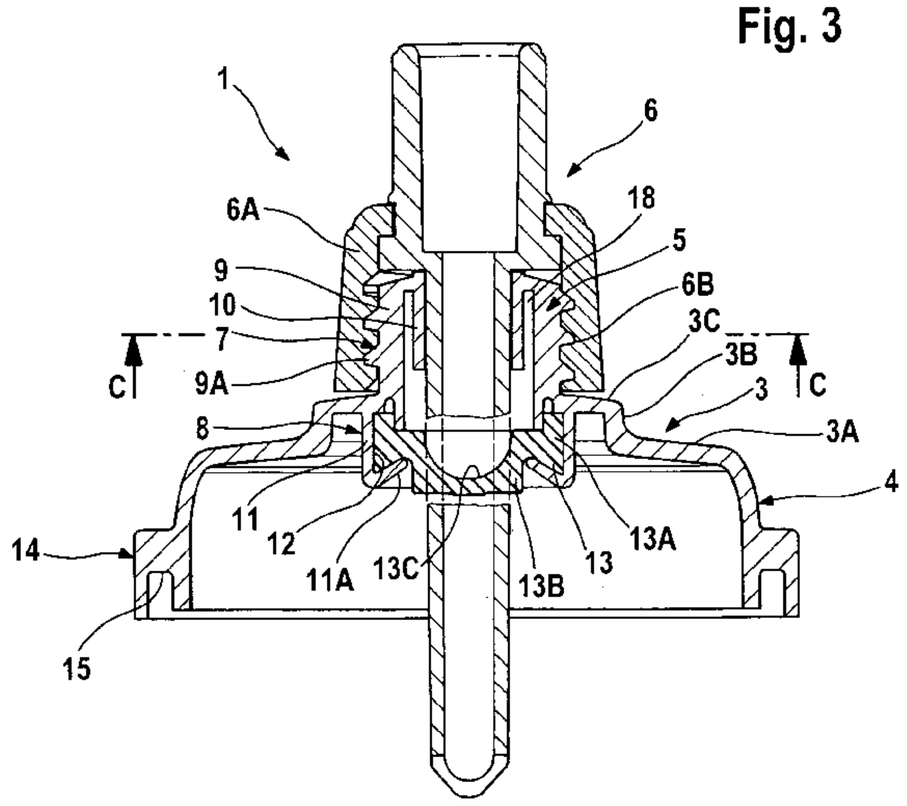
[Fortsetzung auf der nächsten Seite]

(54) Title: CLOSURE CAP FOR A CONTAINER FOR RECEIVING FLUIDS, PARTICULARLY AN ENTERAL NUTRIENT SOLUTION AND CONTAINER HAVING SUCH A CLOSURE CAP

(54) Bezeichnung: VERSCHLUSSKAPPE FÜR EIN BEHÄLTNIS ZUR AUFNAHME VON FLÜSSIGKEITEN, INSBESONDERE EINER ENTERALEN NÄHRLÖSUNG UND BEHÄLTNIS MIT EINER DERARTIGEN VERSCHLUSSKAPPE

Fig. 3



(57) Abstract: The invention relates to a closure cap for a container for receiving fluids, particularly a container for receiving a fluid for the enteral nutrition, comprising a lid part (3) and an edge part (4). The lid part (3) is provided with a removal part (5) for removing a fluid, comprising a connecting part (7) for a spike of a hose line of a transfer device and a closure part (8) having a membrane that can be punctured for closing the recess (12) of the closure part. The removal part (5) comprises a receiving part (12) for receiving the spike, designed as a ring-shaped body tightly surrounding the spike and connected to the upper edge of the connecting part and extending to the inside into the edge part. The receiving part for the spike ensures that no enteral nutrient solution escapes from the closure cap when the spike is introduced in the removal part (5) of the closure cap.

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Erklärung gemäß Regel 4.17:

— *Erfindererklärung (Regel 4.17 Ziffer iv)*

Veröffentlicht:

— *mit internationalem Recherchenbericht*

(57) Zusammenfassung: Die Erfindung betrifft eine Verschlusskappe für ein Behältnis zur Aufnahme von Flüssigkeiten, insbesondere ein Behältnis zur Aufnahme einer Flüssigkeit für die enterale Ernährung, die einen Deckelteil (3) und einen Randteil (4) aufweist. Der Deckelteil (3) ist mit einem Entnahmeteil (5) zum Entnehmen einer Flüssigkeit versehen, der einen Anschlussteil (7) für einen Spike einer Schlauchleitung eines Überleitgeräts und einen Verschlussteil (8) mit einer durchstechbaren Membran zum Verschließen der Ausnehmung (12) des Verschlussteils aufweist. Der Entnahmeteil (5) weist ein Aufnahmestück (10) zur Aufnahme des Spike auf, das als ringförmiger den Spike dicht umschließender Körper ausgebildet ist, der an den oberen Rand des Anschlussteils angeschlossen ist und sich nach innen in den Randteil erstreckt. Das Aufnahmestück für den Spike stellt sicher, dass auch beim Einfuhren des Spike in den Entnahmeteil (5) der Verschlusskappe keine enterale Nährlösung aus der Verschlusskappe austreten kann.

Closure cap for a container for receiving liquids and in particular an enteral nutrient solution, and container having such a closure cap

The invention relates to a closure cap for a container for receiving liquids, and in particular for a container for receiving a liquid for enteral nutrition, which has a cover part and a rim part. As well as this, the invention also relates to a container for receiving a liquid for enteral nutrition, and in particular a BFS container, which has such a closure cap.

There is a process, known as the blow-fill-seal process (BFS process), in which, in a single operation and sterilely and while remaining pyrogen-free, containers, such for example as bottles of extruded PE or PP, are blown to a desired shape and immediately on cooling are filled aseptically with a sterile filling and are hermetically sealed. The containers, and in particular the bottles, which are produced by the blow-fill-seal process are also referred to as BFS containers.

When known BFS containers are used to receive sterile medical liquids, such for example as enteral nutrient solutions, they require a closure cap system which allows the enteral nutrient solution to be transferred to the patient by means of a transfer device.

To allow enteral nutrient solutions to be supplied, there are known nutrient solution bags which have a connecting part referred to as a port to which a transfer device for feeding the nutrient solution to the patient can be connected.

The known transfer devices for feeding the enteral nutrient solution to the patient have a flexible line which is provided at one end with a spike which can be connected to the connecting part of the nutrient solution bag. The other end of the flexible line is provided with a connector for connection to a probe for enteral nutrition.

The known connecting parts of known nutrient solution bags are closed off with a seal by a membrane which is pierced by the spike of the transfer device when the flexible line is connected in.

Known from DE 20 2004 003 267 U1 is a closure cap for a BFS container which has a cover part and a rim part, a slit membrane which allows the spike of a transfer device to be inserted being inset into the cover part. The slit membrane is seated in the cover part of the closure cap flush therewith.

The object underlying the invention is to provide a closure cap for a container for receiving liquids, and in particular a BFS container for receiving an enteral nutrient solution, in which the handling of the container when the spike of a flexible line of a transfer device is being connected in is simplified. As well as this, it is also an object of the invention to provide a container for receiving liquids, and in particular a BFS container for receiving an enteral nutrient solution, which can be handled easily when the spike of the transfer device is being connected in.

The closure cap according to the invention for a container for receiving liquids, and in particular a BFS container for receiving an enteral nutrient solution, has a cover part and a rim part, with a withdrawal part for the withdrawal of a liquid, and in particular the enteral nutrient solution, being arranged in the cover part. Basically, the closure cap according to the invention may also comprise, as well as the withdrawal part, an injection part for the injection of a medicinal liquid into the enteral nutrient solution.

The withdrawal part of the closure cap according to the invention has a connecting part for a spike of a flexible line of a transfer device and a closing-off part having a pierceable membrane for closing-off the recess in the connecting part.

The closure cap according to the invention is distinguished by the fact that the withdrawal part has a receiving piece for receiving the spike which takes the form of an annular body which surrounds the spike and makes a seal as it does so and which is connected to the top edge of the connecting part and extends inwards into the rim part of the closure cap. This ensures that the closure cap is closed off with a seal when the membrane is punctured by the spike. It is true that the closure cap is closed off with a seal by the membrane when the spike is in the state where it is connected to the closure cap, but there is a risk of the membrane not being sealed in relation to the spike when the membrane is being punctured. The annular body

which surrounds the spike and makes a seal as it does so then ensures that no enteral nutrient solution will escape from the closure cap.

In a preferred embodiment, the annular body which surrounds the spike and makes a seal as it does so is connected to the top edge of the connecting part in such a way that a narrow gap is formed between the inner wall of the connecting part and the outer wall of the annular body. As a result, the annular body is able to deform slightly when the spike is inserted and the spike is thus surrounded by the body with a seal made. The wall thickness of the annular body may be so sized, or the material of which the annular body is composed may be so selected, that the annular body is endowed with a certain elasticity.

In a further preferred embodiment, the annular body which surrounds the spike and makes a seal as it does so is of a non-circular, and in particular substantially square-cornered, cross-section and the spike, which is likewise of a square-cornered cross-section, is thus held in the annular body in such a way as to be secure against rotation. In principle, a circular cross-section is also possible, but the spike is not secured against rotation in this case.

A further preferred embodiment makes provision for the connecting part to have a substantially cylindrical portion which extends outwards from the cover part of the closure cap. Preferably, the annular body which surrounds the spike and makes a seal as it does so is connected to the top edge of the cylindrical portion of the connecting part. It is however also possible for the annular body to extend inwards from the cover part of the closure cap.

A further preferred embodiment makes provision for the substantially cylindrical portion of the connecting part to be provided with an outside thread. By this means it is possible for a spike which has a screw cap to be screwed tightly to the closure cap so that the spike is secured against slipping out.

For the pierceable membrane to be closed off aseptically, the connecting part is preferably closed off by a break-off part which is referred to as a tamper-evident part and which is connected to the top edge of the connecting part by an annular zone for fracture. Once the break-off part has been broken off or twisted off, the membrane is exposed, thus allowing the spike to be inserted.

To improve handling, the break-off part preferably has wings for gripping which project sideways from the closing-off part. The lateral wings for gripping are preferably connected to a central disc-like portion of the break-off part.

The wings for gripping preferably extend as far as the cover part of the closure cap, thus leaving only a narrow gap between the bottom edge of the wings for gripping and the cover part. This rules out the possibility of the flexible line of the transfer device being able to be trapped between the wings for gripping and the closure cap.

In a further embodiment, which is a particular preference, the closing-off part has a substantially cylindrical portion which extends inwards from the cover part of the closure cap. The pierceable membrane is seated in the cylindrical portion of the closing-off part in this embodiment.

In a further embodiment which is a particular preference, the substantially cylindrical portion of the closing-off part takes the form of a beaded-over rim which fits over the pierceable membrane and which clamps the membrane solidly in the recess in the closing-off part. This simplifies the production of the closure cap. The membrane is first inserted in the cylindrical portion of the closing-off part and the rim of the latter is then beaded over. The rim of the cylindrical portion of the closing-off part may for example be deformed thermally.

Basically, it is however also possible for the pierceable membrane to be inserted in the cylindrical portion of the closing-off part by snapping-in and/or for it to be clamped radially.

The closure cap according to the invention can be inexpensively produced in large numbers from plastics material as a one-piece injection moulding.

The container according to the invention has the closure cap according to the invention which is described above. The container preferably takes the form of a bottle, and in particular a BFS bottle, the closure cap being connected to the container with a seal. The closure cap may be bonded and/or welded to the container in this case or may take the form of a screw cap.

An embodiment of the invention will be explained in detail below by reference to the drawings. In the drawings:

Fig. 1 is a view from the side of an embodiment of screw cap according to the invention which is closed off by the break-off part,

Fig. 2 is a view from the side of the closure shown in Fig. 1, the break-off part having been broken off and the spike of a flexible line of a transfer device having been screwed to the closure cap,

Fig. 3 is a section through the closure cap shown in Fig. 2 on line A-A,

Fig. 4 is a section through the closure cap shown in Fig. 2 on line C-C,

Fig. 5 is a perspective view of the closure cap shown in Fig. 2, and

Fig. 6 shows an embodiment of container according to the invention having the closure cap according to the invention.

Fig. 1 is a view from the side of the closure cap 1 according to the invention, which is closed off with a seal by a break-off part 2. The closure cap 1 has a cover part 3 and a rim part 4. The cover part 3 has an outer portion 3A with which an inner portion 3C merges via an outwardly curved portion 3B. The inner portion 3C of the cover part 3 is provided with a withdrawal part 5 to allow a liquid, and in particular an enteral nutrient solution, to be withdrawn. The enteral nutrient solution is withdrawn by using a spike (not shown in Fig. 1) which is connected to the closure cap once the break-off part 2 has been broken off.

The closure cap will be described in detail below by reference to Figs. 2 to 5, in which the spike 6, which is connected to one end of a flexible line (not shown) of a transfer device (not shown), has been screwed to the closure cap.

The withdrawal part 5 for withdrawing the enteral nutrient solution has a connecting part 7 and a closing-off part 8. The connecting part 7 has a substantially cylindrical portion 9 which extends outwards from the inner portion 3C of the cover part 3. Connecting up with the top edge of the cylindrical portion 9 there is an annular body 10 which extends inwards. The annular body 10 is of a substantially square cross-section which corresponds to the cross-section of the spike 6. The annular body 10, which surrounds the spike and makes a seal as it does so is integrally moulded into the top edge of the cylindrical portion 9 in such a way that a narrow gap 18 is left between the inner wall of the cylindrical portion 9 and the outer wall of the annular body 10.

The closing-off part 8 of the closure cap 1 has a substantially cylindrical portion 11 which extends inwards from the inner side of the inner portion 3C of the cover part 3. Seated in the recess 12 in the cylindrical portion 11 of the closing-off part 8 is a pierceable membrane 13. The membrane 13, which is self-sealing, has an outer, annular portion 13A and an inner portion 13B which has a bowl-like depression 13C and which is slit.

At the time of assembly, once the membrane 13 has been inserted in the cylindrical portion 11 the bottom rim 11A of the latter is bent over and the bottom rim 11A thus fits under the membrane 13. The outer portion 13A of the membrane 13 is thus held in the recess 12 in the closing-off part 8 by a clamping action.

The rim part 4 of the closure cap 1 has a bottom bulged edge 14 which has in its underside a groove 15 extending round in a circle. The closure cap can be fitted onto a bottle, in which case the top edge of the neck of the bottle fits into the groove in the bulged edge of the closure cap.

The closure cap 1 has had the spike 6 screwed to it. The spike 6 has a ring nut 6A which is secured in such a way as to be unlosable and which has an inside thread 6B, while the outer wall of the cylindrical portion 9 of the connecting part 7 is provided with a corresponding outside thread 9A, thus enabling the ring nut 6A to be screwed onto the connecting part 7 of the closure cap 1.

The closure cap 1 is sealed off not only by the membrane 13 but also by the annular portion 10 which surrounds the spike 6 and makes a seal as it does so. This ensures that enteral solution itself cannot escape when the spike is being inserted in the withdrawal part of the closure cap.

Before the enteral nutrient solution is withdrawn, the closure cap 1 is in a state where it is closed off with a seal by the break-off part 2 (Fig. 1). The break-off part 2 has an inner, disc-like portion 2A which is connected to the top edge of the cylindrical portion 9 of the connecting part 7 by an annular zone 19 for fracture. Connected to the inner disc-like portion 2A of the break-off part 2 via narrow fillets 2B are two wings for gripping 2C which project on two sides. The wings for gripping 2C are in the form of flat bodies which width is equal to the width of the outer portion 3A of the cover part 3. The wings for gripping 2C extend as far

as the outer portion 3A of the cover part 3, with a narrow gap being left between the bottom edge of the wing for gripping 2C and the upper side of the outer portion 3A of the cover part 3. Both the wings for gripping 2C have a cut-out in the form of an outward pointing arrow to identify the closure cap as a withdrawal part.

Fig. 6 shows the closure cap according to the invention together with a container according to the invention, which in the present embodiment is a BFS bottle. The closure cap 1 is firmly seated on the neck 16 of the bottle 17, the latter being filled with an enteral nutrient solution. The closure cap 1 is welded to the neck 16 of the bottle, with the top edge 16A of the neck of the bottle fitting into the groove 15 in the bulged edge 14 of the closure cap.

Claims

1. System comprising a spike and a closure cap for a container for holding liquids, in particular a container for holding a liquid for enteral nutrition, having a cover part (3) and an edge part (4), wherein the cover part (3) has a withdrawal part (5) having a recess (12) for withdrawing a liquid, said withdrawal part (5) having a connector part (7) having a holding piece (10) for holding the spike of a tube line of a transfer device, and the withdrawal part (5) has a closure part (8) having a pierceable membrane (13) for closing the recess (12) in the withdrawal part (5), wherein the closure part (8) has a substantially cylindrical portion (9) which extends outwardly from the cover part (3), wherein the holding piece (10) is integrally formed on the upper edge of the substantially cylindrical portion (9) of the closure part (8) and extends inwardly into the connector part (7), wherein the holding piece for the spike is in the form of an annular body (10) that encloses the spike, wherein the annular body (10) that encloses the spike is connected in such a way to the upper edge of the substantially cylindrical portion (9) of the connector part (7) and extends in such a way inwardly into the connector part (7) that when the pierceable membrane (13) is pierced the annular body (10) encloses the spike for closing the recess (12) in the withdrawal part (5), wherein the annular body (10) that encloses the spike is integrally formed on the upper edge of the connector part (7), forming a narrow gap (18) between the inner wall of the connector part (7) and the outer wall of the holding piece (10), characterized in that the closure cap is sealed off not only by the membrane (13) but also by the annular body (10) that tightly encloses the spike, when the spike has been introduced into the withdrawal part (5) of the closure cap, and in that the wall thickness of the annular body (10) is dimensioned such that the annular body (10) is given a certain elasticity, such that the annular body (10) deforms slightly when the spike is introduced, such that the spike is enclosed tightly by the annular body (10).

2. System according to Claim 1, characterized in that the annular body (10) that tightly encloses the spike has a cross section in the form of a circular ring.

3. System according to Claim 1, characterized in that the annular body (10) that tightly encloses the spike has a non-round cross section.

4. System according to Claim 3, characterized in that the annular body (10) that tightly encloses the spike has a substantially rectangular cross section.

5. System according to any one of Claims 1 to 4, characterized in that the substantially cylindrical portion (9) of the connector part (7) is provided with an external thread (9A).

6. System according to any one of Claims 1 to 5, characterized in that the connector part (7) is closed off with a break-off part or twist-off part (2) which is connected to the upper edge of the connector part via an annular break zone (19).

7. System according to Claim 6, characterized in that the break-off part (2) has a central plate-like portion (2A) to which there are connected gripping tabs (2C) that protrude laterally from the plate-like portion (2A).

8. System according to Claim 7, characterized in that the gripping tabs (2C) extend as far as the cover part (3) of the closure cap.

9. System according to any one of Claims 1 to 8, characterized in that the closure part (8) has a substantially cylindrical portion (11) which extends inwardly from the cover part (3), wherein the pierceable membrane (13) sits in the cylindrical portion (11) of the closure part (8).

10. System according to Claim 9, characterized in that the lower edge of the substantially cylindrical portion (11) of the closure part (8) is in the form of a flanged edge (11A) that engages over the pierceable membrane (13).

11. System according to Claim 9 or Claim 10, characterized in that the cover part (3) has an outer portion (3A) which is adjoined by an inner portion (3C) via an

outwardly curved portion (3B), wherein the substantially cylindrical portion (11) of the closure part (8) is connected to the inner portion (3C) of the cover part (3).

12. System according to any one of Claims 1 to 11, characterized in that the closure cap (1) is a one-piece injection-moulded part.

13. Container, in particular a BFS bottle, having a system according to any one of Claims 1 to 12.

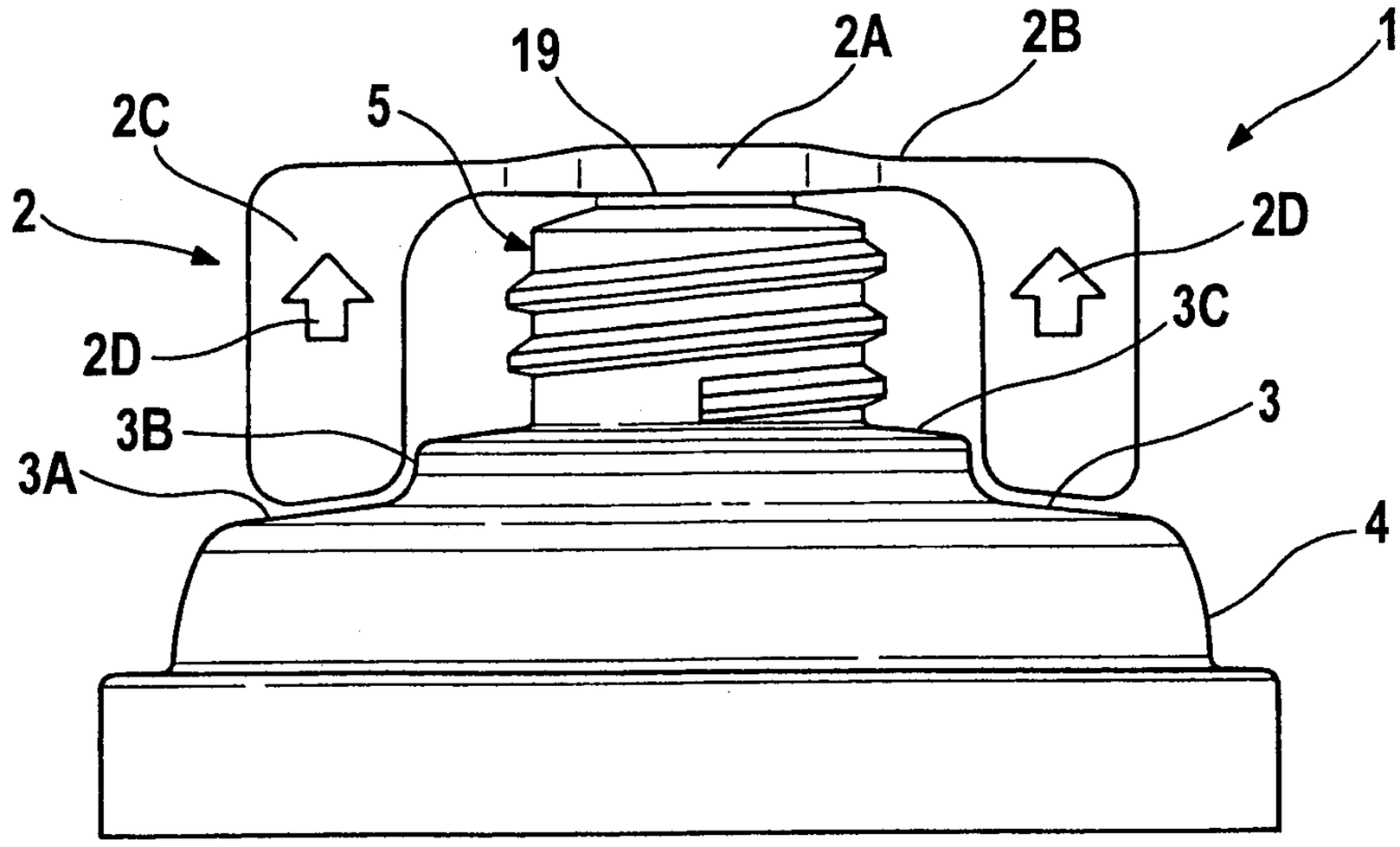

Fig. 1

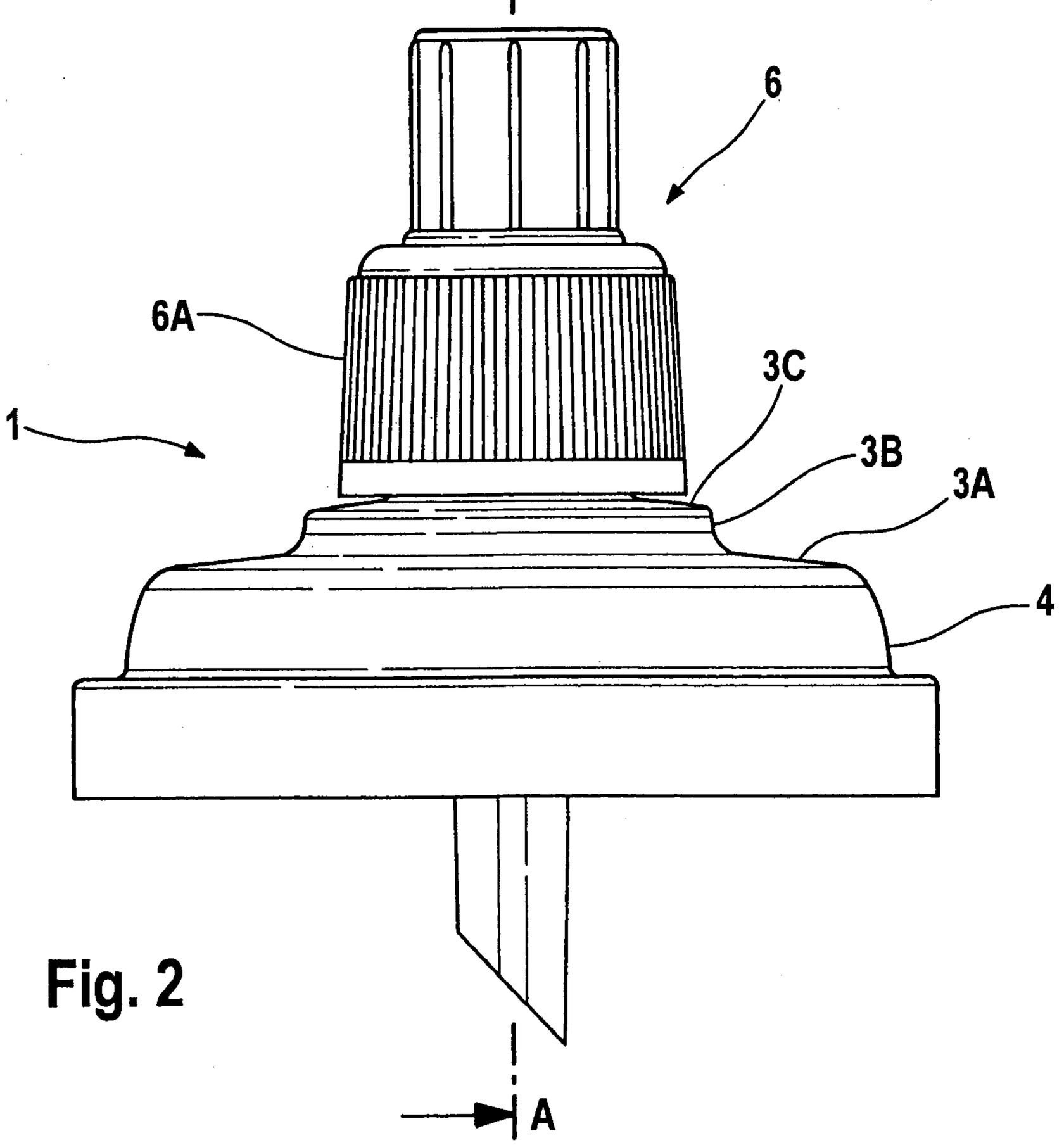

Fig. 2

Fig. 3

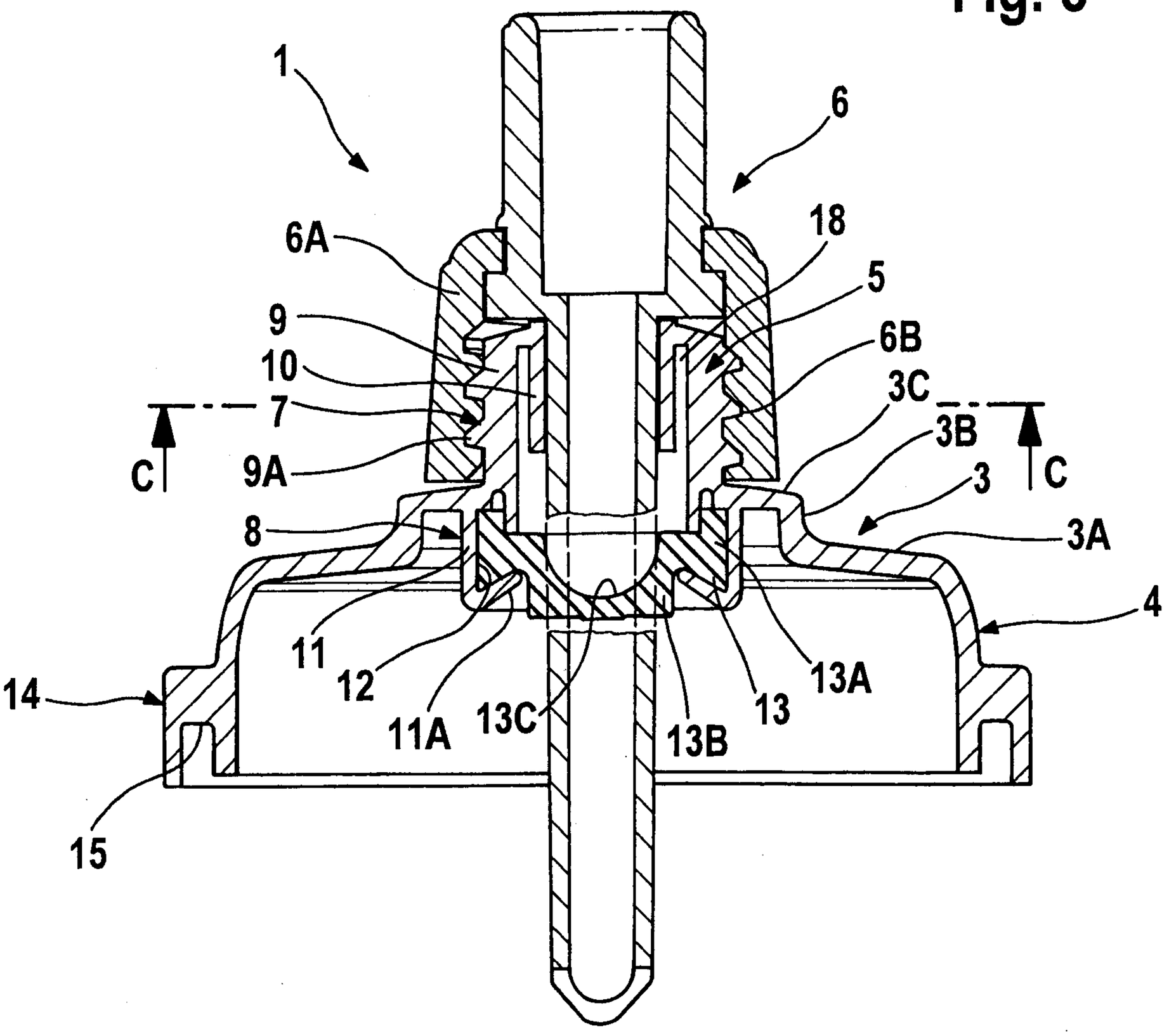
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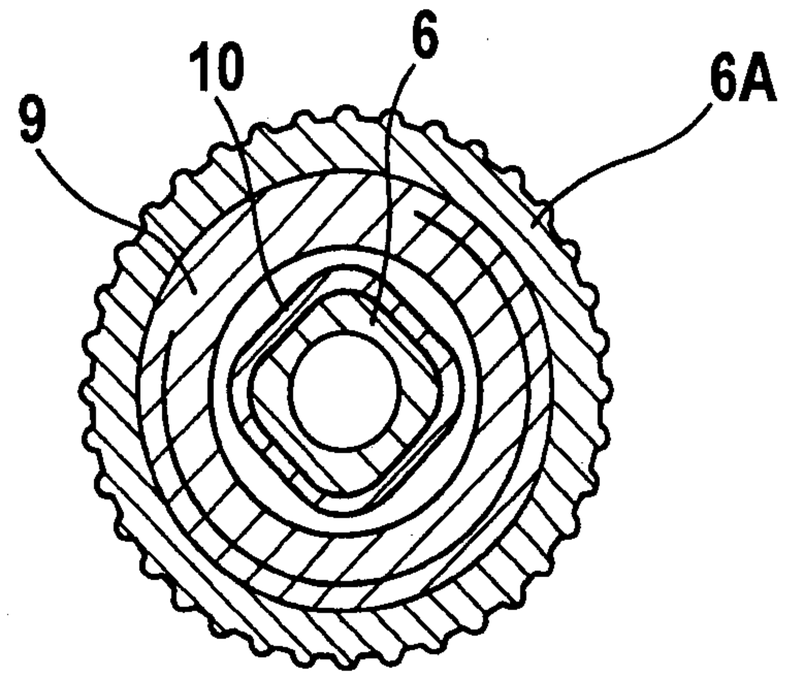
Fig. 4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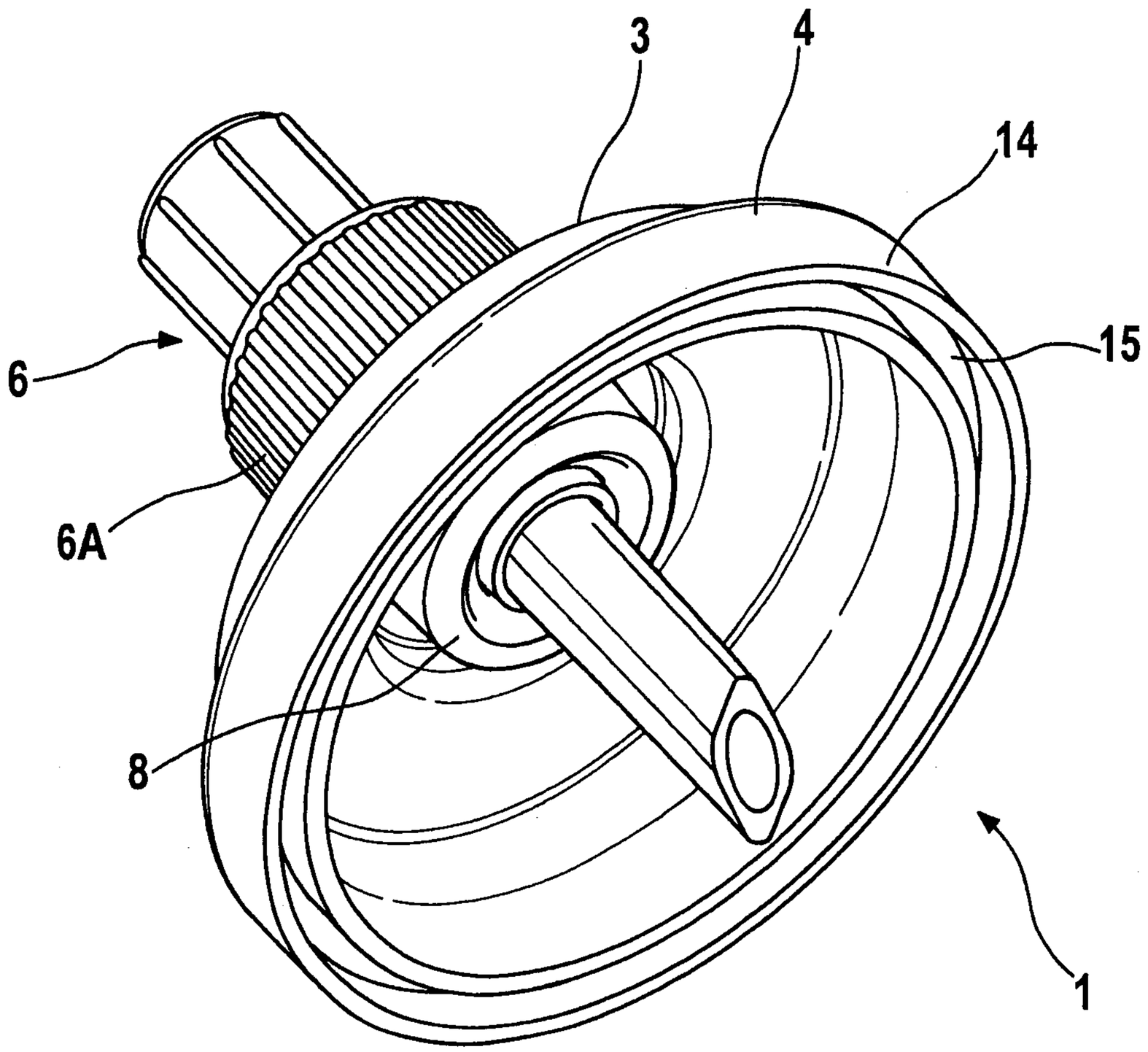
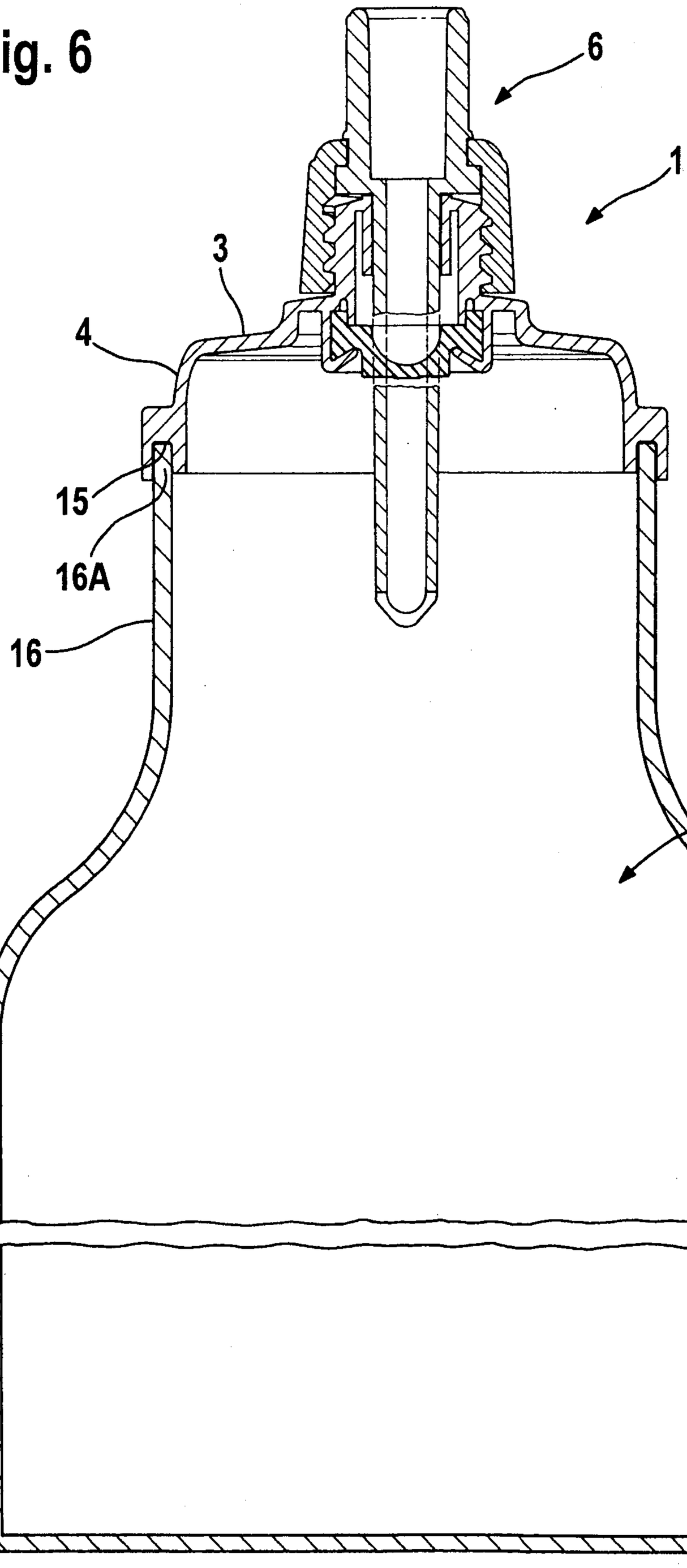
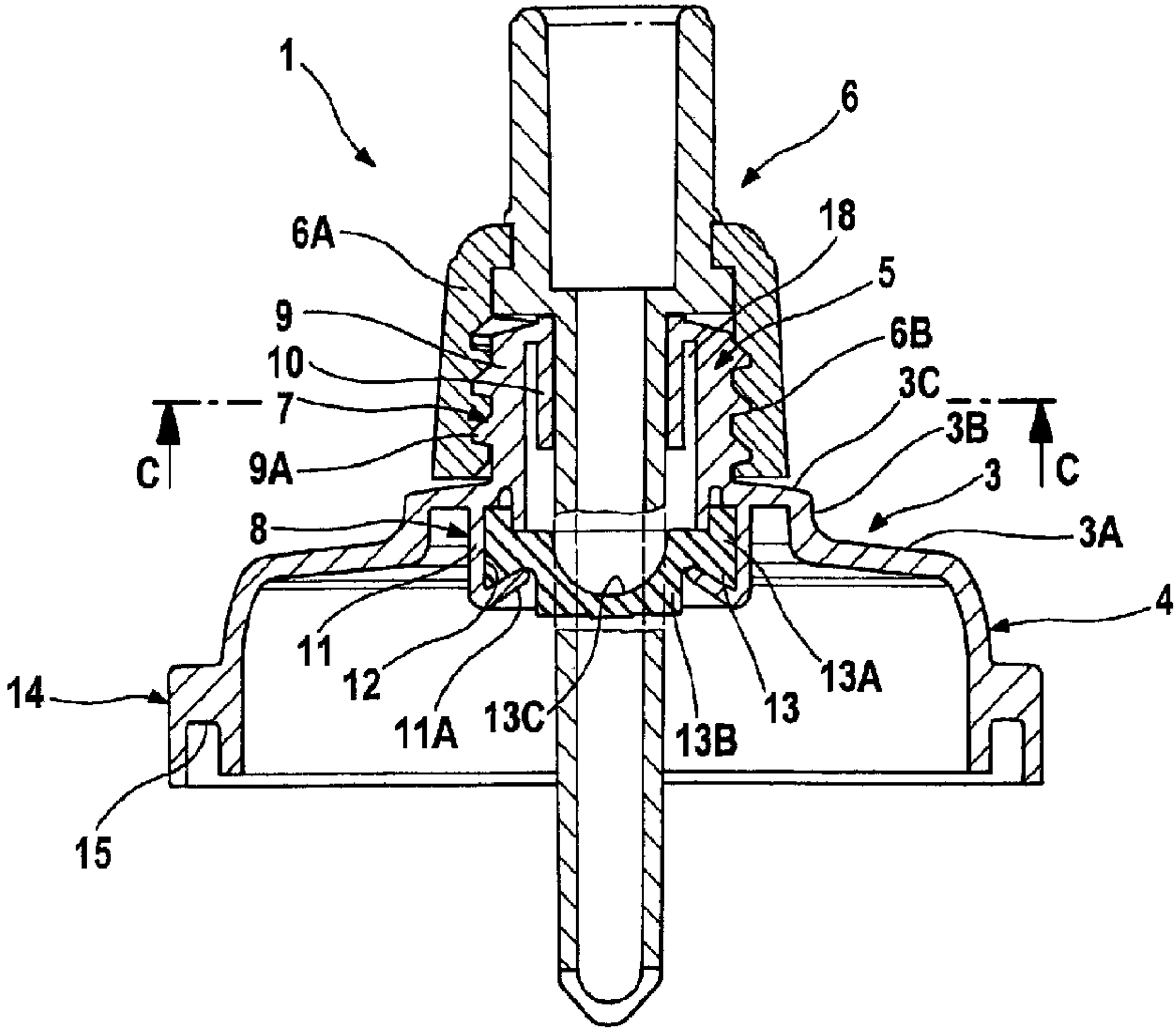


Fig. 5

Fig. 6

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3B
C
9A
3
C
8
3A
4
11
12
13A
14
11A
13C
13
13B
15