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CA 2442543 C 2007/10/02

(11)(21) **2 442 543**

(12) **BREVET CANADIEN**
CANADIAN PATENT

(13) **C**

(86) Date de dépôt PCT/PCT Filing Date: 2002/04/17
(87) Date publication PCT/PCT Publication Date: 2002/12/12
(45) Date de délivrance/Issue Date: 2007/10/02
(85) Entrée phase nationale/National Entry: 2003/09/26
(86) N° demande PCT/PCT Application No.: EP 2002/004233
(87) N° publication PCT/PCT Publication No.: 2002/098748
(30) Priorité/Priority: 2001/06/07 (DE101 27 823.3)

(51) Cl.Int./Int.Cl. *B65D 51/00* (2006.01), *A61J 1/14* (2006.01), *B29C 45/16* (2006.01), *B65D 47/10* (2006.01), *B65D 5/00* (2006.01)

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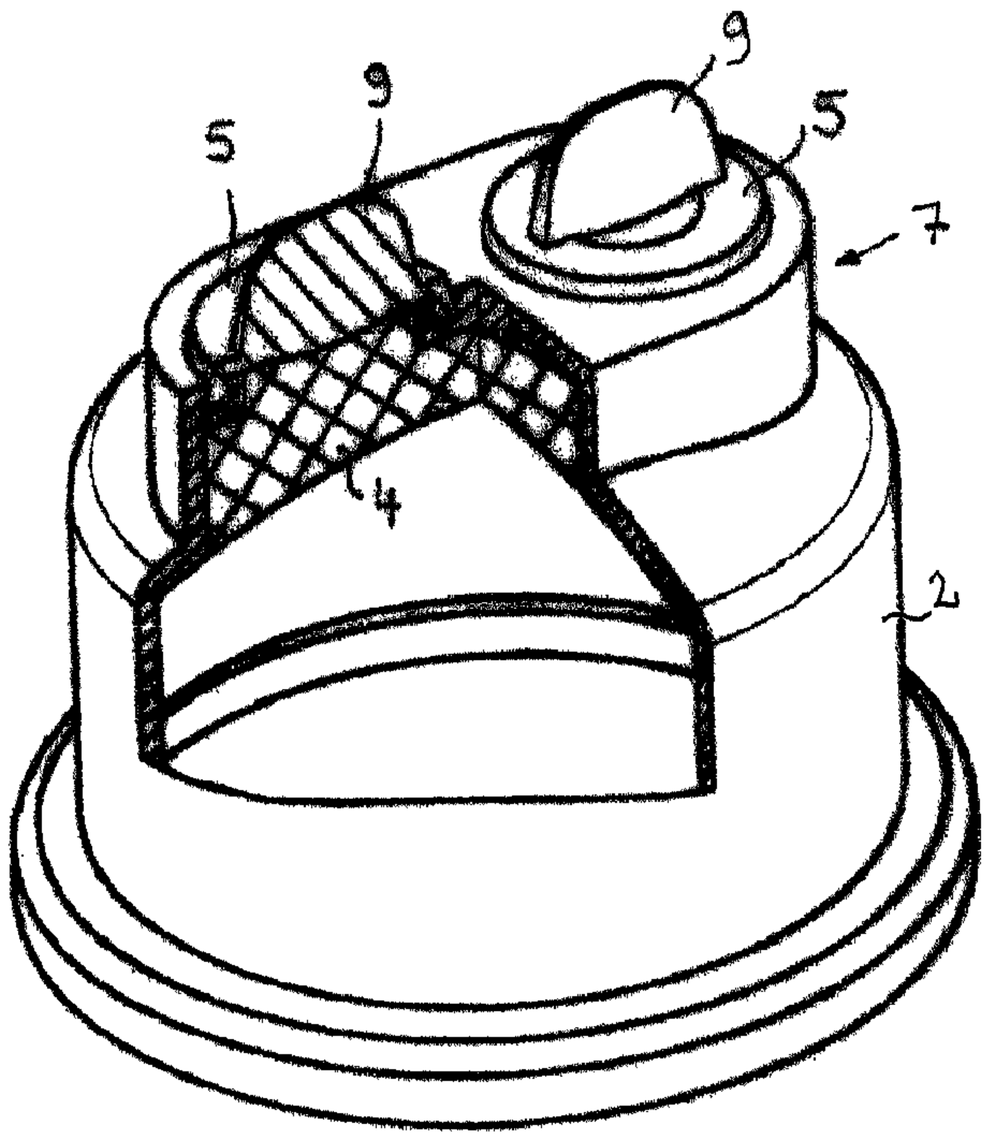
(54) Titre : SYSTEME DE BOUCHAGE POUR FLACON DE MEDICAMENTS ET PROCEDE PERMETTANT DE LE PRODUIRE

(54) Title: CLOSURE FOR A MEDICINE BOTTLE AND PROCESS FOR THE PRODUCTION THEREOF



(57) Abrégé/Abstract:
A closure (1) for a medicament bottle has a cap part (2), which can be joined to the bottle and which has at least one opening (3) that is closed by an elastic puncturable sealing layer (4). The opening (3) is covered on the exterior of the cap by a covering element (5) which, with its edge area (6) that encircles the opening (3), is joined with positive fit, however, without material fit to the opening edge (8) of the cap opening (3). The sealing layer touches the rear side of the covering element, said rear side facing the opening, in a manner that is flat, sterile and without material fit.

Abstract

A closure (1) for a medicament bottle has a cap part (2), which can be joined to the bottle and which has at least one opening (3) that is closed by an elastic puncturable sealing layer (4). The opening (3) is covered on the exterior of the cap by a covering element (5) which, with its edge area (6) that encircles the opening (3), is joined with positive fit, however, without material fit to the opening edge (8) of the cap opening (3). The sealing layer touches the rear side of the covering element, said rear side facing the opening, in a manner that is flat, sterile and without material fit.

Closure for a medicine bottle and process for the production thereof

The invention relates to a process for producing a closure for a medicine bottle having a cap portion with at least one cap opening sealed off by a perforatable sealing layer and covered by a cover element, wherein the at least one cover element and the cap portion are produced and joined together, and then the elastic sealing layer is injected into the cap portion. The invention further relates to a closure for a medicine bottle, which has a cap portion connectable to the bottle, which has at least one opening which is sealed off by an elastic, perforatable sealing layer, the opening being closed off on the outside by a cover element which is tightly and releasably connected to the rim of the opening.

DE 98 35 720 C2 discloses a closure of this kind which has a pot-shaped cap portion, which has on its wall overlapping the opening of the medicine bottle in the position of use an opening which is sealed off by a perforatable sealing layer. On the outside of the cap portion is provided, as the cover element, a removable film which covers the perforatable area of the sealing layer provided on the opening. On its edge region surrounding the opening the cover film is firmly but releasably attached to the rim of the opening of the cap portion. The perforatable area of the sealing layer is thereby protected from dirt and from the penetration of pathogens.

As a rule the contents of a medicine bottle of this kind are removed by means of a hollow needle or a cannula which is used to pierce the sealing layer. First of all

the cover film has to be pulled upwards or torn off to expose the perforatable part of the sealing layer.

When producing the closure cap, first the cover film is placed in a moulding tool for the cap portion and then, to mould the cap portion, hot plastics material is injected into the moulding tool. The cover element then bonds firmly but releasably to the cap portion. However, it is difficult to adjust the removal or retaining forces for the cover film so that the film can easily be pulled away from the cap portion, but is still attached to the cap portion firmly enough so that it cannot become detached during transportation or during the handling of the medicine container. If the removal forces are too great, the gripping tab provided on the cover element can tear off when the cover film is torn off, with the result that the contents of the bottle cannot be removed. However, if the removal forces are too small, there is no longer any guarantee of biological safety and the perforatable part of the sealing layer may become soiled or come into contact with bacteria, pathogens or the like when the cover film comes away from the cap portion.

The problem is therefore to provide a closure of the type mentioned hereinbefore which has high biological safety and is easy and safe to handle. A further aim is to provide a process of the type mentioned hereinbefore which allows a closure of this kind to be manufactured easily.

The solution to this problem in terms of the process comprises first producing the cap portion, then, when producing the at least one cover element, injecting the material of the cover element around the edge portion of the cap portion surrounding the cap opening, in order to form an interlocking joint between the cover element and

the cap portion, and selecting the materials of the cover element, cap portion and sealing layer so that the material of the cover element does not enter into a materially integrated joint either with the material of the cap portion or with the material of the sealing layer.

Advantageously, the injection of the material of the cover element around the cap portion forms an interlocking joint between the cap portion and the cover element, which securely seals the connecting area. As any materially integrated connection or welding of the cover element to the cap portion and/or the sealing layer is avoided, the cover element can be pulled off the cap portion with a defined removal force to expose the perforatable part of the sealing layer. As the elastic sealing layer is injected into the cap portion connected to the cover element after the production of the cover element and cap portion, the reverse side of the cover element facing the sealing layer is sterilised by the material of the cover element which is still hot during the injection process. At the same time, this material comes into direct contact with the reverse side of the cover element, resulting in an easily releasable flat connection between the cover element and the sealing layer extending over the entire cross section of the opening. There is no gap between the cover element and the sealing layer in which pathogens, bacteria, viruses or the like could survive.

The problem mentioned above may also be solved, in terms of a process of the kind described wherein the at least one cover element and then the cap portion are produced first, by injecting the cap material around the edge region of the cover element in order to form an interlocking connection between the cover element and the cap portion during the manufacture of the cap

portion, and selecting the materials of the cover element, cap portion and sealing layer so that the material of the cover element does not enter into a materially integrated connection either with the material of the cap portion or with the material of the sealing layer.

By this solution, too, a reliably sealed positively interlocking connection can be achieved between the cap portion and the cover element, in which the cover element can be pulled off the cap portion with a defined removal force to expose the sterile, perforatable part of the sealing layer.

It is advantageous if the sealing layer is welded to the cap portion when injected into it. The sealing layer is then tightly connected to the cap portion on the inside of the cap, thus avoiding even tiny gaps between the sealing layer and the cap portion. This ensures improved biological reliability of the closure.

The solution to the problem mentioned above in terms of the closure comprises connecting the cover element to the rim of the opening of the cap opening by interlocking engagement, with no material bonding, by its edge region surrounding the opening, and having the sealing layer make flat, sterile contact with the reverse side of the cover element facing the opening, without any material bonding.

The cover element is thus connected by interlocking engagement and free from any material bond to the rim of the opening of the cap opening along its edge region surrounding the opening, thereby ensuring on the one hand a reliable seal between the cover element and the cap portion and thus ensuring a high degree of biological safety of the closure. On the other hand,

however, the removal force that has to be exerted between the cap portion and the cover element to open or remove the cover element from the cap portion is precisely defined, thus enabling the cover element to be removed easily from the cap portion. This removal force is determined on the one hand by the shape and dimensions of the interlockingly engaging areas of the cover element and cap portion and on the other hand by the materials of the cover elements and cap portion. When developing or constructing the closure the removal force can be set by a suitable choice of dimensions and/or by a suitable choice of materials.

It is advantageous if the rim of the opening of the cap portion engages behind an undercut of the cap portion preferably formed on an encircling groove of the cover element. In this way a good seal is achieved between the cover element and the cap portion, on the one hand. On the other hand, however, the cover element is permanently deformed in the region of the undercut as it is pulled away from the cap portion, so that after being removed from the cap portion it cannot be fitted back onto the undercut and connected thereto. The cover element then also acts as a tamper-evident seal.

In another advantageous embodiment of the invention the cover element is constructed as a cover cap which engages with its edge region behind at least one undercut in the cap portion formed around the groove encircling the cap portion opening. In this embodiment, too, the cover element is permanently deformed in the region of the undercut as the cap portion is pulled off. Here again, a tight seal is produced between the sealing element and the cap portion.

The at least one cover element may consist of a duroplastic material and the sealing layer may consist

of a thermoplastic material. In this way, when the closure is produced, a connection between the cap portion and the cover element which is free from any material bond may easily be achieved.

In another advantageous embodiment of the invention, the at least one cover element and the sealing layer may consist of different thermoplastic materials which cannot be welded together. The cover cap may then consist of polyamide or polyacetate, for example, and the sealing layer may consist of polyethylene or polypropylene.

In one embodiment of the invention the sealing layer is welded flat onto the cap portion on the inside of the cap. This produces a particularly tight and firm connection between the sealing layer and the cap portion.

It is particularly advantageous if the cap portion has at least one gripping tab arranged to extend transversely and particularly at right angles to the plane spanned by the opening, preferably centrally to the opening of the cap portion. The cover element can then be held comfortably by the gripping tab in order to remove it from the cap portion.

According to one aspect of the present invention, there is provided a process for producing a closure for a medicine bottle having a cap portion with at least one cap opening, an elastic, perforatable sealing layer and at least one cover element, wherein the at least one cap opening is sealed off by the elastic, perforatable sealing layer and each respective cap opening of the at least one cap opening covered by a respective cover element of the at least one cover element, and wherein the at least one cover element and the cap portion are produced and joined together, and then the elastic, perforatable sealing layer is injected into the cap portion, wherein first the cap portion is produced, then during the manufacture of the at least one cover element the material of the at least one cover element is injected around an edge region of the cap portion surrounding the at least one cap opening, to form an interlocking engaging connection between the at least one cover element and the cap portion, and in that the materials of the at least one cover element, the cap portion and the elastic, perforatable sealing layer are selected so that the material of the at least one cover element is free of a materially integrated bond with the material of the cap portion.

According to another aspect of the present invention, there is provided a process for producing a closure for a medicine bottle having a cap portion with at least one cap opening, an elastic, perforatable sealing layer and at least one cover element, wherein the at least one cap opening is sealed off by the elastic, perforatable sealing layer and each respective cap opening of the at least one cap opening covered by a respective cover element of the at least one cover element, and wherein the at least one cover element and the cap portion are produced and

joined together, and then the elastic, perforatable sealing layer is injected into the cap portion, wherein first the cap portion is produced, then during the manufacture of the at least one cover element the material of the at least one cover element is injected around an edge region of the cap portion surrounding the at least one cap opening, to form an interlocking engaging connection between the at least one cover element and the cap portion, and in that the materials of the at least one cover element, the cap portion and the elastic, perforatable sealing layer are selected so that the material of the at least one cover element is free of a materially integrated bond with the material of the elastic, perforatable sealing layer.

According to another aspect of the present invention, there is provided a closure for a medicine bottle which has a cap portion connectable to the bottle, which has at least one opening, an elastic, perforatable sealing layer and at least one cover element, wherein the at least one opening is closed off by the elastic, perforatable sealing layer, and each respective opening of the at least one opening is covered on an outside of the cap portion by a respective cover element of the at least one cover element which is releasably connected to a rim of the respective opening, wherein the at least one cover element is interlockingly connected, by an edge region of the at least one cover element encircling the at least one opening, to the rim of the at least one opening of the cap portion, wherein the at least one cover element is free of any material bond with the cap portion, and wherein the elastic, perforatable sealing layer makes flat, sterile contact, free from any material bond, with a reverse side of the at least one cover element facing the at least one opening.

Some embodiments exemplifying the invention are described more fully hereinafter with reference to the drawings, wherein:

Fig. 1 shows a cap portion of a closure for a medicine bottle, partly in section, in which openings in the cap portion are tightly sealed by cover elements,

Fig. 2 shows the finished closure after a sealing

layer has been injected into the cap portion shown in Fig. 1, the closure being shown partly in section,

Fig. 3 is a detail from Fig. 2 on an enlarged scale, in which the interlockingly engaging connection between the cover element and the cap portion is shown particularly clearly,

Fig. 4 is a view of a closure similar to Fig. 2, but with the opening edges of the cap portion interlockingly engaging in grooves in the cover element, and

Fig. 5 is a detail from Fig. 4 on an enlarged scale, in which the interlockingly engaging connection between the cover element and the cap portion is shown particularly clearly.

A closure for a medicine bottle or similar container, generally designated 1, has a cap portion 2 connectable to the container, which has two substantially circular openings 3 on its wall portion which overlaps the container opening in the position of use, these openings 3 being closed off by an elastic sealing layer capable of being perforated with a hollow needle. The openings are each covered on the outside of the cap portion 2 by a cover element 5 which is connected in positively interlocking and releasable manner with its edge region 6 surrounding the opening 3 to the edge region of the cap opening 3 surrounding the opening 3. At the connecting points between the cap portion 2 and the cover element 5 the materials of the cap portion 2 and cover element 5 are present separately from each other, i.e. there is no materially integrated connection between these materials. At its free edge the cap portion 2 has a seal (not shown in detail in the

drawings) which fits closely against the container in the position of use.

Figs. 2 to 5 show that the sealing layer is disposed in the inner cavity of the cap portion 2 and makes contact with the reverse side of the cover element 5 facing the inner cavity, without any material bond. The sealing layer rests flat and sterile on the cover element 5 over the entire cross section of the openings 3. At the points where the sealing layer 4 makes contact with the cap portion 2, it is welded to the cap portion 2, so as to produce a strong and leaktight connection over the entire circumference of the cap portion 2 between the latter and the sealing layer 4.

The cap portion 2 has a substantially pot-shaped base member which has, on its wall portion overlapping the container opening in the position of use, a recess 7 that enlarges the inner cavity of the base member, this recess forming a projection or a step on the outside of this wall portion. Figs. 2 and 4 show that the openings 3 are provided on the wall of this recess 7 that projects furthest and that the sealing layer 4 is disposed in the inner cavity of the recess 7.

In the embodiment according to Figs. 2 and 3 the rim of the opening 8 of the cap portion 2 is surrounded by an annular groove encircling the openings 3 which is let into the outside of the cap portion 2. The cross section of the annular groove widens out from the adjacent surface region of the cap portion 2 towards the deepest point of the annular groove. Fig. 3 shows that this is achieved by the fact that at least one lateral boundary wall of the annular groove has an undercut. The cover elements 5 are in the shape of caps and engage with their edges in the annular groove, where they engage behind the undercut. Fig. 3 shows that the edge

of the cover element 5 completely fills the annular groove of the cap portion 2. The cover elements 5 consist of a material that is softer than that of the cap portion 2 and irreversibly deforms, at least at an edge region engaging in the annular groove associated with the cover element 5, when a cover element 5 is pulled off from the cap portion, so that after the cover element has been pulled off the cap portion 2 it cannot be re-inserted in the annular groove.

Figs. 4 and 5 show another embodiment by way of example wherein the cover elements 5 have, on their reverse side facing the cap portion in the position of use, an annular groove encircling the opening 3 of the cap portion which is associated with them. A collar-shaped projection surrounding the opening 3 and provided on the rim of the opening 8 of the cap portion 2 engages in this annular groove. Fig. 4 shows that the side walls of the annular groove in a diametric plane containing the central longitudinal axis of the cap portion extend diagonally with respect to this central longitudinal axis so as to form undercuts behind which the rim of the opening 8 of the cap portion 2 engages. Fig. 5 shows that the rim of the opening 8 of the cap portion 2 totally fills the annular groove of the cover element 5.

Integrally formed on each of the cover elements 5 is a gripping tab 9 the plane of which extends substantially at right angles to the plane of the cover element 5. Figs. 2 and 4 show that the gripping tab 9 is connected roughly in a T-shape to the cover element 5. The plane of the gripping tab extends substantially in a diametric plane of the opening 3 containing the central longitudinal axis of the opening 3.

When producing the closure shown in Fig. 2, first of all a hot liquid plastics composition, preferably

acrylonitrile-butadiene-styrene copolymer (ABS), polyamide (PA) or polyoxymethylene (POM), is injected into the mould cavity of a first moulding tool to produce the cover elements 5. After the plastic has solidified the cover elements 5 are taken out of the first moulding tool and placed in the mould cavity of a second moulding tool in order to mould the cap portion 2 on. The mould cavity of this second moulding tool is larger than the mould cavity of the first moulding tool by the amount of space needed for the cap portion. A hot, liquid plastics composition, preferably polyethylene (PE) or polypropylene (PP), is injected into the second moulding tool in order to mould the cap portion. The plastic composition of the cap portion 2 is injected around the edge of the cover elements 5. The materials of the cover elements and cap portion 2 are chosen so that they do not enter into any materially integrated connection while the cap portion 2 is being moulded. Consequently, after the plastics composition has hardened, there is merely an interlockingly engaging connection between the cap portion 2 and the cover elements 5.

Then, in another manufacturing step, the elastic sealing layer 4 is injected into the cap portion thus connected to the cover elements 5, as shown in Fig. 1. For this, the cap portion 2 with the cover elements 5 is removed from the second moulding tool and placed in a third moulding tool. To form the sealing layer 4 a hot, liquid plastics composition, preferably TPE, is injected into this moulding tool. The material of the sealing layer 4 enters into a materially integrated bond with the material of the cap portion 2 and is welded thereto. The materials of the cover elements 5 and the sealing layer 4 are selected so that there is no materially integrated bond between the cover elements 5 and the sealing layer 4. As a result, the cover elements 5 are

easily detachable from the sealing layer 4. As the sealing layer 4 is formed, the hot material of the sealing layer, which is preferably at a temperature of about 250°, is applied to the surface regions of the cover element 5 covering the opening 3 and sterilises them.

In the manufacture of the closure shown in Fig. 4, first of all a hot, liquid plastics composition, preferably PE or PP, is injected into the mould cavity of a first moulding tool to produce the cap portion 2. After the plastic has solidified, the cap portion 2 is taken out of the first moulding tool and placed in the mould cavity of a second moulding tool in order to mould the cover elements 5 on. The mould cavity of this second moulding tool is larger than the mould cavity of the first moulding tool by the amount of space needed for the cover elements 5. A hot liquid plastics composition, preferably ABS., PA., POM, is then injected into the second moulding tool in order to mould the cover elements 5. The plastics composition penetrates into the annular grooves of the cap portion 2 bounding the openings 3 and fills them completely. The materials of the cap portion 2 and cover element 5 are chosen so that during the forming of the cover elements 5 onto the cap portion 2 they do not enter into a materially integrated bond with one another. After the plastics composition has solidified, a merely interlocking engagement is thus obtained between the cap portion 2 and the cover element 5.

The cap portion thus connected to the cover elements 5 is taken out of the second moulding tool and placed in a third moulding tool in order to form the sealing layer 4. The other manufacturing steps correspond to those in the embodiment illustrated in Fig. 1 to 3.

Thus, all in all, a closure 1 for a medicine bottle is obtained having a cap portion 2 connectable to the bottle, this cap portion having at least one opening 3 sealed off by an elastic, perforatable sealing layer. The opening is covered on the outside of the cap by a cover element which interlockingly engages, by means of its edge region encircling the opening, with the rim of the opening of the cap opening, without any material bonding thereto. The sealing layer is in flat and sterile contact, with no material bonding, with the reverse side of the cover element facing the opening.

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CLAIMS:

1. A process for producing a closure for a medicine bottle having a cap portion with at least one cap opening, an elastic, perforatable sealing layer and at least one cover element, wherein the at least one cap opening is sealed off by the elastic, perforatable sealing layer and each respective cap opening of the at least one cap opening covered by a respective cover element of the at least one cover element, and wherein the at least one cover element and the cap portion are produced and joined together, and then the elastic, perforatable sealing layer is injected into the cap portion, wherein first the cap portion is produced, then during the manufacture of the at least one cover element the material of the at least one cover element is injected around an edge region of the cap portion surrounding the at least one cap opening, to form an interlocking engaging connection between the at least one cover element and the cap portion, and in that the materials of the at least one cover element, the cap portion and the elastic, perforatable sealing layer are selected so that the material of the at least one cover element is free of a materially integrated bond with the material of the cap portion.

2. A process for producing a closure for a medicine bottle having a cap portion with at least one cap opening, an elastic, perforatable sealing layer and at least one cover element, wherein the at least one cap opening is sealed off by the elastic, perforatable sealing layer and each respective cap opening of the at least one cap opening covered by a respective cover element of the at least one cover element, and wherein the at least one cover element and the cap portion are produced and joined together, and then the elastic, perforatable sealing layer is injected

into the cap portion, wherein first the cap portion is produced, then during the manufacture of the at least one cover element the material of the at least one cover element is injected around an edge region of the cap portion surrounding the at least one cap opening, to form an interlocking engaging connection between the at least one cover element and the cap portion, and in that the materials of the at least one cover element, the cap portion and the elastic, perforatable sealing layer are selected so that the material of the at least one cover element is free of a materially integrated bond with the material of the elastic, perforatable sealing layer.

3. A process according to claim 1 or claim 2, wherein first the at least one cover element and then the cap portion is produced, wherein in order to form an interlockingly engaging connection between the at least one cover element and the cap portion the cap material is injected around the edge region of the at least one cover element during the production of the cap portion.

4. A process according to any one of claims 1 to 3, wherein on being injected into the cap portion the elastic, perforatable sealing layer becomes welded thereto.

5. A closure for a medicine bottle which has a cap portion connectable to the bottle, which has at least one opening, an elastic, perforatable sealing layer and at least one cover element, wherein the at least one opening is closed off by the elastic, perforatable sealing layer, and each respective opening of the at least one opening is covered on an outside of the cap portion by a respective cover element of the at least one cover element which is releasably connected to a rim of the respective opening, wherein the at least one cover element is interlockingly

connected, by an edge region of the at least one cover element encircling the at least one opening, to the rim of the at least one opening of the cap portion, wherein the at least one cover element is free of any material bond with the cap portion, and wherein the elastic, perforatable sealing layer makes flat, sterile contact, free from any material bond, with a reverse side of the at least one cover element facing the at least one opening.

6. A closure according to claim 5, wherein the rim of the at least one opening of the cap portion engages behind an undercut in the at least one cover element.

7. A closure according to claim 6, wherein the undercut in the at least one cover element is formed on an encircling groove of the at least one cover element.

8. A closure according to any one of claims 5 to 7, wherein each of the at least one cover element is constructed as a cover cap and the edge region of the at least one cover element engages behind at least one undercut in the cap portion.

9. A closure according to claim 8, wherein the at least one undercut in the cap portion is formed on a groove in the cap portion surrounding the at least one opening.

10. A closure according to any one of claims 5 to 9, wherein the at least one cover element consists of a duroplastic material and the sealing layer consists of a thermoplastic material.

11. A closure according to any one of claims 5 to 10, wherein the at least one cover element and the sealing layer consist of different thermoplastic materials which cannot be welded together.

12. A closure according to any one of claims 5 to 11, wherein the sealing layer is welded flat to the cap portion on an inside of the cap portion.

13. A closure according to any one of claims 5 to 12, wherein at least one gripping tab is formed on the at least one cover element, and wherein a plane of the at least one gripping tab extends transversely to a plane spanned by the at least one opening.

14. A closure according to claim 13, wherein the plane of the at least one gripping tab extends at right angles to the plane spanned by the at least one opening of the cap portion.

15. A closure according to claim 13 or 14, wherein the at least one gripping tab extends centrally with respect to the at least one opening of the cap portion.

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PATENT AGENTS

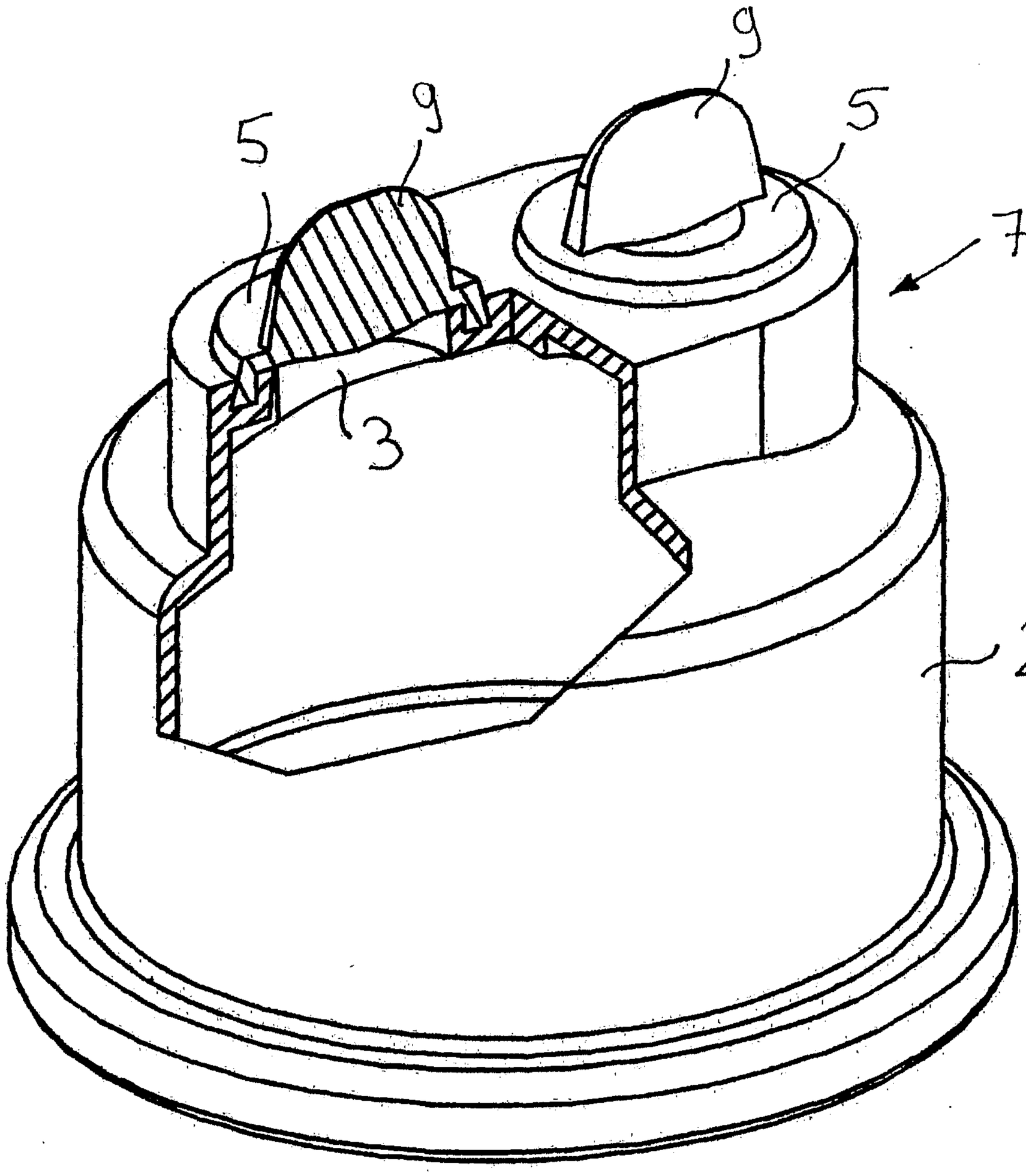


Fig. 1

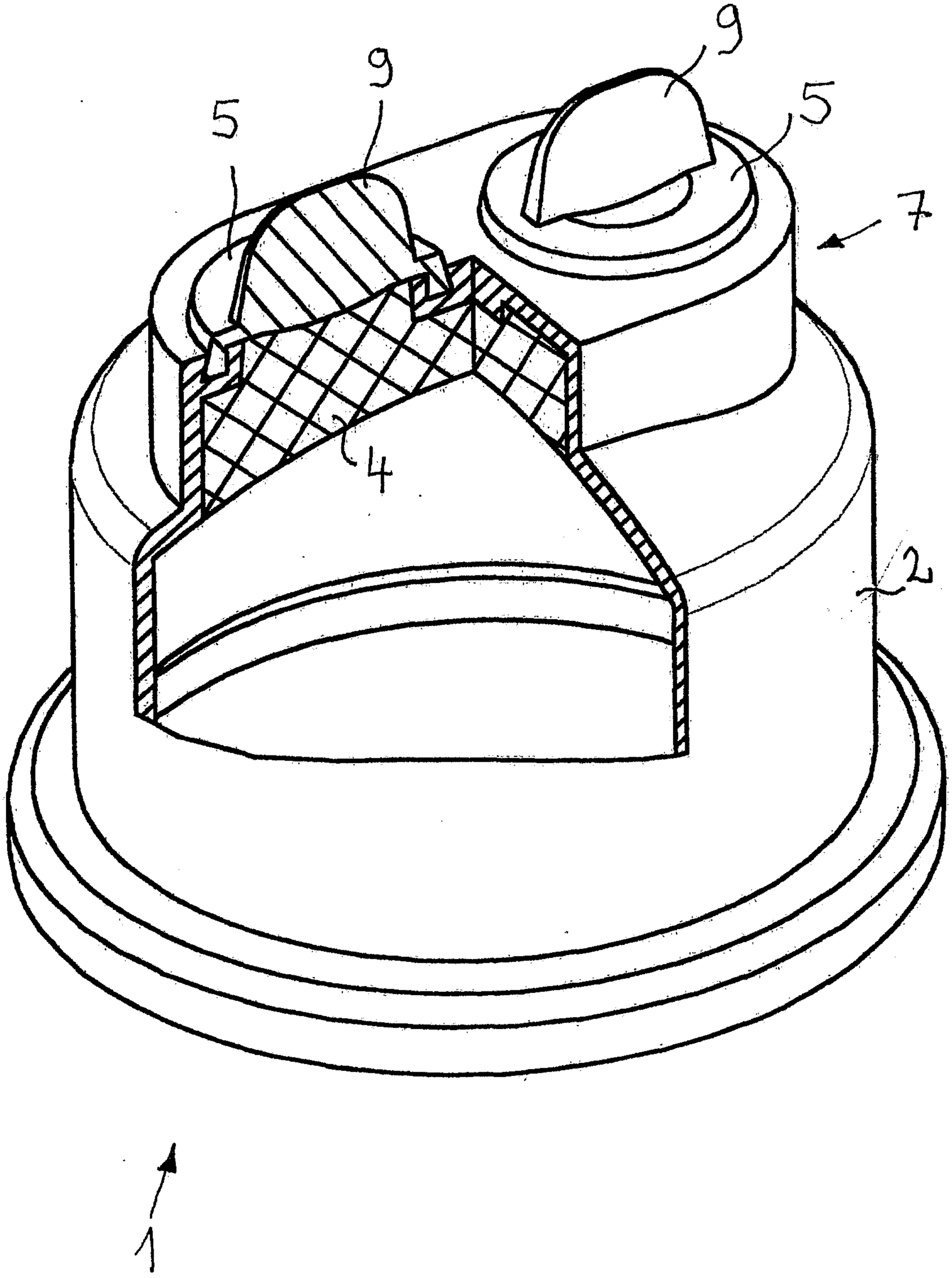


Fig. 2

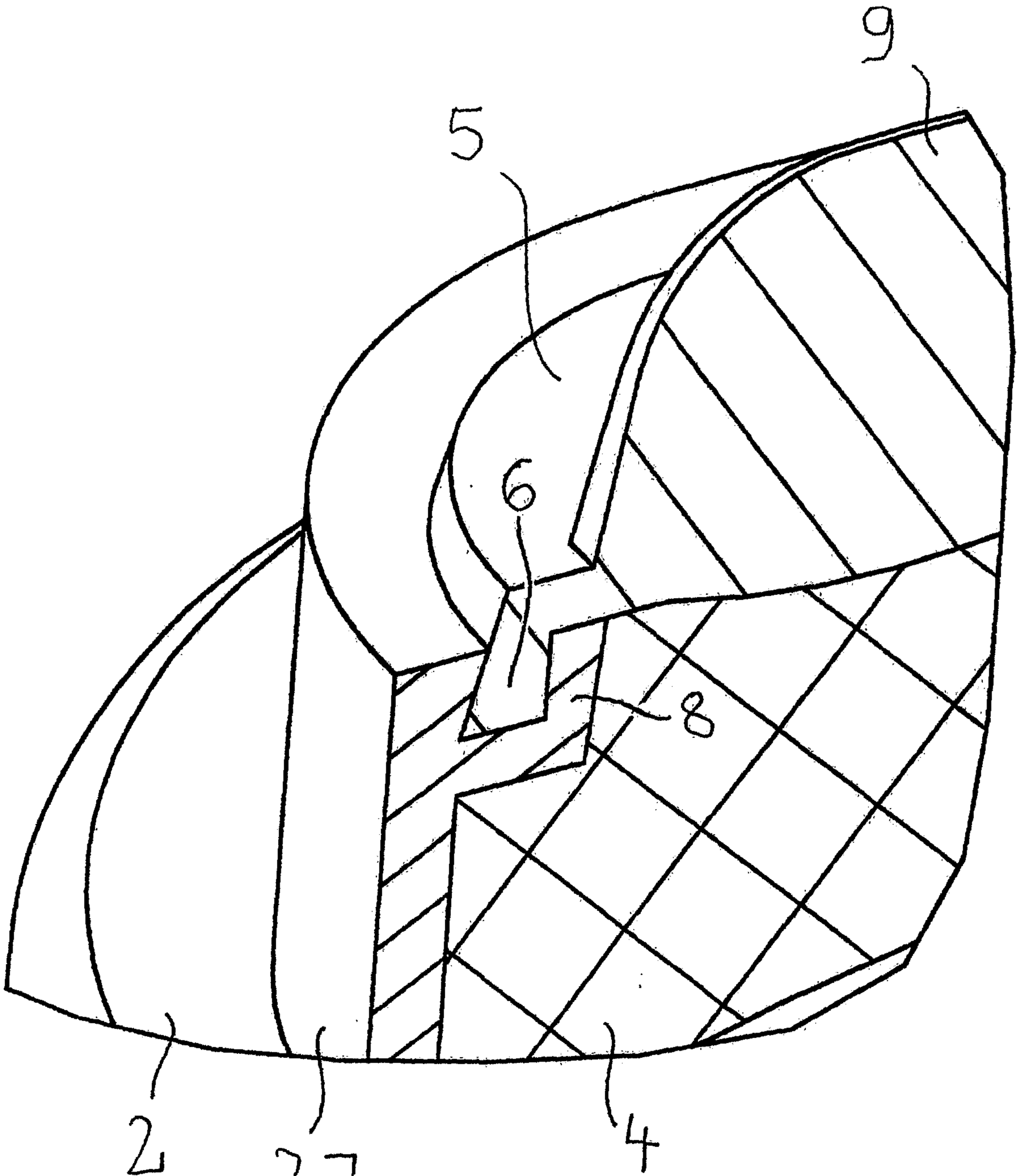


Fig. 3

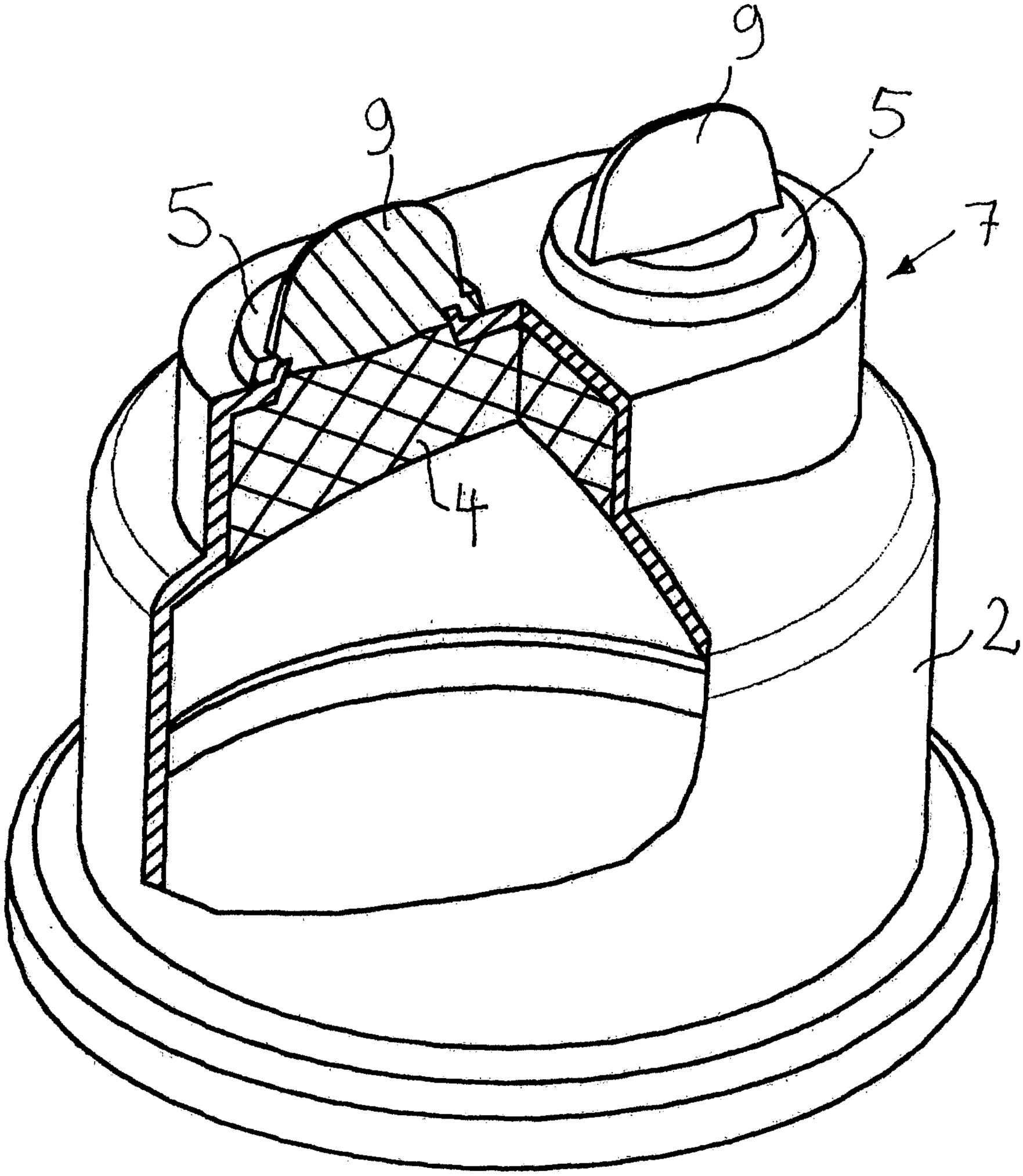


Fig. 4

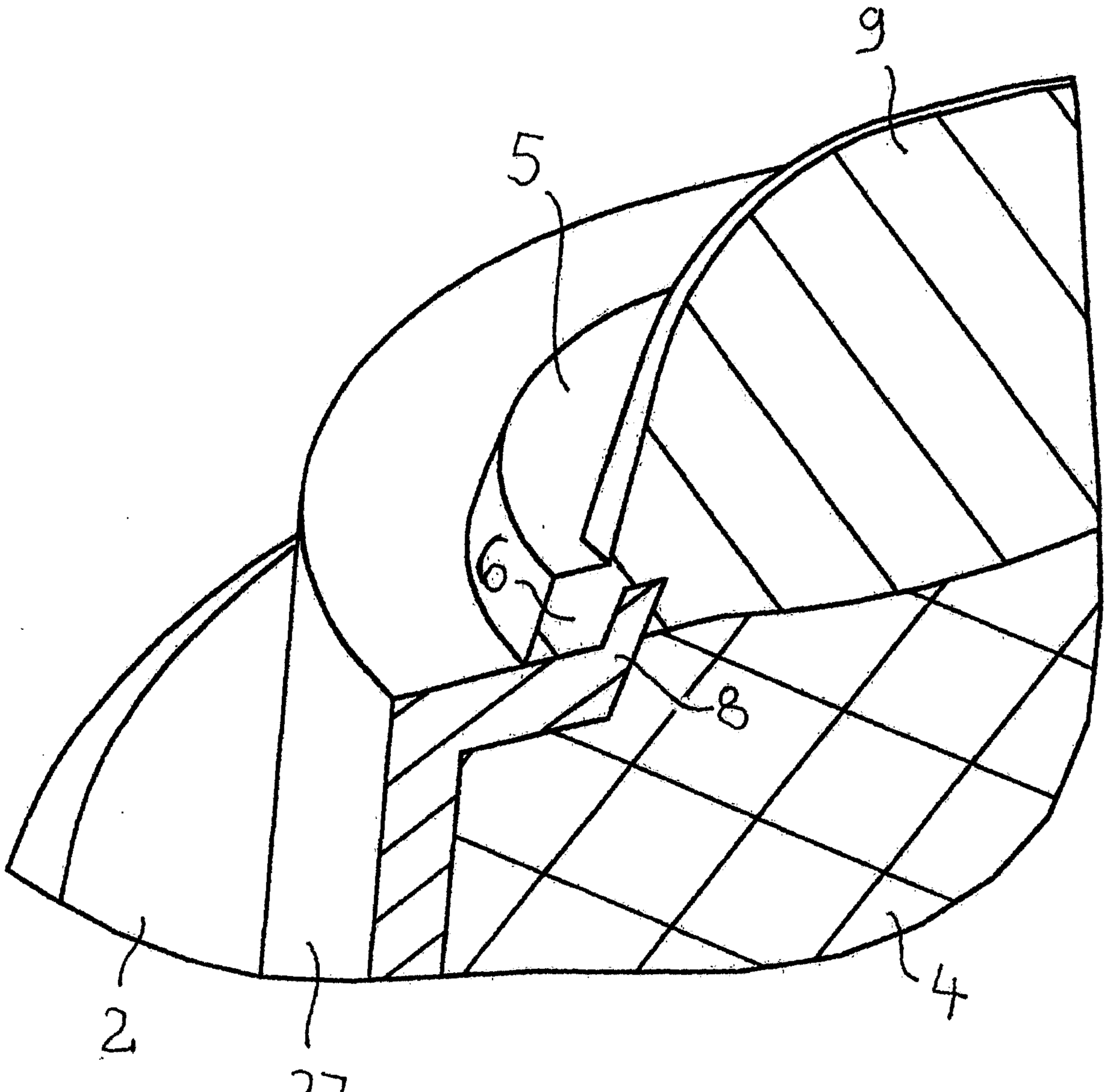
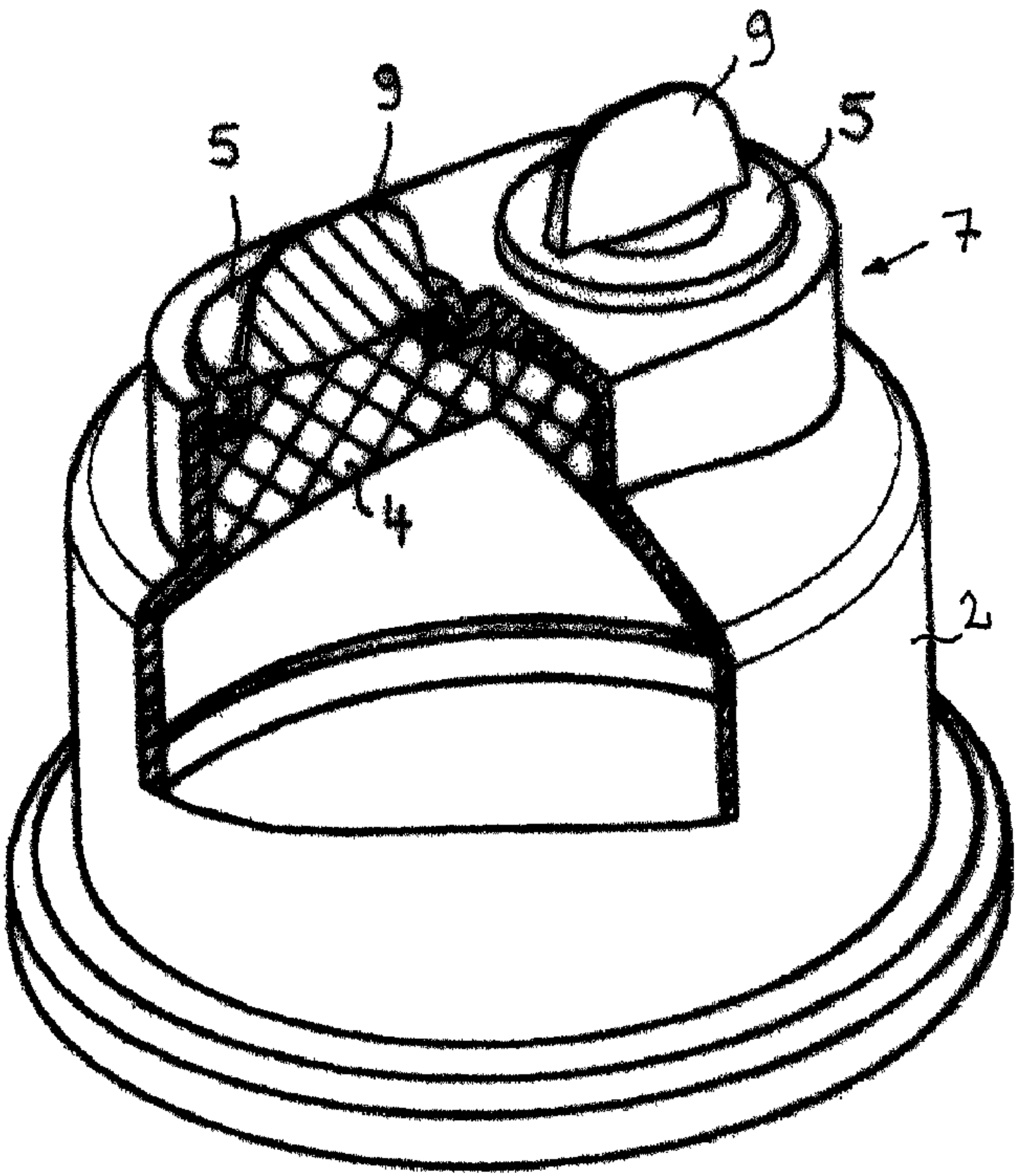


Fig. 5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