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(54) **DISPENSER OF OPHTHALMIC SOLUTIONS APPLICABLE TO SINGLE-DOSE CONTAINERS**

**SPENDER VON OPHTHALMISCHEN LÖSUNGEN FÜR EINZELDOSISBEHÄLTER**

**DISTRIBUTEUR DE SOLUTIONS OPHTALMIQUES APPLICABLES À DES RÉCIPIENTS UNIDOSES**

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**Description**

## FIELD OF INVENTION

**[0001]** The present invention relates to a dispenser of ophthalmic solutions applicable to single-dose containers.

**[0002]** In particular, it relates to a sterile dispenser, which is packaged individually and can be sold either individually or as a set, together with said single-dose containers. The single-dose containers preferably contain an ophthalmic solution, for example, a lissamine green-based solution.

## PRIOR ART

**[0003]** As it is known, there are various solutions or preparations used in the ophthalmic field which can be administered to the patient's eyes in order to verify the state of health thereof.

**[0004]** Among such solutions, colouring agents are a group of substances used in the contact lens field for diagnostic purposes. In particular, vital staining with sodium fluorescein and/or lissamine green is usually used in the diagnosis of corneal and conjunctival anomalies. While fluorescein predominantly shows a loss of epithelial cells, lissamine green identifies devitalized or suffering cells.

**[0005]** For topical use, fluorescein and lissamine green are available in solutions contained in normal eye drop containers, or in the form of small paper strips soaked in the substance. More specifically, lissamine green is an organic acidic dye, which is produced synthetically; the staining properties thereof are very similar to those obtained when using rose bengal. However, unlike rose bengal, lissamine green is painless and offers a better colour contrast to vessels and bleeding. Lissamine green selectively stains suffering and dehydrated cells, guaranteeing observation of the conjunctival epithelium and highlighting abraded or desquamated epithelial areas.

**[0006]** Use of the soaked paper strips is particularly painful and unpleasant for the patient, since during the examination, the strip must be brought into contact with the patient's eye.

**[0007]** As an alternative to the use of strips, dyes are administered to the patient's eye with the aid of commonly known dispensers, for example of the type coupled directly (as a top) to commonly known eye drop containers. Indeed, with this second method, a large drop of dye is deposited on the cornea and much of the solution is lost through the tear duct or outside the eye. In particular, when the dye is lissamine green, which is a very strong dye, if one administers too large a drop of eye drop to the eye there is a risk of temporarily staining the skin on the patient's face.

**[0008]** Last but not least, during administration of the solution to the eye, it is possible that the tip of the dispenser inadvertently touches the surface of the patient's

cornea, thereby compromising the sterility of all the solution present in the container coupled directly to the dispenser.

**[0009]** Document WO 2010/084393 A1, which is considered to be the closest prior art, discloses a dispenser according to the pre-amble of claim 1.

## DISCLOSURE OF THE INVENTION

**[0010]** The object of the present invention is to provide a dispenser of ophthalmic solutions applicable to single-dose containers which overcomes the drawbacks of the prior art.

**[0011]** A further object of the invention is to provide a dispensing device which allows the user to operate in total safety, preventing conveying contaminating agents to a patient.

**[0012]** This and other objects are achieved by means of a dispenser of ophthalmic solutions applicable to disposable containers, made according to the technical teachings of the claims annexed hereto.

**[0013]** Advantageously, the dispenser reduces the waste of ophthalmic solution and prevents dispensing a greater amount of solution than that required into the patient's eye. Furthermore, the invention allows precise and rapid dispensing of the solution, in exactly the spot desired by the doctor.

## BRIEF DESCRIPTION OF THE FIGURES

**[0014]** Further characteristics and advantages of the invention will become clearer in the description of a preferred but not exclusive embodiment of the dispenser, illustrated by the exemplificative and therefore non-limiting drawings annexed hereto, in which:

Figure 1 is a longitudinal lateral section view of the dispenser according to the present invention;

Figure 1A is an enlarged view of the detail circled in Figure 1;

Figure 2 is a lateral view of the dispenser in Figure 1 when placed on a work surface;

Figure 3 is a longitudinal section of a dispenser when coupled to a single-dose container, also sectioned;

Figure 4 shows a perspective view of the dispenser in Figure 1;

Figure 5 is a top view of the dispenser in Figure 1;

Figure 6 is a lateral view of a different embodiment of the dispenser in Figure 1;

Figure 7 is a longitudinal section of a different embodiment of the dispenser in Figure 1;

Figure 8 is a view of a sterile bag within which the dispenser in Figure 1 may be marketed;

## 55 DETAILED DESCRIPTION OF THE INVENTION

**[0015]** With reference to the figures stated, reference number 1 is used to denote, as a whole, a dispenser of

ophthalmic solutions.

**[0016]** The dispenser 1 may be advantageously applied to single-dose containers of ophthalmic solutions, in particular those containing staining solutions, to be used during eye examinations. A solution for which the dispenser 1 is particularly effective comprises lissamine green.

**[0017]** More specifically, the single-dose container 2 may be a vial (possibly of the re-sealable type) made of polymeric material, of a soft, semi-transparent type, which contains an ophthalmic solution.

**[0018]** Such vials 2 may comprise a body 2A for containing the solution, with an elongated, tubular conformation, which has an end having a neck 2B, at the top of which a product dispensing outlet 2C is formed. The opposite end of the vial to the neck 2B is sealed (e.g. by welding 2D which may be either of the hot or ultrasound variety) following insertion into the vial 2 of the ophthalmic solution 3.

**[0019]** The vials may further comprise sealing means, which can be removably coupled to the vial at the neck, to allow closure of the dispensing outlet 2C.

**[0020]** One type of these commonly known vials features the containment body and the sealing means made as a single piece, by means of injection moulding, and subsequently separated by the user, prior to use.

**[0021]** In practice, the sealing means (not shown here) may be removed by detachment from the containment body 2A, thereby forming the said dispensing outlet 2C.

**[0022]** One vial of this type, presently present on the market, features, at the dispensing outlet, an annular edge projecting inwardly and extending transversely to the containment body, said edge forming a central passage which allows the product to flow out.

**[0023]** Due to the flexibility of the material with which the neck of the vial body is made and to the high stresses and deformations to which the said body is subjected at the dispensing outlet 2C during opening, it is not possible to obtain an identical fluid passage section for all the vials following opening.

**[0024]** Indeed, according to the strains and deformations that occur during the opening, each vial features a different passage section from the others. Moreover, the portion of vial bordering the dispensing outlet, following opening, is jagged and may also feature plastic protrusions, which decrease the passage section for the solution 3.

**[0025]** Moreover, precisely because of the technological limitations deriving from the use of a flexible material (which is also subjected to significant stresses during the opening stage), it is not possible to pre-define very small passage sections in order to dispense drops with a minimal volume.

**[0026]** As a result, the dispensing outlet 2C of a conventional vial 2 has a passage section which allows the dispensing of individual drops with an average volume of about 0.04 ml, but obviously this volume changes depending on the substance to be administered. The

present invention relates to a dispenser of ophthalmic solutions applicable to single-dose containers 2 similar to those disclosed above, i.e. which comprise a dispensing outlet 2C formed as a result of the mechanical breakage of the neck of the said container. The single-dose containers 2 preferred for the use of the dispenser are made of a soft plastic (for example low-density polythene) and as a single, injection-moulded piece.

**[0027]** In the present text, "single-dose container" should be understood as a container designed to hold ophthalmic solution in an amount ranging from 0.2 and 0.5 ml, but in this case the single dose will have a content of about 0.3 ml.

**[0028]** The dispenser 1 comprises a body 4 which defines a cavity 5 connected to a first opening 6; the first opening 6 is coupled, by means of sealing means 7, configured to cooperate, during use, with the neck 2B of said single-dose container 2. The dispenser 1 furthermore comprises a dispensing tip 8 featuring a second opening 9, which is also connected to said cavity 5; the second opening 9 may be configured to dispense drops of a volume between 0.005 ml and 0.02 ml, preferably between 0.01 and 0.015 ml.

**[0029]** More specifically, the second opening 9 (which can be seen in Figure 1A) may be a hole with a diameter D2 of between 0.25 and 0.75 mm, preferably between 0.4 and 0.6 mm, again more preferably of 0.5 mm.

**[0030]** To obtain a drop with a constant volume, as stated above, the second opening 9 may be defined by means of a first conical surface 10, which is inclined by 1° to 10°, more preferably by 2° to 4°, but still more preferably by 3°, with respect to a longitudinal axis A of said dispenser. The first surface 10 may extend along the entire length B1 of the dispensing tip. Essentially, the first conical surface 10 may extend along an axial length of between 8 and 20 mm.

**[0031]** The first surface 10 may be followed (in the dispensing direction, Arrow E) by a second conical surface 11 inclined by 2° to 45°, more preferably by 8° to 12°, but still more preferably by 10°, with respect to said axis A. The height HA of the second conical surface may be between 0.1 and 0.6 mm.

**[0032]** To keep the dispenser 1 fitted firmly on the neck 2B of the single-dose containers, the first opening 6 may be coupled to sealing means, which may comprise, for example, at least one sealing ring 7, formed as a part of the dispenser body.

**[0033]** According to the embodiment not shown, the sealing means 7 may be simply formed of a conical coupling wall suitable to couple, in a sealed fashion, with the neck of said single-dose container.

**[0034]** It should be noted that the material of which the single-dose container 2 is usually made is rather soft and elastic, as the user must be able to apply pressure to the outside of the container in order to dispense the ophthalmic solution. This material is therefore suitable to provide a good seal at the opening 6, even in the absence of sealing rings 7. Continuing with the description of the

dispenser 1, one may note that at the opposite end of the body 2 with respect to the second opening 9, the said body features a plurality of gripping fins 13A, 13B, 13C ... (denoted, overall, as 13) which facilitate the handling of the dispenser 1.

**[0035]** It should be noted that the optimal number of fins is six, which should be spaced at 60 degree angles. However, it is also possible for a different number of fins to be present, for example from three to twelve.

**[0036]** As can be seen from Figure 2, a barycentre B of the dispenser may be positioned in a portion of the body 2 where the fins 13 are present.

**[0037]** More specifically, the fins 13 have an external surface 14 which defines a support surface for the dispenser 1 (see Figure 2). The outer surface 14 of each fin may be inclined with respect to the axis A so that when the said surface is resting on a surface P (for example a table), said dispensing tip is raised off said surface P, so as to prevent contamination.

**[0038]** Essentially, the inclination  $\alpha$  of the external surface 14 of the fins and the length B1, B2 of the tip are linked so as to prevent the tip (and in particular the second opening 9) coming into contact with the surface P when the surface 14 of the fins is resting on the surface P.

**[0039]** Figure 6 (in which the same reference numbers already used above are used to denote functionally similar parts) shows a variant of the dispenser in Figure 1. The main difference between the dispenser in Figure 1 and that in Figure 6 lies in the tip length. The tip in Figure 1 has a length B1 of 10 mm, while the tip in Figure 2 has a length B2 of 15 mm. The tip length takes on particular importance as a longer tip 8 provides greater precision when positioning the dispensing outlet within a desired area of the cornea. Moreover, a tip with the length described allows the doctor to administer a drop with minimal risk of contact with the patient's eye.

**[0040]** It should be noted that without the dispenser 1 in Figures 1 or 6, it would be extremely difficult for a doctor to administer the drop of solution exactly in the desired area of the cornea (regardless of the volume of the said drop).

**[0041]** In a further embodiment of the dispenser (i.e. the dispenser in Figure 7), the fins 13 extend longitudinally beyond said first opening 6, in the opposite direction to the tip 8.

**[0042]** In this way, the dispenser 1 may also be placed on the surface P by making use of the base B of the fins 13. As can be seen in Figure 7, in this configuration, the opening 6 remains spaced well apart from the support surface 6, and therefore the sterility of the dispenser is maintained.

**[0043]** It should be noted that, according to a preferred embodiment, the entire dispenser 1, and more specifically, the body 2, the tip 8, and the wings 13 are made, by injection moulding, as a single piece of sterilizable plastic.

**[0044]** Suitable plastics for manufacturing the dispenser preferably belong to the polyolefin family (PP, LDPE),

but for some applications, other plastic materials such as PET may also be used. One plastic material which is particularly suitable for manufacturing the dispenser 1 is that used for the single-dose container 2.

**[0045]** Advantageously, it is possible to market the dispenser 1 in a set, which comprises, in addition to the said dispenser (individually packaged in a sterile or sterilizable package 20), at least one single-dose container 2 of ophthalmic solution configured to cooperate with said dispenser.

**[0046]** The use of the dispenser disclosed above is clear to a person skilled in the art, and is essentially as follows.

**[0047]** In a preliminary step, a doctor, or any personnel authorised to examine a patient, may prepare a single-dose container 2, by - for example - separating said container from the others connected thereto via the breakable portions 25A featured on the lugs 25 protruding laterally from the single-dose container 2 or vial.

**[0048]** Subsequently, the doctor can open the single-dose container by detaching a seal (not shown) from the vial 2.

**[0049]** The doctor, subsequently (or even prior to the operations described), can open the sterile package 20 and prepare a dispenser 1. If the situation requires it, the doctor can place the dispenser on a flat surface P, maintaining the sterility thereof by virtue of the fins 13 (or bases B thereof).

**[0050]** After said preliminary operations, the doctor can fit the dispenser 1 onto the neck of the single-dose container 2, thereby obtaining the configuration shown in Figure 3.

**[0051]** At this point, the single-dose container 2/dispenser 1 assembly is ready for use and the doctor can easily administer to the patient's eye, in a precise area of the cornea, a drop of the solution contained in the single-dose container 2. This can be done by exerting slight pressure to the deformable body 2A of the single-dose container.

**[0052]** Using the dispensing 1, it is possible to administer, to the patient's eye, the exact amount of ophthalmic solution necessary for the examination to be carried out.

**[0053]** The possibility of administering drops with a much smaller volume than that of the conventional drops obtainable with the single-dose container 2 alone means savings can be made in terms of the amount of solution used.

**[0054]** In the case of solutions comprising lissamine green, or any other dye visible to the naked eye, the possibility of using solely the amount of solution required for the examination is particularly advantageous. In fact, the dispenser makes it possible to administer, in a very precise way, solely the amount necessary to carry out the examination, thereby preventing the solution overflowing from the patient's eye and staining the skin of the face thereof.

**[0055]** Last but not least, the use of a thin and flexible tip, like that disclosed herein, minimises the risk of injury

in the event that the tip inadvertently comes into contact with the eye. Various embodiments of innovation have been disclosed herein, but further embodiments may also be conceived using the same innovative concept.

### Claims

1. Dispenser (1) of ophthalmic solutions applicable to single-dose containers (2) comprising a body (4) which defines a cavity (5) in communication with a first opening (6), the first opening being associated with sealing means (7) configured to cooperate, in use, with a neck of said single-dose container, and a dispensing tip (8) having a second opening (9), which is also in communication with said cavity (5), **characterised in that** the center of gravity (B) of the dispenser is positioned in a portion of the body (2) where fins are present (13), said fins providing an external surface (14) that defines a support plane of the dispenser, said external surface having an inclination with respect to a longitudinal axis (A) of the dispenser (1) such that, when the external surface of the fins rests on a plane (P), said dispensing tip is raised from said plane, so as to avoid contamination.
2. A dispenser according to the preceding claim, wherein the fins (13) extend longitudinally beyond said first opening (6), in a direction opposite to that of the tip (8) and / or in which said body (2), said tip (8) and said fins (13) are made by injection molding in a single piece of sterilizable plastic.
3. A dispenser according to claim 1, wherein said second opening (9) being configured to dispense drops of a volume between 0,005 ml and 0,02 ml, preferably between 0,010 and 0,015 ml.
4. Dispenser according to the preceding claim, in which the second opening (9) is a hole with a diameter of between 0,25 and 0,75mm, preferably between 0,4 and 0,6 mm, again more preferably of 0,5 mm.
5. Dispenser according to one or more of the preceding claims, wherein the second opening (9) is defined by a first conical surface (10) inclined from 1° to 10°, more preferably from 2° to 4°, still more preferably of 3° relative to a longitudinal axis (A) of said metering device, followed, in a sense of dispensing (E), by a second conical surface (11) inclined from 2° to 45°, more preferably from 8° to 12°, still more preferably of 10° with respect to said axis (A).
6. Dispenser according to the preceding claim, in which said first conical surface (10) extends for an axial length between 8 and 20 mm.

7. Dispenser according to one or more of the preceding claims, wherein the sealing means (7) associated with the first opening comprise a conical coupling wall suitable to cooperate with a neck of said single-dose container.
8. Dispenser according to one or more of the preceding claims, wherein the sealing means comprise at least one sealing ring (7), formed in one piece in the dispenser body.
9. Dispenser according to one or more of the preceding claims wherein the body (2) provides, at an opposite end with respect to said second opening, a plurality of gripping fins (13A, 13B, 13C ...) which facilitate the manipulation of the dispenser (1).
10. Kit comprising at least one dispenser (1) according to one or more of the preceding claims, said dispenser being individually packed in a sterile package (20), and at least one single-dose container (2) of the ophthalmic solution configured to cooperate with said dispenser.

### Patentansprüche

1. Spender (1) für ophthalmologische Lösungen, die auf Einzeldosisbehälter (2) anbringbar sind, der einen Körper (4), der einen Hohlraum (5) definiert, der mit einer ersten Öffnung (6) in Verbindung steht, wobei die erste Öffnung Dichtungsmitteln (7) zugeordnet ist, die konfiguriert sind, um im Gebrauch mit einem Hals des Einzeldosisbehälters zusammenzuwirken, und eine Abgabespitze (8) mit einer zweiten Öffnung (9) umfasst, die ebenfalls mit dem Hohlraum (5) in Verbindung steht, **dadurch gekennzeichnet, dass** der Schwerpunkt (B) des Spenders in einem Abschnitt des Körpers (2) positioniert ist, in dem sich Rippen befinden (13), wobei die Rippen eine Außenfläche (14) bereitstellen, die eine Stützebene des Spenders definiert, wobei die Außenfläche eine Neigung in Bezug auf eine Längsachse (A) des Spenders (1) aufweist, sodass, wenn die Außenfläche der Rippen auf einer Ebene (P) ruht, die Spenderspitze von dieser Ebene erhoben ist, um eine Kontamination zu vermeiden.
2. Spender nach dem vorhergehenden Anspruch, wobei sich die Rippen (13) in Längsrichtung über die erste Öffnung (6) hinaus erstrecken, in einer Richtung, die der der Spitze (8) entgegengesetzt ist, und/oder bei der der Körper (2), die Spitze (8) und die Rippen (13) durch Spritzgießen aus einem einzigen Stück aus sterilisierbarem Kunststoff hergestellt sind.
3. Spender nach Anspruch 1, wobei die zweite Öffnung

(9) konfiguriert ist, um Tropfen mit einem Volumen zwischen 0,005 ml und 0,02 ml, vorzugsweise zwischen 0,010 und 0,015 ml, abzugeben.

4. Spender nach dem vorhergehenden Anspruch, bei dem die zweite Öffnung (9) ein Loch mit einem Durchmesser zwischen 0,25 und 0,75 mm, vorzugsweise zwischen 0,4 und 0,6 mm, wiederum bevorzugter von 0,5 mm ist. 5
5. Spender nach einem oder mehreren der vorhergehenden Ansprüche, wobei die zweite Öffnung (9) durch eine erste konische Fläche (10) definiert ist, die von 1° bis 10°, bevorzugter 2° bis 4°, noch bevorzugter 3° relativ zu einer Längsachse (A) der Dosiervorrichtung geneigt ist, gefolgt, im Sinne einer Abgabe (E), von einer zweiten konischen Fläche (11), die von 2° bis 45°, bevorzugter von 8° bis 12°, noch bevorzugter 10° in Bezug auf die Achse (A) geneigt ist. 10
6. Spender nach dem vorhergehenden Anspruch, bei dem sich die erste konische Fläche (10) über eine axiale Länge zwischen 8 und 20 mm erstreckt. 15
7. Spender nach einem oder mehreren der vorhergehenden Ansprüche, wobei die der ersten Öffnung zugeordneten Dichtungsmittel (7) eine konische Kopplungswand umfassen, die geeignet ist, mit einem Hals des Einzeldosisbehälters zusammenzuwirken. 20
8. Spender nach einem oder mehreren der vorhergehenden Ansprüche, wobei die Dichtungsmittel mindestens einen einstückig im Spenderkörper ausgebildeten Dichtungsring (7) umfassen. 25
9. Spender nach einem oder mehreren der vorhergehenden Ansprüche, wobei der Körper (2) an einem in Bezug auf die zweite Öffnung gegenüberliegenden Ende mehrere Greifrippen (13A, 13B, 13C ...) bereitstellt, die die Handhabung des Spenders (1) erleichtern. 30
10. Set, umfassend mindestens einen Spender (1) nach einem oder mehreren der vorhergehenden Ansprüche, wobei der Spender einzeln in einer sterilen Verpackung (20) verpackt ist und mindestens ein Einzeldosisbehälter (2) der ophthalmologischen Lösung konfiguriert ist, um mit dem Spender zusammenzuwirken. 35

## Revendications

1. Distributeur (1) de solutions ophtalmiques applicables à des récipients unidoses (2) comprenant un corps (4) qui définit une cavité (5) en communication 40

avec une première ouverture (6), la première ouverture étant associée à un moyen d'étanchéité (7) conçu pour coopérer, lors de l'utilisation, avec un col dudit récipient unidosé, et un embout de distribution (8) présentant une seconde ouverture (9), qui est également en communication avec ladite cavité (5), **caractérisé en ce que** le centre de gravité (B) du distributeur est positionnée dans une partie du corps (2) où sont présentes des ailettes (13), lesdites ailettes fournissant une surface externe (14) qui définit un plan de support du distributeur, ladite surface externe présentant une inclinaison par rapport à l'axe longitudinal (A) du distributeur (1) de sorte que, lorsque la surface externe des ailettes repose sur un plan (P), ledit embout de distribution est relevé par rapport audit plan, de manière à éviter une contamination. 50

2. Distributeur selon la revendication précédente, lesdites ailettes (13) s'étendant longitudinalement au-delà de ladite première ouverture (6), dans une direction opposée à celle de l'embout (8) et/ou ledit corps (2), ledit embout (8) et lesdites ailettes (13) étant fabriquées par moulage par injection en une seule pièce de matière plastique stérilisable. 55
3. Distributeur selon la revendication 1, ladite seconde ouverture (9) étant conçue pour distribuer des gouttes d'un volume compris entre 0,005 ml et 0,02 ml, de préférence entre 0,010 et 0,015 ml.
4. Distributeur selon la revendication précédente, ladite seconde ouverture (9) étant un trou d'un diamètre compris entre 0,25 et 0,75 mm, de préférence entre 0,4 et 0,6 mm, encore plus préférentiellement de 0,5 mm.
5. Distributeur selon l'une ou plusieurs des revendications précédentes, ladite seconde ouverture (9) étant définie par une première surface conique (10) inclinée de 1° à 10°, plus préférentiellement de 2° à 4°, encore plus préférentiellement de 3° par rapport à l'axe longitudinal (A) dudit dispositif de dosage, suivi, dans le sens de distribution (E), d'une seconde surface conique (11) inclinée de 2° à 45°, plus préférentiellement de 8° à 12°, encore plus préférentiellement de 10° par rapport audit axe (A).
6. Distributeur selon la revendication précédente, ladite première surface conique (10) s'étendant sur une longueur axiale comprise entre 8 et 20 mm.
7. Distributeur selon l'une ou plusieurs des revendications précédentes, ledit moyen d'étanchéité (7) associé à la première ouverture comprenant une paroi de couplage conique appropriée pour coopérer avec un col dudit récipient unidosé.

8. Distributeur selon l'une ou plusieurs des revendications précédentes, ledit moyen d'étanchéité comprenant au moins une bague d'étanchéité (7), formée d'une seule pièce dans le corps du distributeur.
- 5
9. Distributeur selon l'une ou plusieurs des revendications précédentes, ledit corps (2) présentant, à une extrémité opposée par rapport à ladite seconde ouverture, une pluralité d'ailettes de préhension (13A, 13B, 13C ...) qui facilitent la manipulation du distributeur (1).
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10. Kit comprenant au moins un distributeur (1) selon l'une ou plusieurs des revendications précédentes, ledit distributeur étant emballé individuellement dans un emballage stérile (20), et au moins un récipient unidose (2) de la solution ophtalmique étant conçu pour coopérer avec ledit distributeur.
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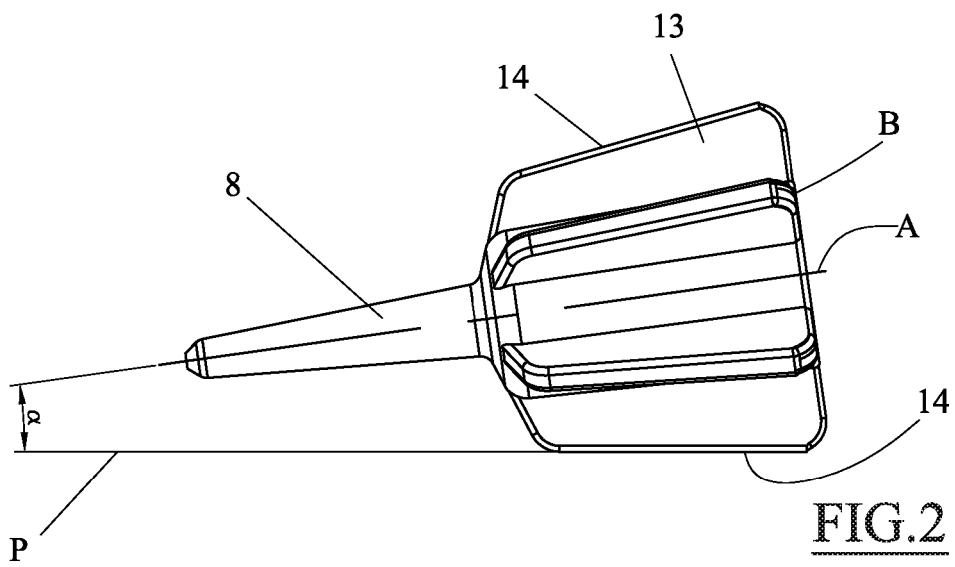
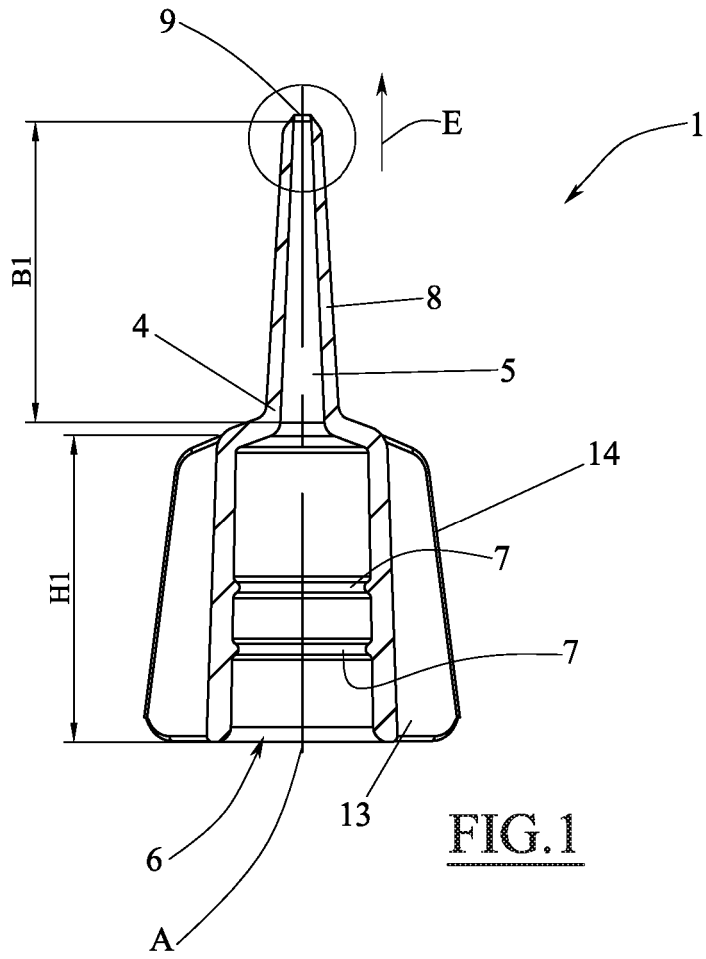
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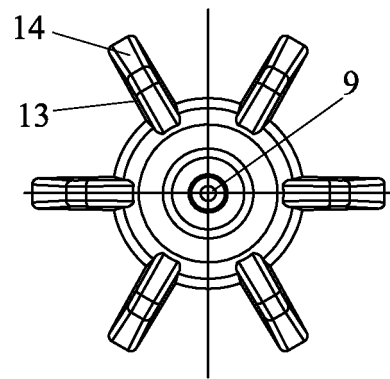
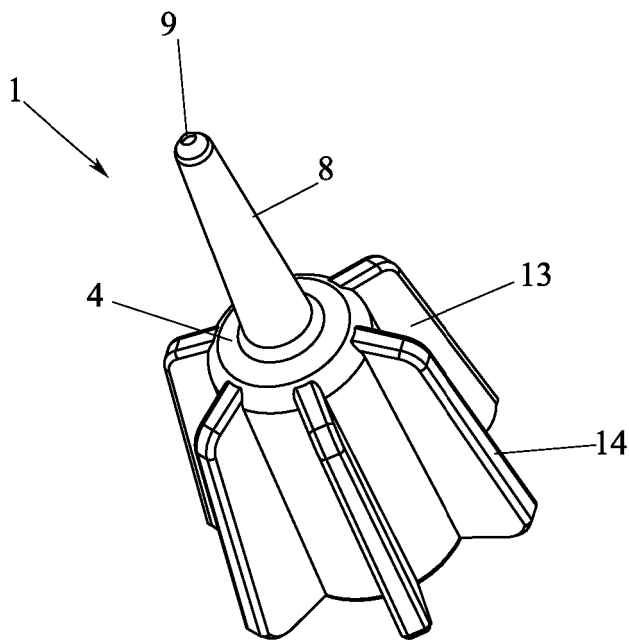
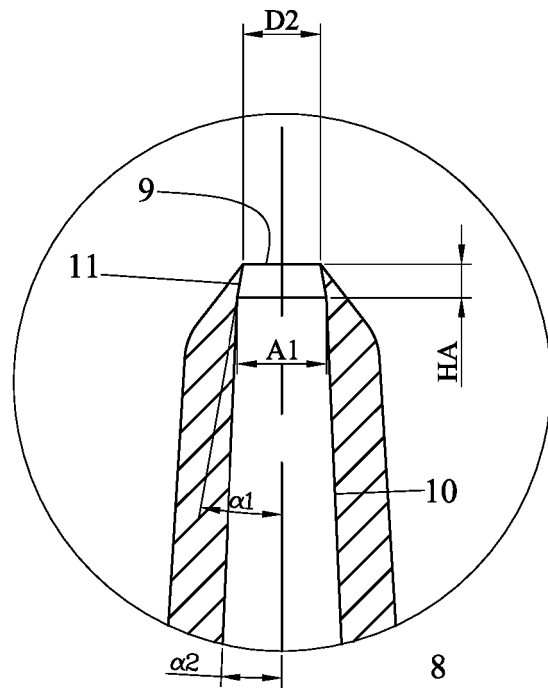
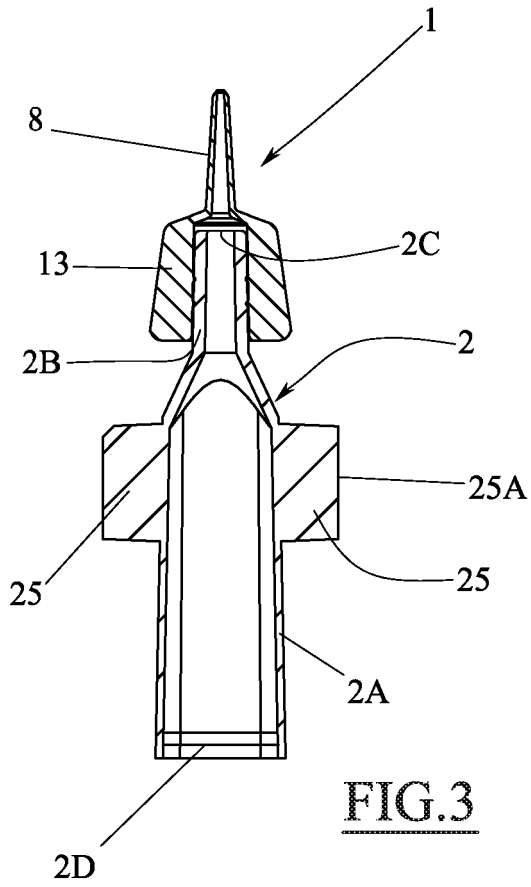
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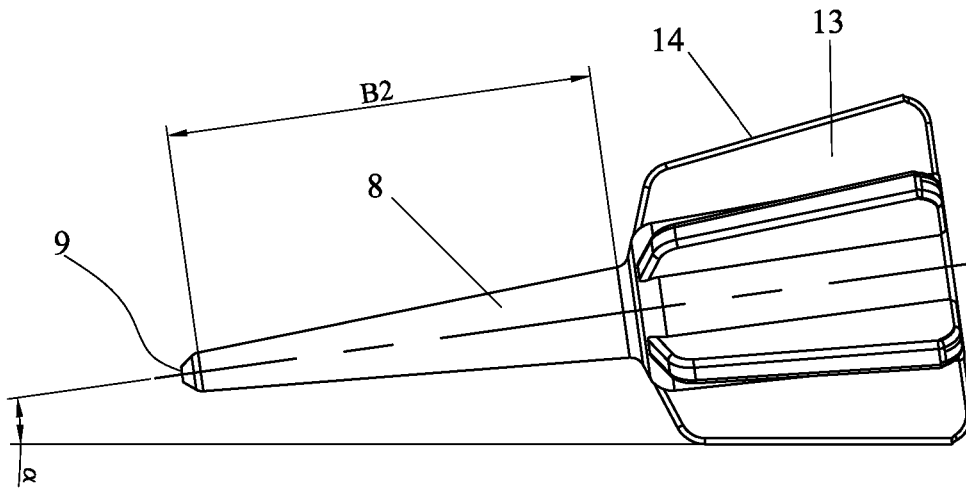


FIG. 6

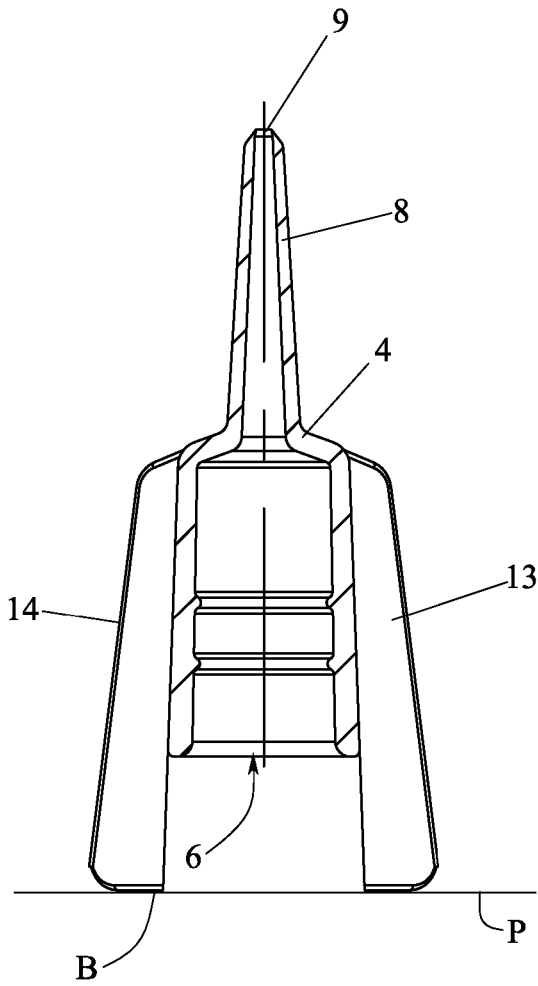


FIG. 7

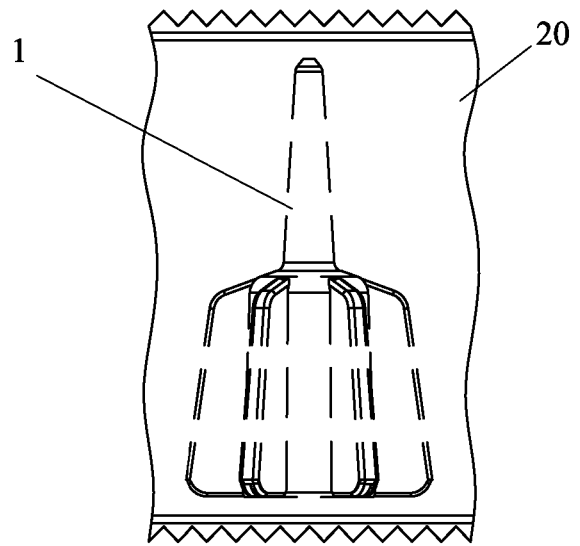


FIG. 8

**REFERENCES CITED IN THE DESCRIPTION**

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**Patent documents cited in the description**

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