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(54) **JAR SEALING DEVICE**

(57) The present invention relates to a device for sealing containers or vials intended for medical use, comprising an outer part (1) lined by two coating parts (10) (11), which are fitted into it, and the inner part (2) engages the outer part (1). The outer part (1) comprises two pierceable areas which have individual protections (8) (9) and give access to the coating parts (10) (11). The inner part (2) comprises two membranes (6) (7) connectable to the injection inlets of the outer part (1), allowing the present invention to achieve a tight and uniform seal of, e.g., parenteral solutions, maintaining the sterility characteristics of the product, without contamination and free of particles. These protections (8) (9) are breakable by the health professional at the time of use and are not reusable, ensuring that the sterility condition of the injection inlet is kept preserved immediately before use. The device has a snap-on assembly, which ultimately forms a cap-like product that allows it to fit onto a container, namely bottles containing liquids such as solutions for medical use.

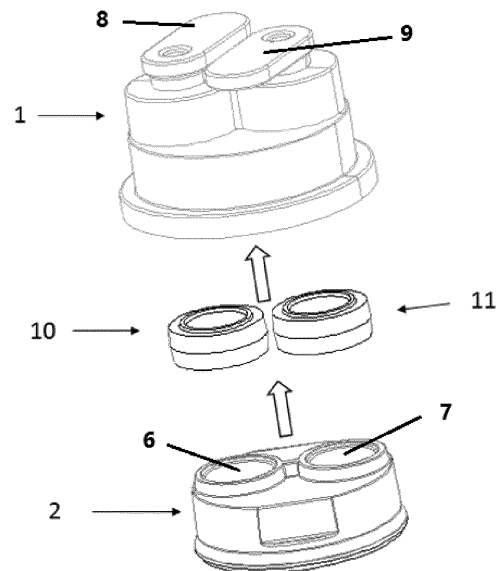


Figure 13

Description**TECHNICAL FIELD OF THE INVENTION**

[0001] A device for medical use, particularly relating to a device intended to seal containers / vials for medical use, more particularly plastic vials, even more particularly to seal plastic vials used for the packaging of parenteral solutions, in a more particular way relating to a device for sealing plastic vials used for the packaging of small volume parenteral solutions (SVPS) and large volume parenteral solutions (LVPS), i.e. sterile and apyrogenic solutions intended for single-dose parenteral administration, where plastic is the primary packaging material used, such as for instance in saline drip bags.

STATE OF THE ART OF THE INVENTION

[0002] The present invention relates to a device for sealing containers / vials intended for medical use, as those used in the packaging of Parenteral Solutions, in a preferred embodiment being small or large volume parenteral solutions. It is usually favourable for these devices to have an inlet for some administration system and to have another inlet, independent of the first one, for the administration of additives/drugs to patients. Most relevant are the documents US2016038373A1, US2014135711, DE202004003267, DE102005015504D1 and EP16825584A, which disclose solutions for sealing medical containers with means for injecting and/or withdrawing solutions.

[0003] This last document, above mentioned, EP16825584A, is particularly relevant and discloses a needleless syringe connector cap for applying to a container having an aperture at its top, said cap comprising an elastically deformable plastic valve body to be coupled to said aperture at the top of the container, said valve body having an upper surface and a lower surface and two orifices, each orifice extending through the valve body from the upper surface to the lower surface thereof, wherein said first orifice comprises a first cross-slit valve at the lower end of said orifice, said first cross-slit valve being incorporated as an aeration valve, and wherein said second orifice comprises a second slit valve at the lower end of said orifice, said second cross-slit valve being incorporated as an aeration valve, and the first orifice is adapted to receive a first syringe tip and the second orifice is adapted to receive a second syringe tip, such that when fluid is withdrawn from a container to which the cap is coupled through one of said orifices, one of said cross-slit valves opens in response to an underpressure in said container resulting from said withdrawal, so as to aerate said container.

[0004] The present invention differs, for the most part, from document EP16825584A in that the latter does not provide for the device to be unfolded into various parts, i.e. it is a single piece, and there is not the fitting of various elements as in the present invention. Another difference has to do with the fact that it does not present the possibility of multiple inlets, which is provided with the present invention, as it has two injection inlets, wherein one inlet may be for the purposes of saline drip and the other for additional medication that the patient needs. Last but not least, the present invention has individual protection from the outside, allowing its independent use with guaranteed protection against contamination. In fact, this invention presents, besides the injection independent inlets, a protection of the same, hereafter detailed as tabs and these injection inlets are coated by two rubber elements, hereafter referred to as coating parts, thus allowing the present invention to achieve a tight and uniform seal of the vial of parenteral solutions, enabling the sterile characteristics of the product to be maintained, without contamination and free of particles (as evidenced in the studies of tightness, sterility and particle testing carried out on the products after production). These protections that are breakable by the health professional are not reusable, ensuring that the sterility of the injection inlet is preserved immediately before use. The invention disclosed in document EP16825584A also does not achieve this effect.

[0005] This device thus guarantees the sealing of plastic containers / vials, in particular if these vials are also made of polypropylene, since in a preferred embodiment the invention is made of polypropylene, therefore the most suitable material of the vial should also be polypropylene because there is an excellent compatibility and it ensures sealing after the hot welding process.

[0006] This device also ensures the sealing of plastic vials used for packaging of Parenteral Solutions, avoiding the contact of the products with the rubber, which covers the injection inlets, since the same have in their surface a polypropylene plastic membrane, important for safety purposes so as to avoid the risk of rubber particles being released during puncture, and also for the final stability of the packaged product, as the product is in contact with one type of material only - the polypropylene, thus avoiding occurrence of leachable and extractable phenomena due to contact with the rubber. For a better understanding, it is referred that extractable substances are chemical compounds that migrate from the packaging to the final product (through the action of solutions or solvents) under controlled and/or exaggerated conditions of temperature, pH, polarity and time, at levels that are not found in the normal production process and storage, and leachable substances are chemical compounds that are present in the packaging or production process and have potential to migrate to the drug or cosmetic during manufacturing or storage time.

[0007] The fact that the injection inlets (3) (4) have individual protections (8)(9), which may be referred to as tabs, which are removable and managed with only one hand, makes it much easier for healthcare professionals to use this

device. It should be added that the protections must be removed to gain access to the pierceable area - the injection inlets (3) (4), so these have a "warning" function, revealing whether the product has been or has not been used, because if these protections no longer exist in the product, the user can automatically check whether the product has been or has not been used by means of visual inspection. In order to understand the importance of this effect, it shall be noted that, according to the good practices of use, this type of product should be used only once, whether the product is fully or partially used, for example a saline drip bottle cannot be reused if it has not been finished, in as much as puncturing the same access twice may imply contamination of the product, and therefore is undesirable and inadvisable.

[0008] The present invention has a lower weight - in terms of the assembled product - compared to other solutions on the market. In a preferred embodiment, it weighs 4.80 ± 0.5 grams. This was carefully studied at the development stage of the invention in order to reduce the "ecological footprint" as much as possible by reducing the amount of material used. Environmentally, it can be recyclable so that it can be reused for other products, since polypropylene is 100% recyclable, and it has a reduced number of components, therefore using less material. The present invention, due to the materials which it is comprised of, provides the possibility for sterilisation being achieved by the preferred and safest method recommended by the pharmacopoeias, so important in these health matters so that the safety of patients is ensured.

[0009] In addition to this, a reduced number of materials are used, i.e. it is a bi-material product (preferably polypropylene + polyisoprene), thus providing for the use of only two manufacturing processes to obtain the final product.

SUMMARY OF THE INVENTION

[0010] Device for sealing containers / vials intended for medical use consisting of four parts:

- an outer part (1) and an inner part (2);
- the outer part (1) is lined with two coating parts (10)(11) which are fitted into place;
- the inner part (2) engages with the outer part (1);
- the outer part (1) and the inner part (2) are made of plastic;
- the two coating parts (10) (11) in the inner part (1) are made of rubber, in polyisoprene;
- - the outer part (1) comprises two pierceable areas, referred to in this document as injection inlets (3) (4) ;
- - the inner part (2) comprises two membranes (6)(7) connectable to the injection inlets (3) (4) of the outer part (1);
- - the injection inlets (3) (4) have individual protections, hereinafter referred to as tabs (8) (9), for sealing these inlets.

[0011] Therefore, this device has snap-on assembly, which ultimately forms a cap-like product that allows it to fit onto a container, namely a bottle containing liquids such as solutions for medical use.

BRIEF DESCRIPTION OF THE FIGURES

[0012]

Figure 1 - Representation of the outer part (1), with the external protections (8) and (9).

Figure 2 - representation of the present invention in sectional and assembled views, wherein the outer part (1) is shown, the injection inlets (3) (4) are not visible in the sectional view, but the arrows are designed to represent the path of injection enabled by them and its direction; also illustrated are the coating parts (10)(11) lining the injection inlets, as well as the outer part (2), which is fitted on, and also an indication of two details A and B.

Figure 3 - Sectional view of the outer part (1) with detail A, which is no more than the tabs' point of breakage.

Figure 4 - Sectional view of the outer part (1) with detail B, which is no more than the fitting system between the outer parts (1) and (2), by clipping.

Figure 5 - Side view of the outer part (1) wherein the tabs (8)(9) are also shown.

Figure 6 - Top view of the outer part (1), wherein the tabs (8)(9) are also shown.

Figure 7 - Representation of the coating parts (10) (11) .

Figure 8 - Perspective view of the inner part (2) wherein the membranes (6)(7) are visible.

Figure 9 - Sectional view of the inner part (2), with indication of detail A.

Figure 10 - illustration of detail A of the inner part (2) with detail A.

Figure 11 - Top view of the inner part (2).

Figure 12 - Sectional view of the sealing device, which is the object of this invention, wherein the relative location of the membranes (6)(7) is shown.

Figure 13 - Exploded view of the sealing device, which is the object of this invention, wherein the outer part (1), the two coating parts (10)(11) and the inner part (2) are illustrated.

DETAILED DESCRIPTION OF THE INVENTION

[0013] The present invention relates to a device for sealing containers / vials intended for medical use, which are used for packaging of Parenteral Solutions, particularly of large or small volume parenteral solutions.

[0014] As stated in the Summary of the invention, this device comprises an outer part (1) and an inner part (2), the two of which fit together, in detail the inner part (2) fits into the outer part (1). Both parts, the outer (1) one and the inner (2) one, are made of plastic or, in a preferred embodiment, of polypropylene.

[0015] In a preferred embodiment, the outer part (1) is a cap.

[0016] The outer part (1), in its external surface, comprises:

- two individual and independent injection inlets (3) (4), each of these injection inlets (3) (4) having an individual protection, referred to as tabs (8)(9) for sealing these inlets. These injection inlets (3) (4) allow the administration of medicines by parenteral route to patients and their independent use with guaranteed protection against contamination. On the outside of the outer part (1) there are uniquely these two tabs (8) (9), for safety reasons, since only by breaking them can the puncture be carried out, and depending on the required use, their main function is to isolate the component (2) from the outside environment and to ensure that it is clearly visible when the product has already been used, since these tabs are breakable and non-reusable.

[0017] Preferably, the outer protective tabs (8) (9) are never in contact with the liquid to be injected, having the only purpose of protecting the coating parts (10)(11) from the external environment.

[0018] For this sealing device to be effective, it features two coating parts (10) (11), which are made of polyisoprene rubber.

[0019] The inner part (2) comprises:

- two membranes (6)(7) which waterproof the coating parts (10) (11) and consequently the injection inlets (3) (4) of the outer part (1), preventing any contact of the bottle product with the coating parts (10)(11).

[0020] The membranes (6)(7) are made of polypropylene so as to ensure that the liquid does not come into contact with the coating parts (10) (11), which are preferably made of polyisoprene rubber.

[0021] The device thus provides a tight and uniform sealing of the parenteral solution bottle, allowing the product to keep its sterility characteristics, without contamination and free of particles, as proven by the tightness, sterility and particle tests and trials performed on the products after production (table 1, 2).

[0022] The present invention, given its composition, is resistant to sterilization by moist heat, as demonstrated by tests carried out on the products before and after production (table 1, 2). In fact, the materials from which the device object of the present invention is made, allow the sterilization which is considered the process of choice in the pharmaceutical industry to be performed, due to a greater effectiveness being guaranteed: sterilization by moist heat at a temperature of 121° C for a minimum of 15 minutes.

Description of the manufacturing process of the device:

[0023] The first phase is a thermoplastic injection process, in this case for the polypropylene material; as such, the injection of the polypropylene components is carried out in fully electric injection machines in order to avoid contamination

of the product through lubrication oils.

[0024] The two polypropylene parts, i.e. the inner (2) and outer (1) parts, are injected in a clean room with positive pressure in order to eliminate contamination through air particles and these materials are processed in electric injection machines which are free of lubricants so as to avoid contact contamination.

[0025] The second phase concerns the assembly, in which the polyisoprene components (the two coating parts (10) (11)) are placed on the outer part (1), the latter being, in a preferred embodiment and as mentioned above, a multi-inlet cap, and the inner part (2) is assembled (said inner part being simply the inside of the outer part (1) with the coating parts (10) (11) fitted between them) in order to avoid the risk of rubber particles being released during puncture and, at the same time, of the liquid coming into contact with the coating parts (10) (11), since this inner part (2) has the two membranes (6)(7) detailed above.

[0026] The rubber must be a rubber complying with the pharmacopoeia requirements (monograph 3.2.9), preferably a polyisoprene for the unique characteristics they confer to the product. There are still no industrial rubbers on the market for injection process that can replace polyisoprene and guarantee the functionality required for this specific type of product.

[0027] Finally, the various components of the device are packaged in double low density polyethylene (LDPE) bags. Packing is also carried out in an ISO class 8 clean room, to avoid contact between the product and the outside environment and thus prevent possible contamination. The double bag provides a greater guarantee of product integrity, e.g. prevention of tearing/perforation. The LDPE Bag complies with the provisions contained in Regulations (EC) No. 1935/2004; No. 2023/2006 and No. 10/2011, ensuring compatibility with the product and guaranteeing that they are 100% recyclable.

[0028] All the processes described above are carried out in an ISO class 8 clean room with positive pressure and controlled temperature.

[0029] The following is information regarding the tests performed on the product, components and working environment (clean room), which ensure the compliance and safety of the product for the user/patient and allow it to be used for administration by the gravity method, manually or automatically and for the use of needles or perfusion systems:

Table 1 - Products and components tests and trials

Product/ Component	Test Identification	Normative Reference
PHYSICOCHEMICAL TESTS: Polyisoprene Rubber	<ul style="list-style-type: none"> • Identification A (Infrared absorption spectrophotometry) • Identification B (Total Ash) • Appearance of solution S • Acidity or alkalinity • Absorbance • Reducing substances • Ammonium • Extractable zinc • Extractable heavy metals • Residue on evaporation • Volatile sulphides 	Mon. Ph. Eur. 3.2.9
PHYSICOCHEMICAL	<ul style="list-style-type: none"> • Identification A (IR) • Appearance of solution 	Mon. Ph. Eur. 3.1.6
TESTS: Inner and Outer Cap	<ul style="list-style-type: none"> • Acidity or alkalinity • Absorbance • Reducing substances • Extractable aluminium • Extractable chromium • Extractable titanium • Extractable vanadium • Extractable zinc • Extractable heavy metals • Sulphated ash • Phenolic Antioxidant (Additive 10) 	

EP 4 124 329 A1

(continued)

Product/ Component	Test Identification	Normative Reference
PHYSICAL TESTS: Cap and Rubber Binomial	<ul style="list-style-type: none"> • PLASTIC CAP: Leak Resistance Test • PLASTIC CAP: Opening force • LINER: Fragmentation (coring) • LINER: Penetration Force • LINER: Dynamic spike retention • LINER: Static spike-retention capability of the liner and leak resistance of the piercing area • LINER: Resealability • Penetrability • Fragmentation • Self-sealing test 	ISO 15759:2005 Mon. Ph. Eur. 3.2.9
MIGRATION TESTS - REGULATION (EU) No. 10/2011: Cap and Rubber	<ul style="list-style-type: none"> • Overall migration - aqueous simulants by total immersion method • Overall migration - aqueous simulants by total immersion method • Overall migration - fatty simulant by total immersion method • Overall migration - substitution simulants by total immersion method 	EN 1186-3: 2002 (Method A) Simulant A (ethanol 10%) EN 1186-3: 2002 (Method A) Simulant B (acetic acid 3%) EN 1186-2: 2002 Simulant D2 EN 1186-14:2002

Table 2 - Other relevant tests and trials to ensure product safety and compliance

Place of production and packaging	Test identification	Normative Reference
CLEAN ROOM TESTS	<ul style="list-style-type: none"> • Particle counting test (0.3; 0.5; 1.0; 5.0 μm) - Classifications according to ISO/GMP • Penetration test 0.01% - HEPA absolute filters integrity test • Recovery test in ISO class 5 and 6 clean rooms • Temperature test ($^{\circ}\text{C}$) - Minute by minute records for 1 hour • Relative humidity test (%) - Minute by minute records for 1 hour • Flow test (m^3/h) with calculation of renewal rates • Room differential pressure test (Pa) • Fumes test • Illuminance test (lux) • LAeq [dB(A)] and LCpk [dB(C)] noise test 	ISO 14644-1 ISO 14644-3 ISO 14644-3 ISO 14644-3 ISO 14644-3 ISO 14644-3 ISO 14644-3 PT SL-IL Ed1 Rev0 PT SL-RU Ed1 Rev5

Claims

1. A device for sealing containers / vials wherein it comprises:

a. an outer part (1) and an inner part (2), wherein the inner part (2) can be fitted into the outer part (1);

b. the outer part (1) on its external surface comprises two individual and independent pierceable areas or injection inlets (3)(4), each of said injection inlets (3)(4) having an individual protection (8)(9) for sealing the injection inlets (3) (4) and isolating the inner part (2) from the external environment; the outer part (1) is covered by two coating parts (10) (11), which are placed on the outer part (1) by fitting into it;
c. the inner part (2) comprises two membranes (6)(7) connectable to the injection inlets (3)(4) of the outer part (1) waterproofing the coating parts (10) (11), preventing any contact of the product from the bottle with the coating parts (10) (11); and

wherein the individual protections (8) (9) are removable to provide access to pierceable areas or injection inlets (3)(4) .

2. A device according to the previous claim wherein the individual protections (8)(9) are tabs.
3. A device according to the previous claims wherein the outer (1) and inner (2) parts are made of plastic.
4. A device according to the previous claim wherein the outer (1) and inner (2) parts are made of polypropylene.
5. A device according to the previous claims, wherein the coating parts (10)(11) are in rubber.
6. A device according to the previous claim, wherein the coating parts (10)(11) are in polyisoprene.
7. A device according to the previous claims, wherein the membranes (6)(7) are in plastic.
8. A device according to the previous claims, wherein the membranes (6)(7) are in polypropylene.
9. A device according to the previous claims, wherein it is a cap.
10. A device according to the previous claims wherein it weighs 4.80 ± 0.5 grams.
11. Use of the device disclosed in claims 1 to 10, in containers made of polypropylene.
12. Use of the device disclosed in claims 1 to 10, in containers with liquids.
13. Use of the device disclosed in claims 1 to 10, in containers containing solutions for medical use.
14. Use of the device disclosed on claims 1 to 10 for sealing plastic vials used for the packaging of Parenteral Solutions, more particularly of large or small volume parenteral solutions.
15. A process for the production of devices intended for sealing vials wherein it comprises the following steps:
 - a. thermoplastic injection of the polypropylene components, on fully electric injection machines;
 - b. injection in a clean room with positive pressure of two parts in polypropylene, a first inner part (2) and a second outer part (1);
 - c. fitting of two coating parts (10) (11) onto the outer part (1);
 - d. fitting of the inner part (2) into the outer part (1) with the coating parts (10)(11) fitted;
 - e. packing in double low density polyethylene bag in clean room.

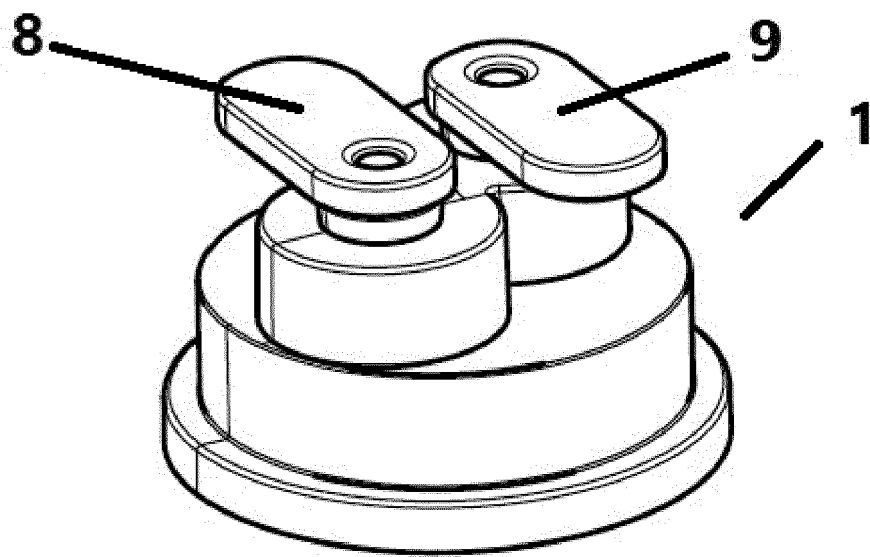


Figure 1

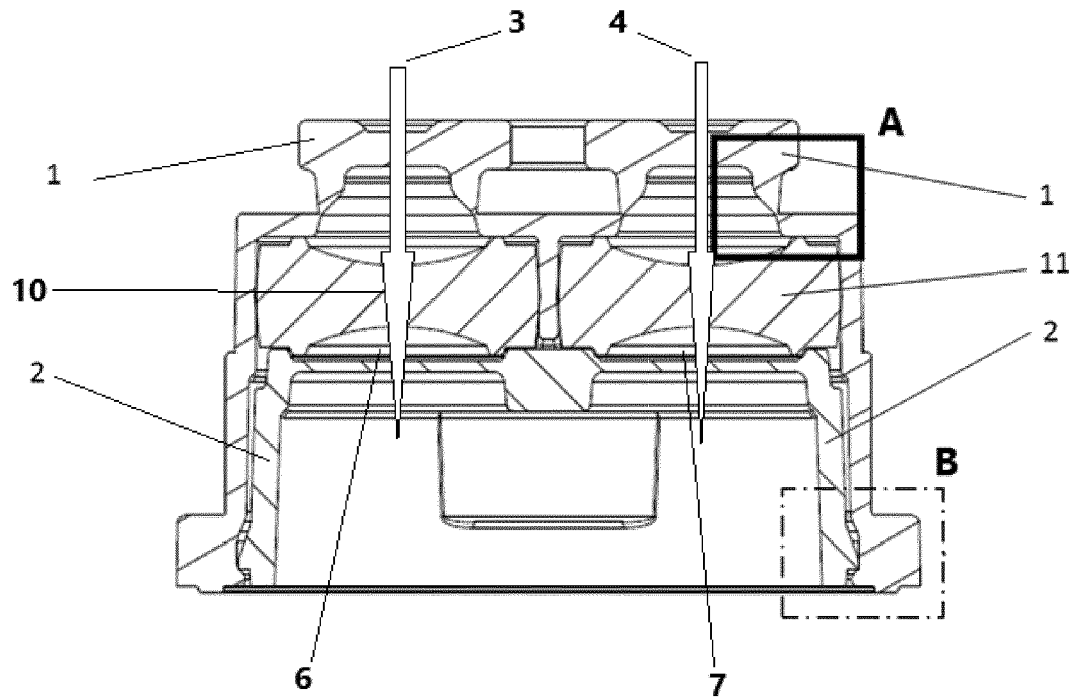


Figure 2

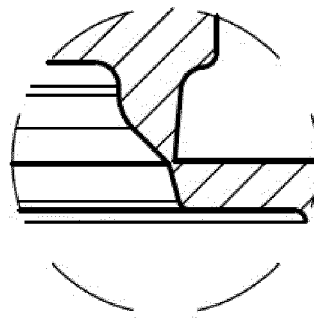
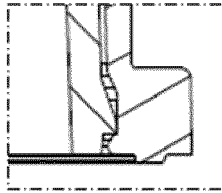


Figure 3



B

Figure 4

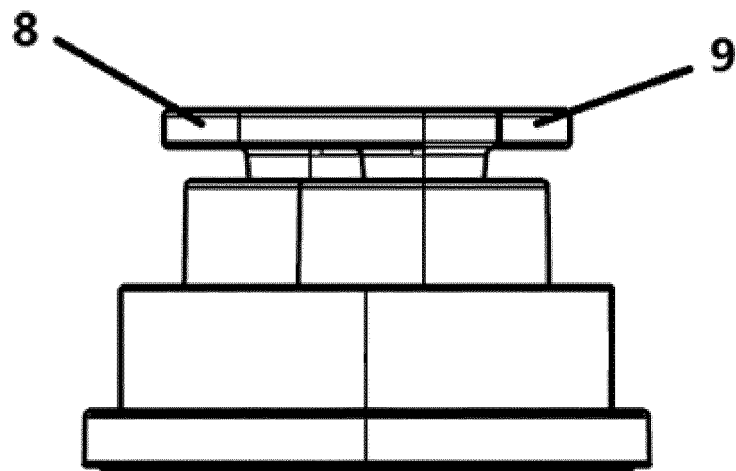


Figure 5

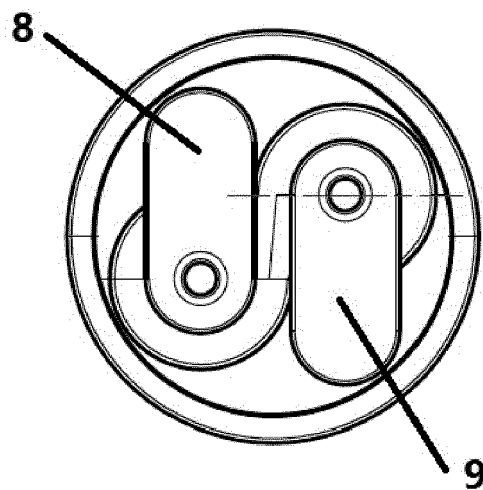


Figure 6

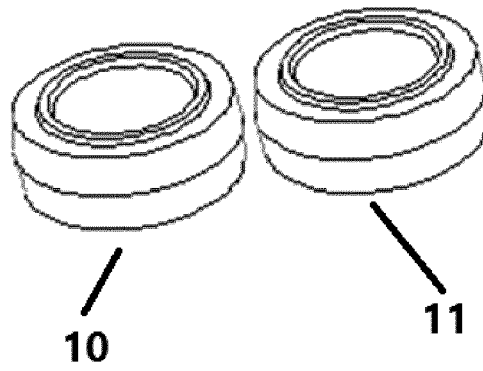


Figure 7

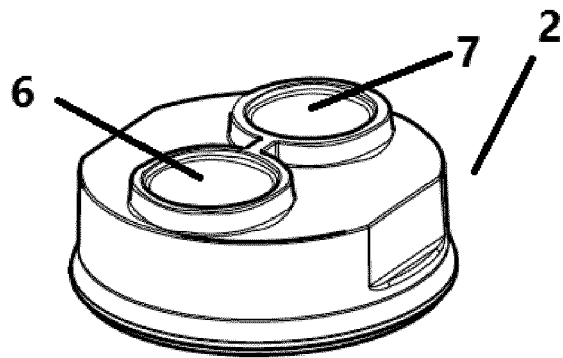
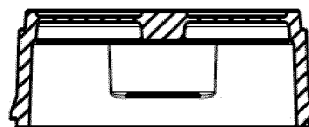


Figure 8

A



A - A

Figure 9

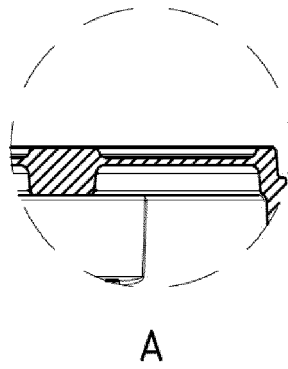


Figure 10

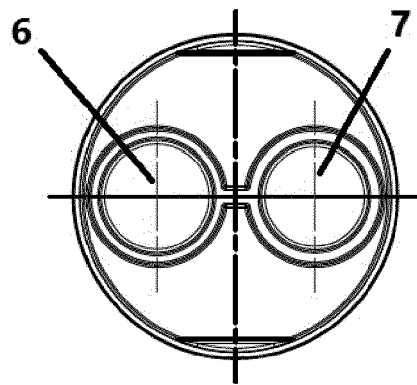


Figure 11

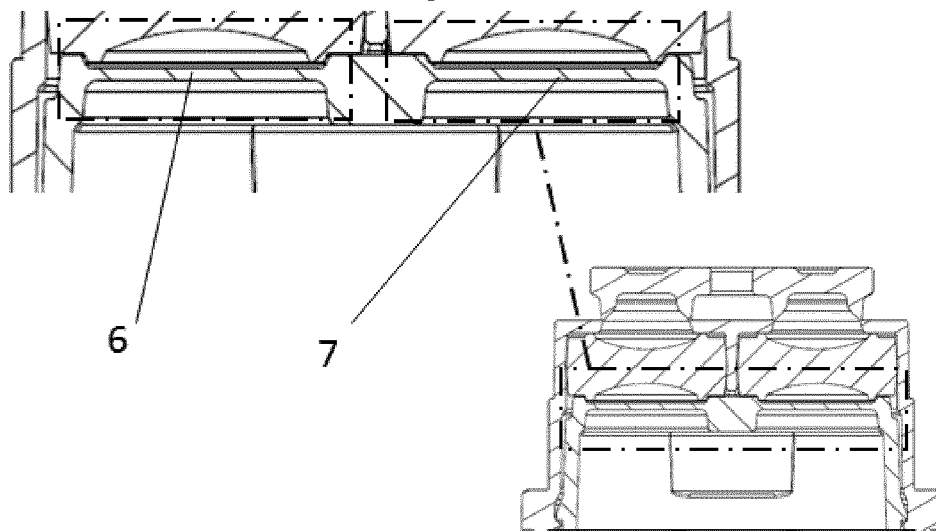


Figure 12

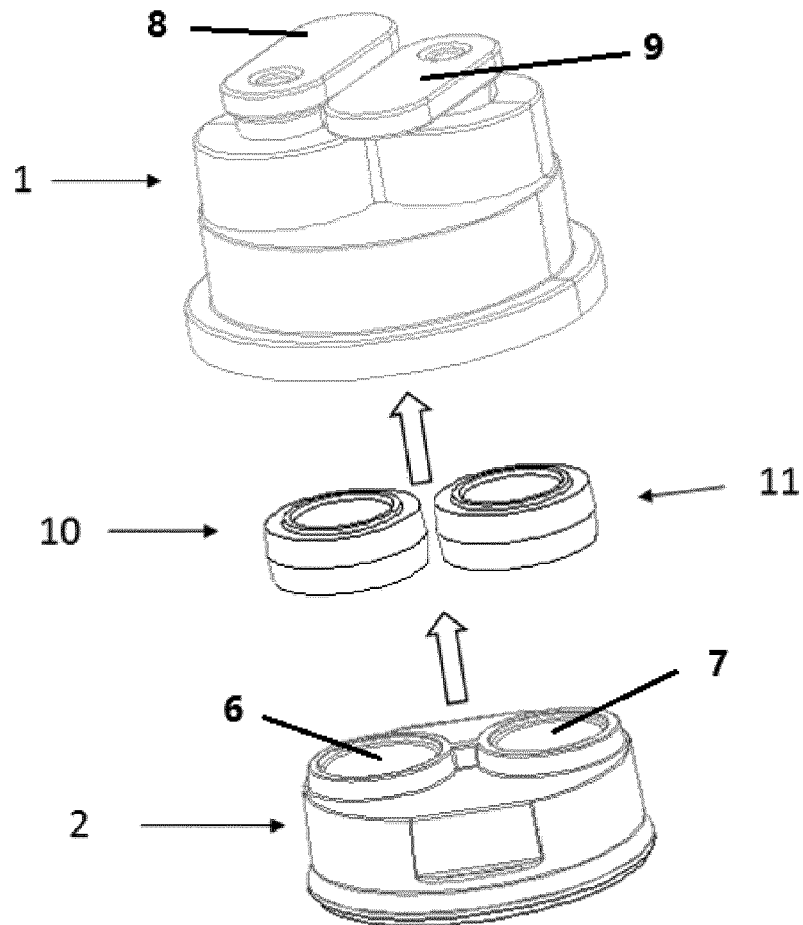


Figure 13



EUROPEAN SEARCH REPORT

Application Number

EP 21 39 8011

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EPO FORM 1503 03.82 (P04C01)

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			TECHNICAL FIELDS SEARCHED (IPC)
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<div>3</div> <div>The present search report has been drawn up for all claims</div>			
<div>Place of search</div> <div>The Hague</div>		<div>Date of completion of the search</div> <div>13 January 2022</div>	<div>Examiner</div> <div>Petzold, Jan</div>
<div>CATEGORY OF CITED DOCUMENTS</div> <div> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document </div>			

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 21 39 8011

5

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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