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(54) **TAMPER-EVIDENT SINGLE-USE CONTAINER FOR HOLDING UNITARY DOSES**

MANIPULATIONSSICHERER BEHÄLTER ZUM ENTHALTEN EINZELNER DOSEN

RÉCIPIENT À USAGE UNIQUE INVIOLABLE DESTINÉ À CONTENIR DES DOSES UNITAIRES

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(73) Proprietor: **Airnov, Inc.**
Wilmington, New Castle DE 19808 (US)

(72) Inventor: **Bois, Dominique**
02310 Montreuil aux Lions (FR)

(74) Representative: **Hoffmann Eitle**
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

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Description

Field of the Invention

[0001] The invention relates to a tamper-evident single-use container for holding unitary dose products and its use.

Prior Art

[0002] Single-use containers for pharmaceutical products are especially known from single-dose containers for holding a vaccine. Vaccine or other types of serum are often stored in single-use containers made of glass which are provided with a breakable head.

[0003] FR 2 639 026 A1 and EP 0 076 418 A2 disclose plastic containers with a breakable head which can be removed before first use.

[0004] Such containers are not useful for holding unitary dose products like loose pills or capsules, lozenges or granules. Such unitary dose products are usually packaged in tubular containers which are closed with a conventional openable cover. However, such prior art containers are not tamper-evident because the cover can be repeatedly opened and closed.

[0005] EP 0 076 418 A2 discloses a tamper-evident single-use container with the precharacterizing features of claim 1 which represents the closest prior art.

Summary of the Invention

[0006] Accordingly, there is a need for a single-use container which is specifically adapted for holding unitary dose products, especially solid pharmaceutical products and which is tamper-evident.

[0007] This object is solved by a tamper-evident single-use container for holding unitary dose products with the features of claim 1 and the use of such a container according to claim 15. Preferred embodiments follow from the other claims.

[0008] An inventive tamper-evident single-use container for holding unitary dose products, especially solid pharmaceutical products, comprises a container body made of plastic material with a bottom end and a tubular top end and a head section closing the top end, wherein the head section is integrally connected to the container body at a connecting region. The thickness of the plastic material at the connecting region is reduced by at least 50% as compared to the wall thickness of the container body.

[0009] Such container made of plastic material is advantageous over single-use containers made of glass in that, when removing the head section from the container body and the material of the connecting region is broken, no sharp-edged chips will be generated. Further, the inventive container is handled in a straightforward way in that it is the perceived top end of the container which is removed. The container is inviolable apart from the connecting region integrally connecting the head section to the container body. Once the head section has been removed, the container can no longer be closed again so that any tampering with the container will immediately become evident.

[0010] The head section is provided with protrusions and/or depressions which promote a firm grip. This feature helps the user to apply the required force to break the container.

[0011] The protrusions and/or depressions can be molded as a part of the head section or can be provided using a further separate part which can be manufactured by bi-injection molding, overmolding or which can be molded in a separate manufacturing step before it is mounted to the container.

[0012] In case that the protrusions and/or depressions are integrally molded as a part of the head section, the container and its head section are molded using a sliding splitmould in order to demould the container.

[0013] In case of the provision of a separate part with the protrusions and/or depressions, this simplifies the moulding of the container and increases the production rate. Further, the separate part can be customized depending on the user or the specific product intended to be contained. To this end, the separate part can be individualized as regards the shape, color, material or texture just to mention some examples.

[0014] According to a preferred embodiment, the body of the container is of a cylindrical shape with a round, oval or polygonal base.

[0015] The plastic material according to the invention is preferably made of a suitable plastic material which is preferably selected from the group comprising radical or linear high and low density polyethylenes, copolymers of ethylene such as for example ethylene vinyl acetates, ethylene ethyl acrylates, ethylene butyl acrylates, ethylene maleic anhydrides, ethylene alpha olefines, regardless of the methods of polymerisation or modification by grafting, homo polypropylene and copolymers, polybutene-1, polyisobutylene. Polyolefines are preferably selected to make the single-use container for cost reasons and because they are easy to use.

[0016] Other polymer materials can be considered however such as polyvinyl chloride, copolymers of vinyl chloride, polyvinylidene chlorides, polystyrenes, copolymers of styrene, derivatives of cellulose, polyamides, polycarbonates, polyoxymethylenes, polyethylene terephthalates, polybutylene terephthalates, copolyesters, polyphenylene oxides, polymethyl methacrylates, copolymers of acrylate, fluoride polymers, polyphenylene sulphides, polyarylsulphones, polyaryletherketones, polyetherimides, polyimides, polyurethanes, phenol resins, melamine resins, urea resins, epoxy resins and unsaturated polyester resins.

[0017] Biodegradable polymer materials, with for example a starch base, are also possible such as polylactic acids (PLA).

[0018] Combinations of these polymers can be used,

if desired. The polymer used to produce the single-use container can also contain one or more additives such as fibers, expanding agents, additives such as stabilizers and colorants, sliding agents, demolding agents, adhesion agents or reinforced catching agents and/or any others according to the requirements of usage.

[0019] The single-use container can also be made from injectable materials made in such a way that they are capable of absorbing various different pollutants such as humidity, oxygen, odour and other possible pollutants. The thermoplastic materials are thus themselves formulated with active agents belonging to a group of humidity absorbers, oxygen scavengers, odour absorbers and/or emitters of humidity or volatile olfactory organic compounds.

[0020] Suitable dehydrating agents are selected from a group comprising silica gels, dehydrating clays, activated alumina, calcium oxide, barium oxide, natural or synthetic zeolites, molecular or similar sieves, or deliquescent salts such as magnesium sulfide, calcium chloride, aluminum chloride, lithium chloride, calcium bromide, zink chloride or the like. Preferably the dehydrating agent is a molecular sieve and/or a silica gel.

[0021] A suitable oxygen collecting agent is selected from a group comprising metal powders having a reducing capacity, in particular iron, zinc, tin powders, metal oxides still having the ability to oxidize, in particular ferrous oxide, as well as compounds of iron such as carbides, carbonyls, hydroxides, used alone or in the presence of an activator such as hydroxides, carbonates, sulfites, thiosulfates, phosphates, organic acid salts, or hydrogen salts of alkaline metals or alkaline earth metals, activated carbon, activated alumina or activated clays.

[0022] Other agents for collecting oxygen can also be chosen from specific reactive polymers such as those described for example in the patents US 5,736,616, WO 99/48963 and WO 98/051758. These specific reactive polymers can be mixed with a thermoplastic polymer used to produce the single-use container according to the present invention.

[0023] The amount of treatment agent introduced into the thermoplastic polymer to produce the single-use container according to the present invention expressed in percentage by weight can advantageously vary from 5% to 70%, preferably from 5% to 55% of the thermoplastic material used to produce the single-use container.

[0024] By reducing the thickness of the plastic material at the connecting region by at least 50% as compared to the wall thickness of the container body, the container will be opened at a well-defined position.

[0025] The plastic material of the container can comprise a plastic polymer composition including an active substance, the active substance preferably being a desiccant. This is especially advantageous because unlike multi-use containers which are opened and closed several times with an accompanying at least partial change of the inner atmosphere of the container, a single-use container only will have to maintain a certain inner atmosphere up to its single use. Since a plastic container always shows a residual amount of permeation based on its material properties (transmission rate), undesired gases might penetrate the walls of the container, such substances can already become trapped before reaching the inside of the container. In such a way, the unitary dose products packaged inside the single-use container can be best protected against an undesired contact with harmful substances, like water vapor or oxygen. The active substance, however, can be a desiccant or can be different from a desiccant. It can be any substance or mixture of substances which trap and/or release certain compounds. It is possible, just to give some examples, to hold the unitary dose products inside the container free of oxygen or free of volatile organic compounds such as for example formaldehydes or other aldehydes.

[0026] Preferably, the head section has a round outer shape, preferably generally spherical outer shape. This makes the head section easy to grip by a user when a certain force will have to be applied in order to break the frangible connecting region between the head section and the container body.

[0027] Preferably, the tamper-evident single-use container further comprises a gorge on the head section. Such design has various advantages. Firstly, a gorge provides some protection of the thin-walled connecting region against an inadvertent mechanical impact. Further, a gorge has the advantage that the circumferential length of the connecting region is reduced. For breaking the single-use container along the connecting region, the overall area of the connecting region, i.e. the product of the wall thickness and the length of the connecting region, is decisive. The provision of a gorge reduces the circumferential length of the connecting region and facilitates the breaking of the connecting region or, when this is not required, makes it possible to increase the wall thickness as compared to a container without a gorge on the head section in the region between the container body and the head section.

[0028] Preferably, the angle A between the wall section of the container body and the wall section of the head section at the connecting region is at least 10°. The angle A corresponds to the maximum possible tilting of the head section around an axis perpendicular to the longitudinal axis of the container relative to the container body before the head section contacts the container body and prevents a further relative tilting motion of the head section. Such minimum angle of at least 10° is sufficient to tilt the head section to a sufficient degree so that the container will break at the connecting region.

[0029] The connecting region bridges a distance between the container body and the head section, the length 1 of the connecting region in the direction of the distance being defined by $0mm < l \leq 1mm$, more preferably $0mm < l \leq 0{,}5mm$. The connecting region is preferably arranged and dimensioned such that the connecting region can be broken by tilting the head section relative to the container body around an axis which is perpendicular to

the longitudinal axis of the container. Examples in the prior art in which the connecting region can be broken by a relative rotation around the longitudinal axis of the tubular container body between the head section and the tubular container body requires a high force so that the wall thickness of the connecting region has to be made very small. This, however, makes the connecting region vulnerable against any inadvertent impacts.

[0030] According to a preferred embodiment, the maximum outer dimensions of the head section are such that the head section does not protrude beyond the outer extension of the tubular container body. In other words, the maximum outer dimensions of the head section is preferably smaller than the outer diameter of the tubular container body. This characteristic feature helps to maintain the integrity of the container because any force acting on a container lying on its side will not generate a force which could break the container. This is especially the case when a high number of containers are stored in a way such that many containers are lying on their side and being stacked in multiple rows in top of each other.

[0031] Furthermore, the maximum outer dimensions of the head section are larger than the inner diameter of the tubular container body. In this manner, the head section, once it has been broken, cannot be used to reclose the container body.

[0032] Preferably, the head section is shaped so that the head section, once removed from the container body, cannot be turned upside down and used to reclose the container body. This can be achieved e.g. by providing the upper part of the head section which is aligned with the fictitious extension of the inner wall surface of the cylindrical container body with a shape which cannot be inserted into the container body and become engaged therein. Specifically, the tangent to that upper part of the head section which is aligned with the fictitious extension of the inner wall surface of the cylindrical container body should form an angle B to the longitudinal axis of the container body which exceeds 30°, preferably 45°.

[0033] According to a most preferred embodiment, the cylindrical container body has an inner diameter d_{in} and an outer diameter d_{out}, and wherein a maximum outer outer diameter d_{head} of the head section is selected to satisfy the equation $d_{in} < d_{head} < d_{out}$.

[0034] Preferably, the wall thickness of the container body at the tubular top end thereof is at least 0.5mm, more preferred 0,8mm. This makes the plastic material of the container body sufficiently rigid in the region of the tubular top end such that the head can be easily broken while the container body maintains its basic shape without deforming or bending during breakage.

[0035] According to a preferred embodiment, the thickness of the plastic material at the connecting region is less than 0.5mm, preferably between 0.1mm and 0.5mm and more preferably between 0.1mm and 0.3mm. As outlined above, it is not the thickness alone of the plastic material of the connecting region, but also the length of the connecting region which determines the resistance of the single-use container against breaking at the contact region. However, single-use containers are usually of relatively small dimensions especially when storing pharmaceutical products. Therefore, on the basis of common sizes for such single-use containers for pharmaceutical substances, the above-mentioned range of the thickness of the plastic material was found to provide a sufficient stability to the container and, at the same time, to make it possible for an average adult to open the container by breaking the connecting region.

[0036] Furthermore, according to a preferred embodiment, the length of the connecting region is 0mm < l < 0.3mm.

[0037] Preferably, the container body is provided with an interior annular shoulder close to its bottom end. The provision of an annular shoulder close to the bottom end provides a stop for receiving and positioning a cover for closing the container at its bottom end, especially if the cover is integrated in the container body without protruding beyond the bottom end.

[0038] According to an alternative preferred embodiment of the invention, the bottom end of the container is closed by (heat) welding together the lower end of the container body. This is an easy-to-perform process step for closing the container once the unitary dose products to be stored inside the container have been inserted into the container. Further, no extra part for closing the container is required.

[0039] In such an embodiment, the wall thickness at the open end of the container body shall not exceed preferably 0,5mm, most preferably 0,3mm. In such an embodiment, the thickness of the container wall is not constant: the open end of the container wall has preferably a wall thickness of 0,5mm or less to allow for the welding operation, whereas the top end of the container has a wall thickness of 0,5mm or more to be sufficiently rigid to allow for breaking the connecting region.

[0040] Preferably, the tamper-evident single-use container comprises a cover closing the bottom end of the container body. The provision of a cover is the easiest option for closing the single-use container after the product to be stored therein has been inserted. Once the single-use container has been closed by means of a cover, it must no longer be possible to reopen the container by removing the cover again. Therefore, according a preferred embodiment of the invention, the cover is received in the bottom end of the container body such that it does not protrude beyond the bottom end in a longitudinal direction of the container body. In this manner, the cover cannot be easily removed and the container cannot be openend unless the user breaks the connecting region to the head section. The container can be filled by placing it on a conveying surface, upside down. After filling, a cover is assembled by e.g. placing the cover above the container opening and pressing the cover onto the container body.

[0041] Preferably, the cover is provided with a recess which, in the assembled state, faces toward the outside

of the container. This recess is used to grip the cover in the process of placing the cover above the container opening and pushing the cover when closing the container.

[0042] As an alternative, the cover has a flat surface facing, in the assembled state, the outside of the container. The assembly of such cover can use a vacuum holder.

[0043] The container and the cover can be provided with interlocking form-fit elements like a circumferential groove on the container body and a corresponding shaped and arranged circumferential rib on the cover. The form-fit connection of the rib and the groove additionally provides a sealing contact between the container body and the cover. The position of the rib and the groove can be exchanged. A further advantage of the form-fit connection is the high resistance of the cover against being removed again from the container body. This increases the safety that the container cannot be opened and tampered with by unauthorized persons.

[0044] According to another preferred embodiment, the cover can be provided with a flexible skirt or a deformable lip around its circumference which further improves the sealing relationship between the cover and the container body because the skirt compensates because of its flexibility manufacturing tolerances as well as unevenness of either the cover or the container body.

[0045] Preferably, the cover is attached to the container body by welding, crimping or a force fit, more preferably by welding or crimping.

[0046] In a system of a tamper-evident single-use container and a cover, the cover is adapted to close the bottom end of the container. The production and the delivery of the basic structure of the container and the provision and delivery of the cover can be carried out separately because the cover will only be attached to the bottom end of the container once the unitary dose product will have been introduced into the interior of the container.

[0047] The cover might comprise gas treating agent. In an embodiment the cover comprises a chamber filled with a gas treating agent or holds a tablet, a canister, a packet filled with a gas treating agent, preferably a gas releasing agent or gas adsorbing agent. In another embodiment, the gas treating agent is entrained within the resin forming the cover. Thus, after the unitary dose product has been inserted into the container, the container will be closed by means of the cover. After this, the closed inner atmosphere of the container will be appropriately treated and maintained by means of the gas treating agent filled into the canister or chamber. in one embodiment, the gas treating agent is an oxygen scavenger so that, once the single-use container has been closed by means of the cover, the inner atmosphere of the container can be brought to and maintained at a reduced oxygen level. In another embodiment, the gas treating agent is a desiccant so that, once the single-use container has been closed by means of the cover, the inner atmosphere of the container can be brought to and maintained at a controlled humidity level. The gas treating agent can be any substance or mixture of substances which trap and/or release component from/into the container headspace.

[0048] Because of its convenient use, the tamper-evident feature and the possibility to tailor the inner atmosphere of the container, it has a specific use for storing a pharmaceutical solid substance, preferably loose pills, pellets, globules, granules, powder or capsules.

Brief Description of the Drawings

[0049] In the following, some preferred embodiments of the invention will be described with reference to the accompanying drawings, in which

Figs. 1 and 2	show a three dimensional view and a cross-sectional view of a first embodiment of the inventive container without a cover;
Figs. 3 and 4	show a three dimensional view and a cross-sectional view of the container according to Figs. 1 and 2 but with a cover 24;
Fig. 5	shows a cross-sectional view of an alternative container similar to that according to Fig. 4 but with a co-moulded head section;
Fig. 6	shows a cross-sectional view of a further embodiment of the inventive container with a different shape of the head section;
Figs. 7 and 8	show a three dimensional view and a cross-sectional view of a further embodiment of the inventive container without a cover;
Figs. 9 and 10	show a three dimensional view and a cross-sectional view of the container according to Figs. 7 and 8 but with a cover 24 heat crimped after filling of the unitary dose product (not shown)
Fig. 11	shows a side view of an embodiment of an inventive container;
Fig. 12	shows another side view of the container according to Fig. 11;
Fig. 13	shows a three dimensional view of the container as shown in Figs. 11 and 12; and

Figs. 14 and 15 show schematic half-cuts of the upper part of the single-use container with different orientations of the connecting region, whereby the illustrative example of Fig. 15 does not form part of the invention.

Description of Specific Embodiments

[0050] Throughout the description the same or similar elements will be denoted by the same reference numerals.

[0051] Fig. 1 shows a single-use container 10 in a three dimensional view. Fig. 2 is the corresponding cross-sectional view. The container 10 consists of a tubular container body 12 with a bottom end or open end 14 and a top end 16. A head section 18 is integrally formed with the container body 12 at the top end 16 of the container body. Between the top end 16 of the container body and the head section 18, there is a connecting region 20 having a wall thickness d_2 which is less than 50% of the thickness d_1 of the tubular container body. Specifically, the thickness d_2 of the material at the connecting region is between 0.1mm and 0.5mm and preferably between 0.1mm and 0.25mm.

[0052] Throughout the embodiments, the connecting region 20, which is the frangible region of the inventive container, is on the inner side of the wall of the container. In other words, it starts from the inner side 28 of the wall forming the container body 12 which faces the interior 30 of the container. This serves the purpose that, when the connecting region is broken, the broken section faces towards the inside of the container so that a user grasping the opened container does not contact possible sharp edges of the broken connecting region. Further, such broken container is suitable for direct oral supply of the medication contained therein.

[0053] The container body is provided close to its bottom end 14 with a shoulder 26 which, as can be seen in Figs. 3 and 4, serves to receive a cover 24 in order to close the container after the unitary dose product or products to be filled into the container have been introduced into the interior 30 of the container. In the specific embodiment as shown in Figs. 3 and 4, the cover 24 is fixed to the container body 12 by means of a press fit. As can be seen from Figs. 3 and 4, the cover 24 does not protrude beyond the bottom end 14 of the container body.

[0054] The head section 18 of the container has a spherical shape forming an annular protrusion 38 to promote a firm grip of the head section 18 by a user. At the lower part of the head section 18, there is a gorge or peripheral depression 22. Further, an angle A is formed between the wall sections of the container body and the head section adjacent to the connecting region 20. This angle is at least 10°.

[0055] According to the invention, the container body 12, the head section 18 as well as the connecting region 20 are made of plastic material, here in a single piece. The same preferably applies to the cover 24.

[0056] As an alternative or in addition to the provision of a plastic polymer composition including an active substance, the cover 24 can hold a gas treating agent. The gas treating agent could be embedded into the composition of the cover and/or container body 12. Further, the gas treating agent could be provided by means of a canister or by means of an active tablet which can for example be made of compressed desiccant or desiccant entrained polymer. Such canister 32 is schematically shown in Fig. 5. The cover 24 is provided with a ring-shaped holding structure 34 which, when the cover 24 is press fit in the container body 12, firmly holds the canister 32.

[0057] In alternative embodiments, the cover comprises a gas treating agent. In an embodiment the cover comprises a chamber filled with a gas treating agent or holding a tablet, a canister, a packet filled with a gas treating agent, preferably a gas releasing agent or gas adsorbing agent. In another embodiment, the gas treating agent is entrained within the resin forming the cover.

[0058] The container 10 as shown in Fig. 5 differs from that as shown in Fig. 4 by the additional provision of a head section 18 which has a further part 36 that can be bi-injected, overmolded or simply attached onto the head section 18 in order to provide another part of a different color or a different material. Different colors can e.g. be used to distinguish different products contained in the container, like different homeopathic products or different medication dosing or strength. A further advantage is that a container with a simple shape can be used before it is later on customized by the further part 36. Such a simple shape of the container can be naturally demoulded.

[0059] The container as shown in Fig. 6 has a head section 18 with a different shape. Unlike the head section as shown in the embodiments of Figs. 1 to 5, the head section according to Fig. 6 does not have a spherical shape. It is provided with protrusions 38 which enable a user to firmly grip the head section of the container before breaking the connecting region 20 in the process of opening the container.

[0060] Throughout the embodiments as shown in Figs. 1 to 6, the bottom end 14 of the container body 12 is provided with a shoulder 26. However, this is not necessarily the case. The container body 12 can also have the same thickness over its interior length without forming a shoulder close to the bottom end 14.

[0061] The embodiment of Figs. 7 to 10 corresponds to that as shown and explained above with reference to Figs. 1 to 4. The only difference, however, is the way in which the cover 24 is fixed to the container body 12. In the embodiment as shown in Figs. 7 to 10, the cover 24 is secured to the bottom end 14 of the container body by "crimping". The term "crimping" is supposed to describe that the cover 24 is inserted into the lower part of the container body and resting against the shoulder 26. After this, it is secured to the container body 12 by applying heat and pressure on the bottom end 14 of the container body 12 so that the bottom end 14 is bent towards the

interior of the container body 12 and generates a form fit which prevents the remove of the cover 24 from the container 10. In order to enable the bending of the section 40 of the container body close to its bottom end 14, it is preferably made longer in the longitudinal direction of the container as compared to the corresponding lower part 40 as shown e.g. in Fig. 2 such that it can be conveniently bent over a sufficient distance so as to firmly hold the cover 24 resting against the shoulder 26 of the container body.

[0062] Throughout the embodiments as shown in Figs. 1 to 10, the container body, once it has been filled with the unitary dose product or products, is closed using a cover 24. Besides the specific embodiments as shown, in which the cover is either press fit into the container body or affixed to the container body by crimping, it could also be fixed to the container body by welding or glueing.

[0063] The embodiment as shown in Figs. 11 to 13 differs from that according to the preceding embodiments in that the container is not closed by means of a cover but by welding the lower end of the container body. Further, the head section 18 has additional depressions 48 to promote a firm grip of the head section by a user. As can be seen in Figs. 11 to 13, a section 42 starting from the bottom end 14 of the container is welded onto itself in order to close the container. In such a way, no additional cover is necessary. For sealing the bottom section 42, the container body should have a certain flexibility. In order to achieve this, the wall thickness d1 of the container body at its bottom end can be made smaller than the wall thickness at the tubular top end of the container. Furthermore, or alternatively, the container body at the tubular top end can be made with a material that is different from the remaining part of the tubular container body, the last being made of a more flexible material. Such a container can be molded in one single shot or in two shots depending on the overall size of the container. For example, the tubular part of the container body can be made by extrusion (for example in LDPE with a constant wall thickness d1a) and then be provided by overmolding with an integrally molded top end and head section (for example in another material such as polypropylene or HDPE and with a wall thickness at the top end d1b which is larger than d1a). It is also possible to manufacture the top end and head section, and to combine it with the extruded tubular part of the container body by welding and especially heat fusing or ultrasonic welding.

[0064] The embodiments according to Figs. 14 and 15 serve to illustrate general principles of the invention and are not limited to any geometries shown in addition to those as described below. As can be seen from Figs. 14 and 15, the connecting region 20 has a distinct length l which is at most 0.3 mm and according to the illustrative example of Fig. 15, can be oriented in a longitudinal direction parallel to the rotational axis O or, according to the embodiment of Fig. 14, the connecting region can be oriented in a radial direction.

[0065] The embodiment according to Fig. 14 is advantageous over that according to Fig. 15 in that a broken connecting region which might have sharp edges seems to be not problematic as long as the connecting region extends towards the interior of the container body. In such a case, the opened container can be brought to the mouth of the user for direct oral supply of medication or single dose product.

[0066] In the embodiment according to Fig. 14, the connecting region 20 is in a radial direction and bridges a distance between the lower end of the head section 18 and the upper end of the tubular container body 12. The maximum diameter of the head section d_{head} is smaller than the outer diameter d_{out} of the container body 12 but smaller than the inner diameter d_{in} of the container body 12. Once broken, the head section cannot be used to reclose the container body.

[0067] When tilting the head section 18 relative to the container body 12, the force F applied by the user will act at the apex position of the head section with the greatest diameter of the head section d_{head}, which forms the protrusion 38 or in the illustrative example according to Fig. 15, will act in the middle of the longitudinal extension of the protrusion 38, i.e. the region with the greatest diameter of the head section. In both cases, there is a considerable longitudinal distance between force F, which is the center of the force applied, and the connecting region 20 which generates a sufficient bending moment on the frangible connecting region. This momentum reduces the effort to open the single-use container. The tamper-evident single-use container according to the invention cannot be closed in a way such that a user will immediately recognize if the container has been tampered with.

Claims

1. Tamper-evident single-use container (10) for holding unitary dose products, especially solid pharmaceutical products, comprising:

- a container body (12) made of a plastic material with a bottom end (14) and a tubular top end (16); and
- a head section (18) closing the tubular top end (16); wherein the head section (18) is integrally connected to the tubular top end (16) of the container body (12) at a connecting region (20);

wherein

- the thickness of the plastic material at the connecting region (20) is reduced by at least 50% as compared to the wall thickness of the container body (12) at the tubular top end (16);
- the head section (18) is provided with protrusions (38) and/or depressions (48);
- the maximum outer dimensions of the head

section (18) are larger than an inner diameter (d_{in}) of the container body (12);
- **characterized in that** the connecting region (20) is on an inner side (28) of the wall of the container body (12) and has a length (l) in a radial direction.

2. Tamper-evident single-use container according to claim 1, **characterized in that** the container body (12) has a cylindrical shape with round, oval or polygonal base.

3. Tamper-evident single-use container according to claim 1 or claim 2, **characterized in that** the head section (18) has a round outer shape, preferably a generally spherical outer shape.

4. Tamper-evident single-use container according to any of the preceding claims, further comprising a gorge (22) on the head section (18).

5. Tamper-evident single-use container according to any of the preceding claims, wherein an angle (A) between the wall section of the container body (12) and the wall section of the head section (18) at the connecting region (20) is at least 10°.

6. Tamper-evident single-use container according to any of the preceding claims, wherein the connecting region (20) bridges a distance between the container body (12) and the head section (18), the length l of the connecting region in the direction of the distance being defined by $0 < l \leq 1$ mm, preferably $0 < l \leq 0.5$ mm.

7. Tamper-evident single-use container according to any of the preceding claims, **characterized in that** the maximum outer dimensions of the head section (18) are such that the head section (18) does not protrude beyond the outer extension of the container body (12).

8. Tamper-evident single-use container according to any of the preceding claims, wherein the container body (12) has an inner diameter d_i, and an outer diameter d_{out}, and wherein a maximum outer diameter d_{head} of the head section (18) is selected to satisfy the equation

$$d_{in} < d_{head} < d_{out}.$$

9. Tamper-evident single-use container according to any of the preceding claims, **characterized in that** the thickness of the plastic material at the connecting region (20) is less than 0.5 mm, preferably is between 0.1 mm and 0.5 mm and more preferably between 0.1 mm and 0.3 mm.

10. Tamper-evident single-use container according to any of the preceding claims, **characterized in that** the container body (12) is provided with an interior annular shoulder (26) close to the bottom end (14).

11. Tamper-evident single-use container according to any of the claims 1 to 10, **characterized in that** the bottom end (14) of the container (10) is closed by welding.

12. Tamper-evident single-use container according to any of the claims 1 to 10, further comprising a cover (24) closing the bottom end (14) of the container body (12).

13. Tamper-evident single-use container according to claim 12, **characterized in that** the cover (24) does not protrude beyond the bottom end (14) in a longitudinal direction of the container body (12).

14. Tamper-evident single-use container according to claim 12 or claim 13, wherein the cover (24) is attached to the container body (12) by welding, crimping or a force fit.

15. Use of the tamper-evident single-use container according to any of the claims 1 to 14, for storing a pharmaceutical or nutraceutical substance, preferably loose pills, pellets, globules, granules, powder or capsules.

Patentansprüche

1. Manipulationssicherer Einwegbehälter (10) zum Halten von Einzeldosisprodukten, insbesondere festen pharmazeutischen Produkten, umfassend:

- einen Behälterkörper (12), hergestellt aus einem Kunststoffmaterial mit einem unteren Ende (14) und einem rohrförmigen oberen Ende (16); und
- einen Kopfabschnitt (18), der das röhrenförmige obere Ende (16) verschließt; wobei der Kopfabschnitt (18) an einem Verbindungsbereich (20) integral mit dem rohrförmigen oberen Ende (16) des Behälterkörpers (12) verbunden ist;

wobei

- die Dicke des Kunststoffmaterials am Verbindungsbereich (20) im Vergleich zur Wanddicke des Behälterkörpers (12) am rohrförmigen oberen Ende (16) um mindestens 50 % reduziert ist;
- der Kopfabschnitt (18) mit Vorsprüngen (38) und/oder Vertiefungen (48) versehen ist;
- die maximalen Außenabmessungen des Kopfabschnitts (18) größer sind als ein Innendurch-

messer (d_{in}) des Behälterkörpers (12);
- **dadurch gekennzeichnet, dass** der Verbindungsbereich (20) auf einer Innenseite (28) der Wand des Behälterkörpers (12) liegt und in einer radialen Richtung eine Länge (l) aufweist.

2. Manipulationssicherer Einwegbehälter nach Anspruch 1, **dadurch gekennzeichnet, dass** der Behälterkörper (12) eine zylindrische Form mit runder, ovaler oder polygonaler Grundfläche aufweist.

3. Manipulationssicherer Einwegbehälter nach Anspruch 1 oder Anspruch 2, **dadurch gekennzeichnet, dass** der Kopfabschnitt (18) eine runde äußere Form, vorzugsweise eine im Allgemeinen kugelförmige äußere Form aufweist.

4. Manipulationssicherer Einwegbehälter nach einem der vorstehenden Ansprüche, weiter umfassend eine Kehle (22) am Kopfabschnitt (18).

5. Manipulationssicherer Einwegbehälter nach einem der vorstehenden Ansprüche, wobei ein Winkel (A) zwischen dem Wandabschnitt des Behälterkörpers (12) und dem Wandabschnitt des Kopfabschnitts (18) am Verbindungsbereich (20) mindestens 10° beträgt.

6. Manipulationssicherer Einwegbehälter nach einem der vorstehenden Ansprüche, wobei der Verbindungsbereich (20) einen Abstand zwischen dem Behälterkörper (12) und dem Kopfabschnitt (18) überbrückt, wobei die Länge l des Verbindungsbereichs in der Richtung des Abstands definiert ist durch $0 < l \leq 1$ mm, vorzugsweise $0 < l \leq 0{,}5$ mm.

7. Manipulationssicherer Einwegbehälter nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die maximalen Außenabmessungen des Kopfabschnitts (18) derart sind, dass der Kopfabschnitt (18) nicht über die äußere Ausdehnung des Behälterkörpers (12) hinausragt.

8. Manipulationssicherer Einwegbehälter nach einem der vorstehenden Ansprüche, wobei der Behälterkörper (12) einen Innendurchmesser d_{in} und einen Außendurchmesser d_{aus} aufweist, und wobei ein maximaler Außendurchmesser d_{Kopf} des Kopfabschnitts (18) so gewählt ist, dass die Gleichung

$$d_{in} < d_{Kopf} < d_{aus}$$

erfüllt ist.

9. Manipulationssicherer Einwegbehälter nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die Dicke des Kunststoffmaterials am Verbindungsbereich (20) weniger als 0,5 mm beträgt, vorzugsweise zwischen 0,1 mm und 0,5 mm und bevorzugter zwischen 0,1 mm und 0,3 mm liegt.

10. Manipulationssicherer Einwegbehälter nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** der Behälterkörper (12) nahe dem unteren Ende (14) mit einer inneren ringförmigen Schulter (26) versehen ist.

11. Manipulationssicherer Einwegbehälter nach einem der Ansprüche 1 bis 10, **dadurch gekennzeichnet, dass** das untere Ende (14) des Behälters (10) durch Schweißen verschlossen wird.

12. Manipulationssicherer Einwegbehälter nach einem der Ansprüche 1 bis 10, weiter umfassend eine Abdeckung (24), die das untere Ende (14) des Behälterkörpers (12) verschließt.

13. Manipulationssicherer Einwegbehälter nach Anspruch 12, **dadurch gekennzeichnet, dass** die Abdeckung (24) in einer Längsrichtung des Behälterkörpers (12) nicht über das untere Ende (14) hinausragt.

14. Manipulationssicherer Einwegbehälter nach Anspruch 12 oder Anspruch 13, wobei die Abdeckung (24) durch Schweißen, Crimpen oder Presspassung an dem Behälterkörper (12) angebracht ist.

15. Verwendung des manipulationssicheren Einwegbehälters nach einem der Ansprüche 1 bis 14 zum Aufbewahren einer pharmazeutischen oder nutrazeutischen Substanz, vorzugsweise von losen Tabletten, Pellets, Globuli, Granulaten, Pulver oder Kapseln.

Revendications

1. Récipient (10) inviolable à usage unique pour contenir des produits en dose unitaire, en particulier des produits pharmaceutiques solides, comprenant :

- un corps (12) de récipient en matière plastique présentant une extrémité inférieure (14) et une extrémité supérieure tubulaire (16) ; et
- une section de tête (18) fermant l'extrémité supérieure tubulaire (16) ; dans lequel la section de tête (18) est reliée d'un seul tenant à l'extrémité supérieure tubulaire (16) du corps (12) de récipient au niveau d'une région de liaison (20) ;

dans lequel

- l'épaisseur de la matière plastique au niveau de la région de liaison (20) est réduite d'au moins 50 % par rapport à l'épaisseur de paroi du corps

(12) de récipient à l'extrémité supérieure tubulaire (16) ;
- la section de tête (18) est pourvue de saillies (38) et/ou de dépressions (48) ;
- les dimensions externes maximales de la section de tête (18) sont supérieures à un diamètre interne (d_{in}) du corps (12) de récipient ;
- **caractérisé en ce que** la région de liaison (20) est sur un côté interne (28) de la paroi du corps (12) de récipient et présente une longueur (l) dans une direction radiale.

2. Récipient inviolable à usage unique selon la revendication 1, **caractérisé en ce que** le corps (12) de récipient présente une forme cylindrique à base ronde, ovale ou polygonale.

3. Récipient inviolable à usage unique selon la revendication 1 ou la revendication 2, **caractérisé en ce que** la section de tête (18) présente une forme externe ronde, de préférence une forme externe généralement sphérique.

4. Récipient inviolable à usage unique selon l'une quelconque des revendications précédentes, comprenant en outre une gorge (22) sur la section de tête (18).

5. Récipient inviolable à usage unique selon l'une quelconque des revendications précédentes, dans lequel l'angle (A) entre la section de paroi du corps (12) de récipient et la section de paroi de la section de tête (18) au niveau de la région de liaison (20) est d'au moins 10°.

6. Récipient inviolable à usage unique selon l'une quelconque des revendications précédentes, dans lequel la région de liaison (20) couvre une distance entre le corps (12) de récipient et la section de tête (18), la longueur l de la région de liaison dans la direction de la distance étant définie par $0 < l \leq 1$ mm, de préférence $0 < l \leq 0{,}5$ mm.

7. Récipient inviolable à usage unique selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les dimensions externes maximales de la section de tête (18) sont telles que la section de tête (18) ne fait pas saillie au-delà de l'extension externe du corps (12) de récipient.

8. Récipient inviolable à usage unique selon l'une quelconque des revendications précédentes, dans lequel le corps (12) de récipient présente un diamètre interne d_{in} et un diamètre externe d_{out}, et dans lequel un diamètre externe maximal d_{head} de la section de tête (18) est sélectionné pour satisfaire à l'équation

$$d_{in} < d_{head} < d_{out}.$$

9. Récipient inviolable à usage unique selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'épaisseur de la matière plastique au niveau de la région de liaison (20) est inférieure à 0,5 mm, de préférence est entre 0,1 mm et 0,5 mm et de manière davantage préférée entre 0,1 mm et 0,3 mm.

10. Récipient inviolable à usage unique selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le corps (12) de récipient est pourvu d'un épaulement annulaire interne (26) proche de l'extrémité inférieure (14).

11. Récipient inviolable à usage unique selon l'une quelconque des revendications 1 à 10, **caractérisé en ce que** l'extrémité inférieure (14) du récipient (10) est fermée par soudage.

12. Récipient inviolable à usage unique selon l'une quelconque des revendications 1 à 10, comprenant en outre un couvercle (24) fermant l'extrémité inférieure (14) du corps (12) de récipient.

13. Récipient inviolable à usage unique selon la revendication 12, **caractérisé en ce que** le couvercle (24) ne fait pas saillie au-delà de l'extrémité inférieure (14) dans une direction longitudinale du corps (12) de récipient.

14. Récipient inviolable à usage unique selon la revendication 12 ou la revendication 13, dans lequel le couvercle (24) est fixé au corps (12) de récipient par soudage, sertissage ou ajustement à force.

15. Utilisation du récipient inviolable à usage unique selon l'une quelconque des revendications 1 à 14, pour stocker une substance pharmaceutique ou nutraceutique, de préférence des pilules, pastilles, globules, granulés, poudres ou capsules en vrac.

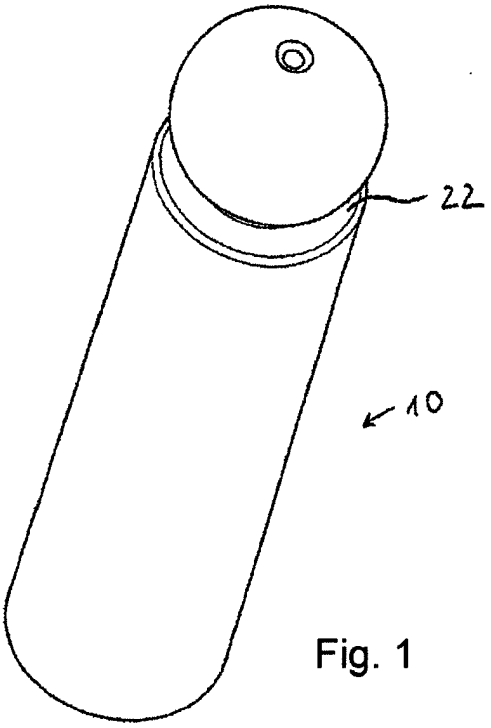


Fig. 1

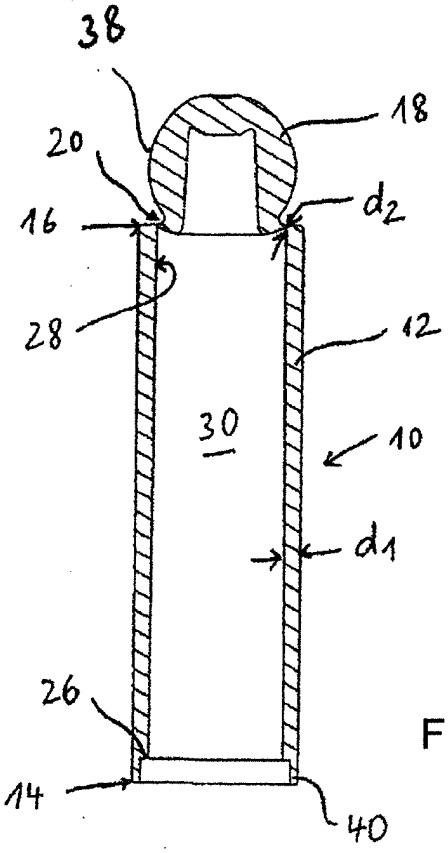


Fig. 2

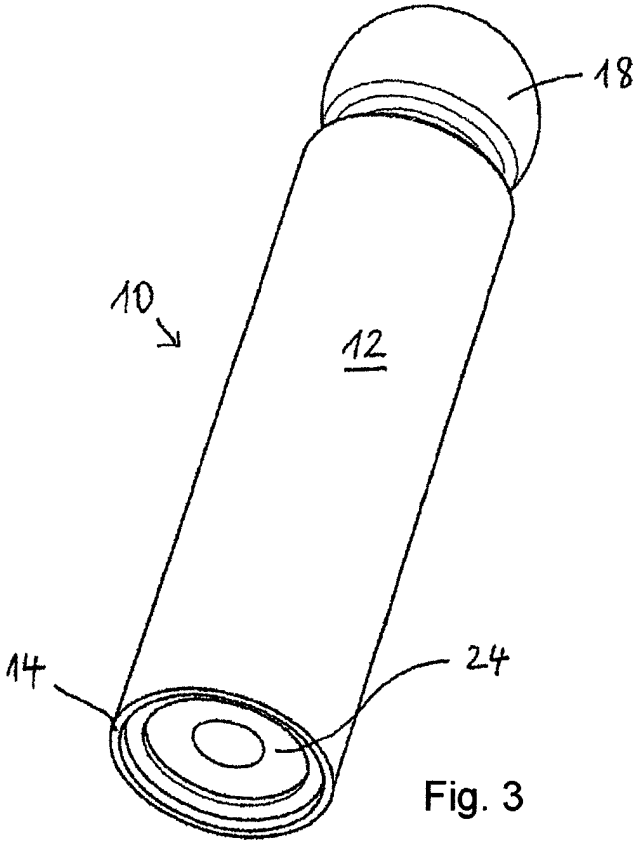


Fig. 3

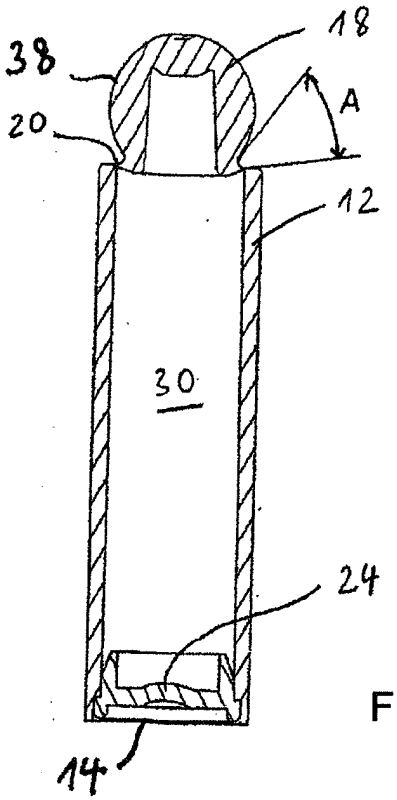


Fig. 4

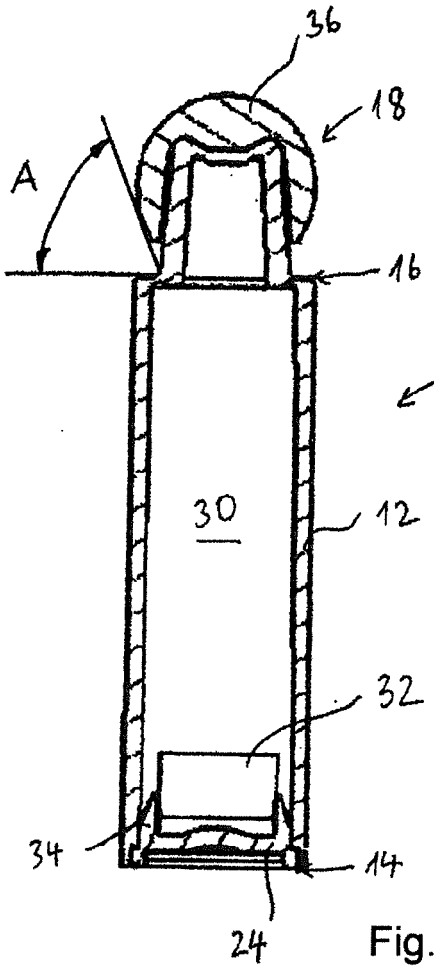


Fig. 5

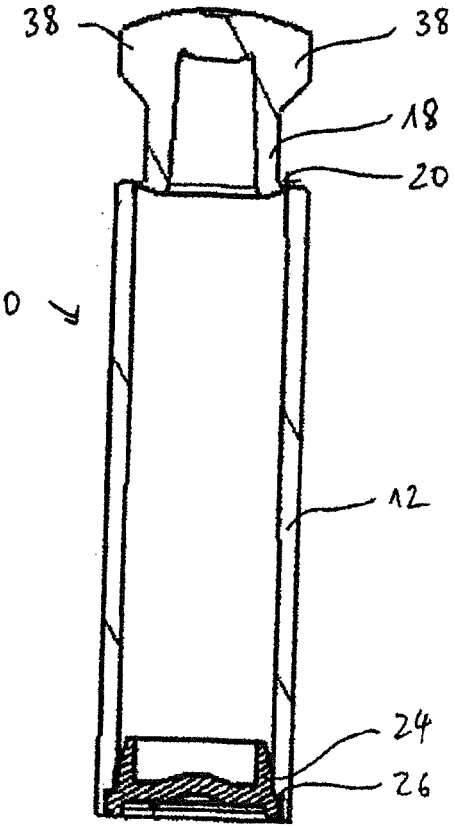


Fig. 6

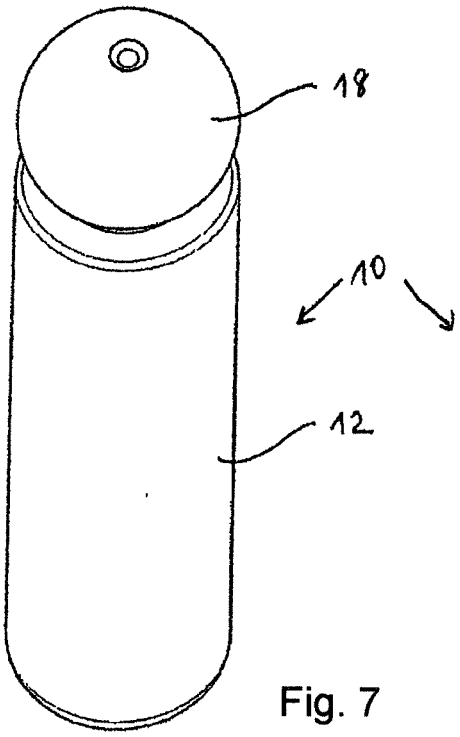


Fig. 7

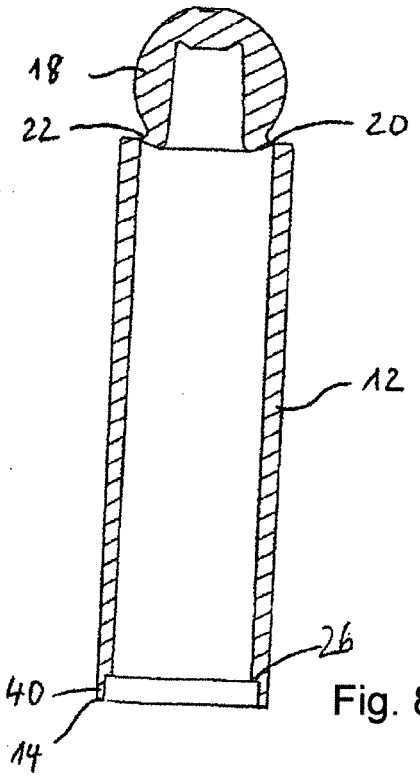


Fig. 8

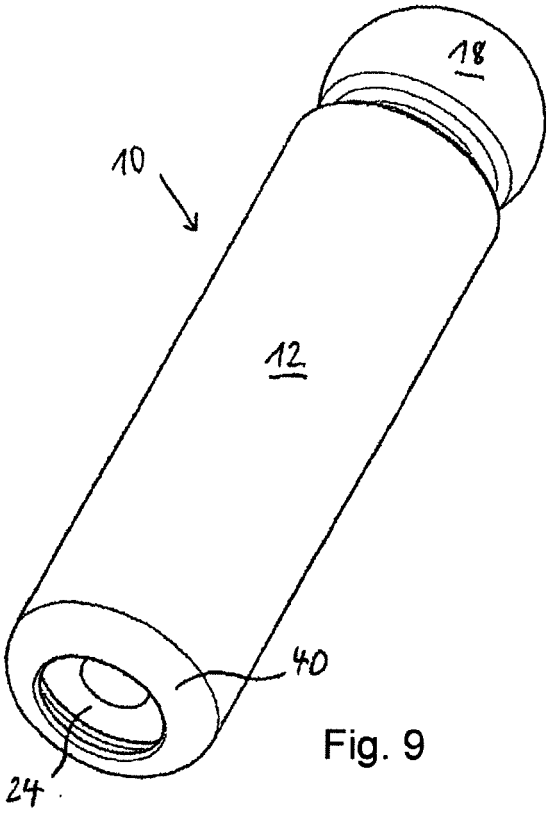


Fig. 9

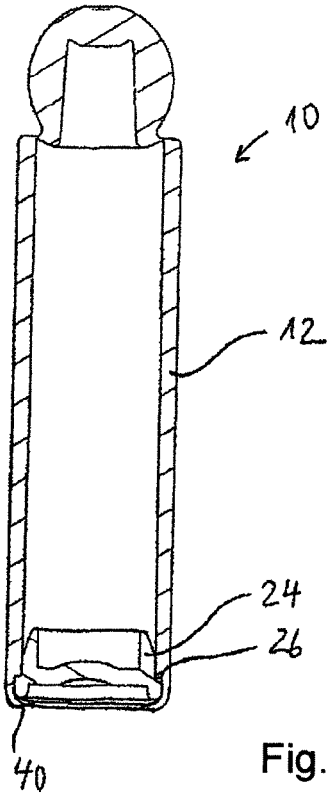


Fig. 10

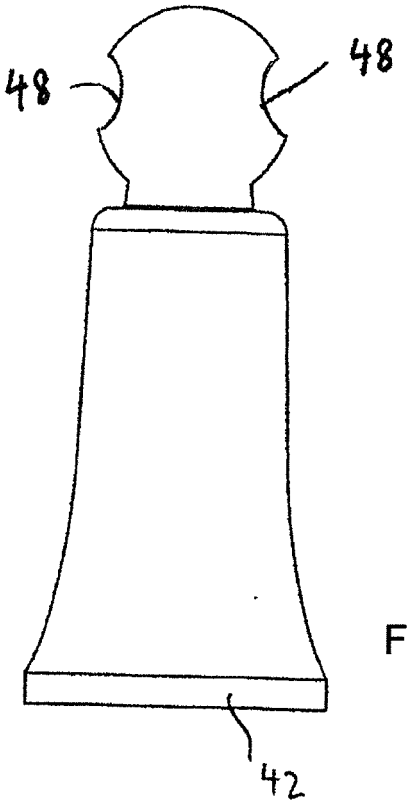


Fig. 11

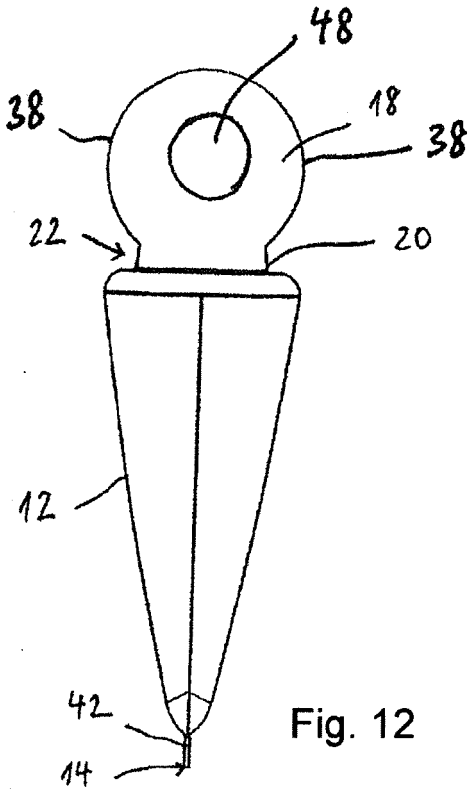


Fig. 12

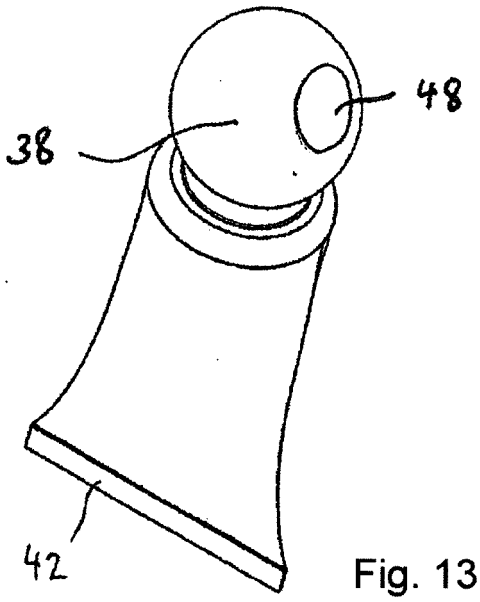


Fig. 13

Fig. 15

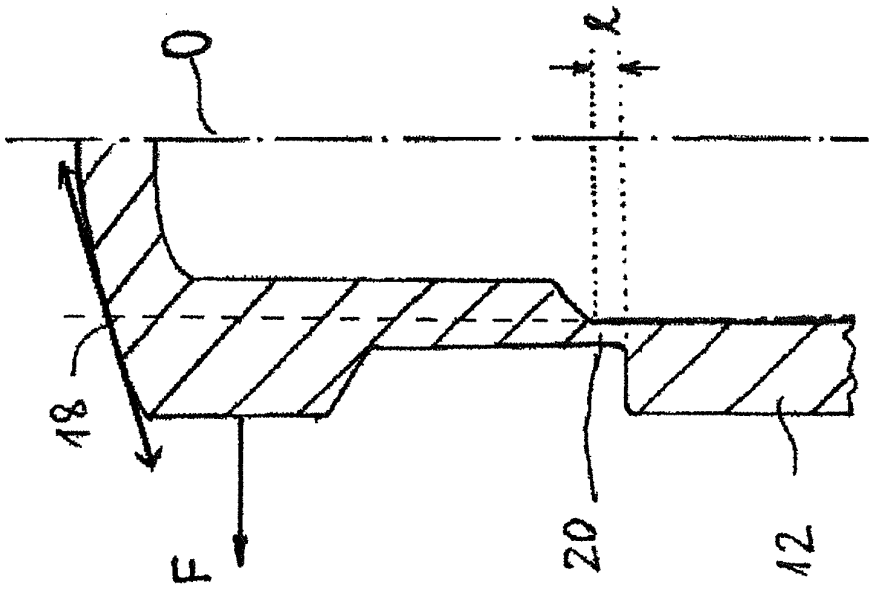
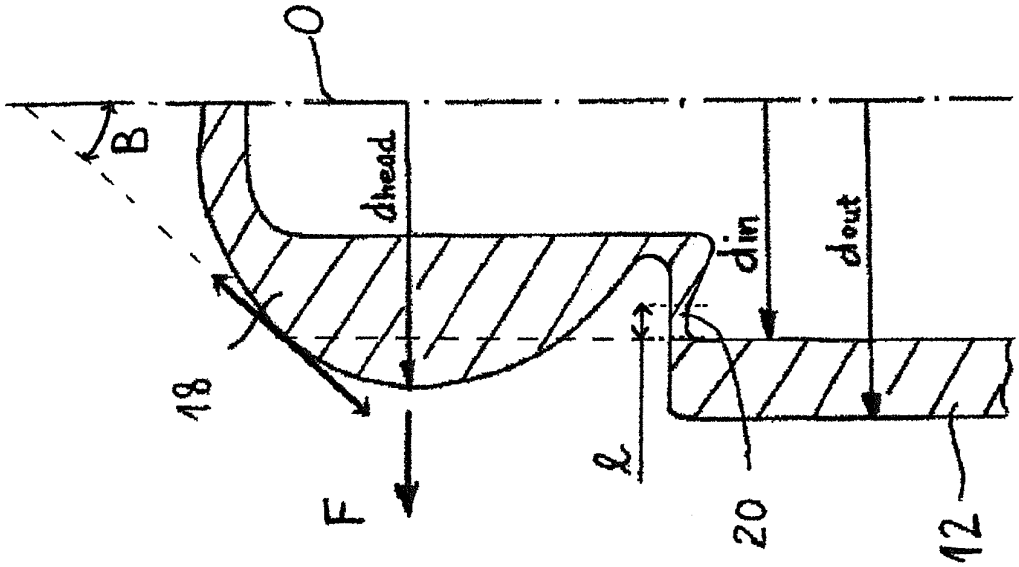


Fig. 14



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