(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 December 2003 (18.12.2003)

PCT

(10) International Publication Number
WO 03/103563 A2

(51) International Patent Classification[7]: A61J

(21) International Application Number: PCT/IN03/00215

(22) International Filing Date: 6 June 2003 (06.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
509/MUM/2002 7 June 2002 (07.06.2002) IN

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i)) for all designations*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

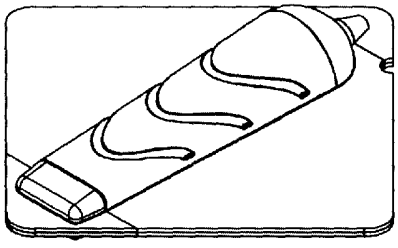
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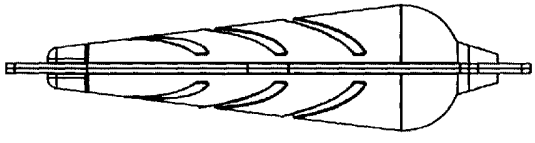
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(54) Title: POWDER INHALER





(57) Abstract: The present invention provides a powder inhaler for administration of a unit dose of a medicament, said powder inhaler comprising:(A) Walls enclosing at least one chamber comprising a medicament containing recess, at one end and a channel extending from the medicament containing recess to the air outlet hole; (B) Air inlet hole(s) located near the medicament containing recess; (C) An air outlet hole; and (D) Means for sealing said air inlet and outlet holes, wherein the location of the air inlet hole(s) with respect to the medicament containing recess is such that upon inspiration by the patient, the air stream directly impacts the powder bed, entrains the particles and carries them to the air outlet for inspiration by the patient.

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *without international search report and to be republished upon receipt of that report*

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POWDER INHALER

FIELD OF THE INVENTION

This invention relates to a powder inhaler.

BACKGROUND OF THE INVENTION

This invention relates to a powder inhaler. Particularly, this invention relates to an inhaler by means of which a solid medicament in particulate form can be introduced into the inhaled air of the user of the inhaler. Still, particularly the present invention is in the field of devices for dispensing medicaments in powder form without the use of propellants, with the medicament dose being inhaled by mouth or nose. Typically, the powder medicament is usually in the form of extremely fine particles, preferably in the size range of from 1 to 10 microns.

The site of administration of the powder medicament is the bronchial tubes and their ramifications in the lungs of the patient being treated including particularly, the bronchi and bronchioles, which are the primary sites of administration or also the nasal passage or nasal mucosa. Typically, when a patient is suffering from asthma or acute or chronic bronchitis, it is essential that the powder dose of medicament reaches and is applied uniformly to as much of the surface of the bronchi and other parts of the lung as possible.

Many known inhalers require the use of propellants to dispense metered doses of a powder medicament with the assistance of a propellant gas. Predominantly, the propellant of choice is Freon, one of various nonflammable fluorocarbons. However, use of this particular propellant has been the object of recently passed environmental laws, which severely restrict its use or even ban it outright. Furthermore, fluorocarbons may actually aggravate the condition of patients suffering from asthma and acute or chronic bronchitis, thus creating a further reason to avoid this nearly universal propellant. While attempts have been made to substitute other propellant gases for the fluorocarbons, these attempts have experienced problems and have not met with uniform success. Thus, there remains a need for efficient powder inhaler devices, which are either breath actuated or powered by a source other than fluorocarbons.

Dry powder inhalers are known in the prior art. Many of the known inhalers, particularly of the cartridge type presently on the market are relatively large in size, are useful for delivery of multiple doses and, as a consequence of their expense, are intended for repeated use.

Dry powder inhalers, which have been used in the past, dispense unit doses of medication from pre-filled capsules. However, in order for such devices to function properly, the capsule must be correctly positioned in the device, which, when actuated, either punctures or pulls the capsules open. Such devices are prone to incorrect dosing, particularly by children, the elderly, and patients with impaired motor function. Moreover, pieces of the gelatin capsule shell may be dispensed with the medication.

Devices utilizing a disc with multiple cavities are also known, each containing a unit dose of medicament covered by aluminum foil. The medication is dispensed by puncturing the aluminum foil covering the cavity. However, such devices have the disadvantage of a potential risk that small pieces of the aluminum foil might be inhaled.

U.S. patent No. 4,265,236 discloses a tubular inhaler comprising a flexible tube, the ends of which normally are sealingly inserted into each other. The seal of the inhaler disclosed may not be moisture-proof. In this inhaler, the air pathway is linear and unidirectional, and there is no medicament recess where the medicament would be preferably located.

PCT Application No. 89/01348 (Teijin Limited) discloses a tubular inhaler which is sealed in both ends by means of twist-off caps. This device suffers from the same disadvantages as that for the inhaler disclosed in the '236 patent. The inhalers do not have a separate medicament recess and an air channel suitably designed for controlling air flow and particle entrainment.

European Patent No. 0404454 (Fisons) discloses a disposable inhaler comprising a chamber for a medicament powder, said chamber being provided with an air inlet and multiple air outlet holes. The air outlet holes and the air inlet are sealed by tape. The medicament powder is disposed loosely in the chamber. The inhaler does not have a separate medicament recess near the air inlet source and the incoming air first flows through a channel and then impacts the powder. Following aerosolization there is no air channel suitably designed for controlling or moderating air flow and particle entrainment.

U.S. Patent No. 5,533,505 (Astra Aktiebolag) discloses a disposable breath-actuated inhaler comprising a housing forming an air flow path open at both ends, wherein one end forms an air inlet and one end forms an air outlet. The housing has projections between the air inlet and the medicament compartment and a constriction adjacent the medicament compartment in order to impart turbulence to the inhaled air. In the disclosed device, the inhaled air does not impact the medicament powder directly but will impinge on the projections in the air path before entraining the medicament. The device has an air flow pathway, which is unlike the present invention's inhaler where the air stream directly impacts the medicament powder bed. In embodiments of the patent, the housing of the inhaler has a compartment for storing the medicament, which is sealed from the airflow path by a tape covering the compartment outlet. This is unlike the present invention's inhaler wherein only the airflow inlet is sealed off from the external environment by either a peel-off piece of lidding material or by sealing of the lower wall of the inhaler with the upper wall.

U.S. Patent No. 5,660,169 (Astra Aktiebolag) discloses a disposable breath-actuated inhaler comprising a housing forming an air flow path open at both ends, wherein one end forms an air inlet and one end forms an air outlet. The housing further comprises a compartment for storing medicament, wherein the compartment is sealed from the airflow path by a tape covering the compartment outlet, wherein the inner end of the tape is attached to the lower part of the housing between the air inlet and the compartment. The tape is bent backward away from the air outlet so as to extend through the air inlet. This is unlike the present invention's inhaler wherein only the airflow inlet is sealed off from the external environment by either a peel-off piece of lidding material or by sealing of the lower wall of the inhaler with the upper wall. The inhaler of the patent also has the same structural features as described in U.S. Patent No. 5,533,505, including the projections in the air path and constriction adjacent the medicament compartment.

OBJECT OF THE INVENTION

It is an object of the present invention to provide a powder inhaler of a design which is such that, it can be made much smaller than known inhalers and which is sufficiently simple and inexpensive, such that, if desired, it can be used only once for a single dose application and then disposed of, and also to provide a device by means of which, a uniform and reproducible dose may be dispensed.

It is further another object of this invention is to provide a powder inhaler device, which is simple and economical to manufacture, capable of isolating the powder medicament dose in a tamper-proof and moisture-proof environment.

SUMMARY OF THE INVENTION

The present invention provides a powder inhaler for administration of a unit dose of a medicament, said powder inhaler comprising:

(A) Walls enclosing at least one chamber comprising a medicament containing recess, at one end and a channel extending from the medicament containing recess to the air outlet hole;

(B) Air inlet hole(s) located near the medicament containing recess;

(C) An air outlet hole; and

(D) Means for sealing said air inlet and outlet holes,

wherein the location of the air inlet hole(s) with respect to the medicament containing recess is such that upon inspiration by the patient, the air stream directly impacts the powder bed, entrains the particles and carries them to the air outlet for inspiration by the patient.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

The present invention discloses a inhaler which comprises powdered medicament, said inhaler being breath actuated or driven by a power source other than fluorocarbon propellants and which permits a patient to inhale through the mouth or nose, a medication in powder form for administration to the bronchia and lungs. The inhaler of the invention is made up of walls enclosing at least one chamber comprising a medicament containing recess at one end and a channel extending from the medicament containing recess to the air outlet hole. The inhaler has a lower wall, an upper wall and side walls. These may be formed by the sealing of the upper and lower walls or may be parts of a single one-piece body formed by moulding methods known to those skilled in the art. The lower wall forms the lower wall of the medicament containing recess and the channel leading to the air outlet hole. In preferred embodiments, the upper wall has a shape and size so as to be suitable for holding the device conveniently. For example, in a

preferred embodiment, the body of the inhaler acquires mainly a flat configuration because the larger element in the inhaler is the upper wall of the body which is flat and of suitable size for holding the device conveniently. In an alternative embodiment, the upper wall of the inhaler may be curved.

In one embodiment of the present invention, the medicament containing recess and the channel leading to the air outlet hole, form a single aerodynamically streamlined chamber. The chamber has a medicament containing deep end and a shallow end extending to the air outlet hole. In another embodiment, the inhaler has two chambers wherein the first chamber is the medicament containing recess and the second chamber is the channel leading into the air outlet hole. Typically in this embodiment, there is an obstruction or a constriction in the region between the two chambers. The obstruction may be in the form of a baffle between the two chambers placed at suitable angle, for example the medicament recess itself may be cup shaped and the walls of the cup may form an obstruction. The baffle-type obstruction only partially segregates the two chambers and allows open space between them. Alternatively, the obstruction may extend wall to wall to fully segregate the two chambers, in this case, the obstruction is in the form of a sieve and with breath actuation and/or air from the power source the aerosolized particles pass through this mesh-like or sieve-like obstruction.

In one embodiment of the present invention, typically, the lower wall of the body is formed into a medicament containing recess and a channel from a single sheet element and the upper wall is formed from a second sheet element. Alternatively, the body with the air inlet holes may be a single one-piece body formed by suitable moulding methods known to those skilled in the art. Air inlet holes may be provide as single or multiple air inlet holes in the upper wall and are suitably located and designed to lead the incoming air into the medicament containing recess to directly impact the medicament powder bed and aerosolize the powder medicament. In embodiments, where the air inlet hole is located on the upper wall of the body, it may be sealed from the environment by a peel-off piece of lidding material, typically a metal foil. Alternatively the air inlet hole(s) may be designed so that they can be closed or sealed by a cap. The air inlet hole(s) which is sealed by a cap may be further designed such that it/they can be connected to a power source other than a fluorocarbon, for example it may be connected to a can containing compressed air and having an actuation device. More simply it can be connected to a bulb which can be compressed by the patient to blow air for aerosolization of the powder medicament in coordination with the inhalation by the patient. The upper wall of the body is preferably designed in shape and size to be suitable for

convenience in holding by the patient. The medicament containing recess and channel lead into an air outlet hole, over which the mouth of the patient is placed to receive the powder medication by inhalation. The body of the inhaler at this end serves as the mouthpiece itself. The mouthpiece may be designed so that it extends and can be placed inside the mouth of the patient with the mouthpiece opening placed in the rear of the mouth. This avoids any waste due to particle deposition in the buccal cavity.

Advantageously, the walls of the body comprising the medicament containing recess and the channel have scored formation therein adapted and arranged to modify the air passageway to cause changes in the direction of the airflow and the flow of the particles through the passageway. The medicament containing recess and the channel may have scored formation on the lower walls, the upper walls or on both the upper and lower walls or on all the walls. Where the medicament containing recess and the channel form a single aerodynamically streamlined chamber, the chamber is so designed that air from air inlet leaves the curvilinear chamber in a centripetal direction under swirling motion. Further, in preferred embodiments the airflow at the upper part of the recess or air pathway is laminar whereas in the lower part, regions of turbulence are formed due to the scored formations.

In a preferred embodiment of the invention, the air inlet holes communicate with the curvilinear recess tangentially so that air enters the recess perpendicularly to the upper wall and will of its own accord, enter the curvilinear chamber tangentially and impact the medicament powder bed directly. The significance of tangential entry of air into the curvilinear chamber is that this helps to ensure laminar air flow within the curvilinear medicament recess, which is advantageous in terms of providing easy aersolization and circulation of the particulate substance in a manner to give rise to turbulence of the particles of the medicament. In particular embodiments of the present invention, there is means for improving the incoming air flow so as to directly impact the medicament powder bed. For example, the air inlet hole may have a short tubular extension into the medicament containing recess, angled and designed to direct the stream of incoming air directly on to the medicament powder bed. The diameter of the short tubular extension may be uniform or may be tapered. The means for directing the air directly on to the powder bed may also include suitably designed airflow deflectors.

Typically, the air outlet hole leading to the recess is surrounded by a raised ridge, over which the mouth of the patient is placed when the powder medicament is dispensed by inhalation. The air

outlet hole is typically located at suitable locations at the end of the channel. In an embodiment, the air outlet hole may be shaped or configured in order to make the inhaler convenient for use in nasal inhalation. The air outlet holes are typically sealed by sealing of the upper wall with the lower wall. Alternatively, the air outlet hole may be designed so that they can be closed or sealed by a cap. The cap may be a tight fit, screw on or twist off cap.

Typically the air inlet hole(s) are smaller than the air outlet hole to prevent powder medicament particles from escaping. The air inlet hole(s) are so disposed with respect to the air outlet hole that the powder medicament will not readily fall out of the recess, but is so disposed that ingress of air will aerosolize said powder medicament bed directly during inhalation and the aerosolized medicament powder will be agitated under turbulence and will be drawn into the breath of the user. A moisture-proof peel-off piece of lidding material may be provided for blocking the air inlet hole(s) in their inoperative configuration, which can be manually peeled off so as to expose the air inlet holes for use. Alternatively, the air inlet hole(s) may be designed so that they can be closed or sealed by cap(s). The cap may be a tight fit, screw on or twist off cap.

In an embodiment of the invention, the channel of the inhaler may have additional air inlet holes. The additional air inlet holes may be on the upper wall or the side walls of the channel. The additional air inlet holes may be sealed by a moisture proof peel-off piece of lidding material or alternatively they may be designed so that they can be closed or sealed by a cap. These additional air inlet holes may also be designed in the form of a flow indicator that produces a whistling sound on inhalation by the patient.

In preferred embodiments, the inhaler according to the present invention may permit small amount of medicament to be administered in accurate doses and thus undiluted medicament could also be used.

The powder inhaler of the present invention may be disposable or may be designed such that the air inlet holes may cooperatively engage with a dose dispensing device such that it is possible to introduce a dose whenever required for repeated administration. When designed for repeated administration, the air inlet holes are designed so that they can be closed or sealed by a cap. For example, the air inlet may be in the form of a short tubular extension on to which a cap fits. The cap may be removed and the device engaged with a dose dispensing device. For example the device may be engaged with any one of the known powder inhaler devices that have a means for

cutting capsules and wherein such known powder inhaler has been modified to also cooperatively engage with the powder inhaler of the present invention such that the powder from the cut capsule is dispensed directly into the air inlet hole or holes of the powder inhaler of the present invention. The patient then can use the powder inhaler instantly or can again close the air inlet hole by means of the cap for use at a later time in the day, for example when he is traveling or is outside his place of residence. Such use enables the patient to carry only the compact device instead of bulkier inhalers that are known to those skilled in the art. The known powder inhaler may be a breath actuated powder inhaler or one that is powered by a source other than fluorocarbon propellant. When disposable, the device does not require a separate cartridge or other container for the active substance, nor does it require specific positioning when in use, which makes it simple and safe to handle. Due to its almost immediate action it is suitable for use in emergency situations. The device can be simply constructed at low cost, which can permit it, if desired to be used once and then disposed of. Furthermore, the design of the inhaler allows production in a very small size, so that the inhaler may conveniently be carried by a user at any time.

Further the powder inhaler of the present invention may be breath-actuated or powered by a source other than a fluorocarbon. For example, the air inlet holes may be designed so that they are adapted for connection with the powered source such as a can containing compressed gas or for connection to a bulb or other such mechanical source. More preferentially in such embodiments having an external source, there may be air inlet holes at the medicament recess end and additional air inlet hole(s) at the channel. The latter may be designed such that when the patient inhales air, a whistle sound is produced when a certain rate of flow of air is exceeded, and on hearing the sound the patient can activate simultaneously the powered source. In this case the additional air inlet hole itself may be designed in the form of an airflow indicator for example an air flow indicator such as that disclosed in PCT publication No. WO 88/02267. Particularly in this instance the sound signal or whistle may be produced when the patients respiration air exceed a certain air flow rate. Alternatively, the air inlet hole may be such that it can be closed or sealed by a cap, the cap can be removed and the additional air inlet hole engaged to a flow indicator. In this way the forced aerosolization of the powder by the power source can be synchronized with the inhalation by the patient. This alerting means makes the inhaler more suited for use by children, elderly patients or patients who have difficulty in coordinating the triggering of the power source with their inhalation.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described with reference to the accompanying drawings, in which

Figure 1 shows a side view of a powder inhaler having a single chamber wherein the means of sealing is achieved by sealing of the layers;

Figure 2 shows a bottom plan view of the powder inhaler of Figure 1;

Figure 3 is the blown up view of the powder inhaler of Figure 2 illustrating the three layers of the powder inhaler;

Figures 4, 5, 6 and 7 are alternative embodiments of the powder inhaler of Figure 1 with different configurations of the scored formation of the chamber wall;

Figures 8 and 9 explain the construction features of the powder inhaler of Figure1;

Figures 10 and 11 illustrate the operational features of the powder inhaler of Figure 1;

Figures 12, 13 and 14 explain the in use configuration of the powder inhaler of the powder inhaler of Figure 1;

Figure 15 shows alternative embodiments of the powder inhaler of Figure 1 with various configurations of the air inlet holes;

Figure 16 shows a preferred embodiment with scored formation in the lower wall;

Figure 17 shows an alternative embodiment of the inhaler having two chambers and an obstruction between the chambers;

Figure 18 shows an alternate embodiment of the inhaler;

Figure 19 shows an embodiment of the inhaler having two chambers and a constriction between the two chambers;

Figure 20 and 21 show alternate embodiment of the inhaler of Figure 17 with the air inlet hole located between the upper wall and the lower wall of the powder inhaler;

Figure 22 shows an alternate embodiment of the powder inhaler with an upper curved wall and scored formation on the upper wall and lower wall.

The Figures only represent embodiments of the present invention. The embodiments are meant only for the purpose of illustration of the present invention. Different parts of the powder inhaler of these embodiments are labeled in Figures 1 to 15 and the labeling is described herein below.

In Figure 1

10: inhaler

12: peel-off piece of lidding material

14: upper wall

16: lower wall

22: aerodynamically streamlined chamber containing medicament

In Figure 2

10: inhaler

16: lower wall

18: tab

19: fracture line along the tab

20: corner piece along the air outlet

21: fracture line along the corner piece

22: aerodynamically streamlined chamber containing medicament recess and a channel

26: scored formations on wall of the chamber

In Figure 3

12: peel-off piece of lidding material

14: upper wall

16: lower wall

18: tab

19: fracture line along the tab

20: corner piece along the air outlet

21: fracture line along the corner piece

22: aerodynamically streamlined chamber containing medicament recess and a channel

24: air inlet hole

In Figure 4

10: inhaler

18: tab

20: corner piece along the air outlet

26: scored formations on wall of the chamber

In Figure 5

10: inhaler

18: tab

20: corner piece along the air outlet

26a: scored formations on wall of the chamber

In Figure 6

10: inhaler

18: tab

20: corner piece along the air outlet

26b: scored formations on wall of the chamber

In Figure 7

10: inhaler

18: tab

20: corner piece along the air outlet

26c: scored formations on wall of the chamber

In Figure 8

22: aerodynamically streamlined chamber containing medicament recess and a channel

24: air inlet hole

28: unsecured area between the peel-off piece of lidding material and upper wall

In Figure 9

22: aerodynamically streamlined chamber containing medicament recess and a channel

24: air inlet hole

30:secured area between upper wall and lower wall

In Figure 10

24: air inlet hole

32: strip of the peel-off piece of lidding material

32a: exposed unsecured area along the air inlet hole

In Figure 11

18: tab

24: air inlet hole

32: strip of the peel-off piece of lidding material

34: air outlet hole

In Figure 12

18: tab

22: aerodynamically streamlined chamber containing medicament recess and a channel

32: strip of the peel-off piece of lidding material

36: medicament contained in the aerodynamically streamlined chamber

In Figure 13

18: tab

22: aerodynamically streamlined chamber containing medicament recess and a channel

24: air inlet hole

32: strip of the peel-off piece of lidding material

34: air outlet hole

36: medicament contained in the aerodynamically streamlines chamber

In Figure 14

18: tab

22: aerodynamically streamlined chamber containing medicament recess and a channel

24: air inlet hole

32: strip of the peel-off piece of lidding material

36: medicament contained in the aerodynamically streamlined chamber

38: direction of the flow of medicament into the buccal cavity of the user

In Figure 19

39: constriction between the medicament containing recess and the channel

In Figure 20

40: air inlet hole between the upper wall and the lower wall

In Figure 21

41: air inlet hole in operative configuration

42: entry of air in the operative air inlet hole

Referring to the Figures, a powder inhaler in accordance with this invention is indicated generally by the reference numeral 10. Figure 1 illustrates an embodiment of the inhaler having a single chamber. As seen in Figure 1, the inhaler (10) has mainly a flat planar shape consisting of the lower wall (16) and an upper wall (14). In this embodiment, the medicament containing recess and the channel leading to the air outlet hole form a single aerodynamically streamlined chamber (22) which contains the medicament. The chamber has a shallow end extending into the air outlet hole and a medicament containing deep end. The lower wall (16) is covered and secured by the upper wall (14) which is flat in this embodiment. A peel-off piece of lidding material (12) for example, a metal foil typically an aluminum foil is adhered to the top surface of the upper wall (14). Figure 2 shows the bottom plan view of the inhaler of Figure 1. As seen in the Figure 2, the practical embodiment of the inhaler is in the form of a square or a rectangle having the medicament containing chamber (22) diagonally placed on the lower wall (16). The two ends of the inhaler (10) form the operative feature of the invention. The corner piece (20) constitutes the shallow end having the sucking and air outlet hole. The air outlet hole is sealed as a result of the sealing between the lower wall and the upper wall. Likewise the air inlets are sealed from the environment by the peel-off piece of lidding material, thus providing a moisture-proof environment within the chamber. The air outlet hole is opened by breaking of the corner piece (20) along the fracture line (21). This embodiment has only one air inlet hole (24), which is made operative by peeling of a portion of the lidding material (12) as seen in Figure 3. The walls of the chamber (22) are scored with formations (26) for aerosolizing medicament placed in the chamber (22).

Figure 3 shows the blown up view of the inhaler (10) of an embodiment in accordance with this invention. The flat upper wall (14), the lower wall (16) forming the walls of the aerodynamically streamlined chamber (22) and also the peel-off piece of lidding material (12) are seen. The air inlet hole (24) can also be seen. The tab (18) is bent along the fracture line (19) and stripped off to make the air intake hole (24) operative. The corner piece (20) is broken off at fracture line (21) to make the air outlet hole operative.

The wall of the aerodynamically streamlined chamber or the channel leading into the air outlet hole can have various configurations of the scored formations. The scored formation acts to add turbulence to the medicament entrained in the air stream. The formation may be in the form of protrusions or projections of various shapes, for example, spiral, single or multiple ribs, linear, helical, circular, cone, wedge, rectangular and the like. The formation can also be in the form of

depressions or dimples of various shapes, for example, spiral, linear, helical, circular, cone, wedge, rectangular and the like. Figures 4 to 7 show different configurations of the scored formations of the wall of the aerodynamically streamlined chamber, particularly the formations (26 and 26a, 26b and 26c).

Figures 8 and 9 show the areas highlighted to demarcate the secured areas. Figure 8 shows the demarcated areas between the peel-off piece of lidding material (12) and the upper wall (14). The area (28) is the unsecured area between the lidding material and the upper wall lying above the air inlet hole (24). As seen in Figure 9, the area (30) is the secured area between the upper wall (14) and the lower wall (16), and the remaining area of the upper wall that bears the air inlet hole (24) and lies above the aerodynamically streamlined chamber (22) is not secured.

Figures 10 and 11 illustrate the two step operation needed to make the inhaler operative. The tab (18) is fractured at the fracture line (19) and the strip (32) of the peel-off piece of lidding material (12) is stripped off. As can be understood by examining Figures 10 and 11 with respect to Figure 8, since the demarcated area (28) is not secured to the peel-off piece of lidding material (12), the strip (32) can be peeled off to expose the unsecured area (32a) and make the air inlet hole (24) operative. In the second step of the operation, the corner piece (20) is broken off at the fracture line (21) to make the air outlet hole (34) operative as seen in Figure 11.

The operation of the inhaler (10) can be explained with reference to Figures 12, 13 and 14. Figure 12 is the side view of the inhaler in the operative configuration as seen in Figure 11. The particulate medicament (36) is seen in the aerodynamically streamlined chamber (22). In Figure 13, a user sucks at the air outlet hole (34) causing intake of air tangentially to the aerodynamically streamlined chamber (22) through the air inlet hole (24). The air stream impacts the medicament powder bed directly, causes agitation and turbulence of the medicament (36) which causes aerosolizing of the particles as seen in Figure 14 and the aerosolized particles are ejected in the direction (38) into the buccal cavity of the user [not seen].

In one embodiment of the invention as shown in Figure 8, 9, 10, 11, a single air inlet hole was exemplified. The size, number, location and the configuration of the air inlet holes can be varied to obtain the best results with a specific medicament composition. The air inlet holes may be arranged in configurations selected from shapes like linear, triangular, circular, square, rectangular, diamond, pentagonal, hexagonal, other polygonal figures and the like. Some of the

preferred embodiments with varying air inlet configuration are shown in Figure 15. In one embodiment, the single air inlet hole of 4.5 mm diameter was used. In another embodiment, two air inlet holes of diameter 4 mm each with distance of 1 mm between them were used. In yet another embodiment, three air inlet holes of 2.5 mm each arranged in a row were used. Another embodiment used four air inlet holes of 2.5 mm diameter, each arranged in a line. In another embodiment, six air inlet holes of 2 mm diameter each were arranged in the shape of a triangle. In yet another embodiment, nine air inlet holes of 1.5 mm diameter each were arranged in the shape of a four-sided figure such as a diamond or a square or a rectangle. The embodiment with an air inlet hole of 4.5 mm diameter and two air inlet holes of 2.5 mm diameter arranged in the shape of a triangle was found to be a preferred embodiment for a specific medicament composition.

In an embodiment of the inhaler of the present invention as shown in Figure 16, the tab for breaking open the air inlet hole is incorporated into the square body of the inhaler and does not protrude out of the body, as exemplified in the previous embodiments. Figure 16 shows a preferred embodiment of the powder inhaler with the tab incorporated in the square body and with spiral formation scored on the wall of the aerodynamically streamlined chamber. In a preferred embodiment, the inhaler of the Figure 16 has a square planar body with the dimensions of about 40 mm X 40 mm X 8.5 mm.

In the inhaler of the present invention, the shape of the inhaler may be modified or may be different from that disclosed in the previous embodiments. Typically, the inhaler may be cylindrical, capsule-shaped, rectangular, spoon-shaped, polygonal, cone shaped or funnel-shaped and the like. Figure 18 shows an embodiment with a different shape of the inhaler.

Other embodiments of the inhaler of the present invention having two chambers are shown in Figure 17 and 19. The inhaler has an obstruction (Figure 17) or a constriction (Figure 19) between the medicament containing recess and the channel. The inhaler in these embodiments has the medicament stored in a recess which is formed by the curved shape of the lower wall of the inhaler. The lower wall after forming the recess, curves upwards towards the upper wall of the inhaler to form an obstruction (Figure 17) or again curves downwards, away from the upper wall, forming a constriction (39) (Figure 19). The structural constriction between the recess and the channel causes a constriction in the air passage and subjects the medicament particles entrained in the air stream to turbulence.

Yet another embodiment of the inhaler of the present invention is shown in Figures 20 and 21. In this embodiment the air inlet hole is located between the lower wall and upper wall of the inhaler so that the air inlet pathway is formed between the sealed upper and lower walls of the inhaler. In this embodiment, the air inlet hole (40) is in the shape of a tubular protrusion in the lower wall as shown in Figure 20. The protrusion is broken off as shown in Figure 21, so that the air inlet hole is in its operative configuration (41) and air will flow in (42) through the air inlet hole. The medicament containing recess is separated from the channel leading into the air outlet hole by an obstruction to the air flow path between the recess and the channel. Typically a single inlet hole or multiple air inlet holes can be provided for the inhaler of this embodiment.

In yet another embodiment of the inhaler of the invention, the upper wall of the inhaler may be curved. In this embodiment, typically both the lower wall as well as the upper wall may have scored formations. The scored formation may be in various configurations as described before. Figure 22 shows an embodiment of the inhaler with a curved upper wall and an aerodynamically streamlined chamber containing medicament. The upper wall and the lower wall of the chamber have spiral design of the scored formation. In this embodiment, particularly, the upper and lower curved walls may not be sealed to each other but may be interlocked mechanically when placed against each other and opened by the user. A dose of medicament may be placed in the recess at the time of does administration by the patient.

The lower wall and the upper wall of the inhaler of the invention may be formed from formable or mouldable materials. The peel-off piece of lidding material used is typically a metal foil like for example, aluminum foil.

In all the embodiments of the present invention, any one or all the components of the powder inhaler can be made photo luminescent to enable the patient to access the inhaler even in darkness. The various components of the powder inhaler can be made transparent or translucent in order to make easy the visualization of the consumption of the medicament. Also a "soft feel" material can be incorporated in any of the components of the powder inhaler. The "soft feel" material used may be a TPE (Thermoplastic elastomer) with a shore hardness of about 30 to about 50.

Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and

modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

5

CLAIMS:

1. A powder inhaler for administration of a unit dose of a medicament, said powder inhaler comprising:

(A) Walls enclosing at least one chamber comprising a medicament containing recess, at one end and a channel extending from the medicament containing recess to the air outlet hole;

(B) Air inlet hole(s) located near the medicament containing recess;

(C) An air outlet hole; and

(D) Means for sealing said air inlet and outlet holes,

wherein the location of the air inlet hole(s) with respect to the medicament containing recess is such that upon inspiration by the patient, the air stream directly impacts the powder bed, entrains the particles and carries them to the air outlet for inspiration by the patient.

2. A powder inhaler as in claim 1, wherein the medicament containing recess and the channel form a single chamber which is aerodynamically streamlined having a shallow end and a medicament containing deep end.

3. A powder inhaler as in claim 1, comprising two chambers, wherein the first chamber is the medicament containing recess and the second chamber is the channel.

4. A powder inhaler as in claim 3, wherein the two chambers are separated by a constriction.

5. A powder inhaler as in claim 3, wherein the two chambers are separated by an obstruction.

6. A powder inhaler as in claim 1, wherein a lower wall forms the lower wall of the channel and the medicament containing recess; and an upper wall has air inlet hole(s) that are sealed by a peel-off piece of a lidding material.

7. A powder inhaler as in claim 1, wherein the upper wall is flat.

8. A powder inhaler as in claim 1, wherein the upper wall is curved.

9. A powder inhaler as in claim 1, wherein the air inlet hole(s) are located between the upper wall and the lower wall.

10. A powder inhaler as in claim 1, wherein the inhaler comprises a single one-piece body molded from a mouldable material.

11. A powder inhaler as in claim 1, wherein the channel has scored formation on its walls.

12. A powder inhaler as in claim 11, wherein the lower wall of the channel has scored formation.

13. A powder inhaler as in claim 11, wherein the lower and upper walls of the channel have scored formation.

14. A powder inhaler as in claim 1, wherein the means for sealing the air outlet hole comprises sealing of upper wall with the lower wall.

15. A powder inhaler as in claim 9, wherein the means for sealing the air inlet hole(s) comprises sealing of upper wall with the lower wall.

16. A powder inhaler as in claim 1, wherein the air inlet hole(s) are designed so that they can be sealed or closed by a cap.

17. A powder inhaler as in claim 16, wherein the air inlet hole(s) is designed such that the cap can be removed and then it can be cooperatively engaged to a power source other than a fluorocarbon.

18. A powder inhaler as in claim 16, wherein the air inlet hole(s) is designed such that the cap can be removed and then it can be cooperatively engaged with a dose dispensing device.

19. A powder inhaler as in claim 1, wherein the air inlet hole(s) allow the incoming air stream to impact the powder bed tangentially.

20. A powder inhaler as in claim 11, wherein the scored formation has a spiral configuration (26b).

21. A powder inhaler as in claim 1, wherein single or multiple air inlet holes are located at the deep end of the medicament containing recess and arranged in configurations selected from linear, triangular, circular, square, rectangular, diamond and other polygonal shapes.

22. A powder inhaler as in claim 1, wherein the incoming air from the air inlet hole(s) is directed to the powder bed by means for improving incoming airflow to the powder bed.

23. A powder inhaler as in claim 22, wherein means for improving incoming airflow is selected from the group consisting of a tubular extension or an air deflector located at the mouth of the air inlet hole.

24. A powder inhaler as in claim 1, wherein the channel further comprises additional air inlet hole(s).

25. A powder inhaler as in claim 24, wherein the additional air inlet hole(s) are on the upper wall.

26. A powder inhaler as in claim 24, wherein the additional air inlet hole(s) are located on the side wall.

27. A powder inhaler as in claim 24, wherein the additional air inlet hole(s) is designed such that it can be sealed or closed by a cap.

28. A powder inhaler as in claim 27, wherein the additional air inlet hole(s) is designed such that the cap can be removed and then the additional air inlet hole can be engaged to a flow indicator capable of producing a sound signal when the patients respiration exceeds a predetermined air flow rate.

29. A powder inhaler as in claim 24, wherein the additional air inlet hole(s) are sealed by a piece of peel-off lidding material.

30. A powder inhaler as in claim 1, wherein any one or all the components of the said powder inhaler are made photoluminescent.

31. A powder inhaler as in claim 1, wherein any one or all the components of the said powder inhaler are transparent or translucent.

32. A powder inhaler as in claim 1, wherein any component of the said powder inhaler may be made of a soft feel material.

33. A powder inhaler as in claim 32, wherein the soft feel material is a thermoplastic elastomer with a shore hardness of about 30 to about 50.

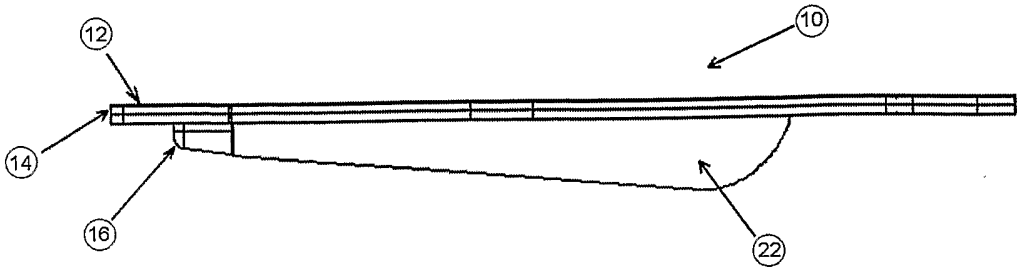


Figure - 1

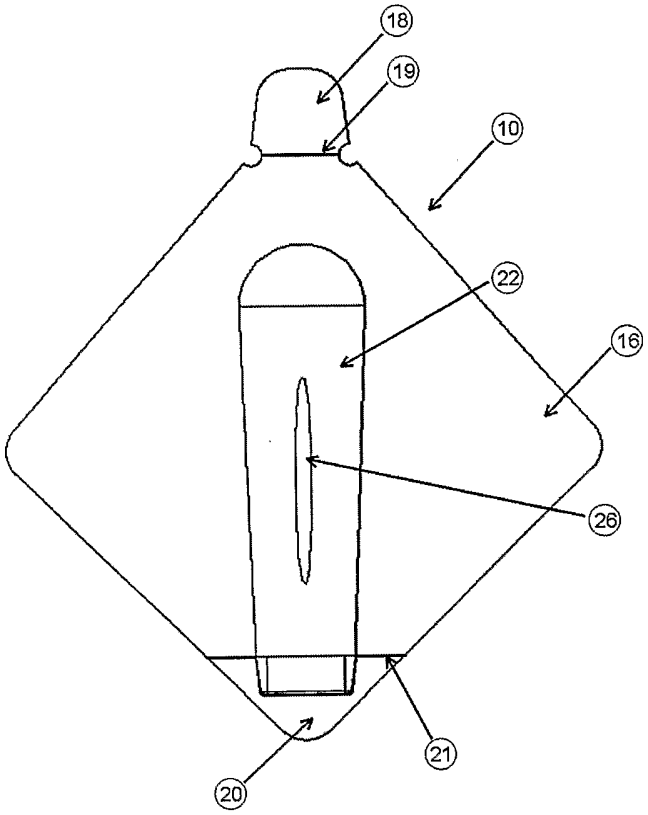


Figure - 2

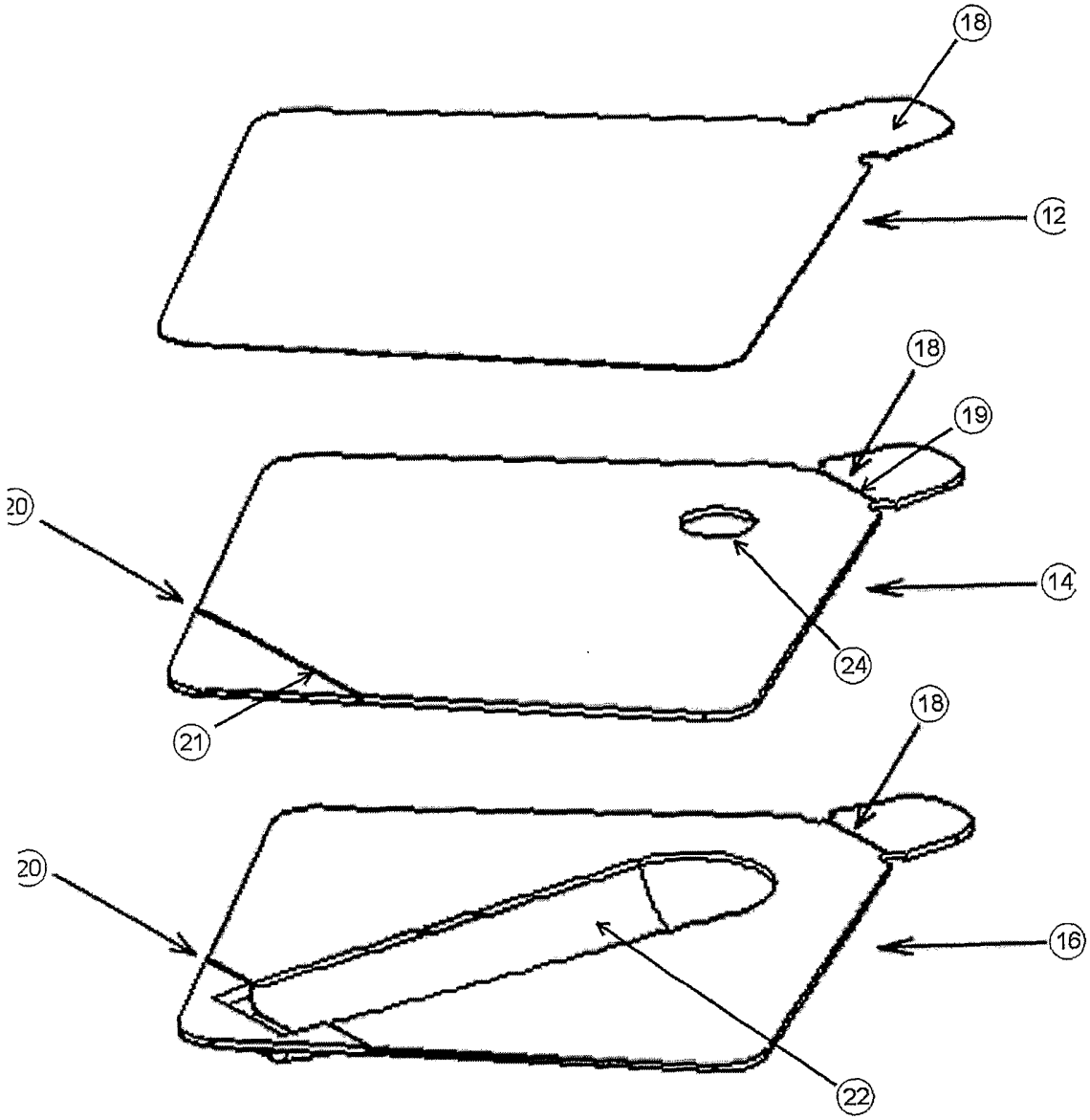


Figure - 3

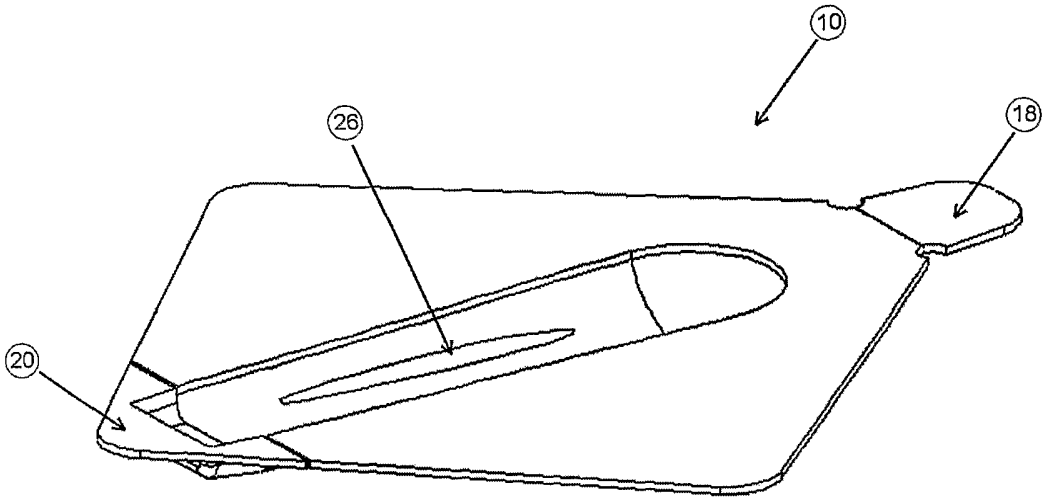


Figure - 4

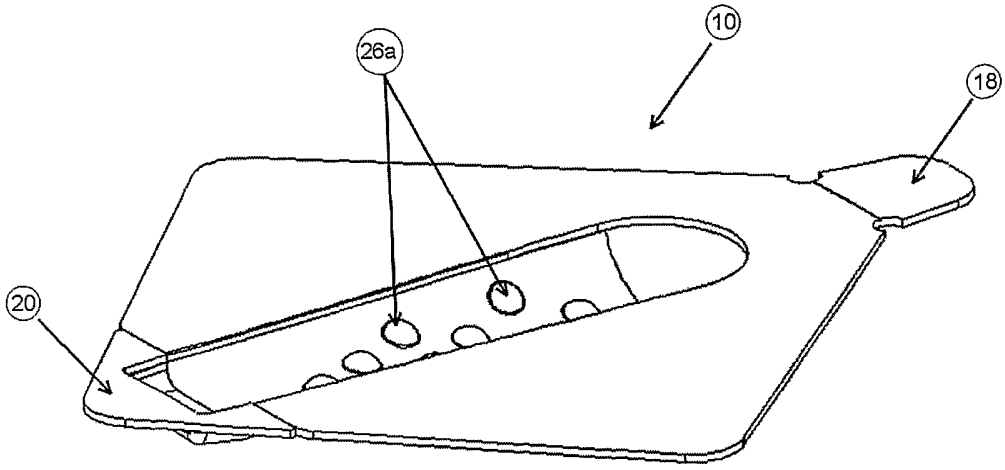


Figure - 5

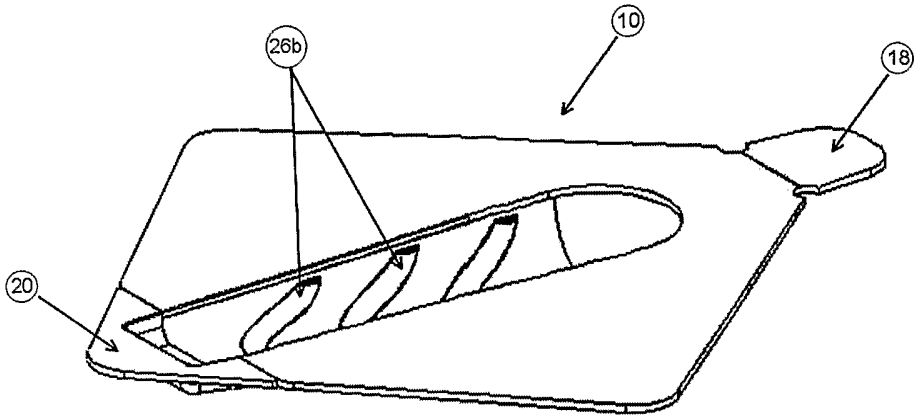


Figure - 6

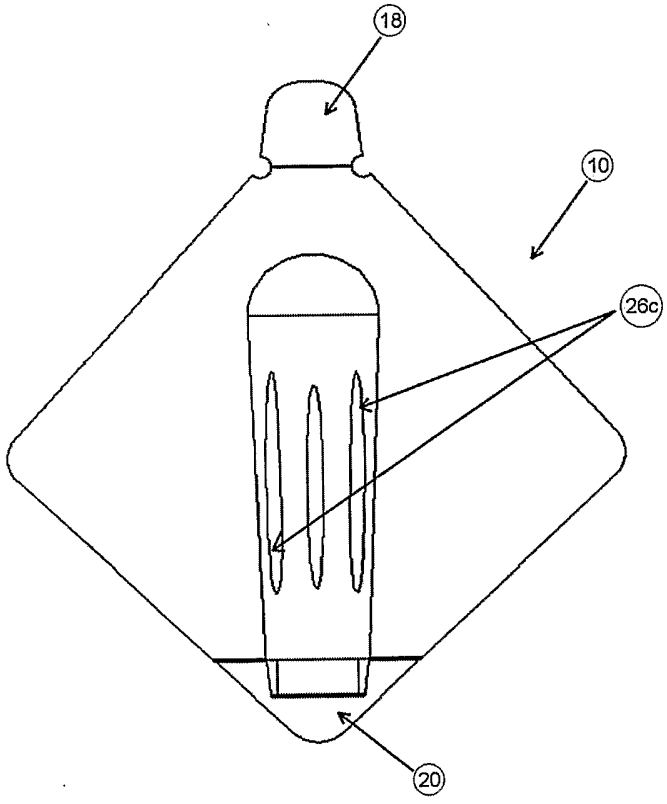


Figure - 7

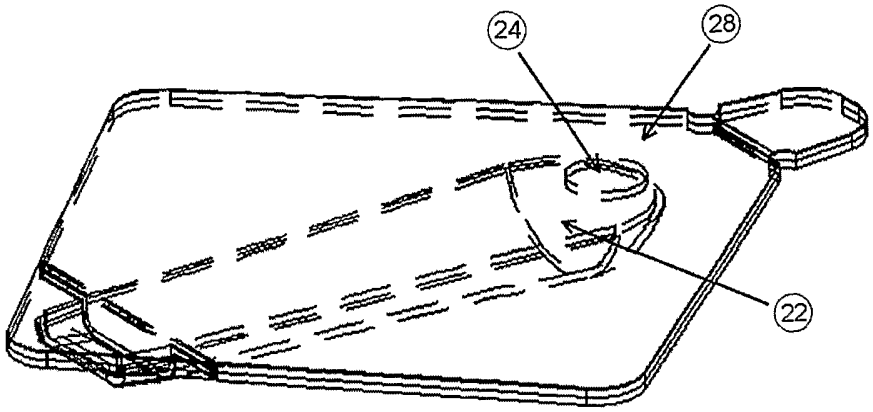


Figure - 8

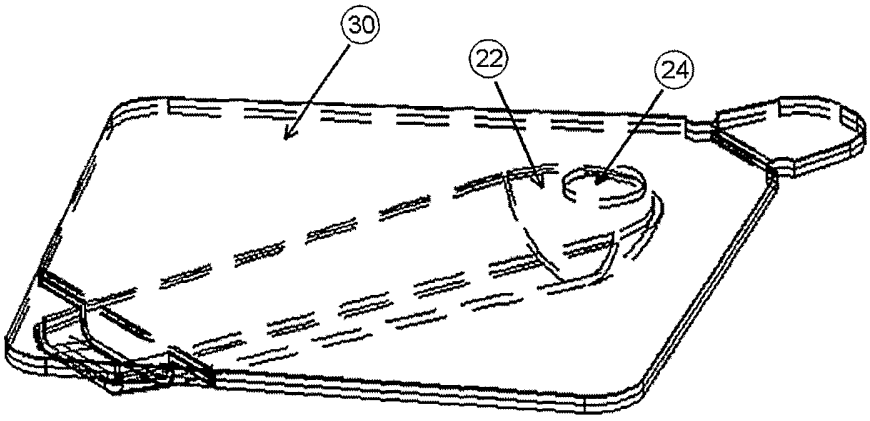


Figure - 9

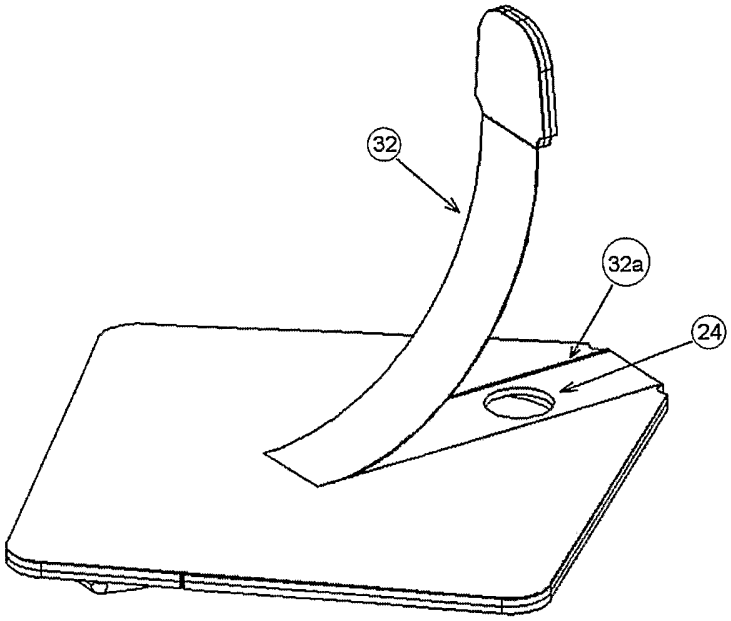


Figure - 10

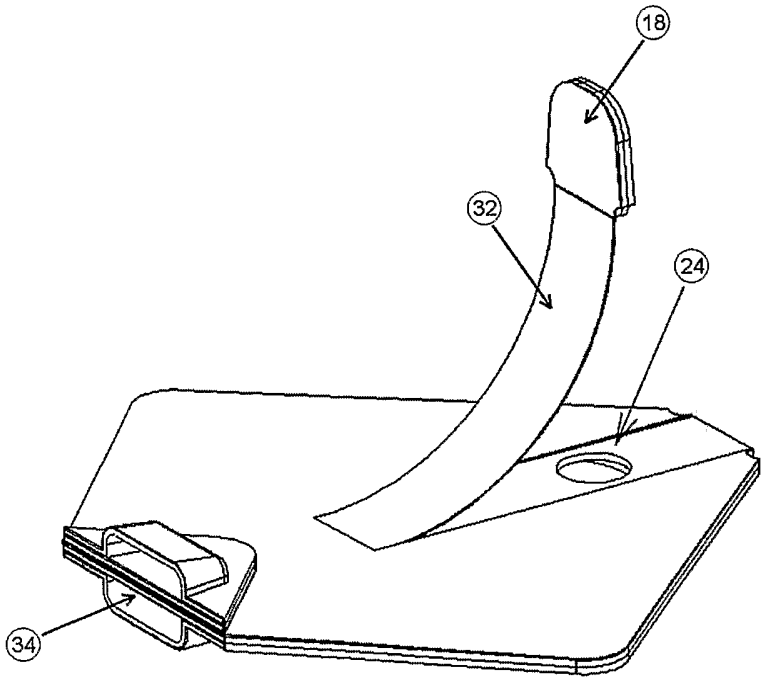


Figure - 11

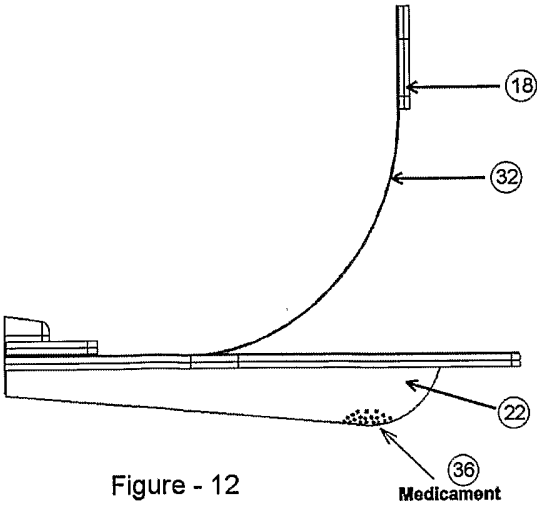


Figure - 12

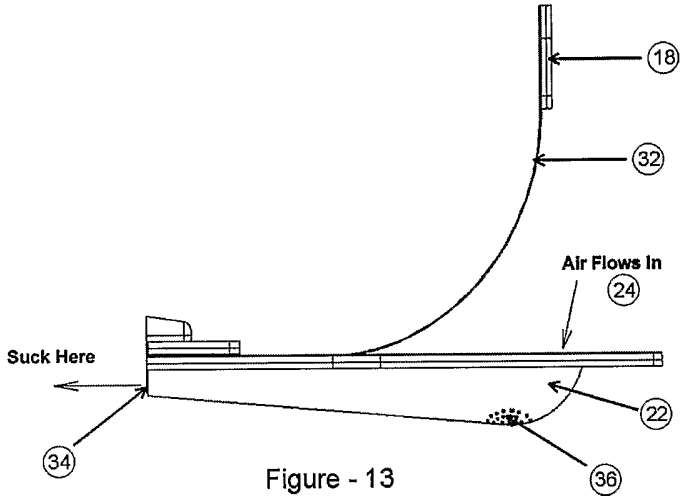


Figure - 13

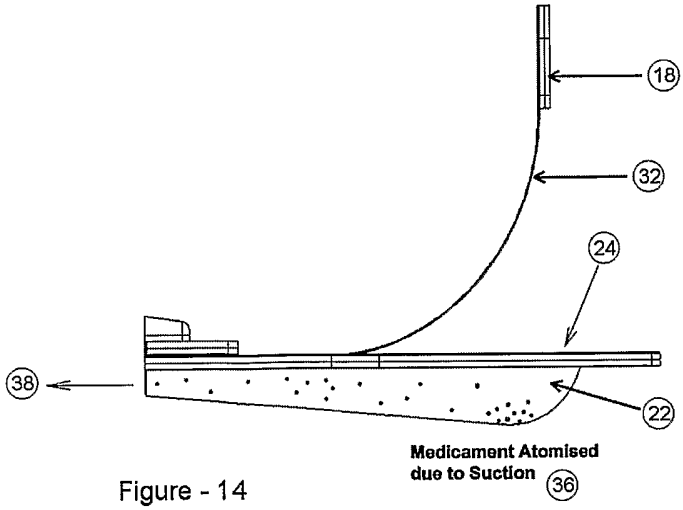


Figure - 14

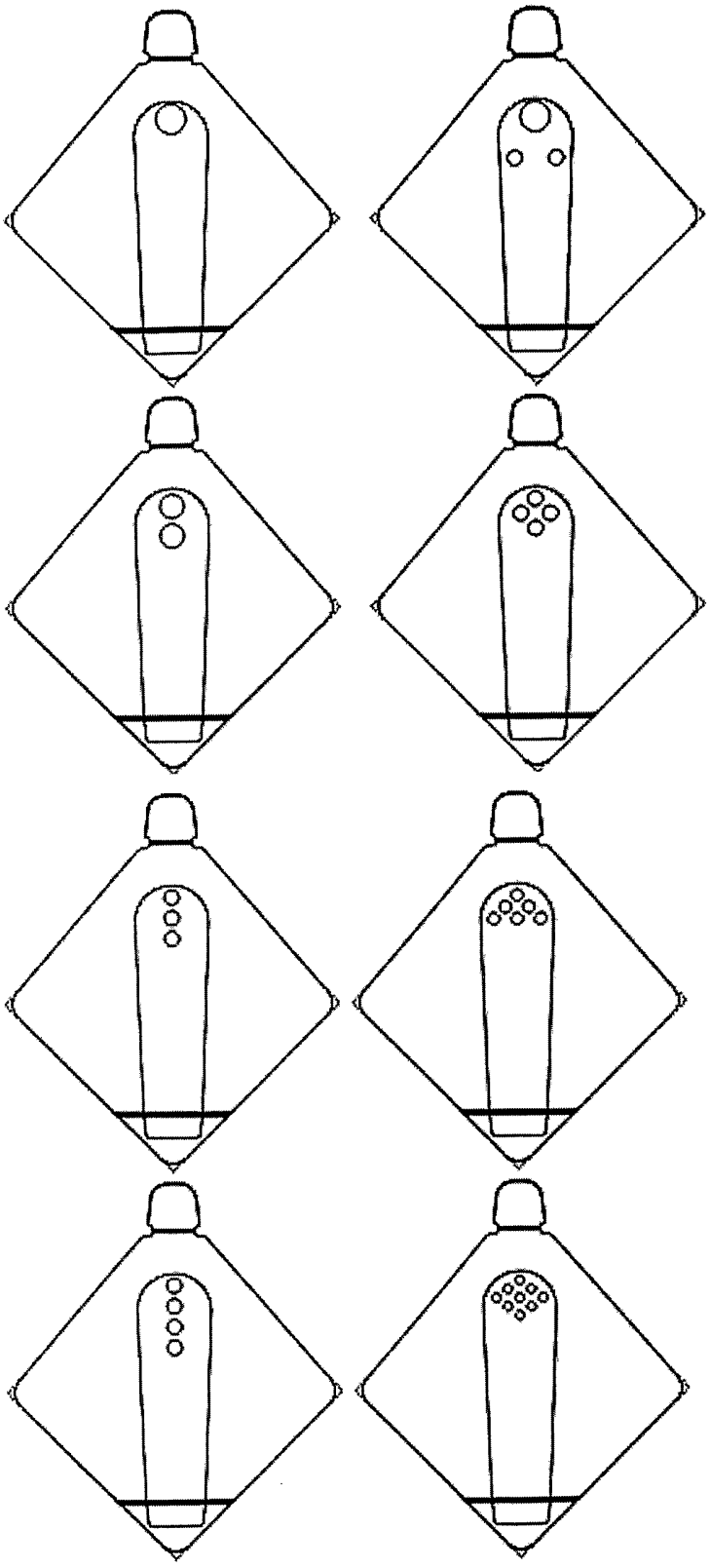


Figure - 15

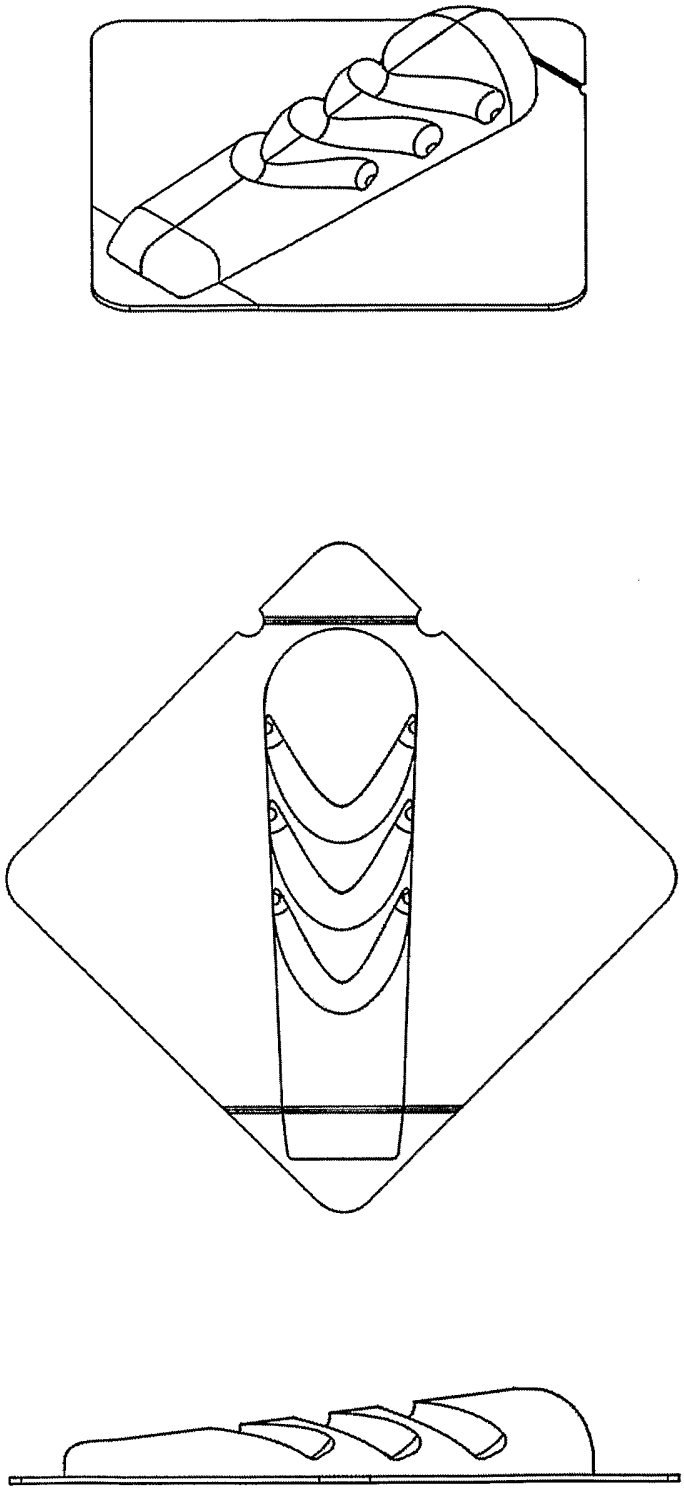


Figure - 16

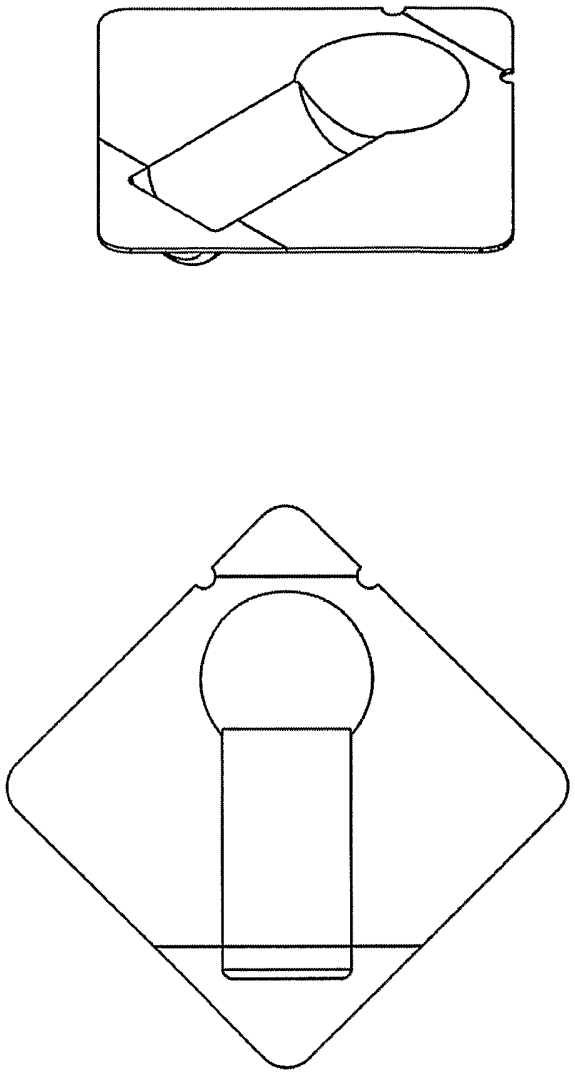


Figure - 17

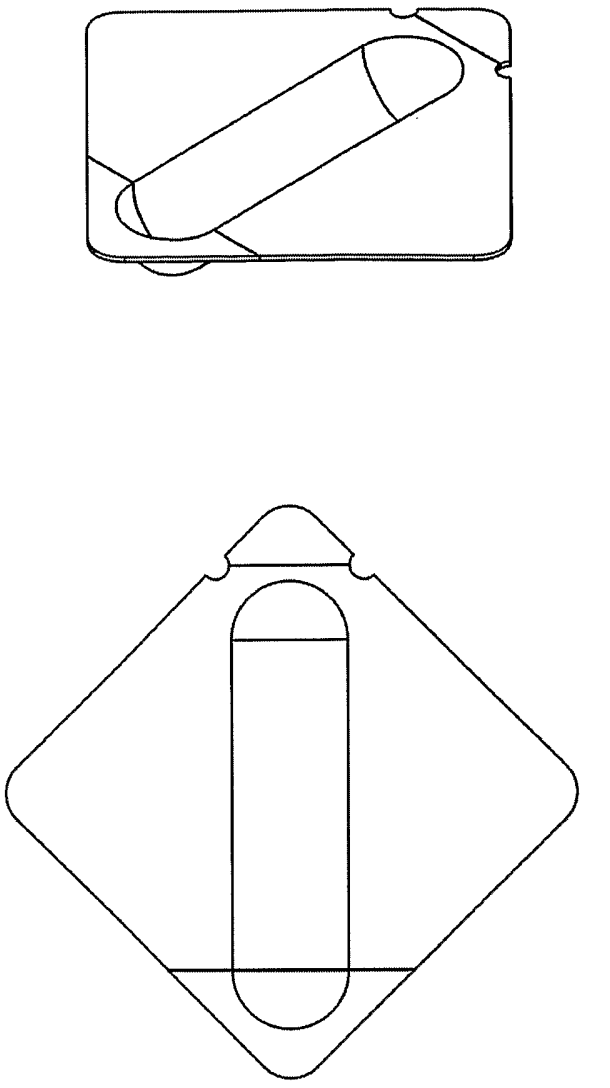


Figure - 18

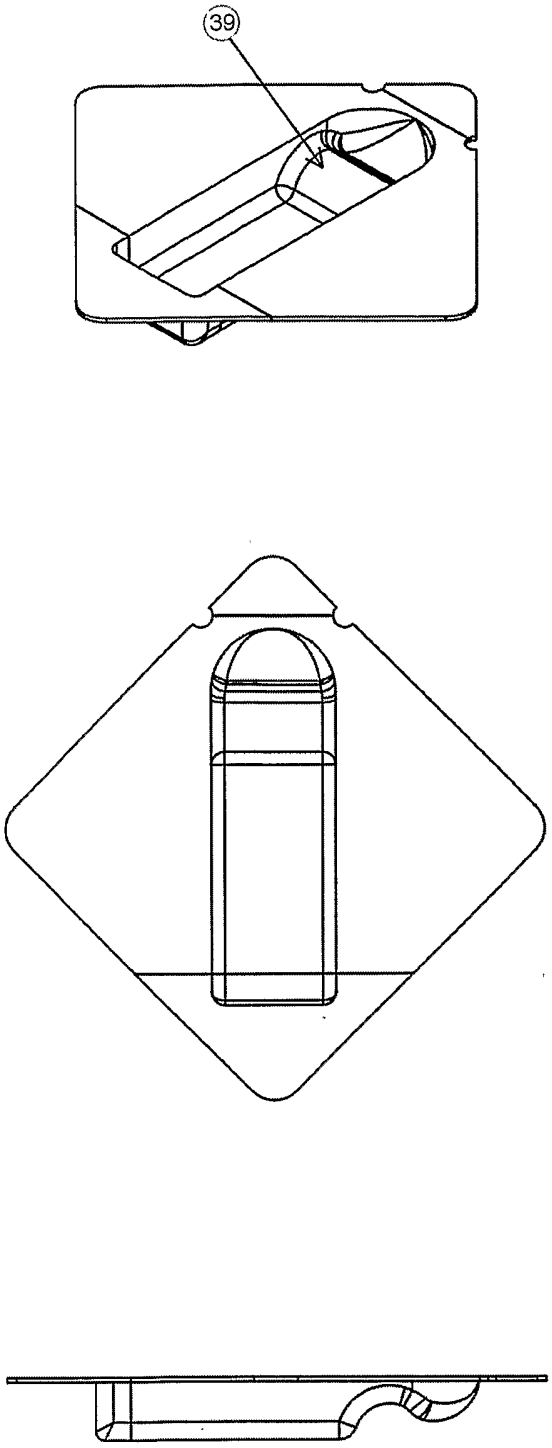


Figure - 19

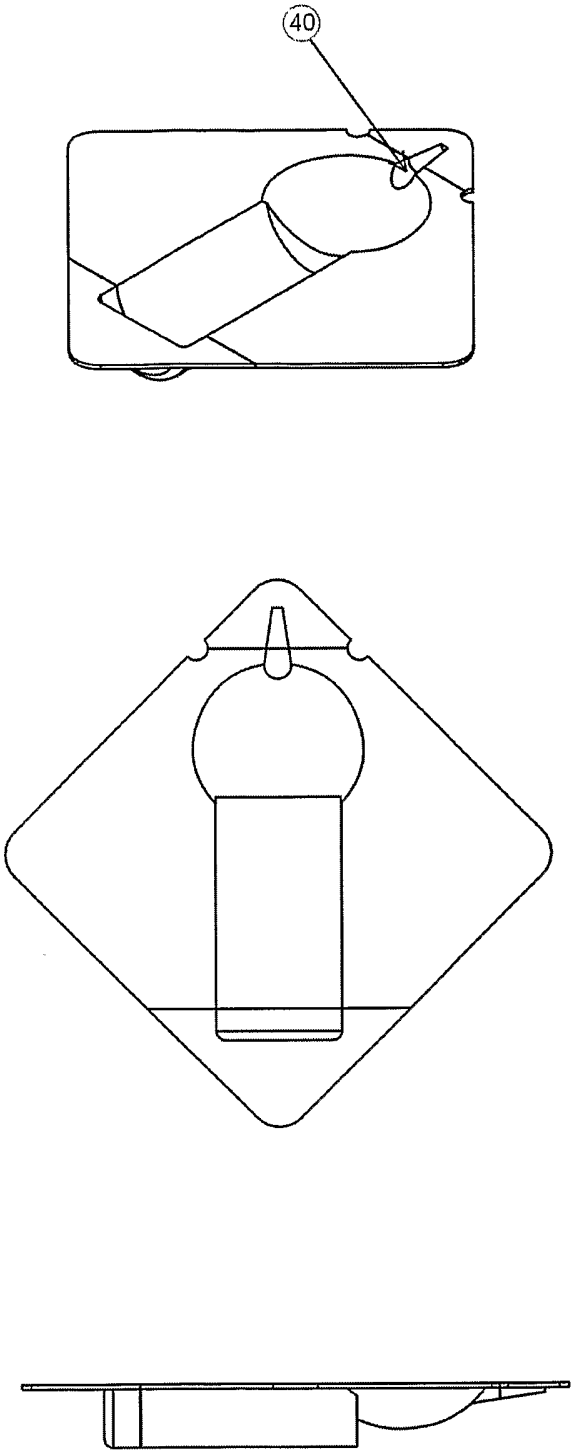


Figure - 20

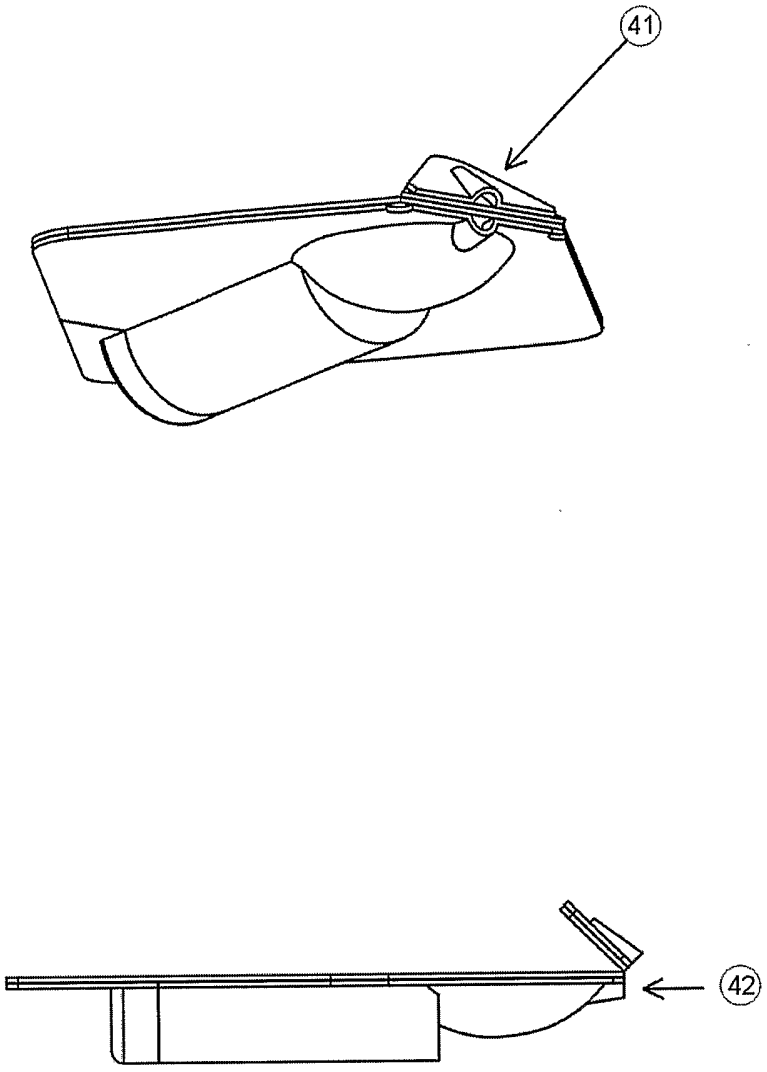
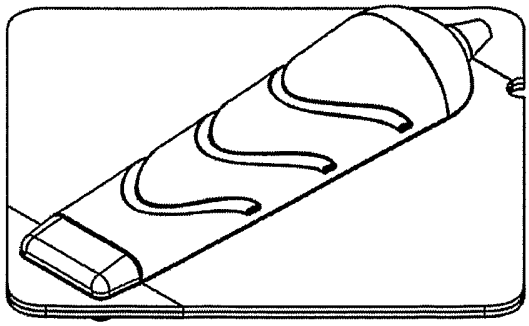


Figure - 21



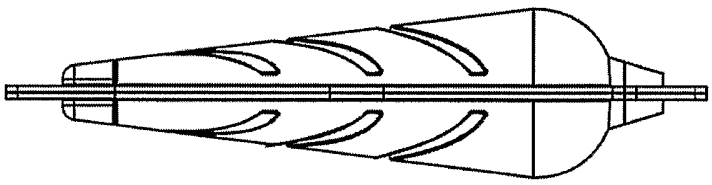


Figure - 22