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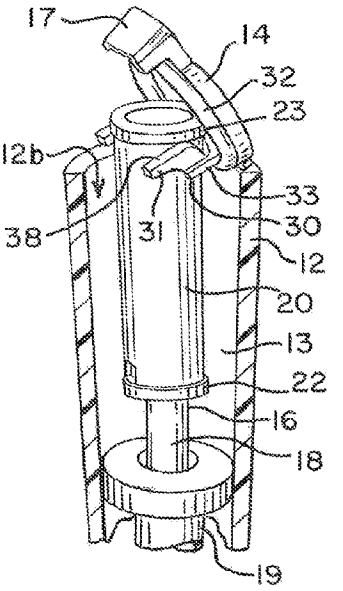
(54) Titre : PRODUIT DE CATHETER ET EMBALLAGE COMPRENANT UN MOYEN HYGIENIQUE DE RETRAIT DE L'EMBALLAGE

(54) Title: A CATHETER PRODUCT AND PACKAGE WITH HYGIENIC MEANS FOR REMOVAL FROM THE PACKAGE



(57) Abrégé/Abstract:
In one aspect there is described a catheter product comprising: a) a package comprising an elongated housing having a closed proximal end and an open distal end and an openable lid attached to said housing for sealing the open distal end of said housing, said lid comprising a top surface and an underside, a tab, a hinge spaced from said tab at a location opposite of said tab, wherein said hinge joins said lid and said housing, and a pivotable lifting member that is movable with said lid during opening of said package, wherein said pivotable lifting member is located opposite of said tab and is attached to the underside of said lid; and b) a catheter comprising a proximal insertable catheter tube and a distal gripping member, said gripping member comprising an engagement surface having at least two points of contact in contact with said pivotable lifting member, wherein said pivotable lifting member contacts the engagement surface at least two points of contact on the engagement surface, wherein two of the points of contact on the engagement surface are located opposite from one another.

ABSTRACT

In one aspect there is described a catheter product comprising: a) a package comprising an elongated housing having a closed proximal end and an open distal end and an openable lid attached to said housing for sealing the open distal end of said housing, said lid comprising a top surface and an underside, a tab, a hinge spaced from said tab at a location opposite of said tab, wherein said hinge joins said lid and said housing, and a pivotable lifting member that is movable with said lid during opening of said package, wherein said pivotable lifting member is located opposite of said tab and is attached to the underside of said lid; and b) a catheter comprising a proximal insertable catheter tube and a distal gripping member, said gripping member comprising an engagement surface having at least two points of contact in contact with said pivotable lifting member, wherein said pivotable lifting member contacts the engagement surface at least two points of contact on the engagement surface, wherein two of the points of contact on the engagement surface are located opposite from one another.

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TITLE

A CATHETER PRODUCT AND PACKAGE WITH HYGIENIC MEANS FOR REMOVAL FROM THE PACKAGE

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FIELD OF THE DISCLOSURE

[0002] The present disclosure is directed to packages for medical products. More particularly, the present disclosure is directed to packages for medical devices that allow for ergonomic presentation and removal of the device from the package. Even more particularly, the present disclosure is directed to packages for urinary catheters such as intermittent urinary catheters, whereby opening of the package presents the non-insertable portion of the catheter such that it can be easily removed from the package by the user.

BACKGROUND

[0003] Intermittent catheters are widely used by individuals who suffer from compromised dexterity caused by injury to the spinal cord. The difficulties associated with manipulating and opening the package, holding the catheter and accessing the catheter in an easy and sterile manner has led catheter manufacturers to consider ways whereby the catheter package can be easily opened and, upon the opening of the package, present the catheter such that the user can easily retrieve the catheter from the package.

[0004] One example of a catheter package that provides for presentation of and access to the catheter upon opening of the package is disclosed in EP 2 686 054 B1. The catheter and catheter package described in EP 2 686 054 B1 includes extracting means coupled to the catheter at one end and a peel away tab of the package at its other end. When the peel-off tab is opened, the extracting member, which is shown as a strip of material, partially pulls the catheter out of the package and into the opening of the package.

[0005] In a second embodiment of the catheter package described in EP 2 686 054 B1, the package includes a cap which seals the open end of the package.

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The extraction means in this embodiment is also provided in the form of a flexible strip, one end of which is attached to the cap and the other end is attached to an insertion aid of the catheter assembly. When the tab on the cap is moved and the package opened, the extracting means partially lifts the catheter out of the package.

[0006] The present disclosure provides further improvements in the packaging of catheters or, for that matter, any medical device that is to be accessed by the user in a way that presents the device for easy and sterile removal from the package.

SUMMARY

[0007] In one aspect, the present disclosure is directed to a package for a medical device. The device includes an elongated housing having a closed proximal end and an open distal end. An openable lid is attached to the housing for sealing the open distal end of the housing. The lid includes a lifting member that is movable with the lid during opening of the package.

[0008] In another aspect, the present disclosure is directed to a catheter product including a package with an elongated housing having a closed proximal end and an open distal. An openable lid is attached to the housing for sealing the open distal end. The lid includes a lifting member that is movable with the lid during opening of the package. The product also includes a catheter having a proximal insertable catheter tube and a distal gripping member or funnel. The gripping member includes an engagement surface that is in contact with the lifting member of the lid. Opening of the package lid partially lifts the catheter out of the package and presents the catheter for hygienic retrieval of the catheter by the user.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 is a plan view of a package for a medical device;

[00010] Figure 2 is a cross-sectional view of the package of Fig. 1 with the medical device disposed therein;

[00011] Figure 3 is a partial, cross-sectional view of the package with medical device of Figs 1 and 2 therein with the lid of the package in a closed position;

[00012] Figure 4 is a partial, cross-sectional view of the package of Fig. 3 with medical device therein with the lid of the package in a partially open position;

[00013] Figure 5 is a partial, cross-sectional view of the package of Fig. 3 with medical device therein with the lid of the package in a fully open position;

[00014] Figure 6 is a perspective view of the lid of the package of Figs. 1 and 2;

[00015] Figure 7 is a cross-sectional view of an alternative embodiment of a package for a medical device with the medical device disposed therein;

[00016] Figure 8 is a partial, cross-sectional view of the package of Fig. 7 with medical device therein with the lid of the package in an open position;

[00017] Figure 9 is a partial, cross-sectional perspective view of the package of Fig. 7 with medical device therein with the lid of the package in an open position;

[00018] Figure 10 is a partial view of yet another embodiment of a package for a medical device in accordance with the present disclosure with the lid in the closed position;

[00019] Figure 11 is perspective view of the lid of the package of Figure 10; and

[00020] Figure 12 is a partial, cross-sectional view of the package and product of Fig. 11 with the lid in the open position.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[00021] The disclosure that follows describes the invention in the context of a urinary catheter and a package for such catheter. However, it will be understood that the invention is not limited to urinary catheters or even catheters. The invention(s) disclosed herein are applicable to any medical device and package for such device wherein the opening of the package presents the device to the user for easy and sterile retrieval from the package.

[00022] Turning now to the Figures, Figures 1-2 show a package for a medical device 10 in accordance with the present disclosure. Package 10 includes a housing 12 for receiving a medical device, such as a catheter. Housing 10 may typically be elongated, having walls that define an interior chamber 13 for housing the catheter. Housing 12 may be generally cylindrically shaped or have a substantially tubular profile as shown herein and/or, for example, in International Publication No. WO 2017/185052. Alternatively, housing 12 may have a more squared cylindrical shape

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with beveled edges, as shown and described in U.S. Patent Publication 2017/0173300.

[00023] Typically, housing 12 may be made of molded plastic to provide a rigid or substantially rigid case for the catheter or other medical device. In one embodiment, housing 12 may be molded from a polymeric material such as polypropylene. Housing 12 may be made from a unitary or multilayer polymeric material.

[00024] Housing 12 has a closed sealed proximal end 12a and an openable distal end 12b (Figs. 4-5). The terms "distal" and "proximal" are used throughout this disclosure. When used in the context of a catheter having a catheter tube that is inserted into the body of the user, the term "proximal" is used to refer to that end or portion of the catheter that during use is closer in proximity to the user's body and/or initially enters the user's body upon insertion. The term "distal" is used to refer to an end or portion of the catheter (or catheter tube) that is opposite the proximal end or portion and is typically further away from the user's body. For the sake of consistency, when the terms "distal" and "proximal" are used in the context of a housing or member that holds the catheter or carries the catheter tube, and which are not intended for introduction into the user's body, a proximal end or proximal portion is that end or portion closer to the proximal end of the catheter and/or catheter tube when the catheter tube is housed in or carried by the member, while the distal end or portion is located opposite to such proximal end or portion.

[00025] As further shown in Figures 1-6, package 10 and more specifically housing 12 will include an openable cap or lid 14. Lid 14 seals distal open end 12b until opened by the user. In one embodiment, lid 14 may be a flat or substantially flat cap hingedly attached to housing 12 by hinge 15. Hinge 15 may be of any type that is commonly used, including a living hinge that can alternately be moved between open and closed positions. Lid 14 may also include a tab 17 located opposite hinge 15 for easy manipulation by the user. By pushing on tab 17, lid 14 is opened to allow access to the medical device housed inside housing 12. As shown in Figures 1-6, lid 14 may further include a sealing element such as O-ring 32 around the perimeter of lid 14 to provide a liquid-tight seal between the lid and the housing. Further examples of suitable hinges and sealing elements that may

be used in device 10 are also disclosed in International Publication No. WO 2017/185052.

[00026] As set forth above, the medical device within housing 12 may be any device that is intended for retrieval and immediate use by the user. In a preferred embodiment, the medical device is an intermittent catheter, such as catheter 16 shown in Figures 1-6 within housing 12. Optionally, housing 12 may further include a hydration liner 19 within interior chamber 13. Liner 19 may receive the insertable portion of catheter 16. Such liners are described in greater detail in U.S. Patent Publication 2017/0173300 and International Publication No. WO 2017/185052.

[00027] Catheter 16 includes catheter tube 18 made of a polymeric material such a polyvinyl chloride (PVC), which is typically made hydrophilic by coating tube 18 with a lubricious coating. Catheter tube 18 further includes one or more eyelets 19 at the proximal end of tube 18 to receive urine from the urinary canal of the user. Catheter tube 18 is insertable into the urethra of a patient.

[00028] Catheter 16 includes a funnel 20 at its distal end. Typically, funnel 20 has a hollow interior that is in flow of communication with the lumen of catheter tube 18. Funnel 20 provides an outlet for urine as it flows out of the urinary canal through the catheter tube 18. In some embodiments, a urine collection bag may be attached to the distal end of funnel 20.

[00029] As shown in the Figures, funnel 20 may further include one or more flanges 22 and 23 at the distal and proximal ends of funnel 20, respectively. Funnel 20 not only serves as a fluid outlet for urine, it also provides and serves as a gripping member that can be held and manipulated by the user when removing a catheter 16 from housing 12, and when inserting catheter tube 18 into the urethra. Thus, funnel 20 will typically include a textured outer surface to enhance gripping by the user. Examples of such texturing are shown and described in International Publication No. WO 2017/185052. By gripping catheter 16 at the funnel 20, user contact with the insertable portion of the catheter, namely catheter tube 18 is avoided.

[00030] As shown in the Figures 3-5 and further described herein, catheter package 10 provides for ready accessibility of the catheter funnel 20, allowing for easy removal by the user upon opening lid 14. It will be appreciated, that prior to

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use, catheter 16 remains completely concealed within package 10, as generally shown in Fig. 3. As further shown in the Figures, flange 23 at the distal end of funnel 20 remains below opening 12b of housing 12. It would be difficult for a user, particularly one of limited dexterity, to insert his/her fingers into the interior chamber 13 of housing 12 to remove catheter 16, nor would this be desired from the standpoint of sterility and avoiding contamination of the catheter tube. Accordingly, as shown in Figures 1-6, in one embodiment, catheter package includes one or more lifting members 30 that contact funnel and lift catheter 16 as lid 14 is being opened. As shown in Figures 1-6, lifting members 30 may include lifting arms 31 carried by support arms 33. Support arms 33 preferably depend downwardly in the direction of chamber 13 when lid 14 is in its closed position. As best seen in Figure 3, support arms 33 are preferably attached to and/or are integral with the underside of lid 14. Lifting arms 31 are preferably attached to the proximal ends of support arms 33. In one embodiment, lifting arms 33 are L-shaped members including a first contacting surface 36 that extends substantially perpendicularly from support arm 33, and a second contacting surface 38 that extends perpendicularly from first contacting surface 36, thus forming the preferable L-shape of lifting arms 31.

[00031] As shown in Figure 3, when lid 14 is in its closed position, first contacting surface 36 of lifting arm 31 is preferably located below and in contact with flange 23 of funnel 20. Lifting member 30 is carried by lid 14 and attached to the underside of lid 14 near hinge 15 joined to lid 14. As shown in Figs. 4-5, as the user flips open lid 14, lifting arms 31 pivot with lid 14 as it moves from the closed to a partially open and then a fully open position. First contacting surface 36 of lifting arms 31 (which is initially in contact with flange 23) lifts funnel 20 out of chamber 13. As the first contacting surface 36 of lifting arms 31 moves with lid 14 out of contact with flange 23, second contacting surface 38 of lifting arms 31, comes into contact with flange 23, further lifting funnel 20 out from the interior chamber 13 of the package 10, as shown in Figures 4-5. Once lid 14 is open, gripping member/funnel 20 has been sufficiently removed from the housing 12 and is presented and accessible to the user for removal of catheter 16.

[00032] Figures 7-9 show an alternative embodiment of the medical device package 110. In many respects, the housing and catheter are identical to the structure and function previously described in connection with the embodiment of

Figures 1-6. Accordingly, identical reference numerals are used for such identical or similar structures. Rather than using lifting arms to lift funnel 20 out from the chamber 13, in the embodiment of Figs. 7-9, an elongated, preferably single connector 130 may be used to lift funnel 20 out from chamber 13. Connector 130 may be attached to the underside of lid 14. Specifically, where connector 130 is a flexible strip or a strap of a polymeric or other material, one end 132 of connector of 130 is attached to the underside of lid 14. The other end 134 of connector 130 terminates in and/or is attached to an engagement member 136. As shown in Figures 7-8, in one embodiment, engagement member 136 may be in the form of a ring or collar. In one embodiment, collar 136 is located below lower funnel flange 22. The length of connector 130 may be selected such that when lid 14 moves from its closed position to its fully opened position, funnel 20 is fully presented and accessible outside of housing 12.

[00033] Figures 10-12 depict yet another embodiment of a medical device package 210 in accordance with the present disclosure. As seen in Figures 10-12, lid 214 is a bulbous or otherwise nonflat closure defining a hollow region 216 within lid 214. Extending from the underside of lid 214 into hollow interior region 216 and further into cavity 13 is a lifting member 230 that includes one or more claws or barbs 232 that extend downwardly from lifting member 230. In the embodiment of Figures 10-12, there are four claws/barbs 232 shown, but it will be understood that any number of claws/barbs 232 may be provided. It is preferred that the claws or barbs 232 be equally spaced from one another around the perimeter of lifting member 230.

[00034] During opening of lid 214 (by applying upward pressure to tab 217), claws/barbs 232 which are initially engaged to the underside of flange 23, lift funnel 20 out from the cavity 13. As lid 214 is flipped open, claws/barbs 232 pull catheter 16 out from the interior chamber 13 and present funnel 20 for removal by the user.

[00035] It should be understood that various changes and modifications to the described embodiments may be made without departing from the spirit and scope of invention(s) disclosed herein.

CLAIMS:

1. A catheter product comprising:

a) a package comprising an elongated housing having a closed proximal end and an open distal end and an openable lid attached to said housing for sealing the open distal end of said housing, said lid comprising a top surface and an underside, a tab, a hinge spaced from said tab at a location opposite of said tab, wherein said hinge joins said lid and said housing, and a pivotable lifting member that is movable with said lid during opening of said package, wherein said pivotable lifting member is located opposite of said tab and is attached to the underside of said lid; and

b) a catheter comprising a proximal insertable catheter tube and a distal gripping member, said gripping member comprising an engagement surface having at least two points of contact with said pivotable lifting member, wherein two of the points of contact on the engagement surface are located opposite from one another.

2. The catheter product of claim 1, wherein said top surface of said lid is flat.

3. The catheter product of claim 1, wherein said lid comprises a sealing element located on the underside of said lid.

4. The catheter product of claim 1, wherein said gripping member comprises a flange.

5. The catheter product of claim 4, wherein the gripping member includes a proximal end and a distal end, and wherein said flange is located at said distal end and comprises said engagement surface.

6. The catheter product of any one of claims 1-5, wherein said pivotable lifting member comprises one or more lifting arms.

7. The catheter product of claim 6, wherein each of the one or more lifting arms comprises a first contacting surface and a second contacting surface substantially

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perpendicular to said first contacting surface.

8. The catheter product of claim 6, wherein the one or more lifting arms includes two lifting arms that are parallel to one another.

9. The catheter product of any one of claims 1-8, wherein said gripping member comprises a substantially cylindrical member having a distal end and proximal end.

10. The catheter product of claim 9, wherein said engagement surface is at the distal end of said gripping member.

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FIG. 1

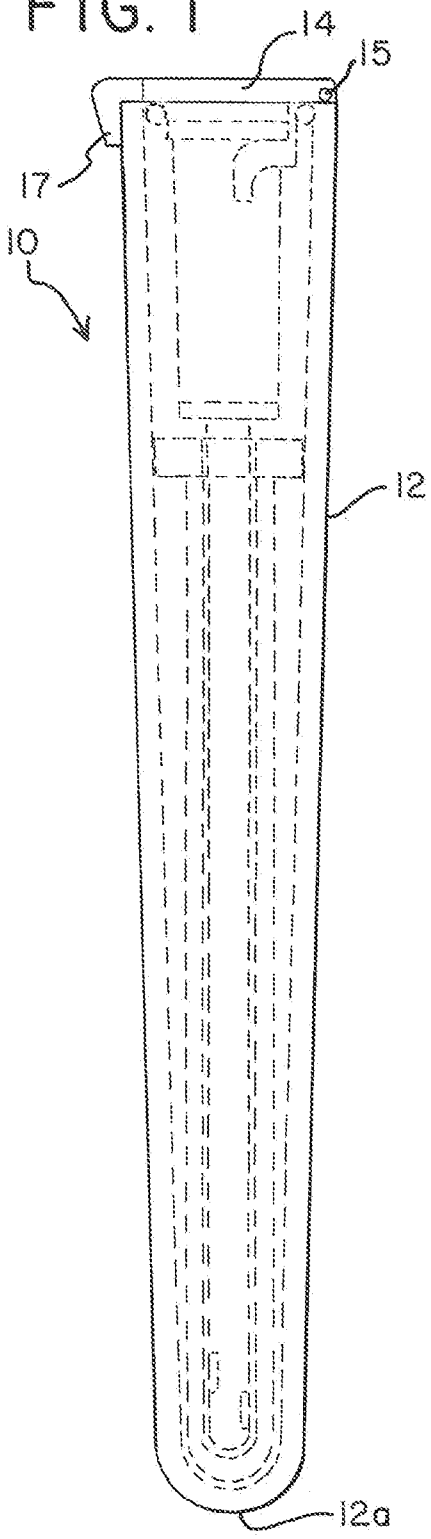


FIG. 2

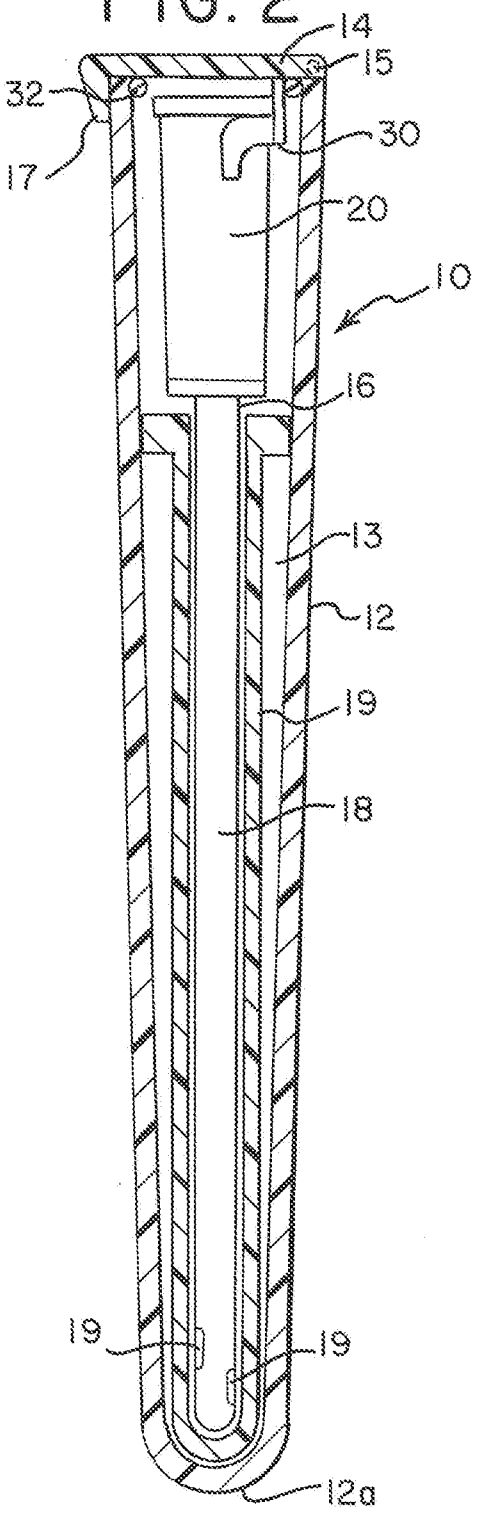


FIG. 3

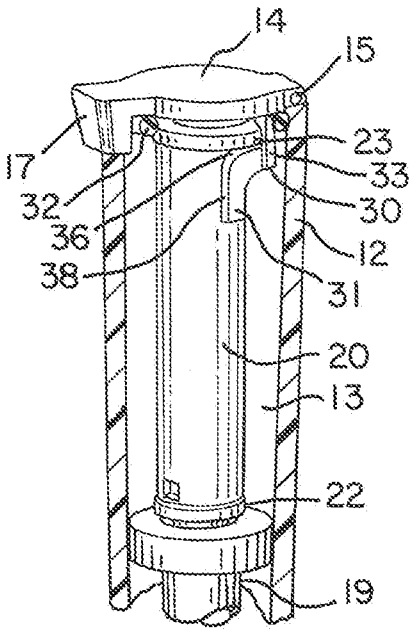


FIG. 4

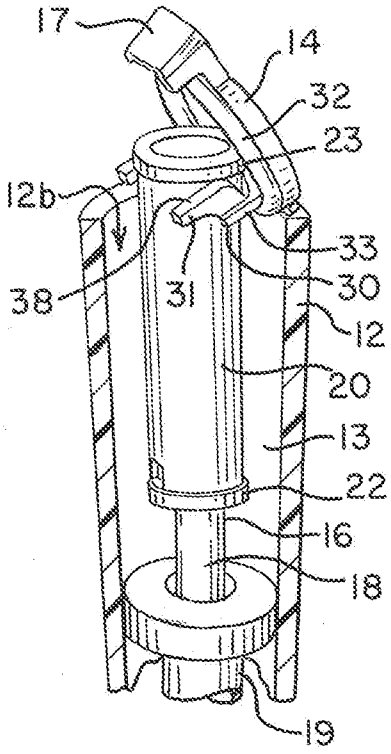


FIG. 5

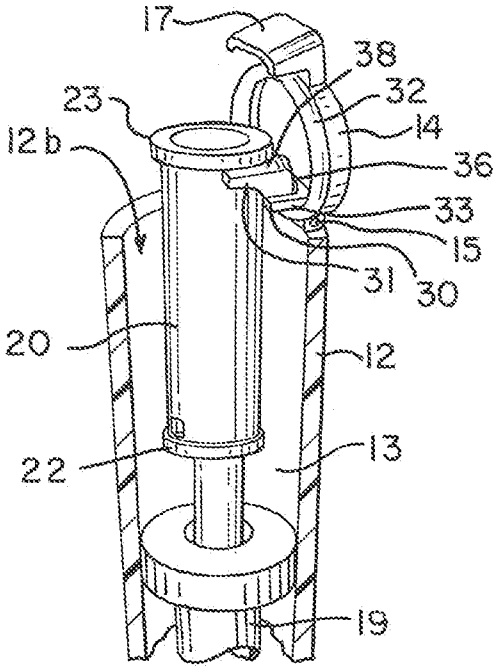


FIG. 6

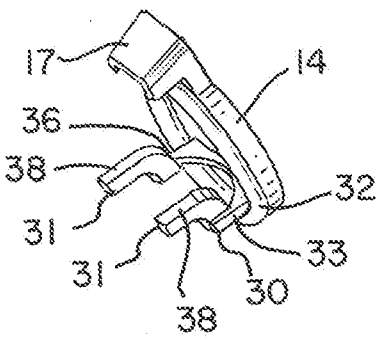


FIG. 7

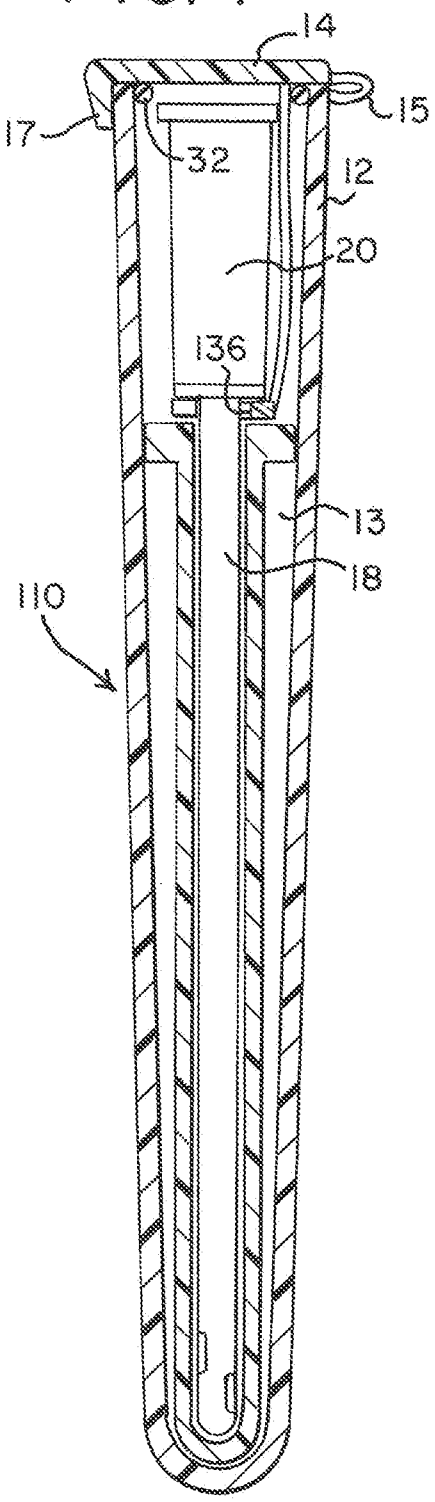


FIG. 8

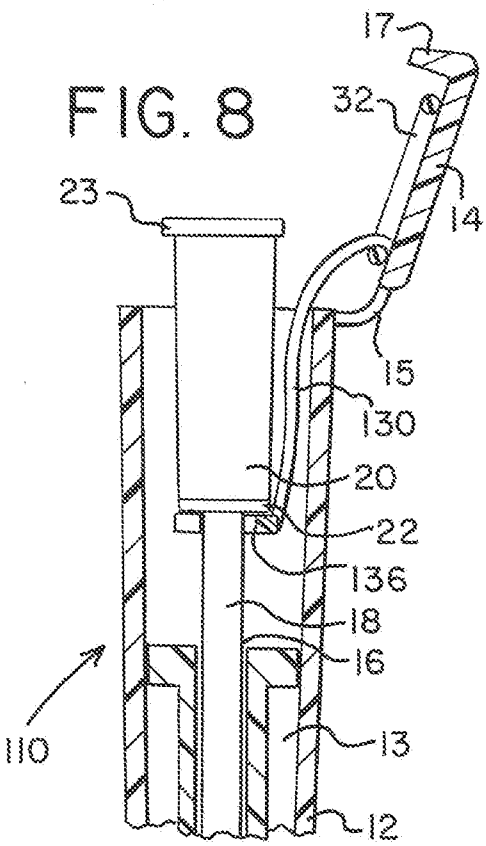


FIG. 9

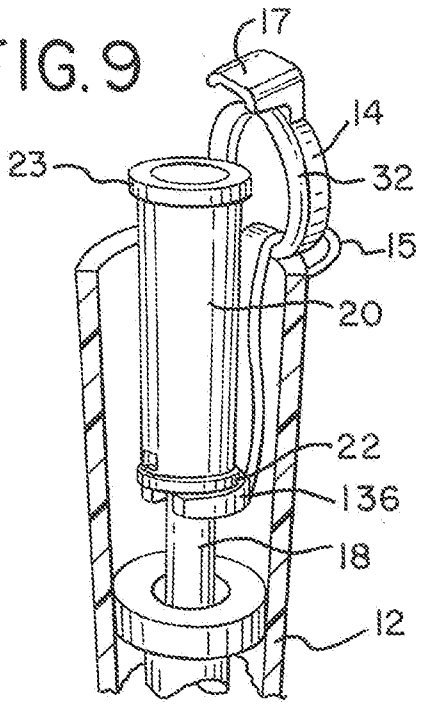


FIG. 10

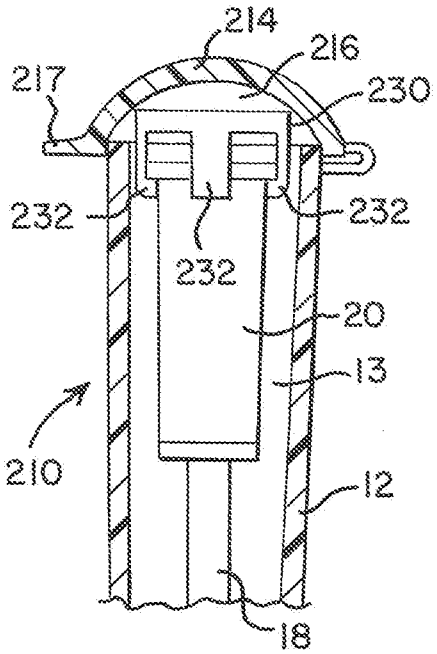


FIG. 11

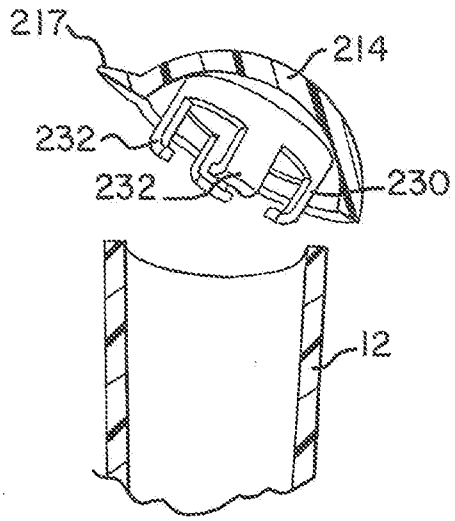
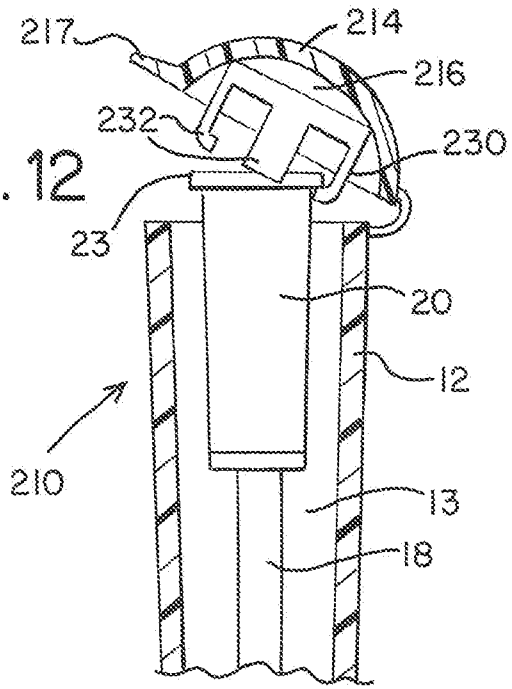
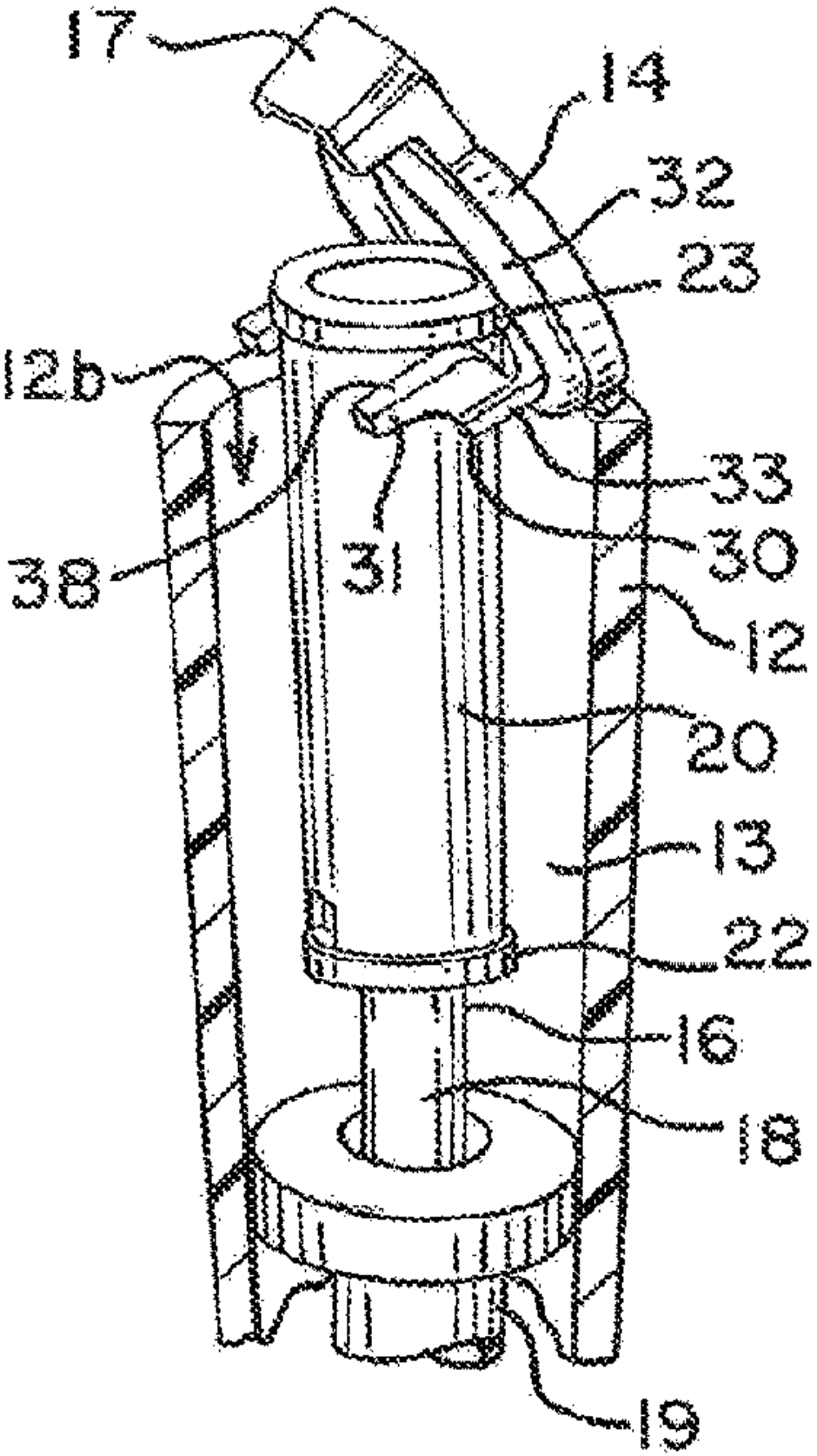


FIG. 12

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