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(54) Title: MEDICAL DEVICE PACKAGE WITH A TWIST CAP

(57) Abstract: A package for a medical device such as an intermittent catheter has a case and a cap connected by threads. The case includes a hollow tube which is closed at one end and open at the other. A shoulder is formed near one end of the case. Above the shoulder is a cylindrical ferrule that includes external threads. The cap has internal threads selectably engageable with the threads on the ferrule to form a liquid-tight seal between the cap and case when the cap is installed on the case.

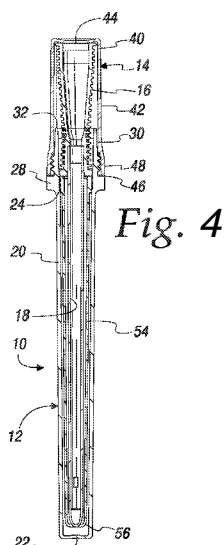


Fig. 4



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Medical Device Package with a Twist Cap

Cross-reference to Related Applications

The present application claims the benefit of and priority to: U.S. Provisional
5 Patent Application No. 62/326,355, filed April 22, 2016; U.S. Provisional
Patent Application No. 62/431,856, filed December 9, 2016; and U.S.
Provisional Patent Application No. 62/448,762, filed January 20, 2017, the
disclosures of all of which are hereby incorporated herein by reference.

Field of the Disclosure

10 **[0001]** This disclosure relates generally to packaging for medical devices
such as urinary catheters. More particularly, this disclosure relates to compact
catheters, such as urinary catheters, and the packaging, storing and
hydrating/lubricating of such catheters.

Background

15 **[0002]** Intermittent catheterization is a good option for many users who
suffer from various abnormalities of the urinary system. Very often, such
abnormalities of the urinary system are caused by a spinal cord injury which
may also result in diminished dexterity of the user.

20 **[0003]** Commonly, in intermittent catheterization, a single use,
individually packaged, sterile catheters are used. Catheters often include a
surface treatment that reduces friction to allow for easier and less traumatic
insertion into and through the user's urethra.

[0004] Regardless of whether a surface treatment is used or what type of
25 surface treatment is used, some type of package for the catheter is required.
In the past various kinds of packages have been used, including molded
containers of assorted sizes and shapes, bags and pouches made of plastic
or metal foil, and similar kinds of devices. While these prior art packages
generally accomplish the objective of protecting the catheter during transport,
30 storage and preparation for use, they suffer from disadvantages that range
from fundamental - the packages break open prematurely; to economic - the

package designs are wasteful of material and labor; to the annoying - the packages confuse users as to how to open them, or the packages tend to spill the hydrating medium upon opening. What is needed is a catheter package that is economical to manufacture and fill, reliable throughout its useful life, and simple and intuitive to use. It is also desirable to have a compact package which is: discreet to carry before use; discrete to dispose of in a waste bin; and intuitive and easy to open. Additional desirable features of the package include easy removal of the catheter from the case; easy reclosing of the case after use; hygienic use; and it should be discreet and clean to carry after use.

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Summary

[0005] In one aspect, the present disclosure includes a hard plastic packaging that holds a short, hydrophilic coated catheter. The catheter may have a length of, by way of example only, about 91 mm of exposed length. A funnel is attached to the catheter. The funnel may be, for example, about 40mm long. The hard packaging includes a case that enables the properties of vapor hydration through a hydration liner that separates a water chamber from the hydrophilic coated catheter. A twist cap is provided that attaches to the case to form a hygienic seal.

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[0006] In one embodiment of the present disclosure, the package case has a hollow plastic tube for receiving the catheter. The tube has a wall closed at one end by a bottom wall. Toward the opposite end of the wall there is a radially extending shoulder. Above the shoulder there is a cylindrical ferrule which is open at its end and defines a rim. External threads are formed on the outer surface of the ferrule. A cap may be removably attached to the ferrule by threads. The cap is selectably installed or removed from the case such that the cap covers or uncovers the open end of the ferrule, respectively. The cap may have a skirt which carries internal threads that engages with the mating threads on the ferrule.

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[0007] The internal wall of the cap has a seal bead extending radially inwardly just above the threads. The seal bead is engageable with the external wall of the ferrule. Alternatively, the external wall of the ferrule could have a seal bead extending radially outwardly just above the threads that is engageable with the internal wall of the cap. The seal beads are located

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above the threads instead of below them. This provides a manufacturing advantage in that the parts can be made narrower. Furthermore, there is no seal between the bottom of the cap and the shoulder on the case. That area is vented so an interior seal can be tested in a vacuum test.

- 5 **[0008]** The product is opened by twisting the cap one quarter turn. The opening torque is selected to be small enough to make the cap easy to open but great enough such that the cap will not release by itself or under normal handling conditions. Once the cap is off the case, it exposes the catheter which can then be picked up by the user. Once the cap is twisted open, the
- 10 sterile seal that existed between the case and cap is breached and the catheter is no longer contained in a sterile environment and is ready to use. During use of the catheter the cap may be temporarily stored on the bottom of the case where the cap may be attached by a snap fit. When the cap is removed and the catheter removed, the user can re-capture the catheter in
- 15 the case for disposal if they so wish. Once the cap is back into its original state the packaging retains its original sealing qualities (meaning it will not leak), with the tamper evident feature the only indicator that the product has been used.

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Brief Description of the Drawings

- [0009]** Fig. 1 is a perspective view of the catheter package of the disclosure, showing the cap installed on the case in a closed condition.
- [00010]** Fig. 2 is a perspective view of the catheter package of the disclosure, showing the cap removed from the case to expose a funnel portion of a catheter in the case.
- [00011]** Fig. 3 is a side elevation view of the package of Fig. 1.
- [00012]** Fig. 3A is a perspective view of another embodiment of a package assembly of the present disclosure.
- 30 **[00013]** Fig. 4 is a vertical section taken along line 4-4 of Fig. 1.
- [00014]** Fig. 5 is a section similar to Fig. 4 showing the cap and upper end of the case on an enlarged scale.

[00015] Fig. 6 is a section similar to Fig. 5 showing the engaging threads of the cap and ferrule on a further enlarged scale.

[00016] Fig. 6A is a perspective view showing a user connecting a urine collection bag to the catheter assembly.

5 [00017] Fig. 6B is a perspective view illustrating that the package assembly may be positioned in different orientations during connection to the urine collection bag.

[00018] Fig. 6C is a perspective view showing the urine collection bag attached to the funnel of the catheter.

10 [00019] Fig. 6D is a perspective view of the catheter being removed from the package assembly.

[00020] Fig. 7 is a perspective view of a hydration liner that can be used in the package of the present disclosure.

[00021] Fig. 8 is a top plan view of the hydration liner of Fig. 7.

15 [00022] Fig. 9 is a side elevation view of the hydration liner.

[00023] Fig. 10 is a longitudinal section through the hydration liner.

[00024] Fig. 11 is a perspective view of another embodiment of a hydration liner that can be used with the packages and assemblies of the present disclosure.

20 [00025] Fig. 12 is a side elevation view of the hydration liner of Fig. 11.

[00026] Fig. 13 is a perspective view of a second embodiment of the disclosure, showing a catheter package with a twist-off cap in a closed position.

25 [00027] Fig. 14 is a longitudinal section taken along line 14-14 of Fig. 13, with a catheter disposed within the package.

[00028] Fig. 15 is a section taken along line 15-15 of Fig. 14; and

[00029] Fig. 16 is a view similar to Fig. 14 showing a further alternate embodiment of a liner.

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Detailed Description of the Embodiments

[00030] The present disclosure is directed to packages for medical devices such as intermittent urinary catheters. The package is shown

generally at 10 in Figs. 1-3. The major components of the package are a case 12 and a cap 14. The cap is threadably engageable with the case such that a user can selectably remove the cap from the case and subsequently replace the cap on the case. Figs. 1 and 3 show the cap installed on the case so the package is in a closed condition. Fig. 2 shows the cap removed from the case and resting adjacent the case so the package is in an open condition. With the case open the funnel 16 of a catheter is visible protruding above the case. The tube portion of the catheter is within the case and thus not shown in Figs. 1-3 but the catheter tube 18 is visible in Figs. 4-6.

10 **[00031]** Fig. 3A illustrates another embodiment of the present disclosure wherein the top 140 of the package 110 has any of features disclosed herein but the bottom 144 of the package 142, which forms or defines the hollow tube that houses the catheter tube, is made from a flexible material. For example, the bottom 144 of the package 110 may be made from one or more
15 flexible polymeric and/or metal foil sheets. The sheet may be a laminate that includes both polymeric and metal layers. In the illustrated embodiment, the bottom 144 of the package 110 may be formed from a front sheet 146 and a back sheet 148 wherein the sheets 146 and 148 are sealed together along the side edges 150 and bottom edge 152. The top edges 154 of the sheets 146
20 and 148 may be attached to the top 140 of the package 142, by for example, adhesive or welding.

[00032] Details of the case 12 will now be described in connection with Figs. 4-6. The case includes a hollow tube 20 which terminates at an end wall 22 that closes the bottom of the tube 20. The tube 20 is shown here with a
25 generally rectangular cross-sectional shape. It will be understood the cross-sectional shape could alternately be cylindrical or otherwise. As can be best seen in Fig. 6 the upper end of the tube 20 has an internal rib 24 that protrudes radially inwardly from the internal wall surface of the tube 20. Just above the rib 24 is a radially inwardly protruding lip 26. The rib 24 and lip 26
30 cooperate to locate and support a hydration liner that will be described below in connection with Figs. 7-10.

[00033] The rib 24 and lip 26 are axially located in an area of the tube 20 where the external wall of the tube has a radially outwardly extending

shoulder 28. Above the shoulder 28 there is a cylindrical ferrule 30. The ferrule terminates at an open end which defines a rim 32. In some respects the ferrule 30 can be considered part of the upper end of the tube 20.

External threads 34 are formed on the external surface of the ferrule 30.

- 5 Above the threads 34 is an external bead 36. A similar internal bead 38 is formed on the internal wall of the ferrule. Internal bead is axially located about even with the bottom thread 34. The internal bead 38 may engage the bottom edge of the catheter funnel 16, as best seen in Figs. 5 and 6, to lightly secure the catheter in the case. This retaining feature will prevent inadvertent
10 removal of the catheter should an open case be turned upside down.

- [00034]** Details of the cap 14 will now be described in connection with Figs. 4-6. The cap includes a hollow shell 40 which has a longitudinal wall 42 and terminates at a top wall 44 that closes the top of the shell 40. The longitudinal wall 42 of the shell 40 is shown here with a generally rectangular
15 cross-sectional shape. It will be understood the cross-sectional shape could alternately be cylindrical or otherwise. The longitudinal wall 42 tapers radially outwardly toward its open bottom end 46. This tapered portion defines a skirt 48. On the interior wall of the shell, axially located about where the skirt 48 begins, there is an internal bead 50. This internal bead 50 cooperates with the
20 external bead 36 on the ferrule 30 to form a liquid-tight seal between an installed cap 14 and the case 12. This axial location of the cooperating beads 36 and 50 affords a more compact construction of the parts than would be the case if the beads were axially located near the open bottom end 46 of the shell 40.

- 25 **[00035]** The skirt 48 of the cap also has on its internal wall three threads 52. These threads are engageable with the threads 34 on the ferrule. As best seen in Fig. 2, the threads 52 are not continuous with one another. Instead, they are separate from one another and extend circumferentially approximately 90°. With this design a quarter turn of the cap will release or
30 engage the threads.

[00036] As shown in Figs. 5 and 6 and explained above, upon opening of the package 10, the distal end of the funnel 16 projects above the rim 32 and extends or projects out of the opening of the package so that the funnel 16

may be accessed and grasped by the user to remove the catheter 18 from the package. As also discussed above, the catheter 18 is retained within the package by, for example, an interaction between the internal bead or rib 38 of case 12 and flange of the funnel 16, until the user applies sufficient force to remove the catheter from the package. For example, axial movement of the catheter to move the flange past the rib 38. One of the benefits of this retention feature is that the engagement between the catheter 18 and the case 12 resists inadvertent removal of the catheter 18 so that the catheter 18 remains within the opened package 10 until the user actively removes the catheter 18 for use. In other words, the retention feature prevents the catheter 18 from inadvertently falling out of the package 10. For in conventional package assemblies wherein the catheter may inadvertently fall out of the package, the catheter is at risk of coming into contact with surfaces that may contaminate the catheter which can result in increasing the risk of infection. Thus, retaining the catheter 18 within the opened package 10 until it is ready for use can assist in reducing the risk of undesired contamination. This is particularly useful for individuals with limited dexterity and for those who have the habit of commencing the catheterization procedure by opening the package and then proceeding with the other steps of the catheterization procedure.

[00037] Referring to Figs. 6A-6D, there are some catheterization procedures that require the use of a urine collection bag 130 and/or the user prefers to use a urine collection bag 130. In catheterization procedures that use a urine collection bag 130, each of the features of the catheter extending beyond rim 32 the opening of the package 10 and the catheter retention feature may provide benefits to the user.

[00038] Turning first to the retaining feature, which retains the catheter 118 within the package 10 until the user applies sufficient force to the catheter 118 to remove it from the package 10. Referring to Fig. 6A, for illustrative purposes, there is shown a typical urine collection bag 130 that includes a urine collection reservoir 132, such as a plastic bag, a tube 134 for the passage of urine into the collection reservoir 132 and a connector 136 that connects the tube 134 to the funnel 120 of the catheter. In the illustrated

embodiment, the connector 136 may include a tapered end portion 138 which is sized to be fitted within the opening of the funnel 120 and be retained within the funnel 120 by a friction fit. Referring to Figs. 6A and 6B, to connect the urine collection bag 130 to the funnel 120, the connector 136 is inserted into
5 the funnel 120 and force is applied to securely fit the connector within the funnel.

[00039] In conventional packages already known in the field, the user first removes the catheter from the package and then attaches the urine collection bag to the funnel by grasping the funnel. While connecting the collection bag
10 to the funnel, the user tries to avoid contact with the catheter tube, so as to avoid contamination thereof. This may be difficult for users with limited dexterity and may lead to an increased risk of contamination.

[00040] Turning back to Figs. 6A-6D, because the catheter 118 is securely retained within the package 10 and the user does not have to be concerned
15 with the catheter 118 inadvertently falling out of the package, the user may grasp the outside of the package 10 (as opposed to only grasping the funnel) to connect the urine collection bag 130 without having to first remove the catheter from the package. The ability to be able to grip the outside of the package 10 provides a larger gripping surface for the user for the user to
20 manipulate the catheter 118 and also reduces the risk of contamination because the catheter 118 remains protected within the package 10 during connection of the connector 136 and the funnel 120. Furthermore, as shown in Fig. 6B, after opening of the catheter package 10, the package 10 may be held in virtually any orientation without the concern of the catheter 118 falling
25 out of the package 10. This can be beneficial to users with limited dexterity, especially those that would need to hold the package 10 upside down or with the opening in a downward orientation in order to connect the urine collection bag 130 to the catheter funnel 120.

[00041] Regarding the distal end of the funnel 120 extending above the rim
30 32 and out of the opening of the package 10, this feature allows the user to see the insertion of the connector 136 into the funnel 120 and visually inspect the connection. Additionally, after the connection has been made, the user may grasp the distal portion of the funnel 120 extending from the opening of

the package 10 to remove the catheter 118 from the package 10, as shown in Fig. 20.

[00042] Turning now to Figs. 7-10, a hydration liner is shown generally at 54. The hydration liner is sized to fit within the tube 20 of the case 12. The
5 liner 54 rests in the tube 20 of the case 20 with the catheter's tube portion 18 (but not the funnel portion) within the liner 54. The liner defines a space between the liner's exterior surface and the case's interior surface within which a hydration mechanism, such as liquid water may reside. This permits hydration of the surface treatment on the catheter.

10 **[00043]** The liner 54 may be a relatively rigid plastic such as LDPE or HDPE or other relevant materials. The Liner has a generally hollow tube 56. At its upper end there is a seat portion 58 of slightly increased outside diameter compared to the remainder of the tube 56. The seat portion 58 is sized to engage the internal wall of the tube 20. Such engagement is
15 enhanced by a pair of interference ribs 60 formed on the external surface of the seat 58. In addition to the ribs 60, the external surface of the seat 58 has at its top edge a crab claw seal 62. The seal 62 provides a moisture-tight seal against the interior wall of the tube 20. The walls of the liner tube 56 have formed therein one or more passages or windows 64. The windows will be
20 covered with a patch (not shown) of liquid impermeable/vapor permeable material such as, but not limited to, calcium carbonate. The patches will allow passage of water vapor (for hydration of the catheter) but will block passage of liquid water droplets. The patch might be heat sealed around the perimeter of the window.

25 **[00044]** Figs. 11 and 12 illustrate another embodiment of a hydration liner that is shown generally at 54a. Similar to hydration liner 54, hydration liner 54a is sized to fit within the case shown in Figs. 1-6 or any other suitable case. The liner 54a rests in the tube of the case with the catheter's tube portion positioned within the liner. The upper seat portion 58a may have a
30 substantially smooth surface that is sized to engage the internal wall of the package case, such as by a friction fit. The upper seat portion may be held in place by fiction fit, heat sealing, adhesive and/or any other suitable manner of attachment. In one embodiment, the substantially smooth surface of the seat

portion 58a may, optionally, include a detent or recess that engages, for example, a protruding lip that may be formed on the interior surface of the tube, such as the lip 26 shown in Fig. 6. The friction fit, heat sealing and/or adhesive between the internal wall of the package and the seat portion 58a may provide a moisture-tight seal or the seat portion 58a may include a seal such as crab the claw seal 62 described above. Similar to liner tube 54, the walls of the liner tube 56a may have formed therein one or more passages or windows 64a that may be covered with a liquid impermeable/vapor permeable material.

[00045] The liner tubes disclosed herein may have one or more mechanisms or features that assist in aligning the liner tube during the manufacturing process. For example, when the one or more windows 64, 64a are covered with a liquid impermeable/vapor permeable material, the alignment features and mechanisms may be used to orientate or align the liner tube during a process for attaching the liquid impermeable/vapor permeable material to the liner tube. In one embodiment, the alignment features assist in aligning and holding the liner tube during a heat sealing process for attaching a liquid impermeable/vapor permeable calcium carbonate material to the liner tube. Such aligning mechanisms and features may also be used to transfer and orientate the liner tube along a production line. Furthermore, the case may also include alignment features, which may correspond to the alignment features of the liner tube, that assist in aligning the liner tube and case relative to one another during assembly of the package so that the liner tube is in a desired orientation relative to the case. In one example, the alignment features may include one or more protrusions 55a located at the closed end 57a of the liner tube 56a. Additionally, the alignment features of the liner tube 56a may include flat surfaces located on the sides of liner tube 56a that, optionally, may be tapered. In the illustrated embodiment, liner tube 56a includes a flat, tapered surface 65a. In other examples, the liner tube 56a may include a plurality of flat surfaces. For instance, the liner tube 56a may include flat, tapered surfaces 65a on opposed sides of the tube. Furthermore, the seat 58a of the liner tube 56a may include alignment features that include

notches or cutouts 67a. It will be understood that the liner tubes may include one or more of above described alignment features.

[00046] This product is helpful as it addresses issues that many intermittent catheter users are experiencing, especially around the areas of hygiene after use, ease of removal of the catheter and the opening of the product. In these criteria the package of the present disclosure is superior to currently available products, especially in discreet female intermittent catheters. For example, a typical intermittent catheter user is a multiple sclerosis sufferer. Multiple sclerosis sufferers have varying levels of dexterity and grip strength which can also vary from day to day in some patients. Having an easy to open package is reassuring that they will always be able to void their bladder confidently.

[00047] The hygienic re-capture of the catheter into its packaging is also an important feature of the packaging that other catheters do not fully address; with the twist cap concept of the present disclosure the catheter can be safely captured after use without fears of spills. Our catheter funnel, unlike many prior art funnels, is also able to be used with drainage bags made by a variety of manufacturers. It is also noted that the case's opening and closing mechanism is familiar to everyone used to dealing with everyday closures. Further, the amount of the funnel presented to the user makes it easy to grasp.

[00048] Among the advantages of the present disclosure are: intuitiveness to open; ease of opening; ease of removal of the catheter from the case; ease of closing of the case after use; discretion and clean to carry after use; and hygienic use.

[00049] Figs. 13 - 15 illustrate a further alternate embodiment of the catheter package according to the present disclosure. This package, shown generally at 84, includes a container 86 and a cap 88. The cap 88 in this embodiment is a twist cap that is threadably connectable to the container 86 and is selectably movable by a user between a closed position, shown in Figs. 13 and 14, and an open position (not shown) wherein the cap 88 is removed from the container 86.

[00050] The container 86 in this embodiment is a three-part structure including a hydration liner 54, a case 90, and a sleeve 92. Each of these three parts is basically an elongated, hollow tube, open at the top end, with the open top end being selectably openable and closable by the cap 88. The
5 hydration liner 54 fits within the case 90 which in turn fits within the sleeve 92, as seen in Figs. 14 and 15. The structure and function of the hydration liner 54 is the same as in Figs. 7 - 10 so the description of the hydration liner 54 will not be repeated here.

[00051] Turning now to the details of the case 90, the case includes a
10 hollow tube 94 which terminates at an end wall 96 that closes the bottom of the tube 94. The tube 94 is shown here with a generally rectangular cross-sectional shape. It will be understood the cross-sectional shape could alternately be cylindrical or otherwise. The upper end of the tube 94 has a radially outwardly extending shoulder 98. Above the shoulder 98 there is a
15 cylindrical ferrule 100. The ferrule terminates at an open end which defines a rim 102. In some respects the ferrule 100 can be considered part of the upper end of the tube 94 except the ferrule is cylindrical, not rectangular. External threads 104 are formed on the external surface of the ferrule 100. The internal surface of the ferrule 100 is engageable with the bottom of the funnel 14 in a
20 press fit while the internal surface of the tube 94 at the location opposite the shoulder 98 engages the seat 32 of the hydration liner 24 in a press fit.

[00052] The sleeve 92 is essentially an enlarged version of the case 90 but without a radial shoulder or cylindrical ferrule. As such the sleeve has a hollow tube 106 that terminates at the bottom at an inwardly directed
25 flange 108. The upper end of the tube 106 has a notch 110 adjacent its top land 112. The notch 110 receives the shoulder 98 of the case 90. The top land 112 has an outer contour that is essentially the same as that shown at 114 in Fig. 7.

[00053] Details of the cap 88 will now be described. The cap includes a
30 hollow shell which has a longitudinal wall 116 and terminates at a top wall 118 that closes the top of the shell. The longitudinal wall 116 of the shell is shown here with a generally rectangular cross-sectional shape on the exterior surface. It will be understood the external cross-sectional shape could

alternately be cylindrical or otherwise so long as it matches the cross-sectional shape of the top land 112 of the sleeve 92. The longitudinal wall 116 of the cap has on its internal surface three helical threads 120. These threads are engageable with the threads 104 on the ferrule.

5 **[00054]** As best seen in Fig. 13, the matching outer contours of the container 86 and cap 88 provides a smooth, continuous shape for the package 84 as a whole. There are no discontinuities, protrusions or interruptions of any kind in the outside of the package, thereby affording an aesthetically pleasing appearance to the package. For certain users of
10 intermittent catheters this provides an extra measure of comfort, security and discretion.

[00055] An alternate version of a liner 54A is shown in Fig. 16. The liner is similar to the liner of Figs 7 and 14 except that the length of the hollow tube 56 (shown in Fig. 7) is truncated when compared to the hollow tube 56 of Fig.
15 7. This truncated version of the liner 54A may be used where direct hydration of the catheter tubing with liquid water is utilized. The upper portion of the seat of the liner 54A will seal against the interior surface of the tube 20. The catheter tubing will seal against the bottom of the funnel. After removal of the catheter if the case is laid on its side the liner 56A will prevent leakage of
20 hydration water out the open top of the case. This is because the inside diameter of liner 54A is small enough to prevent drainage of the small amount of water used for hydration. That is, with the package on its side, there is not enough hydration water to flood the lowermost wall of a horizontally disposed tube to a depth that would leak out through the center of the liner 54A. Thus,
25 the liner 54A serves as a plug to retain hydration water even when the catheter is not in the package.

[00056] It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modification can be made without
30 departing from the spirit and scope of the invention disclosed herein.

Claims:

1. A medical device package, comprising:
a case having a hollow tube which is closed at one end, the other end of the tube extending to a ferrule which has a wall with internal and external surfaces and an open end;
5 a cap having a longitudinal wall and a top wall, the longitudinal wall having internal and external surfaces; and
threads formed on one of the internal and external surfaces of the ferrule and the other of the internal and external surfaces of the cap's longitudinal wall, the threads being releasably engageable with one another to
10 permit selectable installation and removal of the cap on the case.
2. The medical device package of claim 1 wherein the threads are formed on the external surface of the ferrule and the internal surface of the cap.
3. The medical device package of claim 1 further comprising a first bead formed on the ferrule between the threads on the ferrule and the open end thereof, and a second bead formed on the cap between the threads on the cap and the top wall of the cap, the first and second beads cooperating with
5 one another to form a liquid-tight seal between an installed cap and the case.
4. The medical device package of claim 1 further comprising a hydration liner sized to fit within the hollow tube of the case, so as to define a space between the liner's exterior surface and the tube's interior surface within which a hydration mechanism may reside to permit hydration of the surface
5 treatment of a catheter.
5. The medical device package of claim 1 wherein the closed end of the hollow tube and the cap are releasably engageable with one another.
6. The medical device of claim 5 wherein the closed end of the hollow tube and the cap are releasably engageable in a snap fit.

7. The medical device package of any one of claims 1-6 wherein at least a portion of the hollow tube is formed from flexible material.
8. An assembly of a catheter and a package therefor, comprising:
a case having a closed end and an open end that has an opening defined by a terminal a rim;
a cap being selectably movable between an open position wherein
5 access is provided to the opening at the open end of the case and a closed position wherein the cap seals the opening at the open end of the case; and
a catheter contained within the case and being releasably engaged with an interior surface of the case so as to releasably retain the catheter in the case such that when the cap is in the open position, the catheter is
10 releasably retained in the case so as to resist inadvertent removal of the catheter.
9. The assembly of any claim 8 wherein the catheter includes a catheter tube and a funnel wherein the funnel is releasably engaged with the interior surface of the case.
10. The assembly of claim 9 wherein the funnel includes a flange that is releasably engaged with a rib on the interior surface of the case.
11. The assembly of any one of claims 8-10 wherein a distal portion of the catheter extends axially beyond the rim and is exposed when the cap is in the opened position.
12. A medical device package, comprising:
a container having an open end for receiving a medical device, said open end defining an outer contour;
a cap engageable with the open end of the container and movable
5 between an open position, wherein access is provided to the open end of the

container, and a closed position, wherein the cap prevents access to the open end of the container, the cap having an outer contour which matches the outer contour of the container to provide a continuous outer surface of the package at the junction of the cap and container when the cap is in the closed position.

13. The medical device package of claim 12 wherein the container comprises:

a sleeve having a hollow tube which includes said open end defining the outer contour of the container; and

5 a case having a hollow tube disposed at least partially within the sleeve.

14. The medical device package of claim 13 wherein the container further comprises:

a hydration liner having a hollow tube disposed at least partially within the case.

15. The medical device package of claim 12 further comprising a hinge connected to the container and to the cap, the hinge permitting selectable movement of the cap between the open position and the closed position.

16. The medical device package of claim 12 further comprising threads formed on the container and mating threads formed on the cap, the threads permitting selectable movement of the cap between the open position and the closed position.

17. A medical device package, comprising:

a sleeve having a hollow tube terminating at an open end, said open end defining an outer contour of the sleeve;

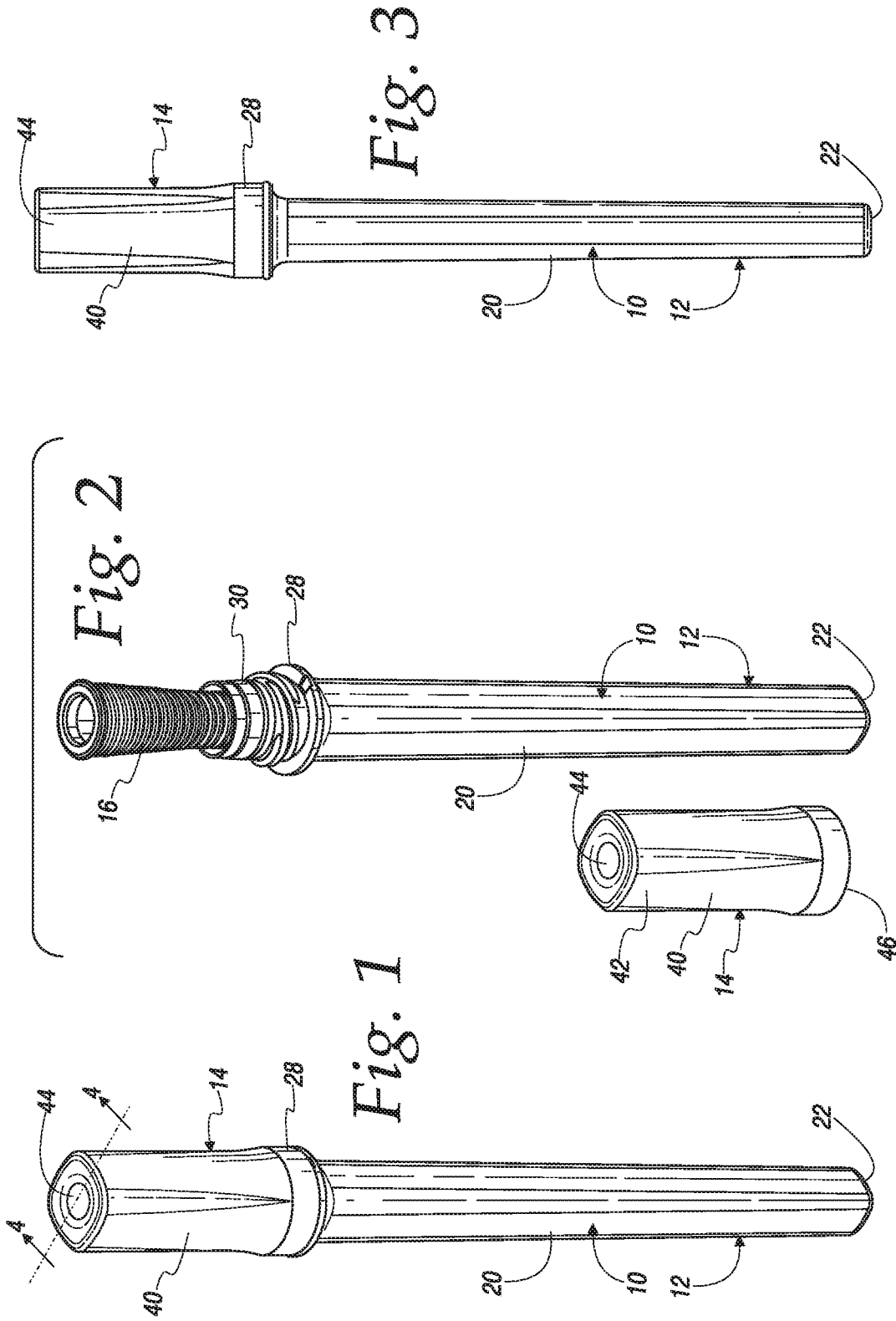
5 a case having a hollow tube which is disposed at least partially within the sleeve, the hollow tube of the case having an open end for receiving a medical device;

a cap engageable with the open end of the case and movable between an open position, wherein access is provided to the open end of the case, and a closed position, wherein the cap prevents access to the open end of the case, the cap having an outer contour which matches the outer contour of the sleeve to provide a continuous outer surface of the package at the junction of the cap and sleeve when the cap is in the closed position.

18. The medical device package of claim 17 further comprising a hydration liner having a hollow tube disposed at least partially within the case.

19. The medical device package of claim 17 further comprising a hinge connected to the case and to the cap, the hinge permitting selectable movement of the cap between the open position and the closed position.

20. The medical device package of claim 17 further comprising threads formed on the case and mating threads formed on the cap, the threads permitting selectable movement of the cap between the open position and the closed position.



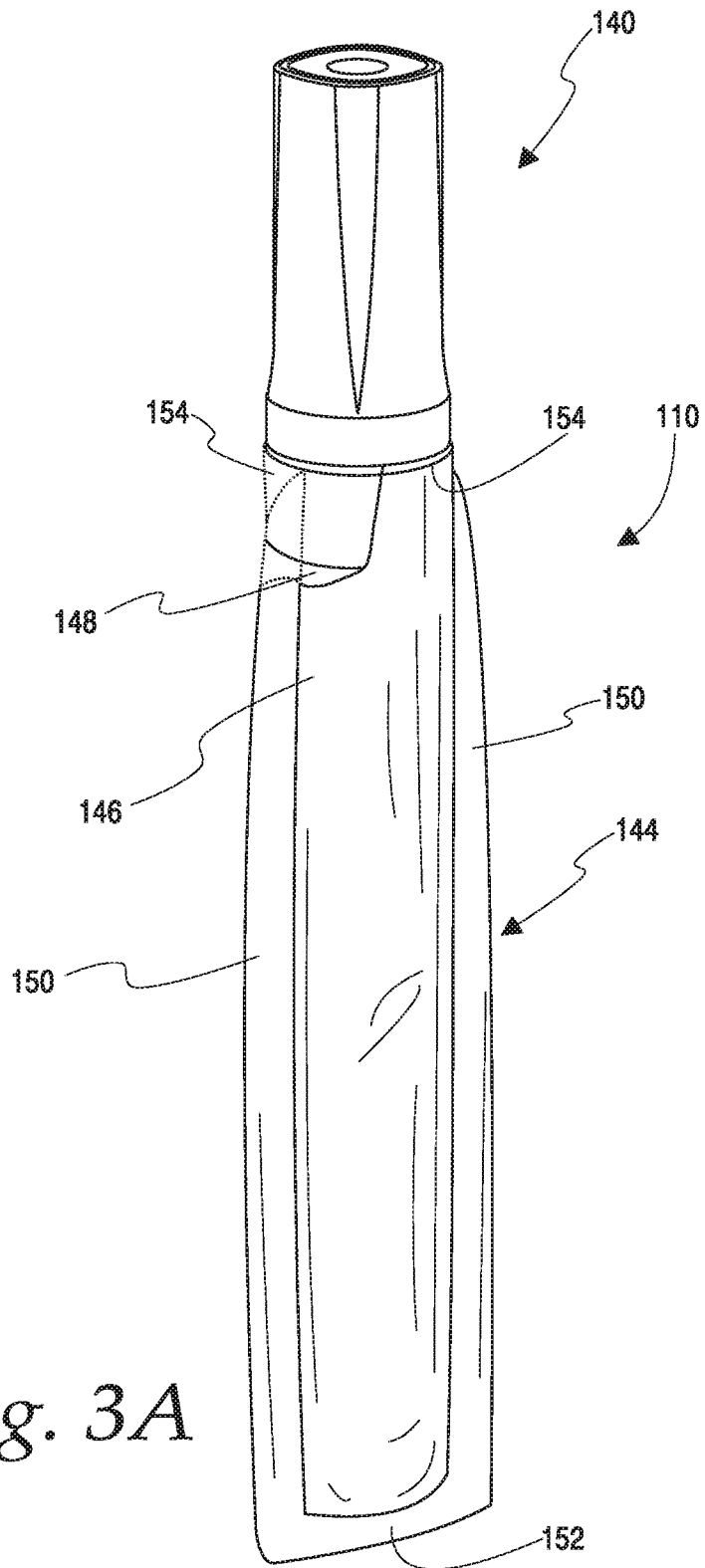
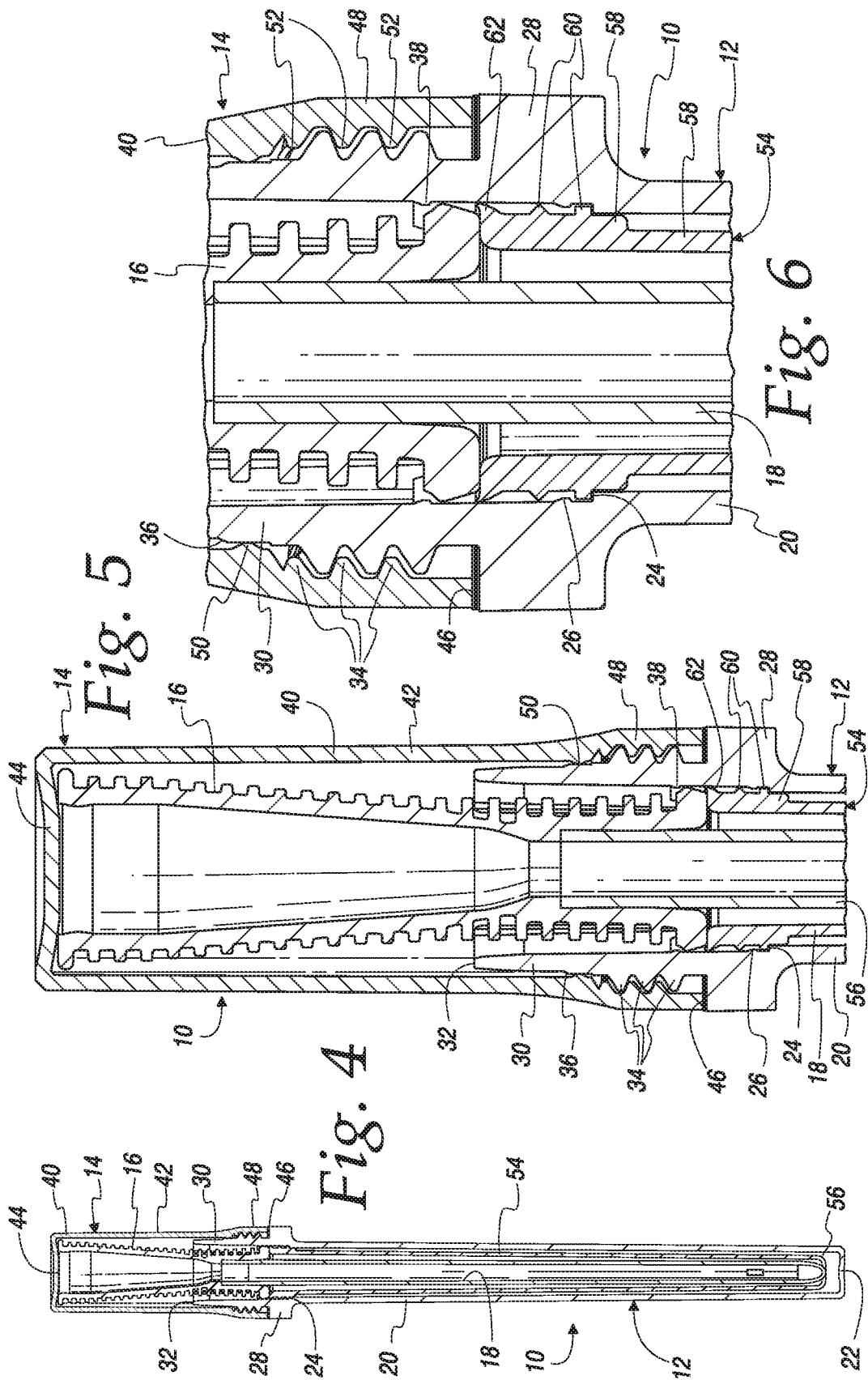
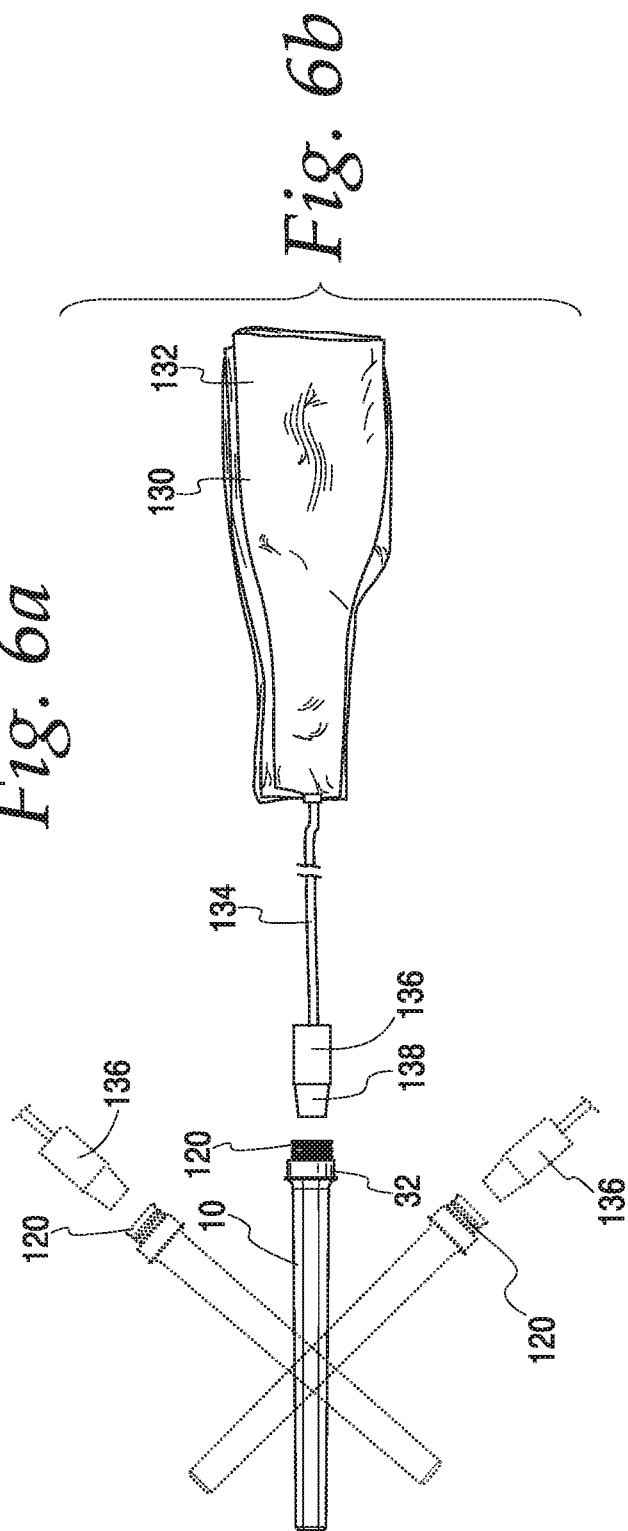
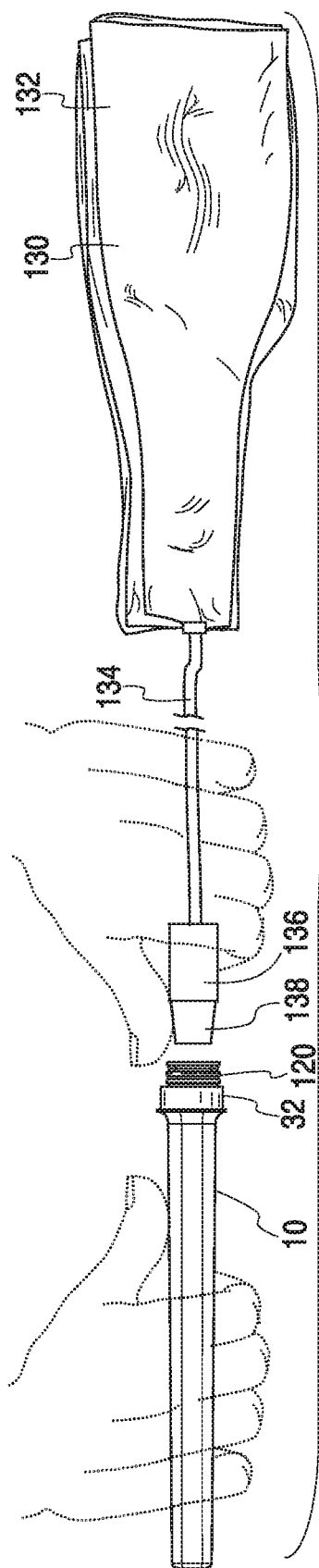
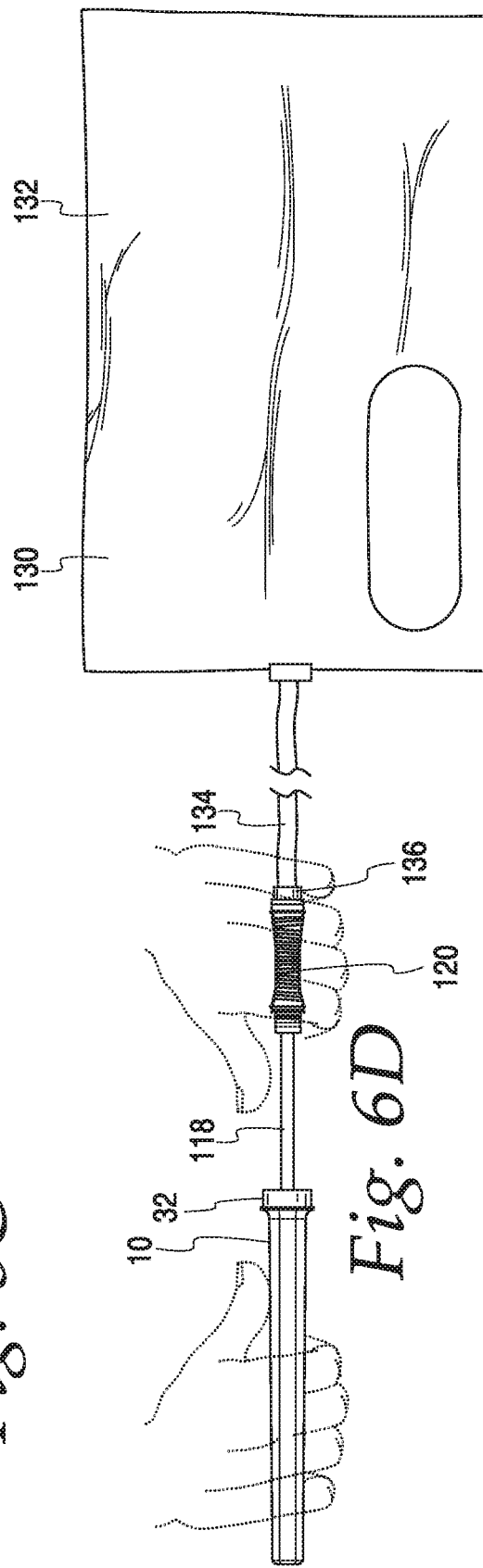
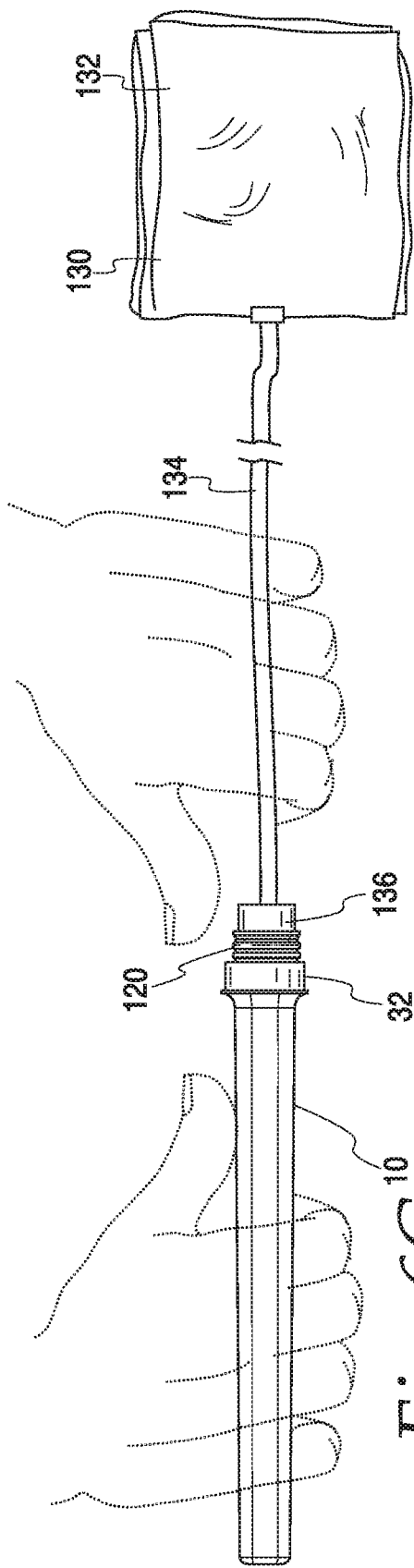
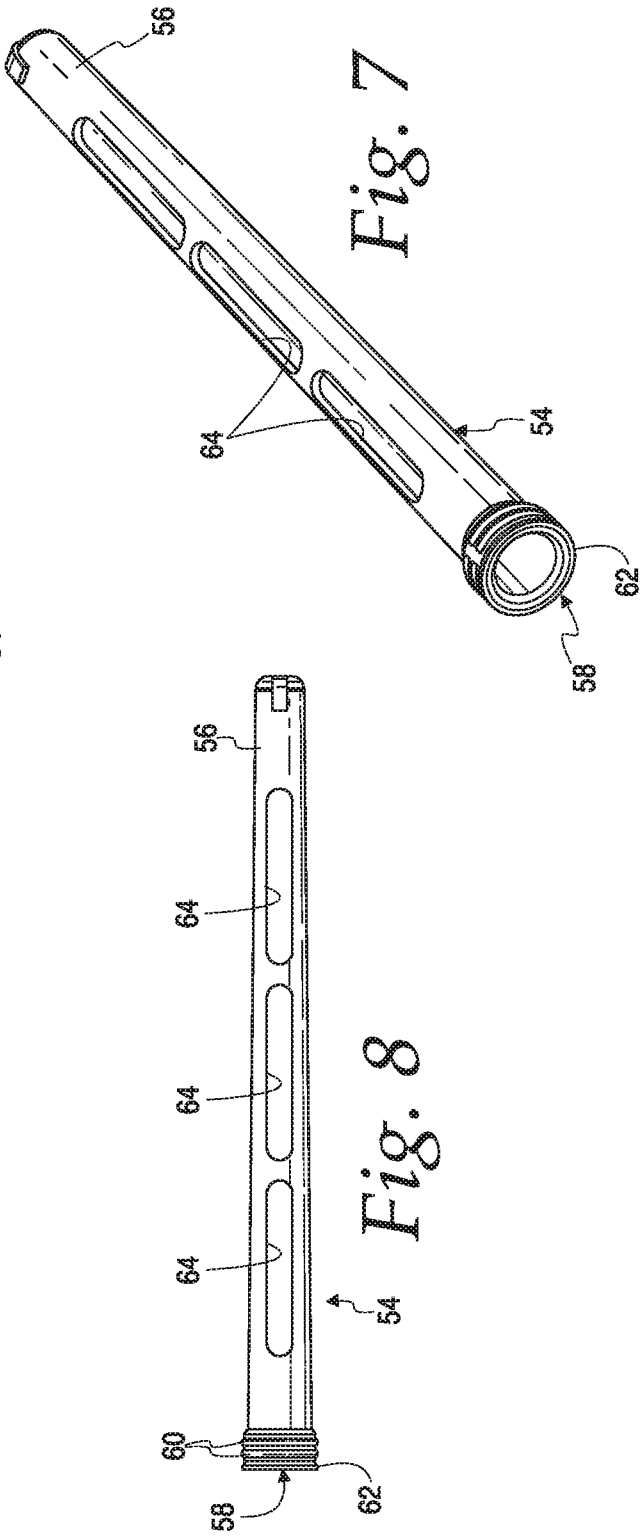
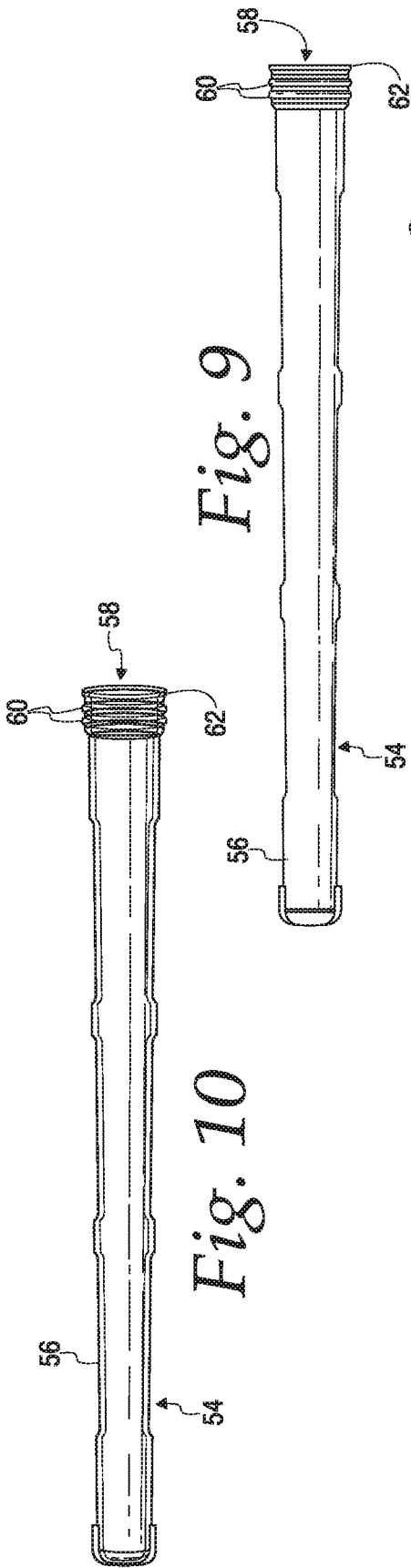


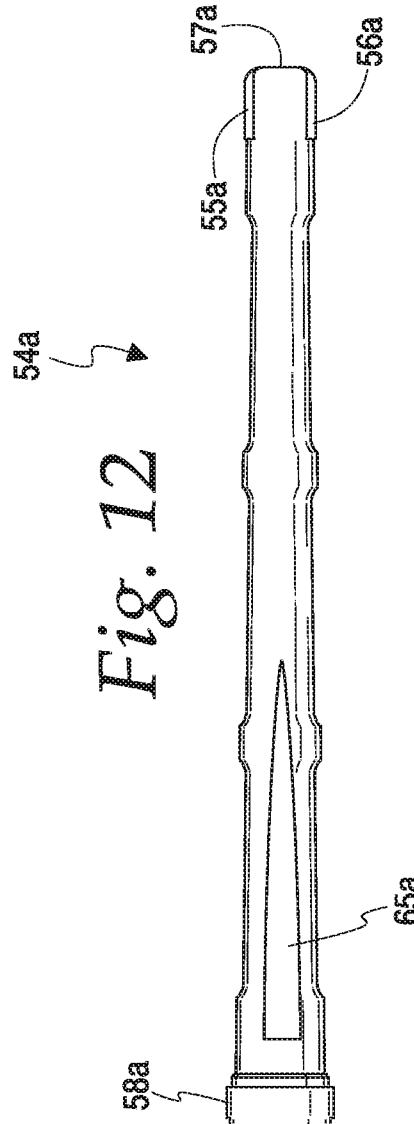
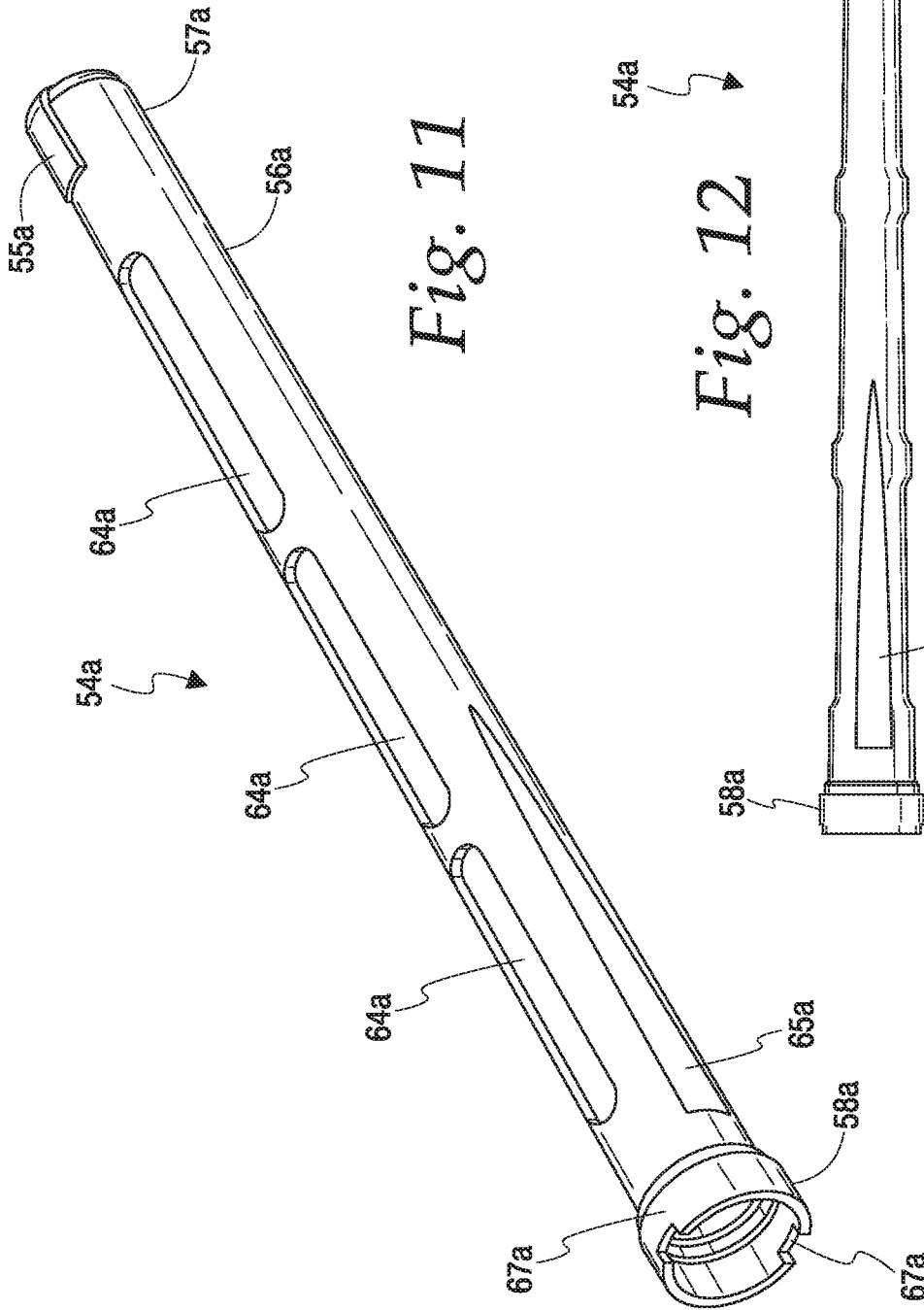
Fig. 3A

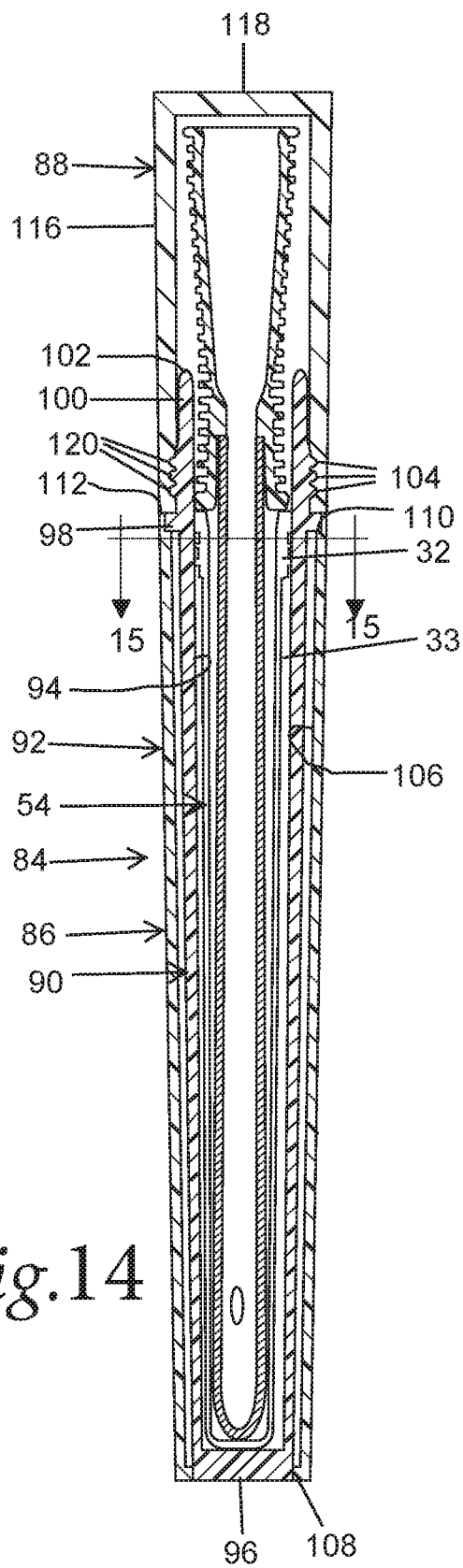
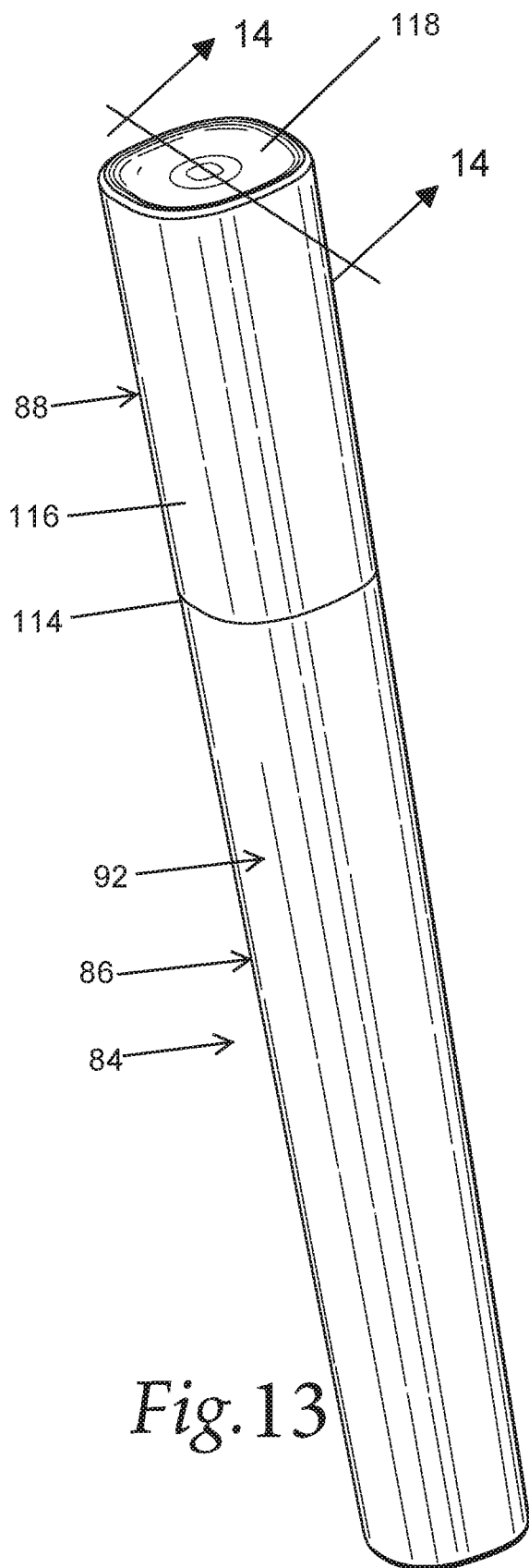












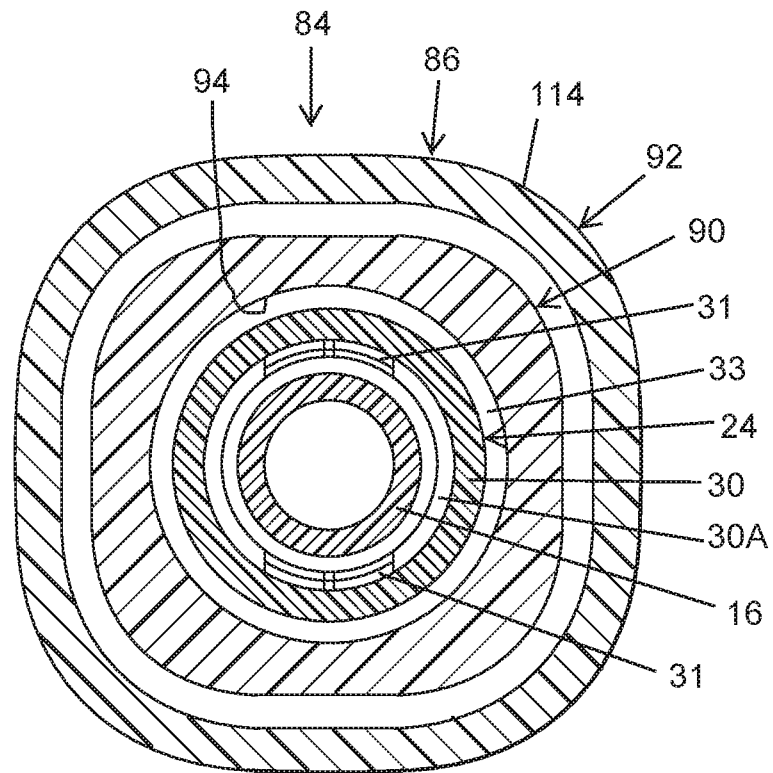


Fig. 15

10 / 10

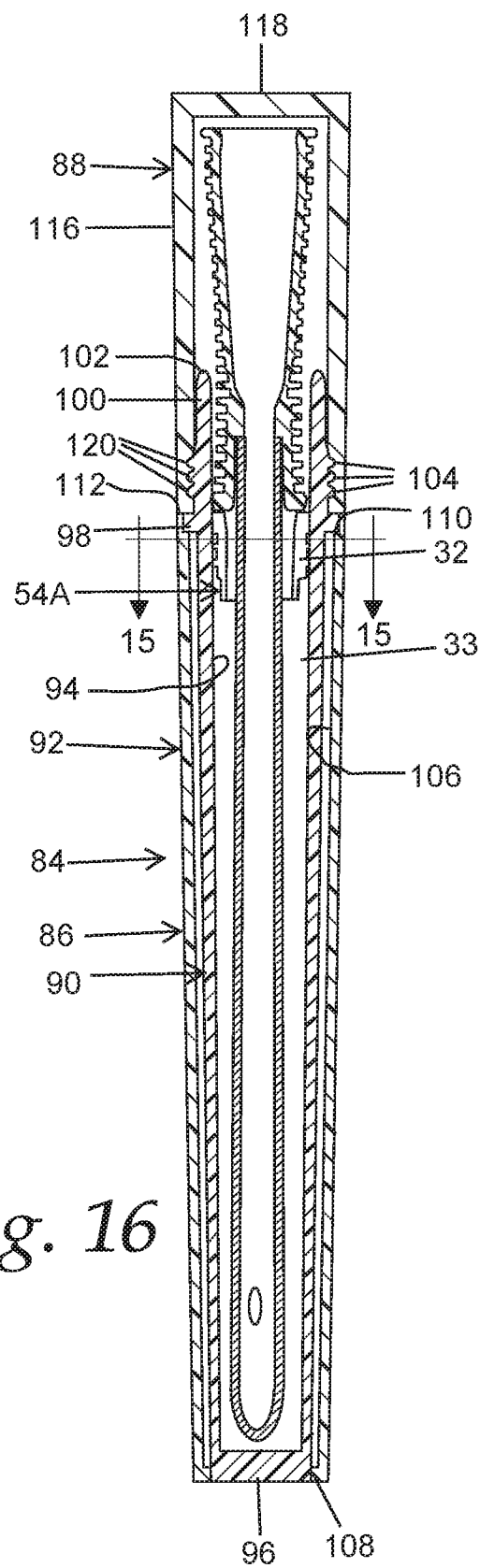


Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/028937

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos. :

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. :
1-7 , 12-20

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2017/028937

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M25/00

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	wo 2012/060699 AI (CURAN B V [NL] ; VAN GRONINGEN DAVID [NL] ; VAN VELTHOVEN AD [NL]) 10 May 2012 (2012-05-10)	1, 2, 5, 6,
Y	page 4, line 27 - line 31	12, 13,
	page 6, line 13 - line 19; figures 1, 2c	16, 17
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X	wo 2007/082540 AI (COLOPLAST AS [DK] ; TANGH0EJ ALLAN [DK])	1-3, 12,
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Y	page 9, line 23 - line 25	17, 18
	page 10, line 30 - page 11, line 15;	
	figures 1a, 9	19, 20

	-/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 June 2017

Date of mailing of the international search report

21/08/2017

Name and mailing address of the ISA/

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Authorized officer

Berndorfer, Urs

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/028937

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	paragraphs [0017] - [0023], [0028]; figure 1 -----	7
X	W0 2016/044379 A2 (HOLLISTER INC [US]) 24 March 2016 (2016-03-24)	12, 13
Y	paragraphs [0019], [0025] - [0026]; figures 1-2 -----	4
Y	W0 2015/184365 A1 (HOLLISTER INC [US]) 3 December 2015 (2015-12-03) paragraphs [0076], [0082] -----	3
X	W0 03/092779 A1 (ASTRA TECH AB [SE] ; NESTENBORG DANIEL [SE] ; SCHMID ANDREA [SE]) 13 November 2003 (2003-11-13)	12, 15
Y	figures 1-3 -----	19

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/028937

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International application No

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7, 12-20

A medical device package, comprising a container having an open end for receiving a medical device, said open end defining an outer contour, a cap engageable with the open end of the container and movable between an open position, wherein access is provided to the open end of the container, and a closed position, wherein the cap prevents access to the open end of the container as well as said cap having an outer contour matching the outer contour of said container.

2. claims: 8-11

A medical device package, comprising a container having an open end for receiving a medical device, said open end defining an outer contour, a cap engageable with the open end of the container and movable between an open position, wherein access is provided to the open end of the container, and a closed position, wherein the cap prevents access to the open end of the container as well as a catheter contained within the case and being releasably engaged with an interior surface of the case.
