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Solomon et al.

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(54) **METHODS FOR DISINFECTING MEDICAL CONNECTORS**

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(65) **Prior Publication Data**

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Related U.S. Application Data

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(60) Provisional application No. 60/880,541, filed on Jan. 16, 2007.

(51) **Int. Cl.**

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A61M 5/14 (2006.01)
A61M 25/16 (2006.01)

A61M 25/18 (2006.01)

A61M 39/00 (2006.01)

A61M 39/10 (2006.01)

(52) **U.S. Cl.** **604/500**; 604/256; 604/533; 604/905

(58) **Field of Classification Search** 604/905, 604/29, 283, 256, 403, 533

See application file for complete search history.

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Primary Examiner — Kevin C Sirmons

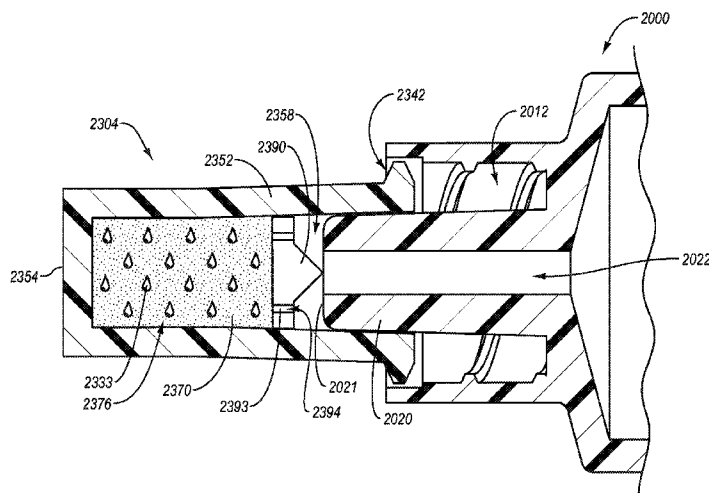
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(57) **ABSTRACT**

Caps can be used to cover and sterilize the male luer of a medical connector. Some caps can create a seal with the male luer to prevent antiseptic from entering a lumen of the male luer. A biasing element can aid in creating or maintaining the seal.

10 Claims, 44 Drawing Sheets



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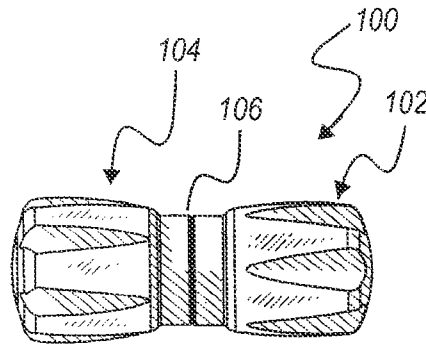


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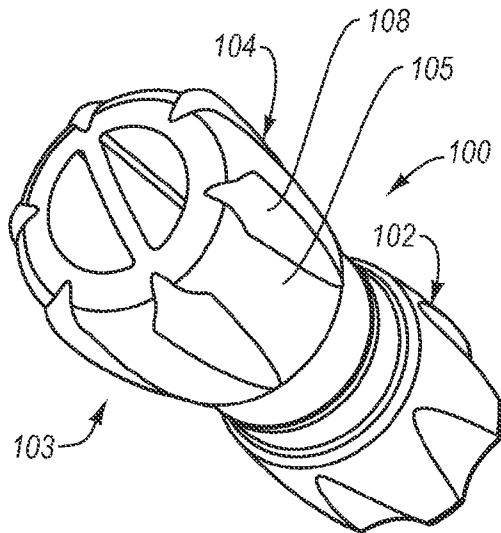


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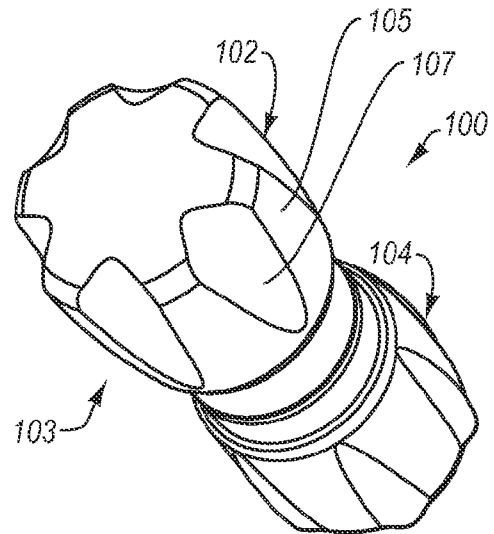


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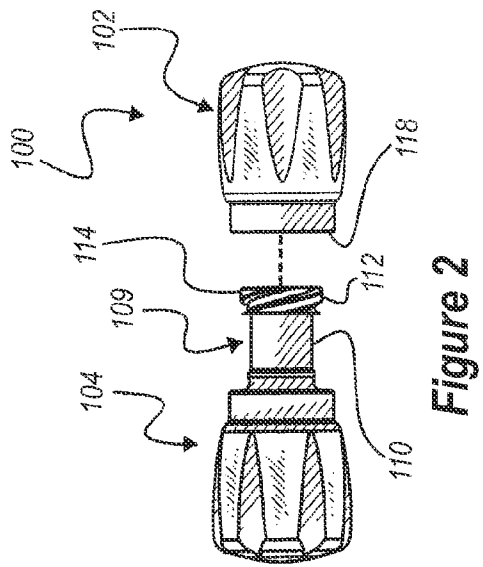


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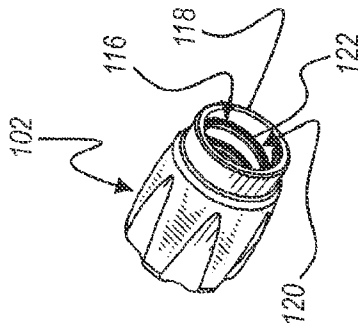


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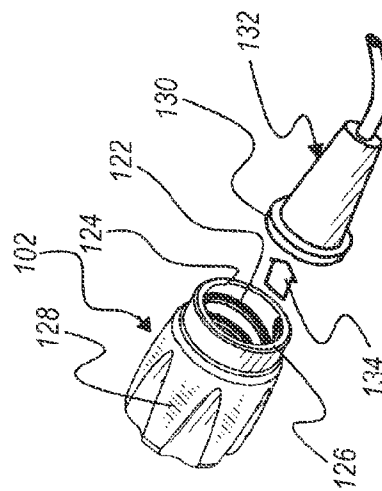


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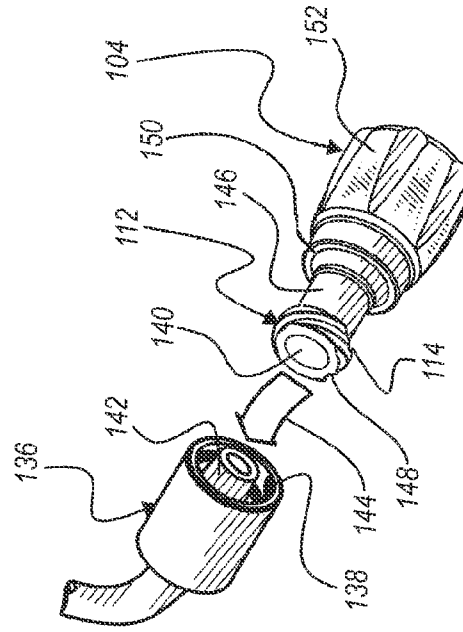


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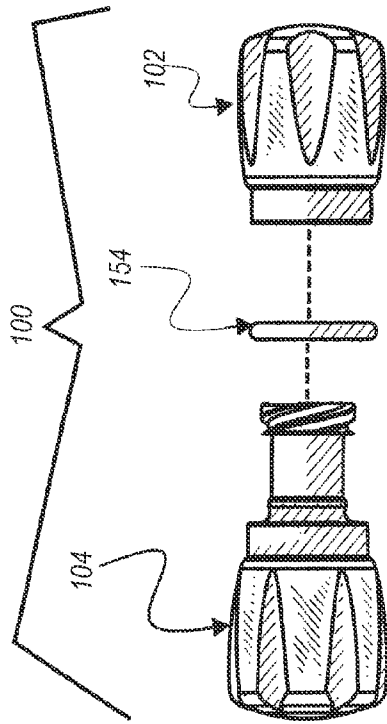


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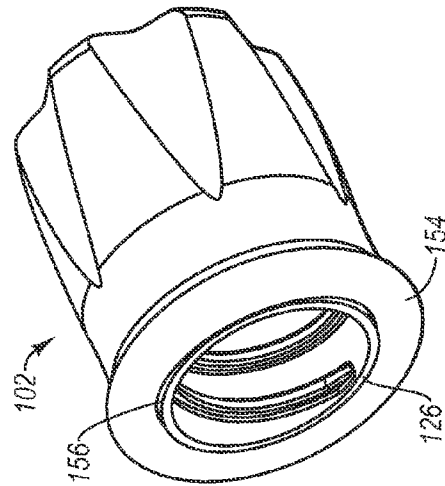


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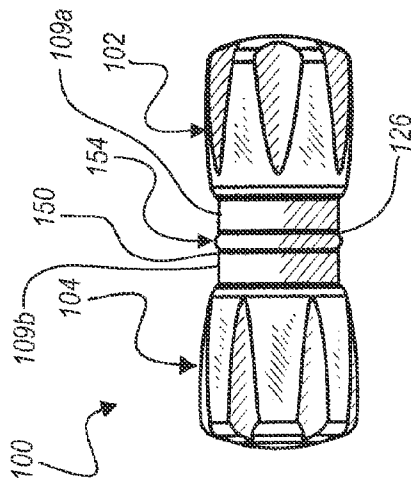


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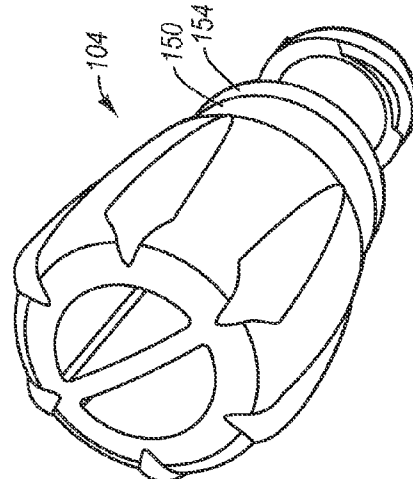


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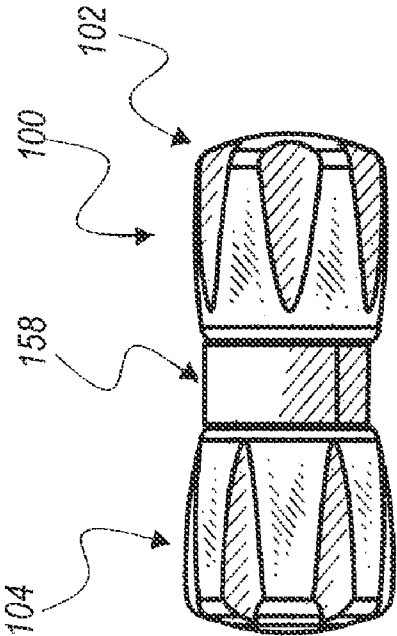


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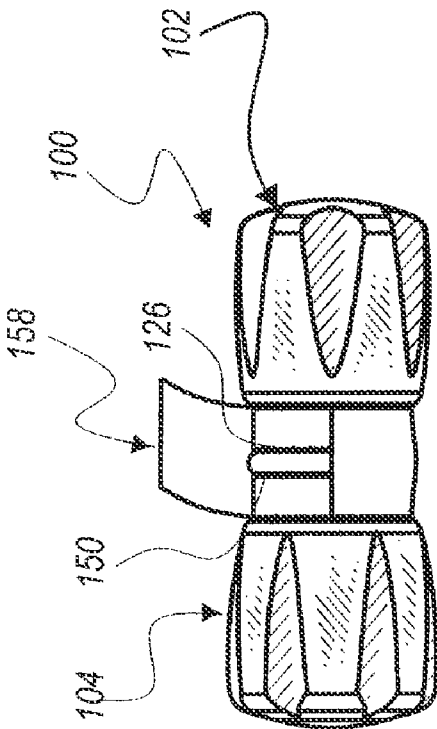


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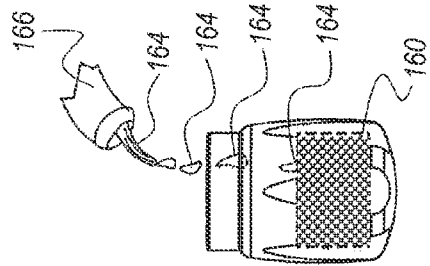


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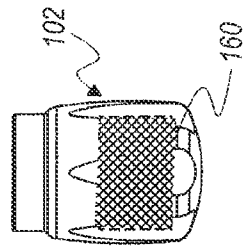


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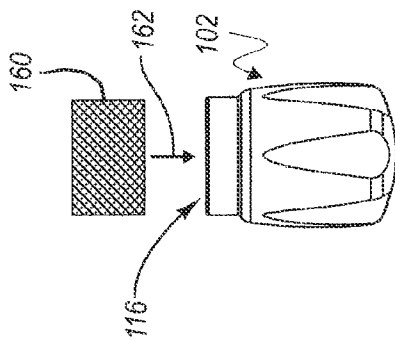


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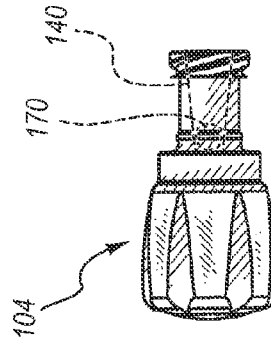


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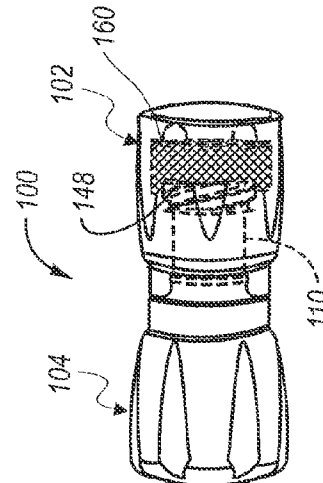


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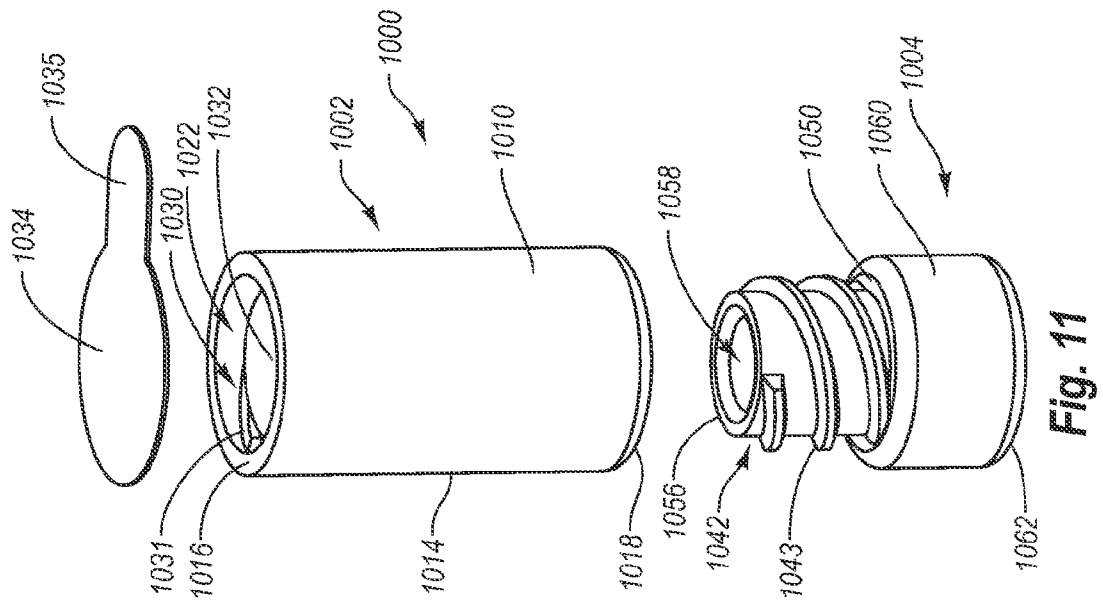


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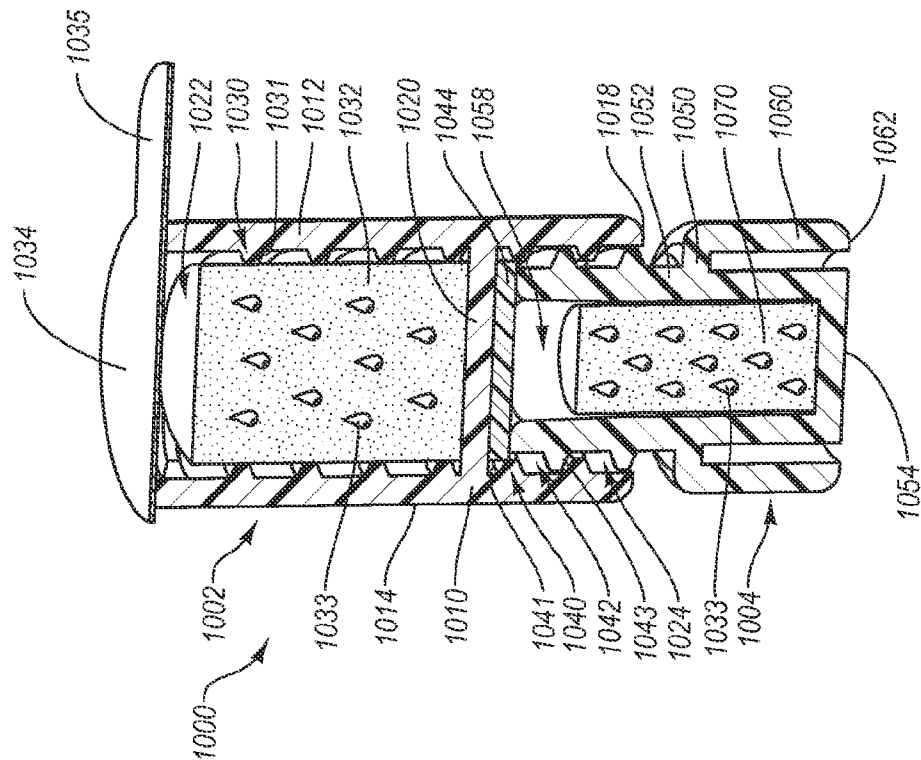


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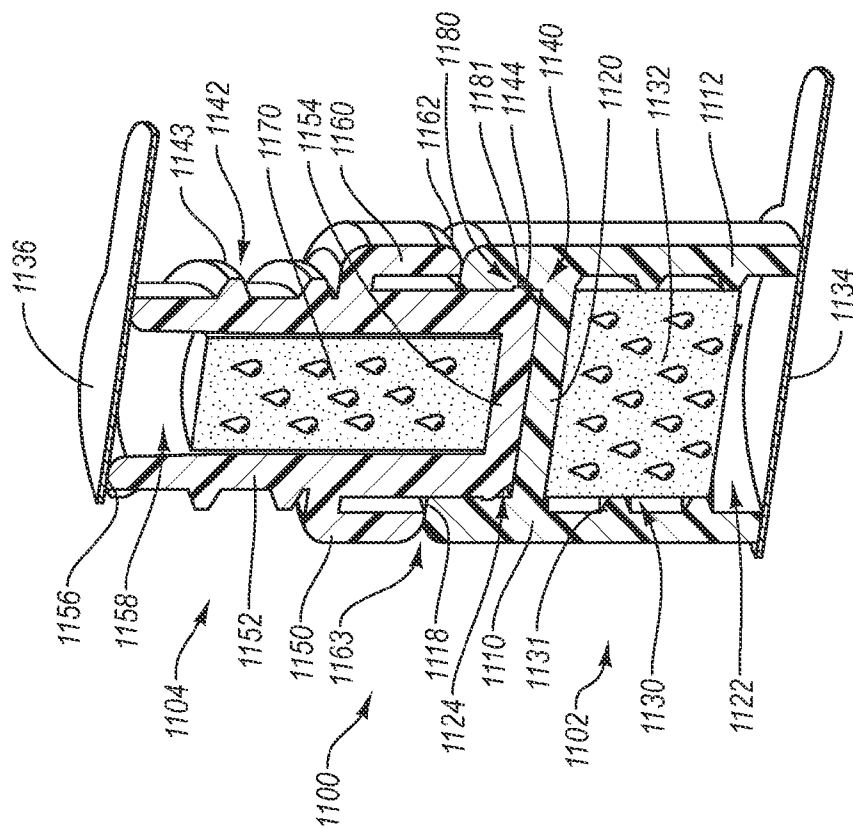


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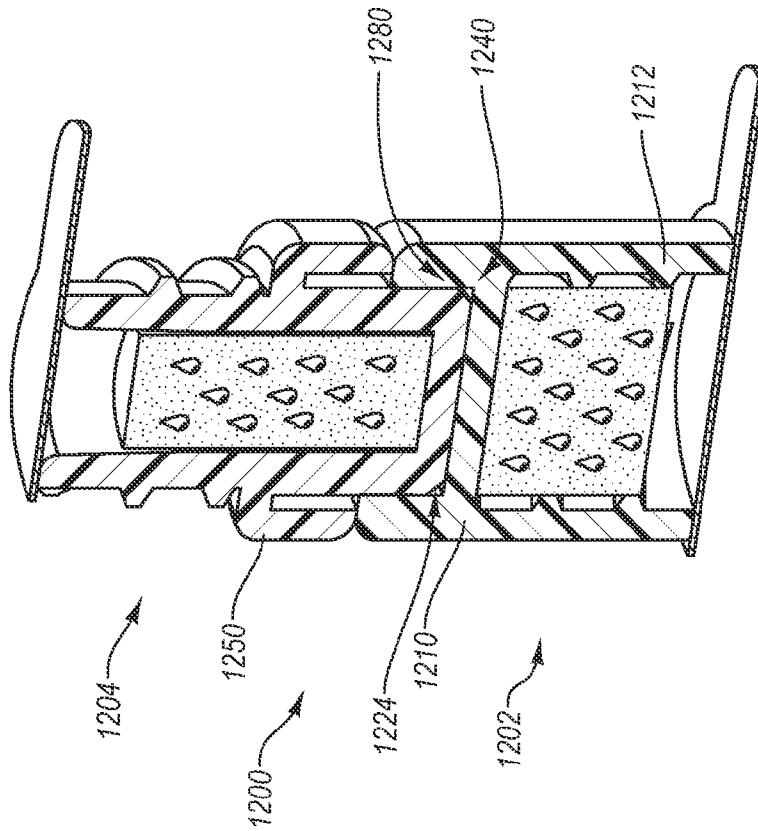


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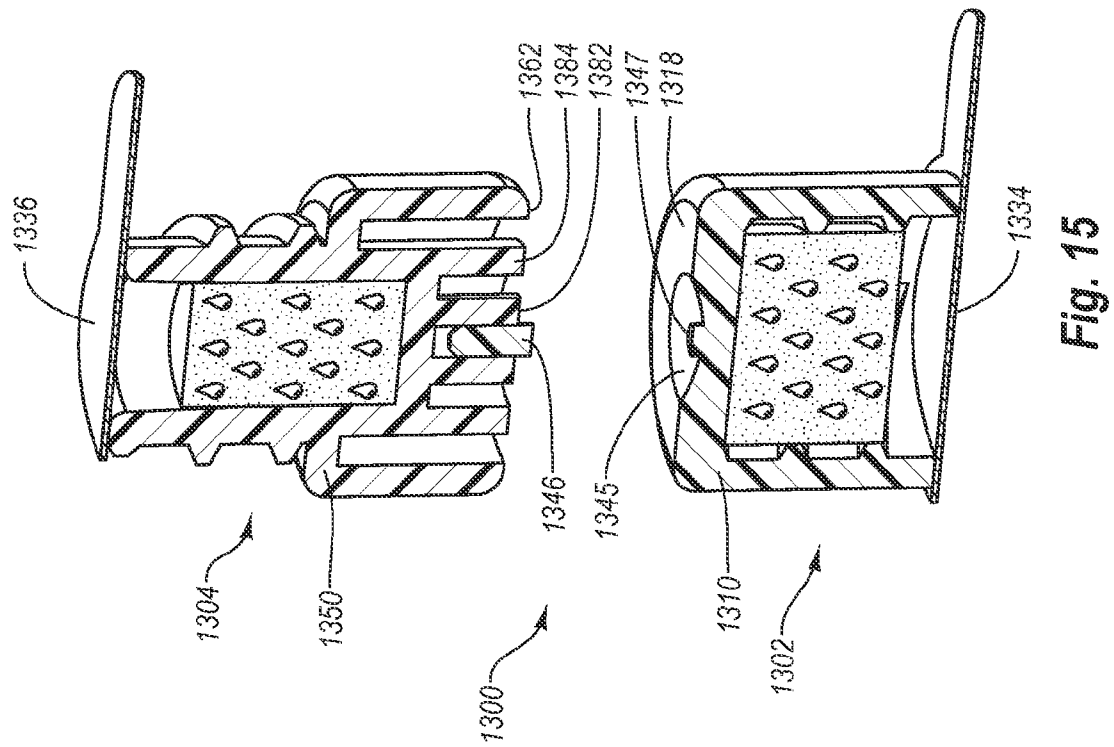


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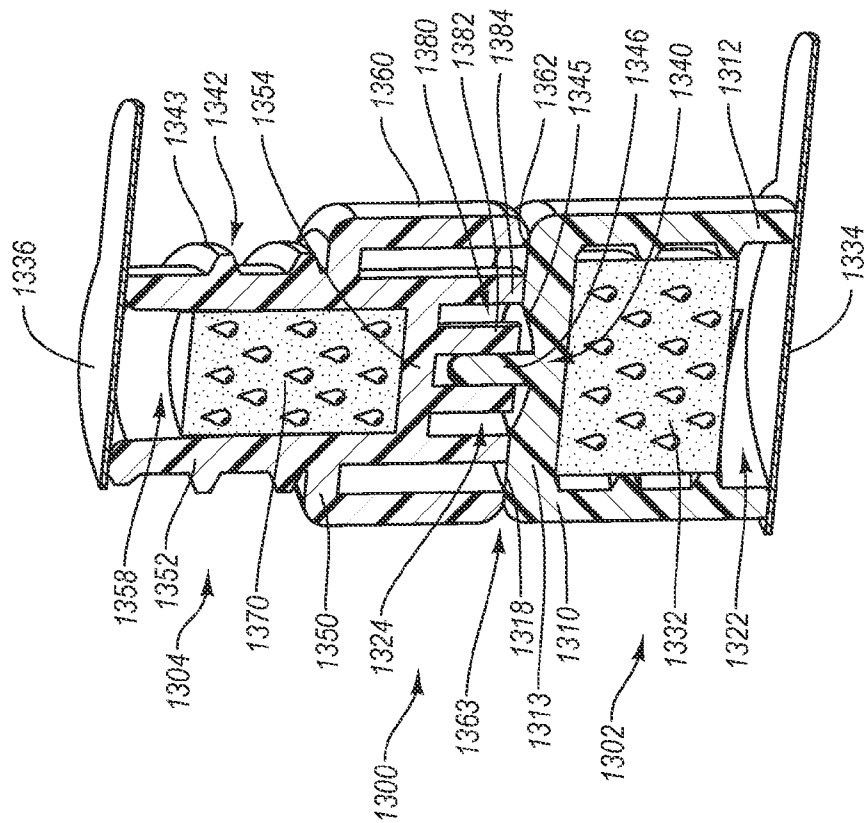


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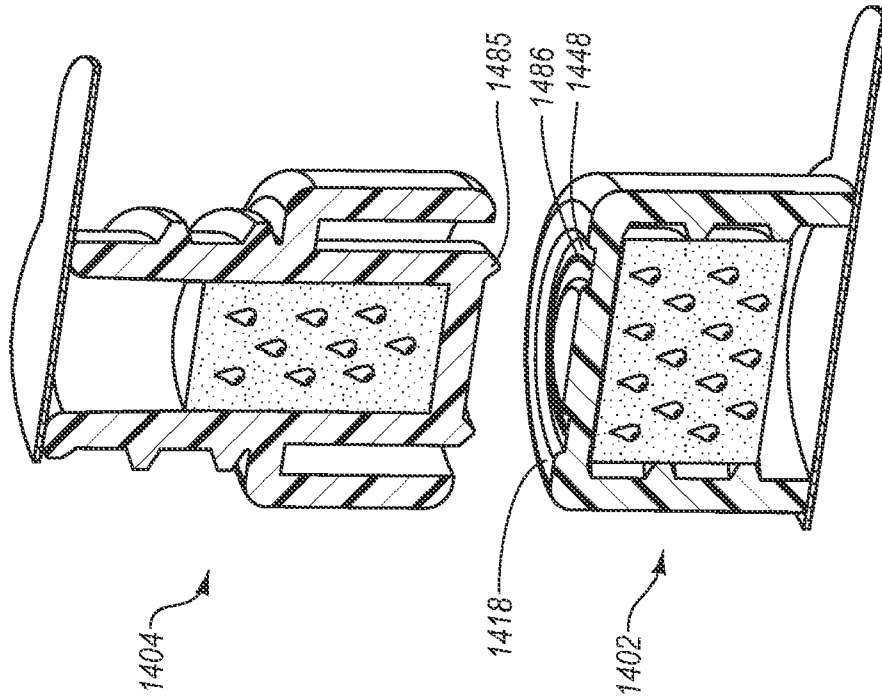


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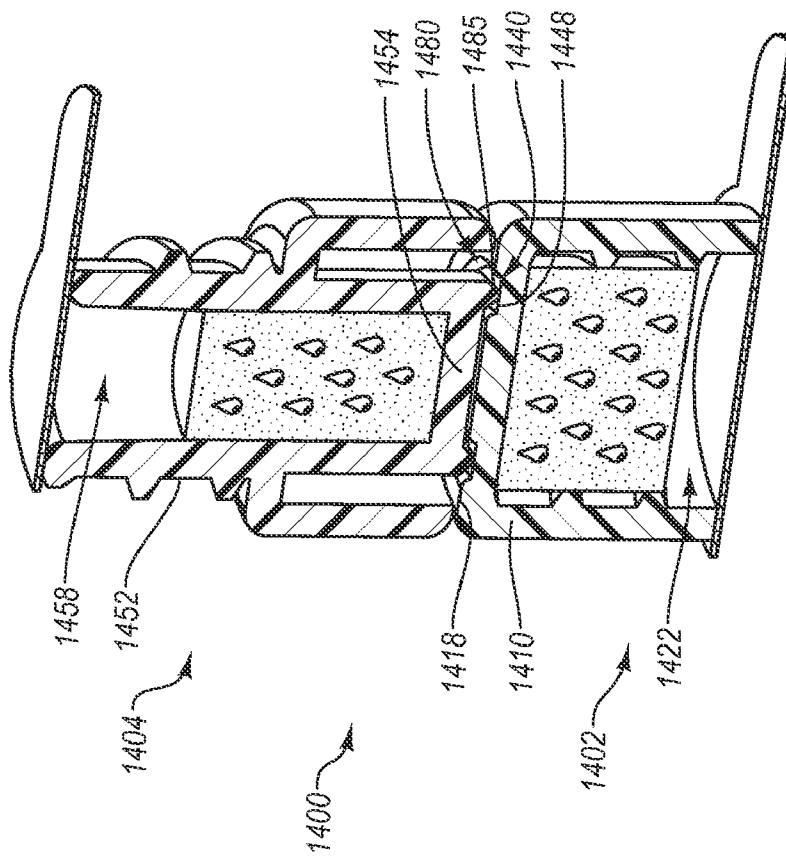


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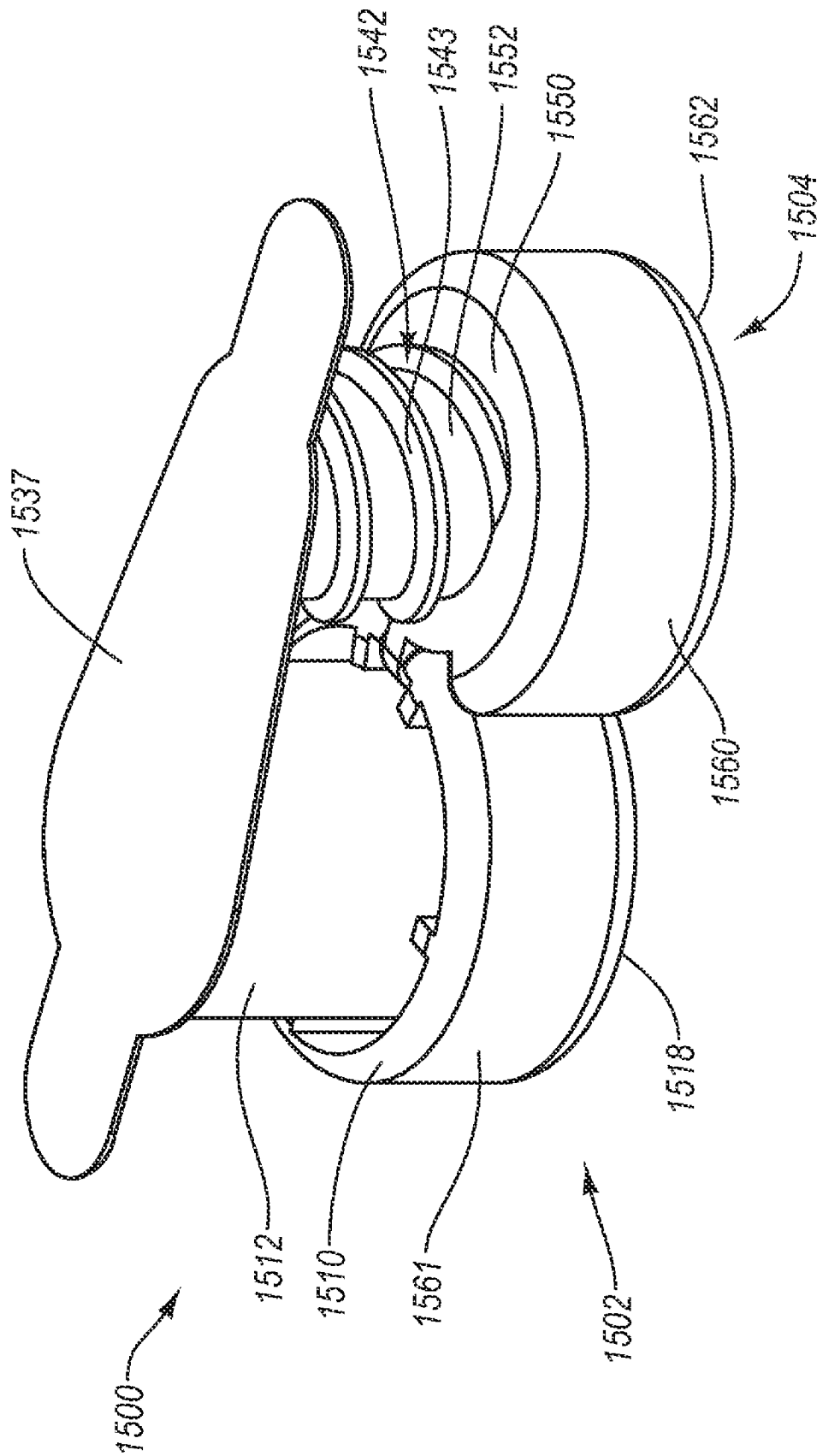
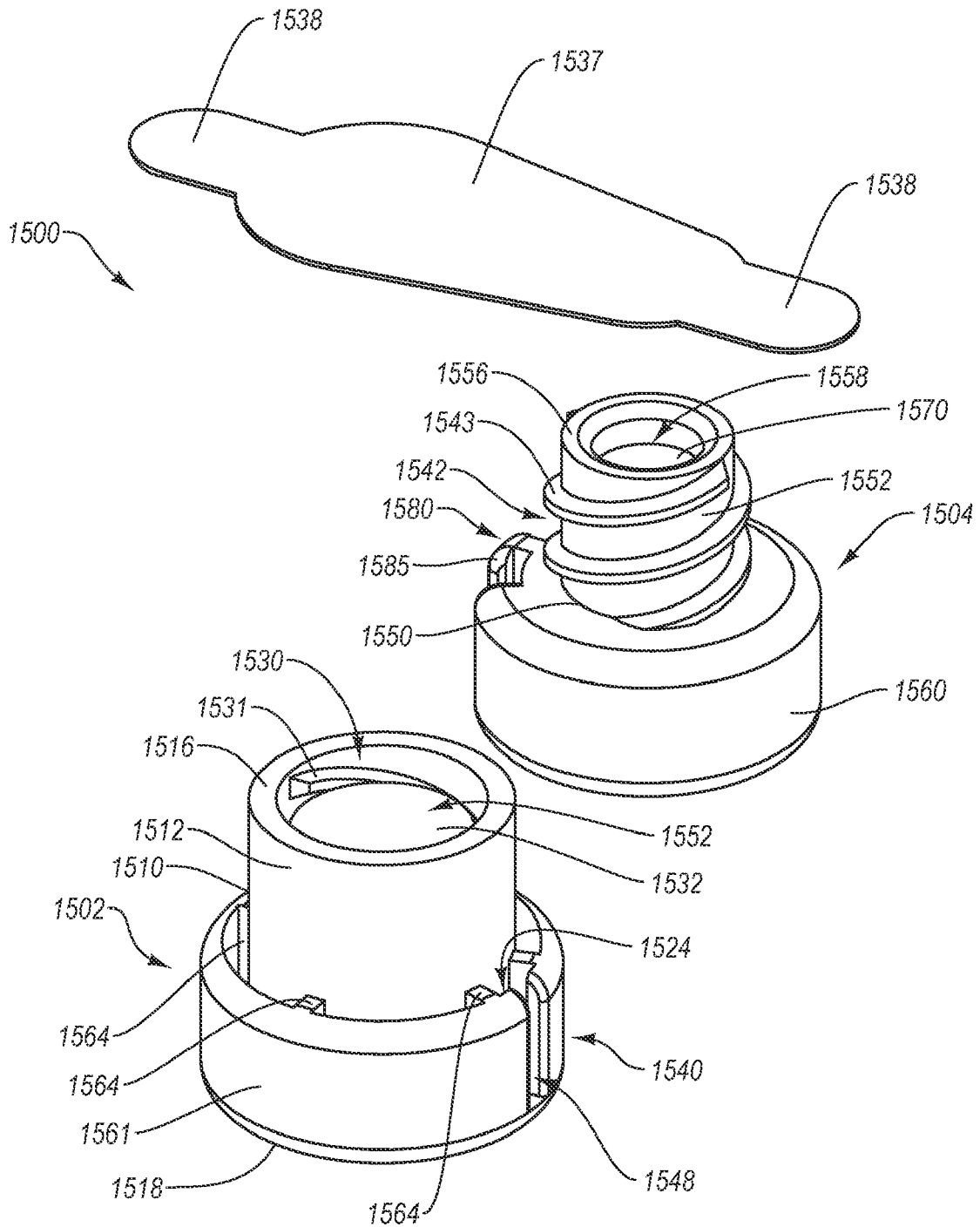


Fig. 18

**Fig. 19**

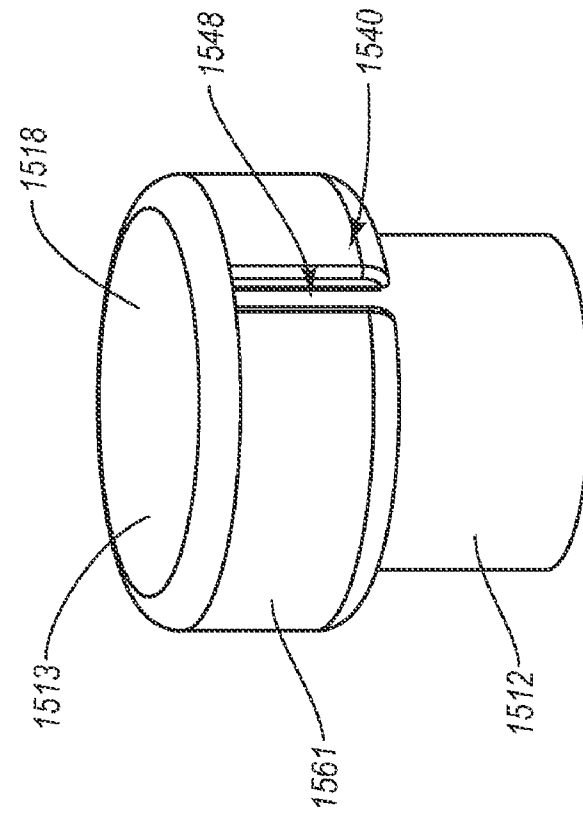


Fig. 21

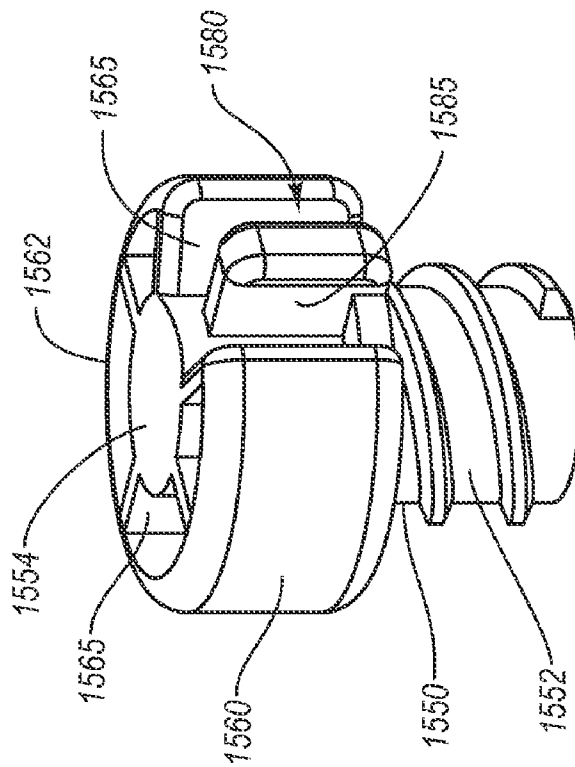


Fig. 20

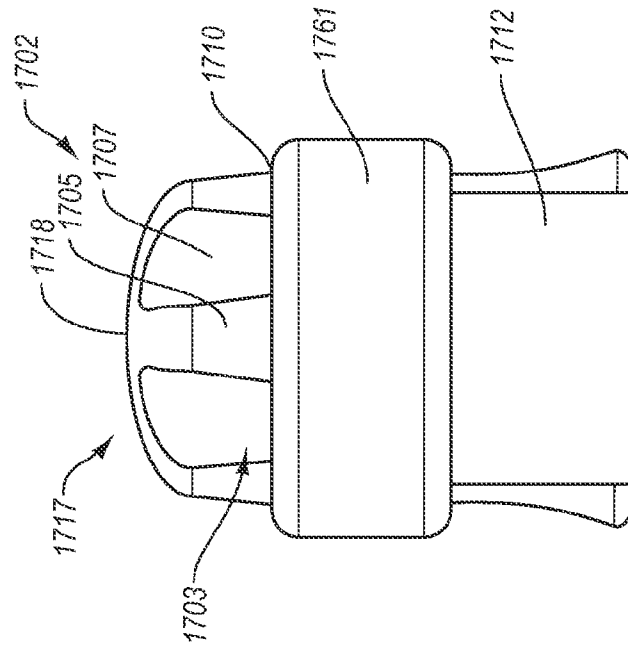


Fig. 23

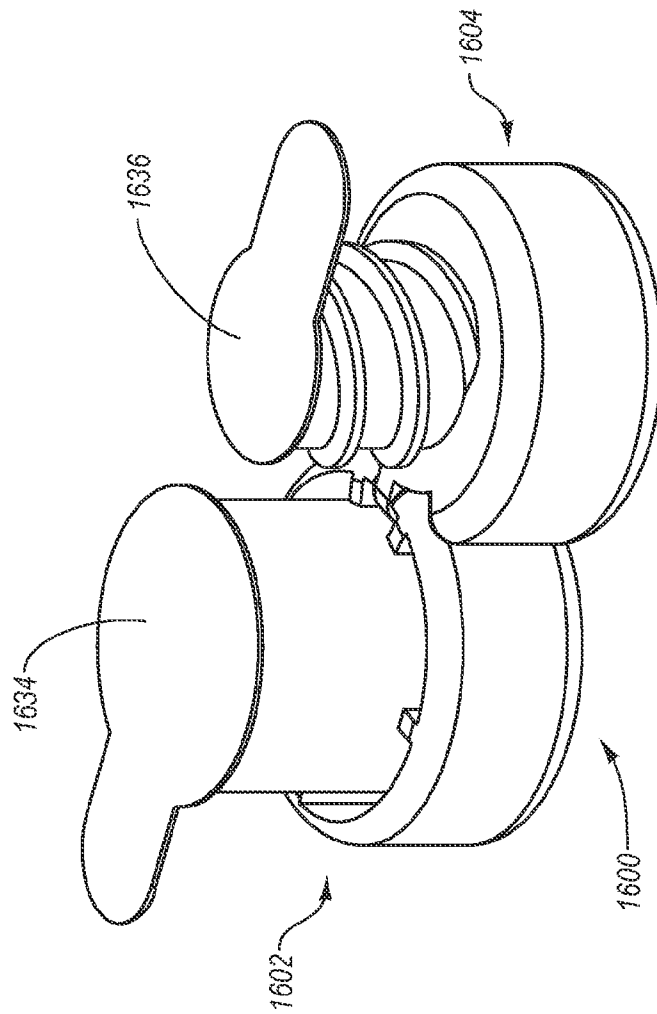


Fig. 22

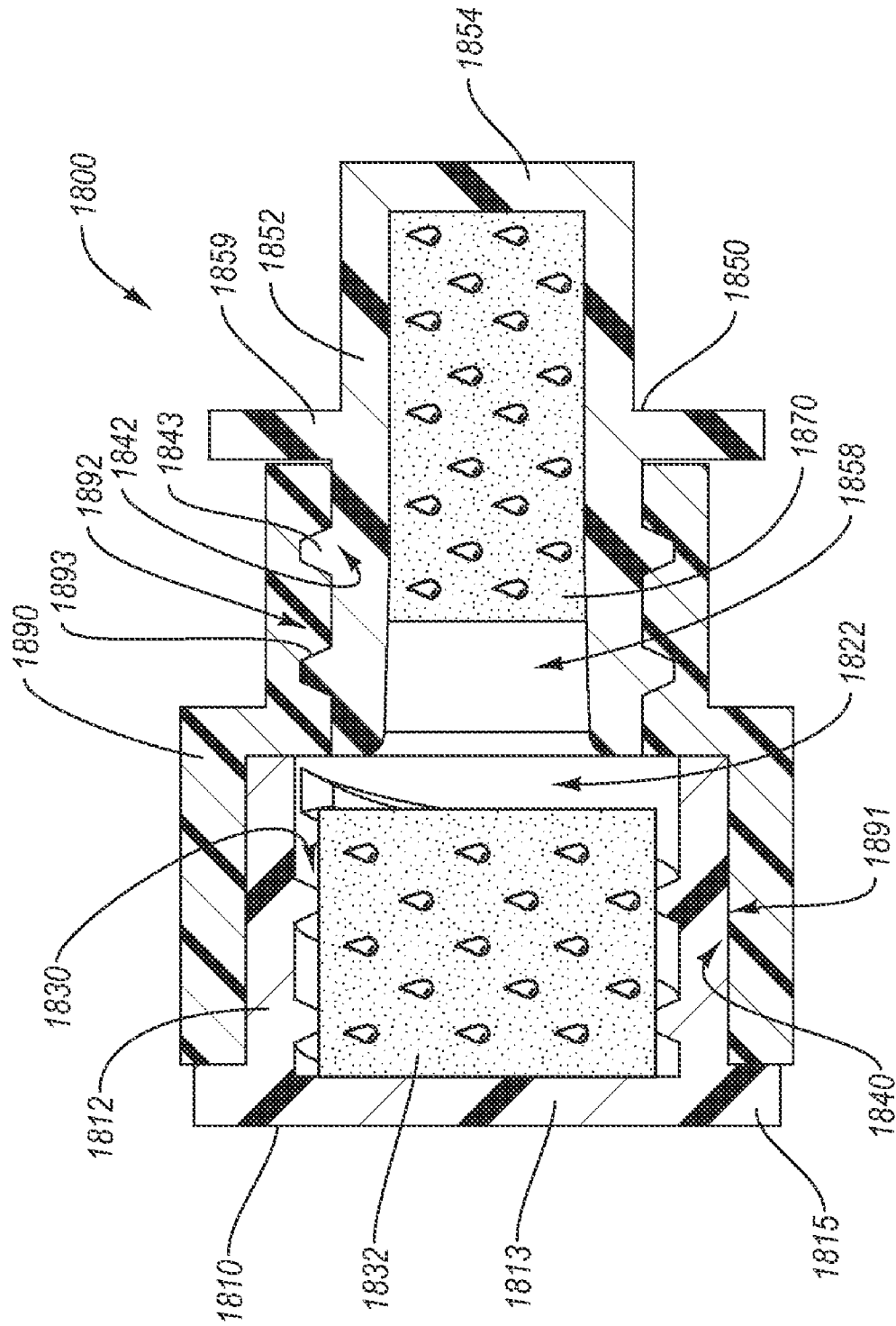


Fig. 24

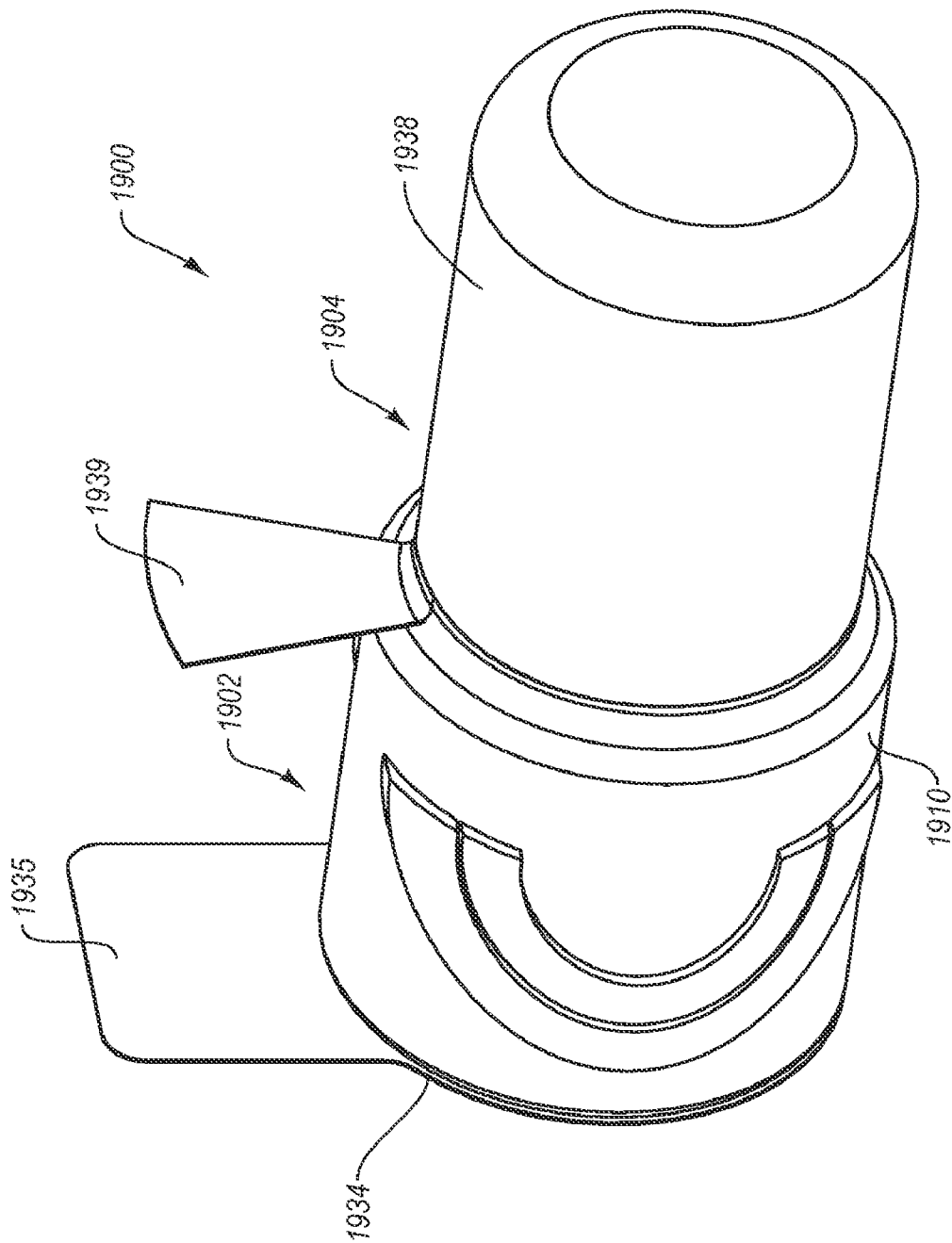


Fig. 25

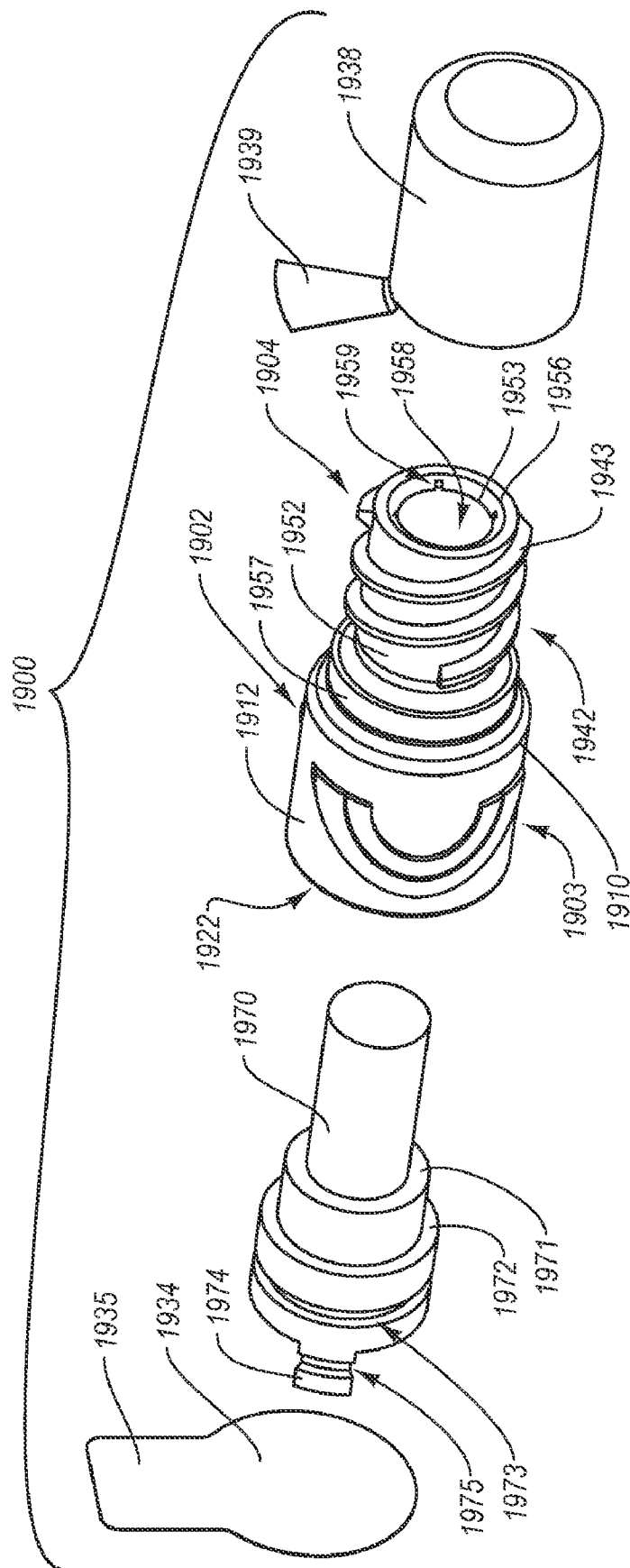


Fig. 26

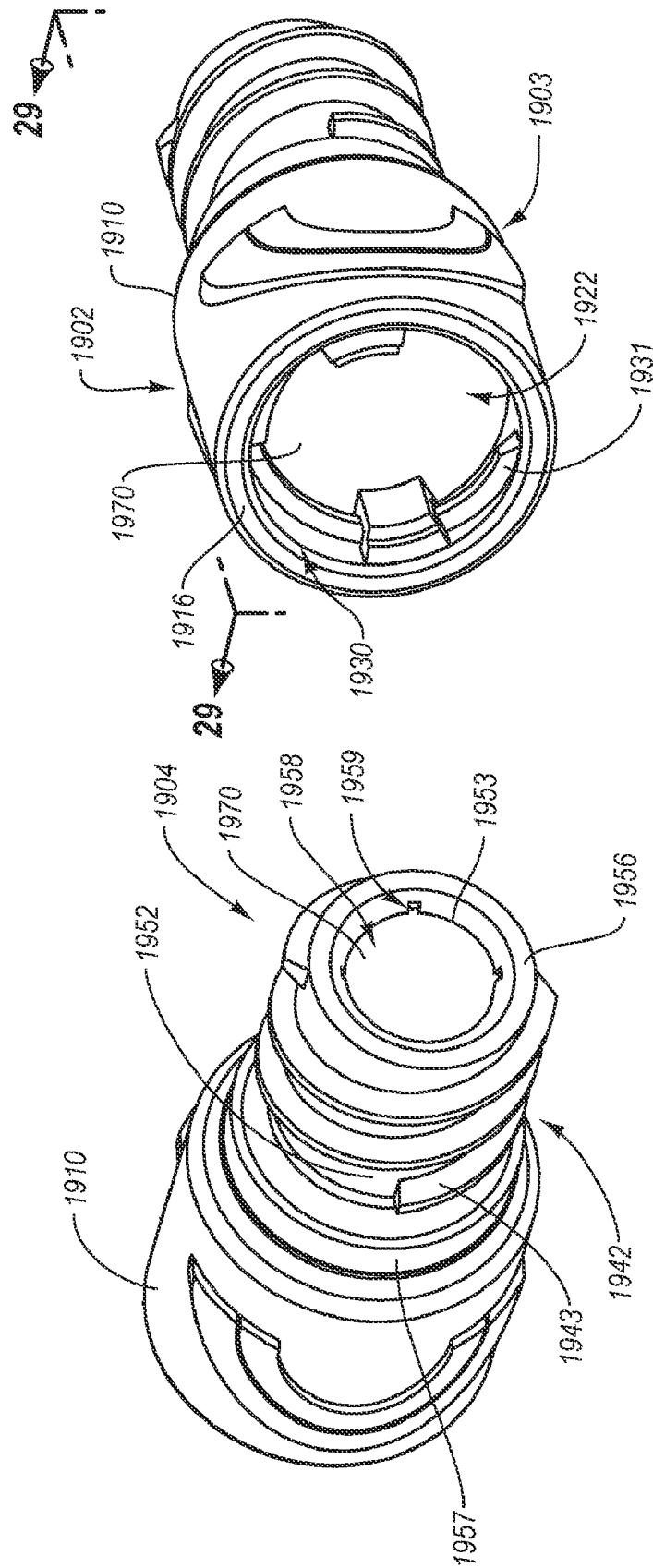


Fig. 28

Fig. 27

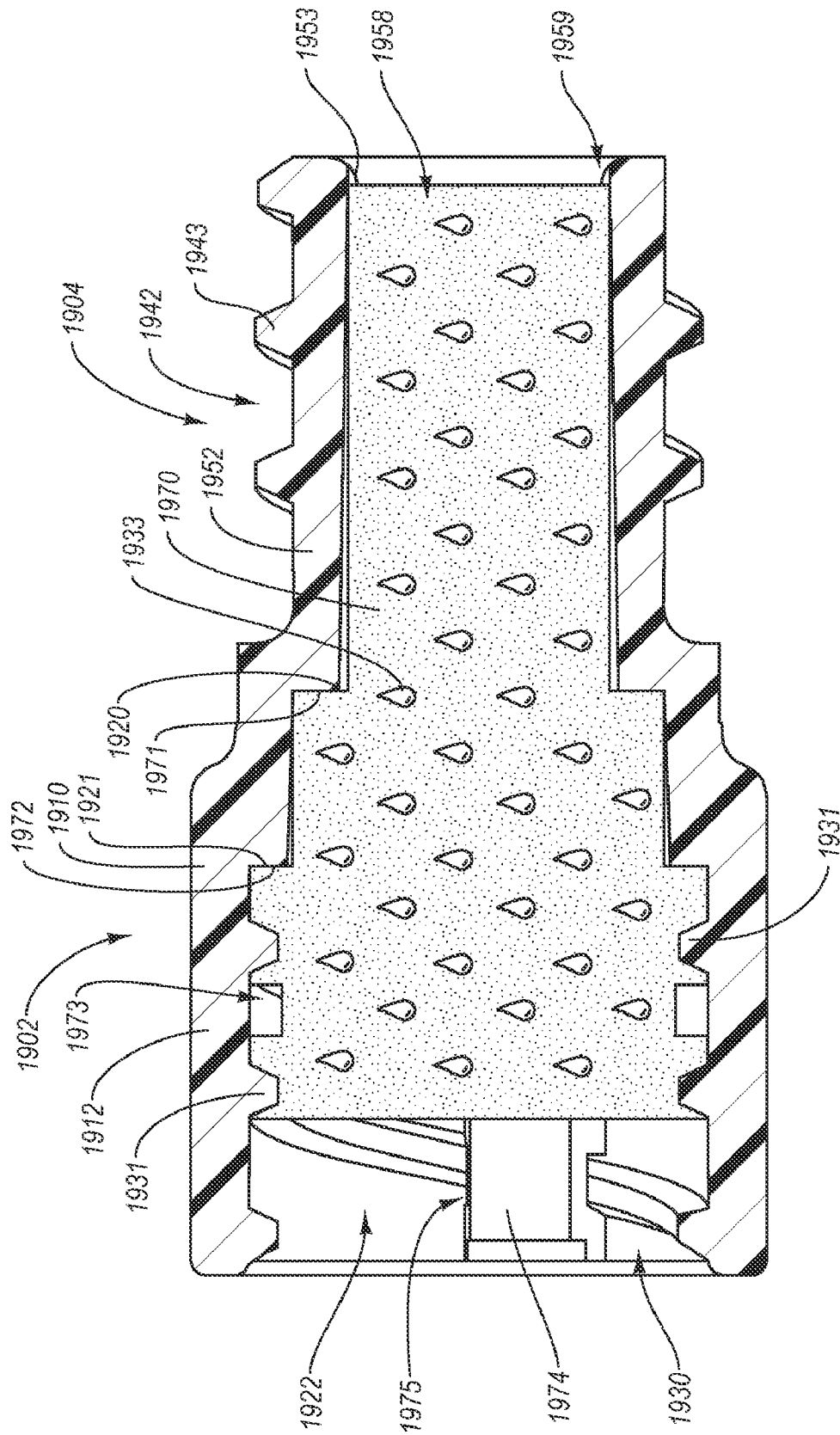


Fig. 29

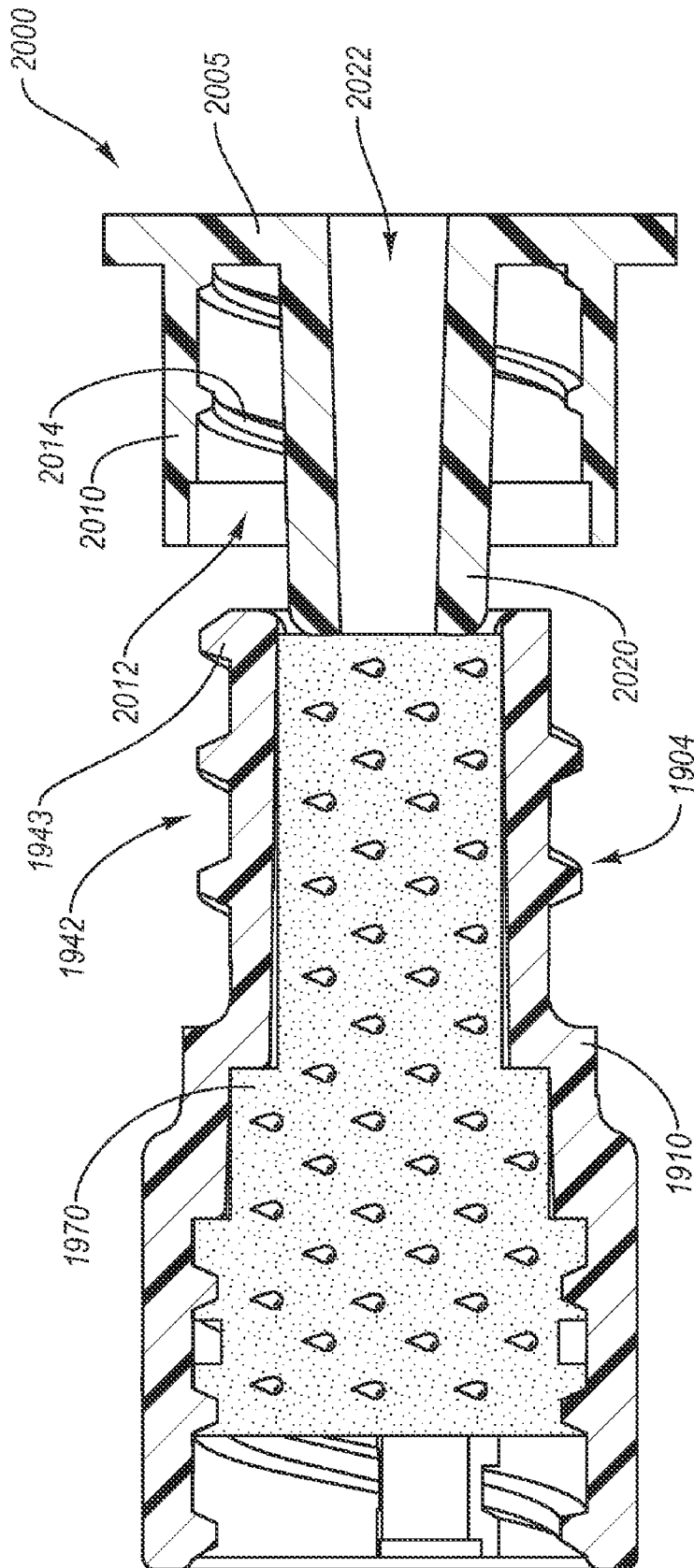
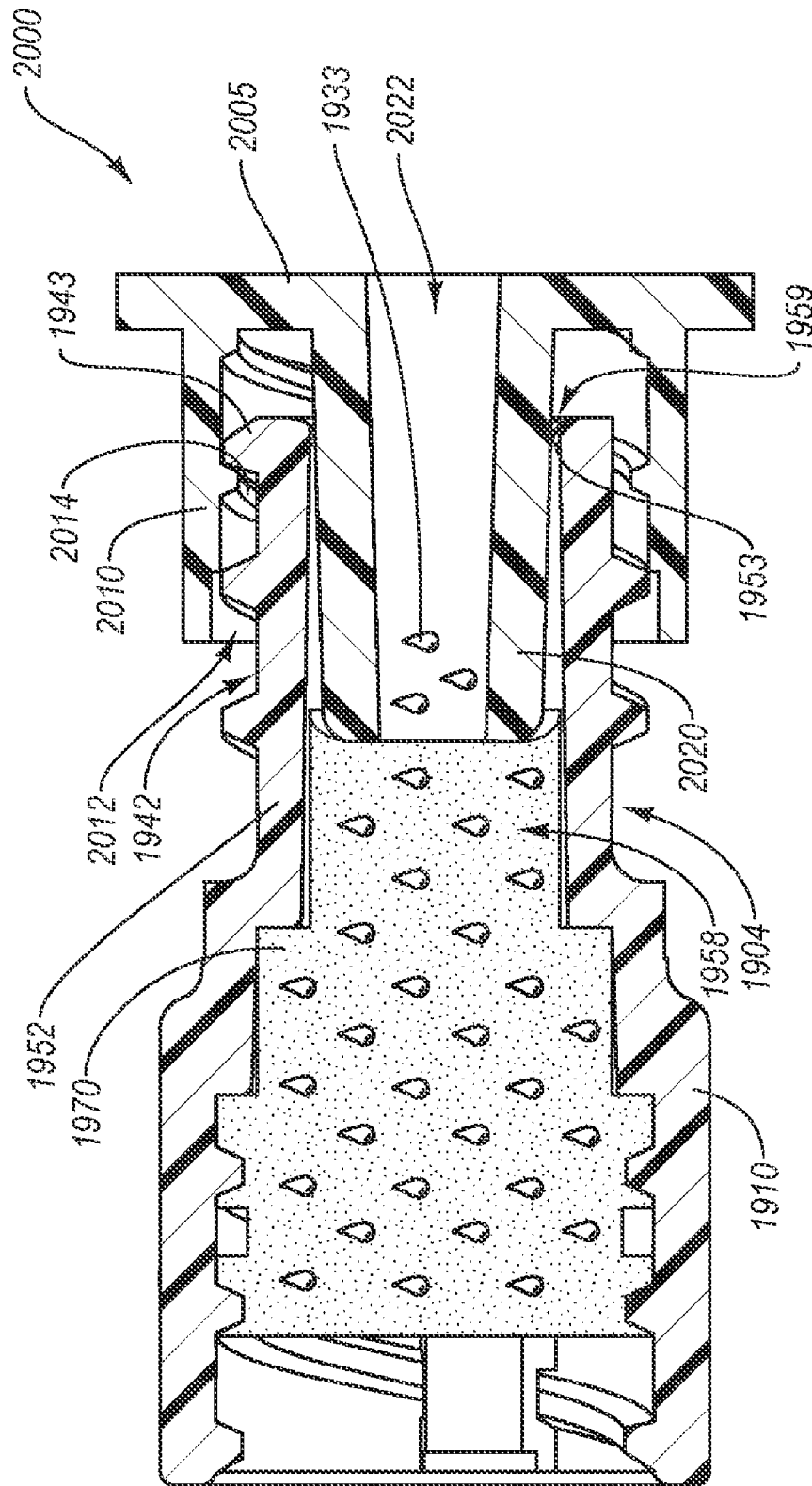


Fig. 30



1301

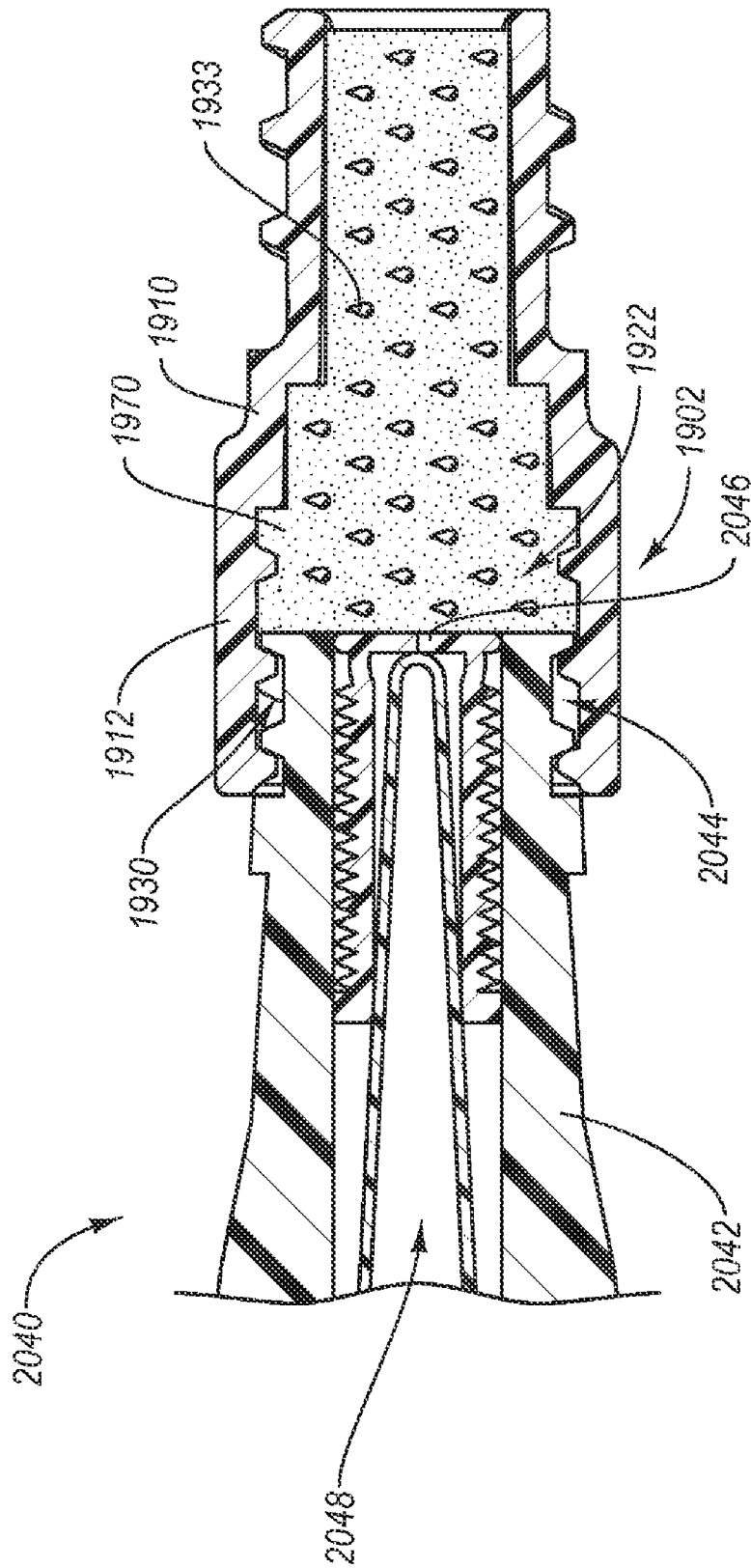


Fig. 32

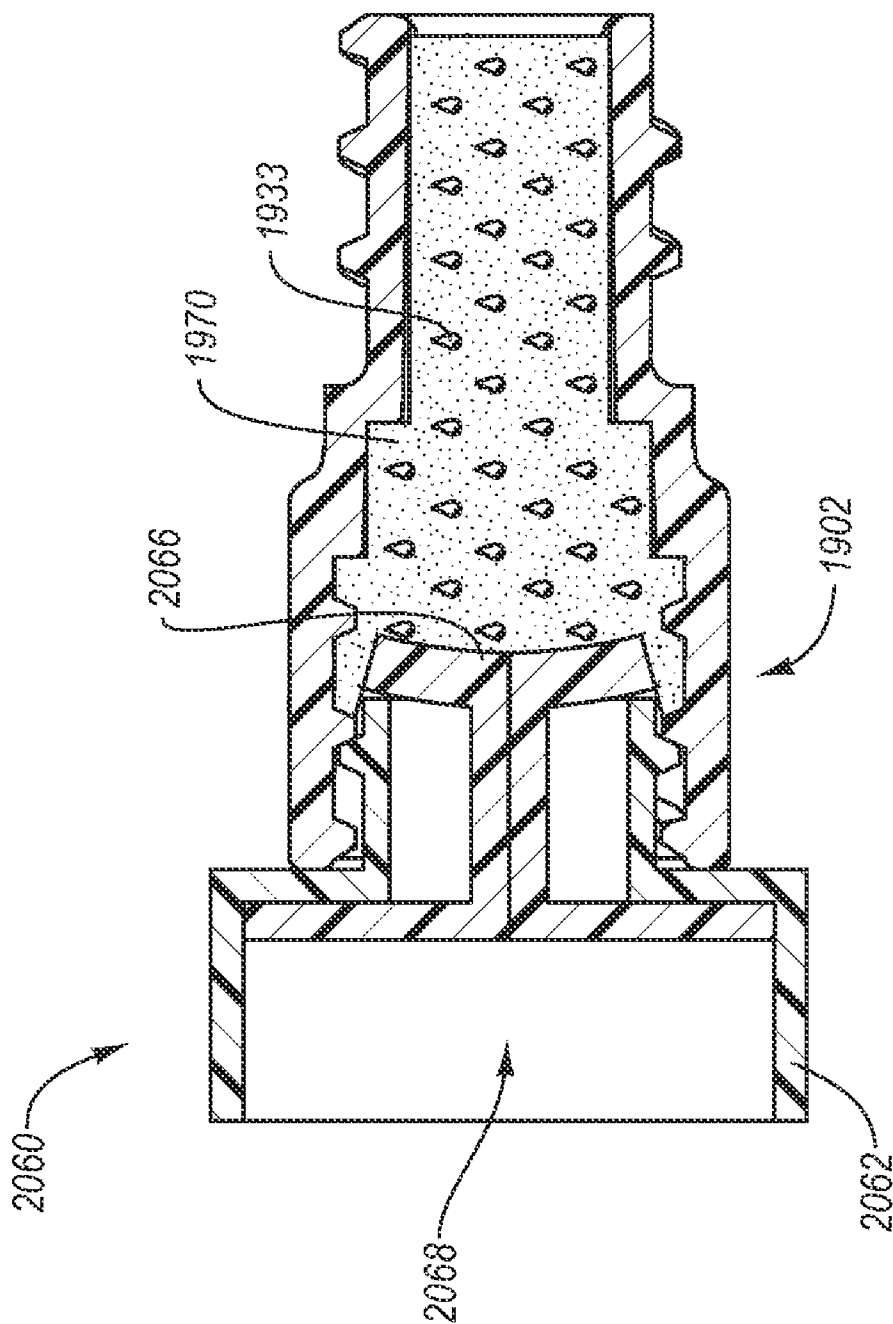


Fig. 33

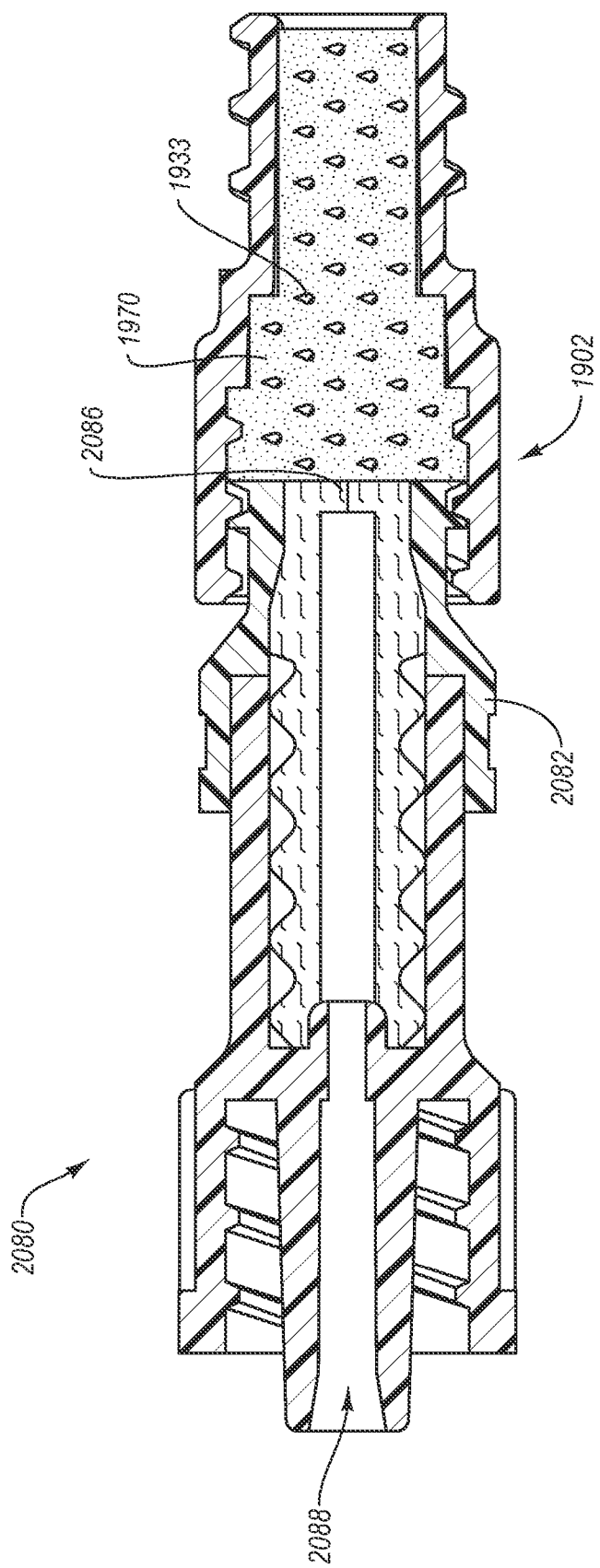


Fig. 34

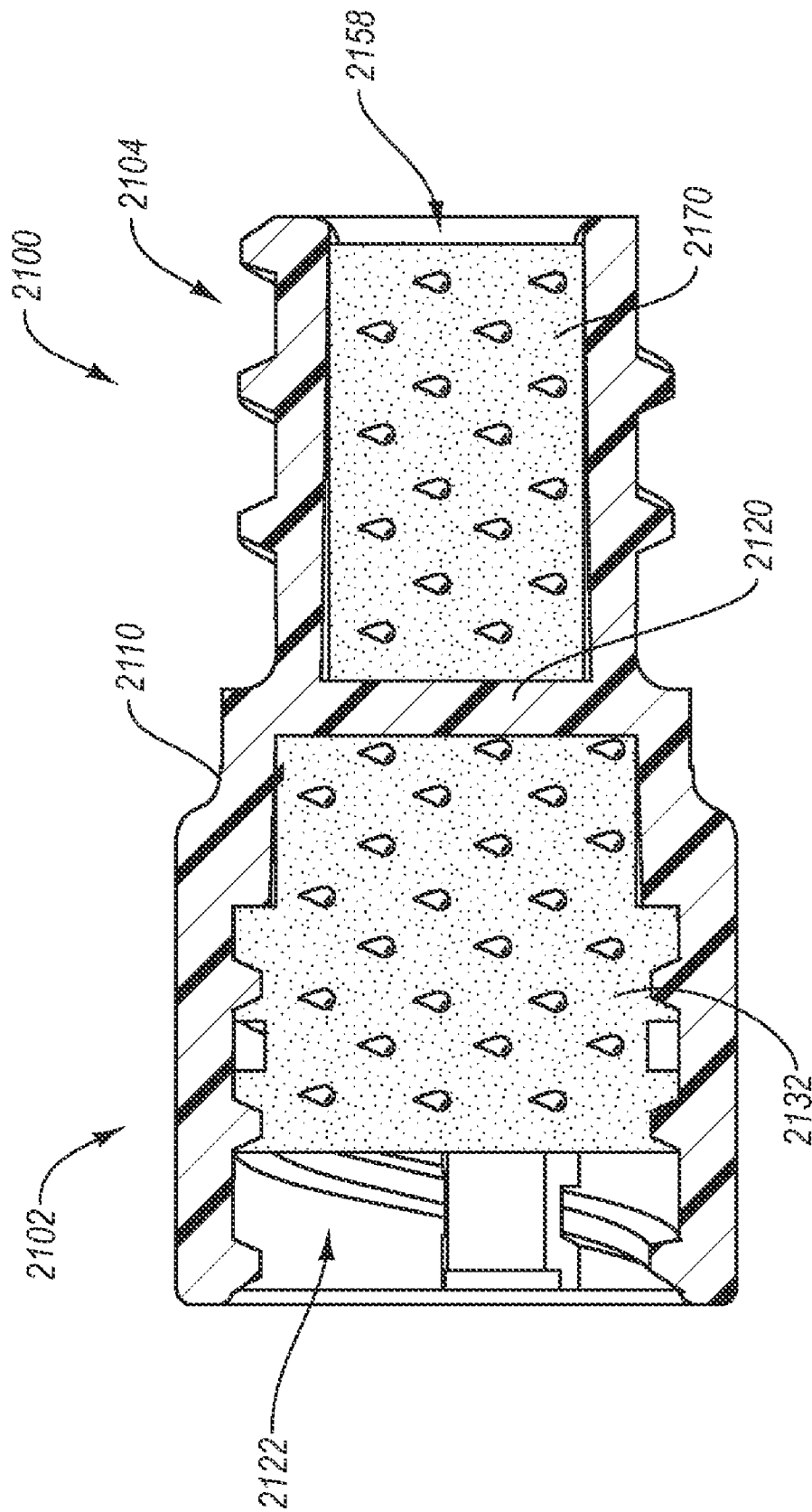


Fig. 35

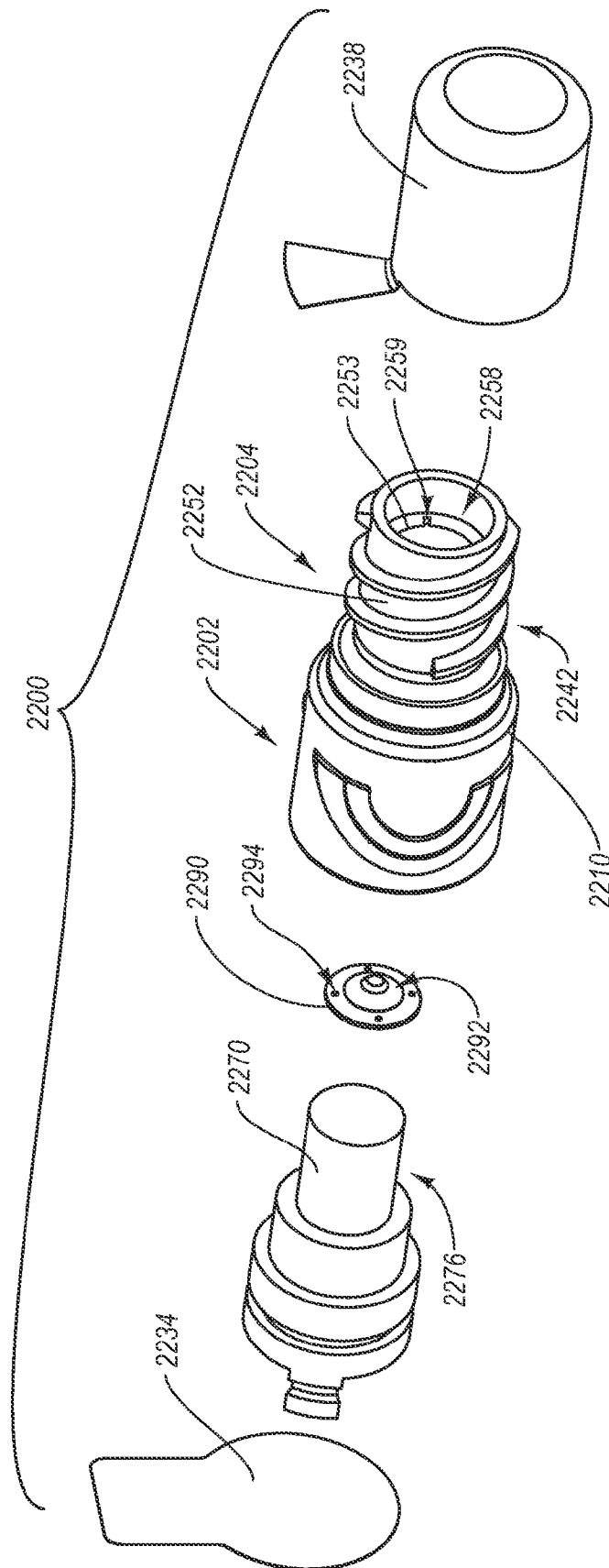


Fig. 36

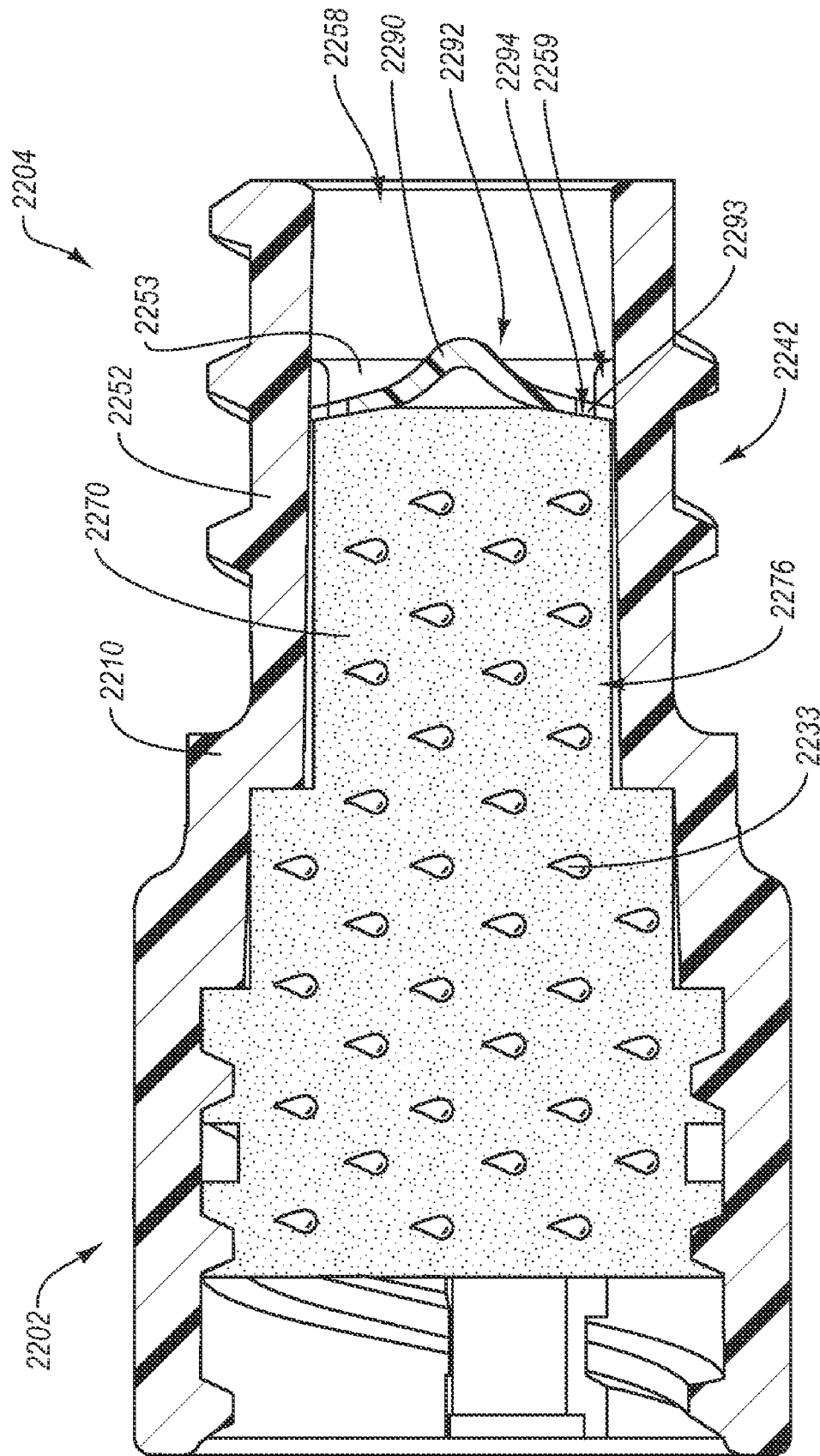


Fig. 37

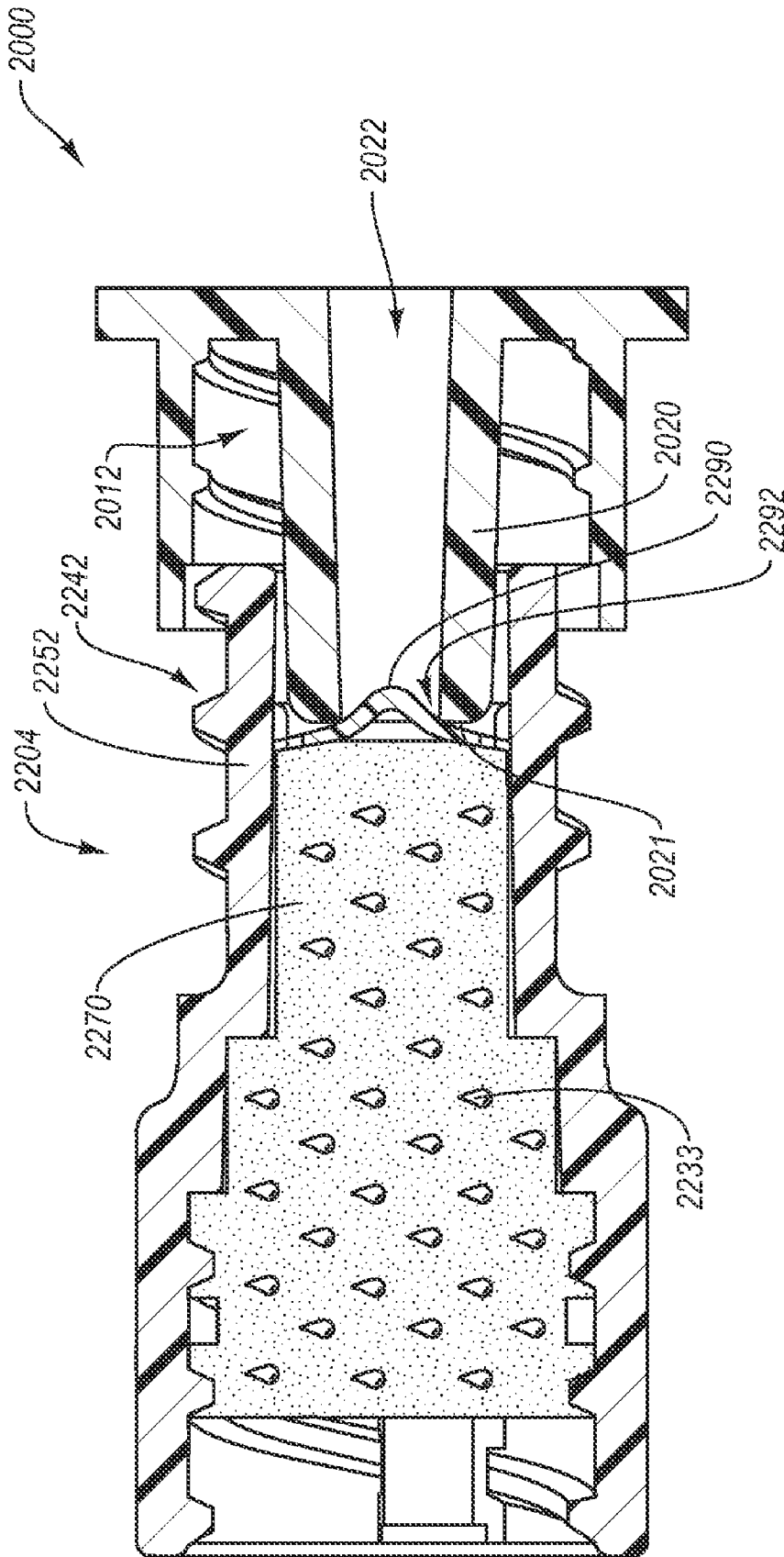


Fig. 38

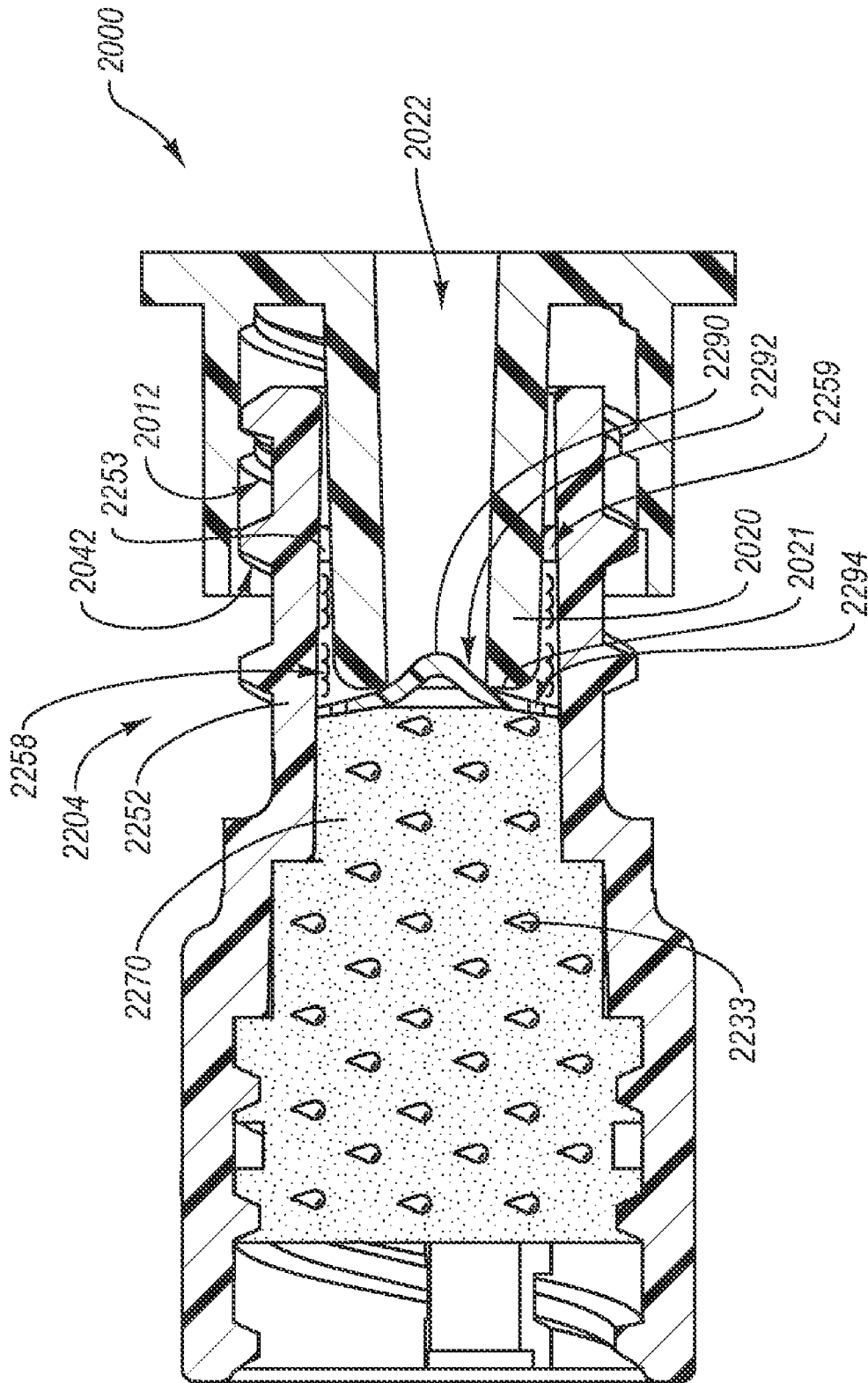


Fig. 39

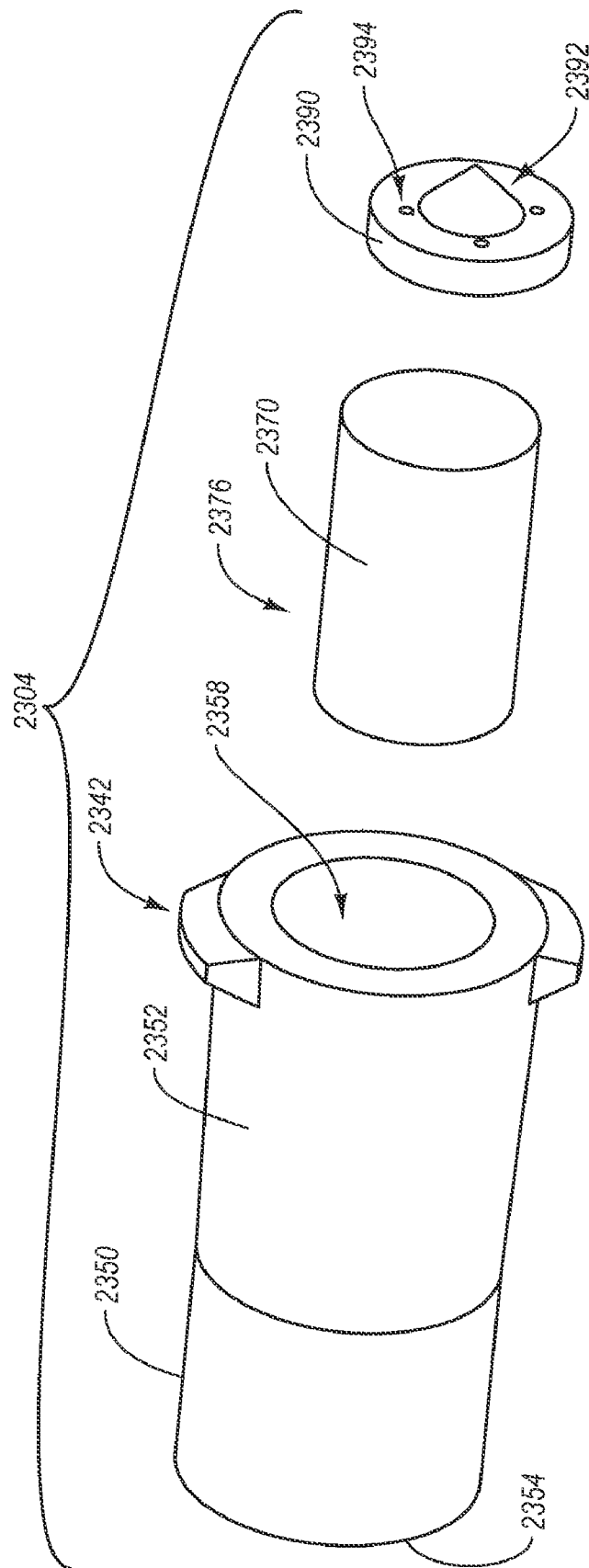


Fig. 40

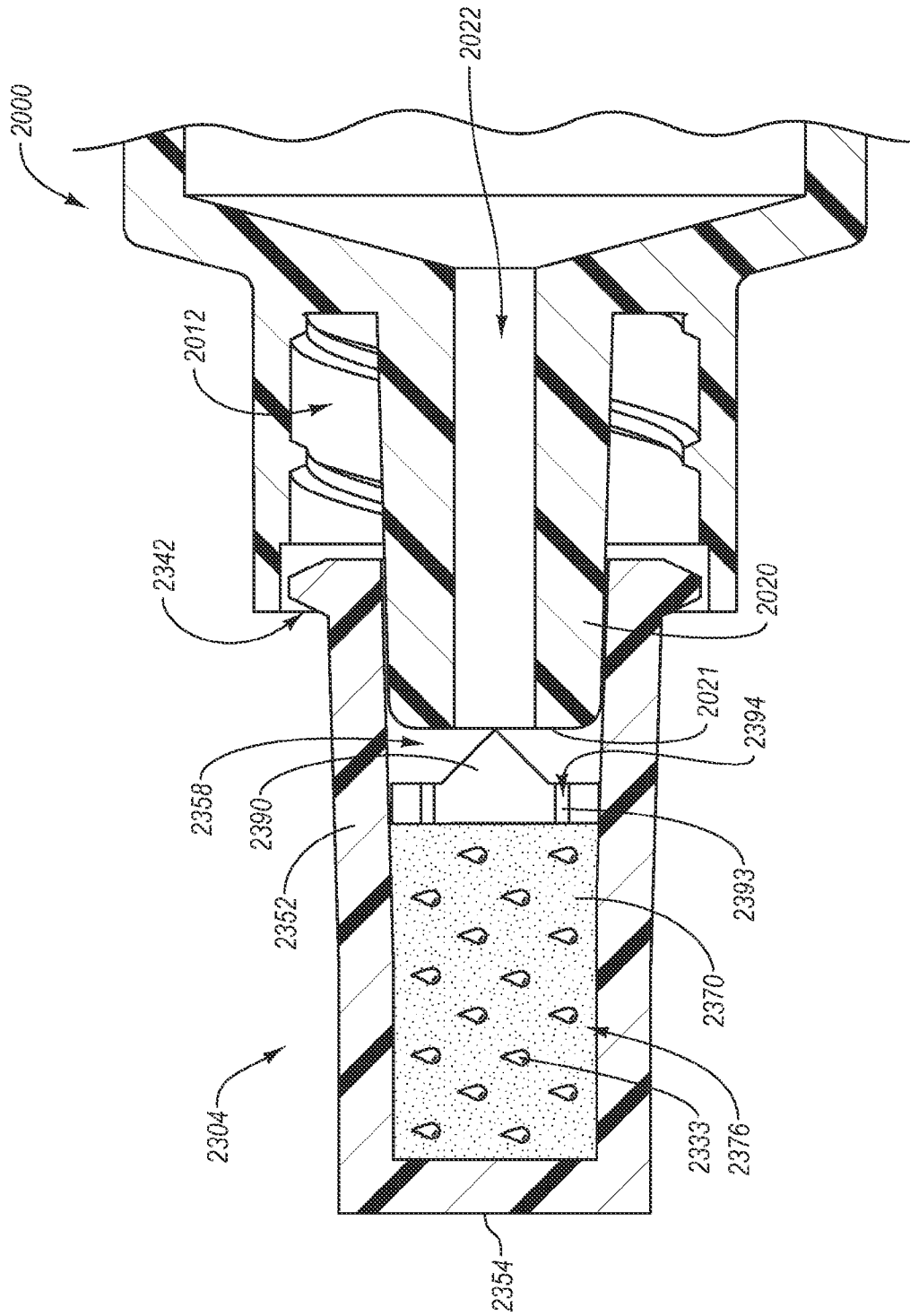


Fig. 41

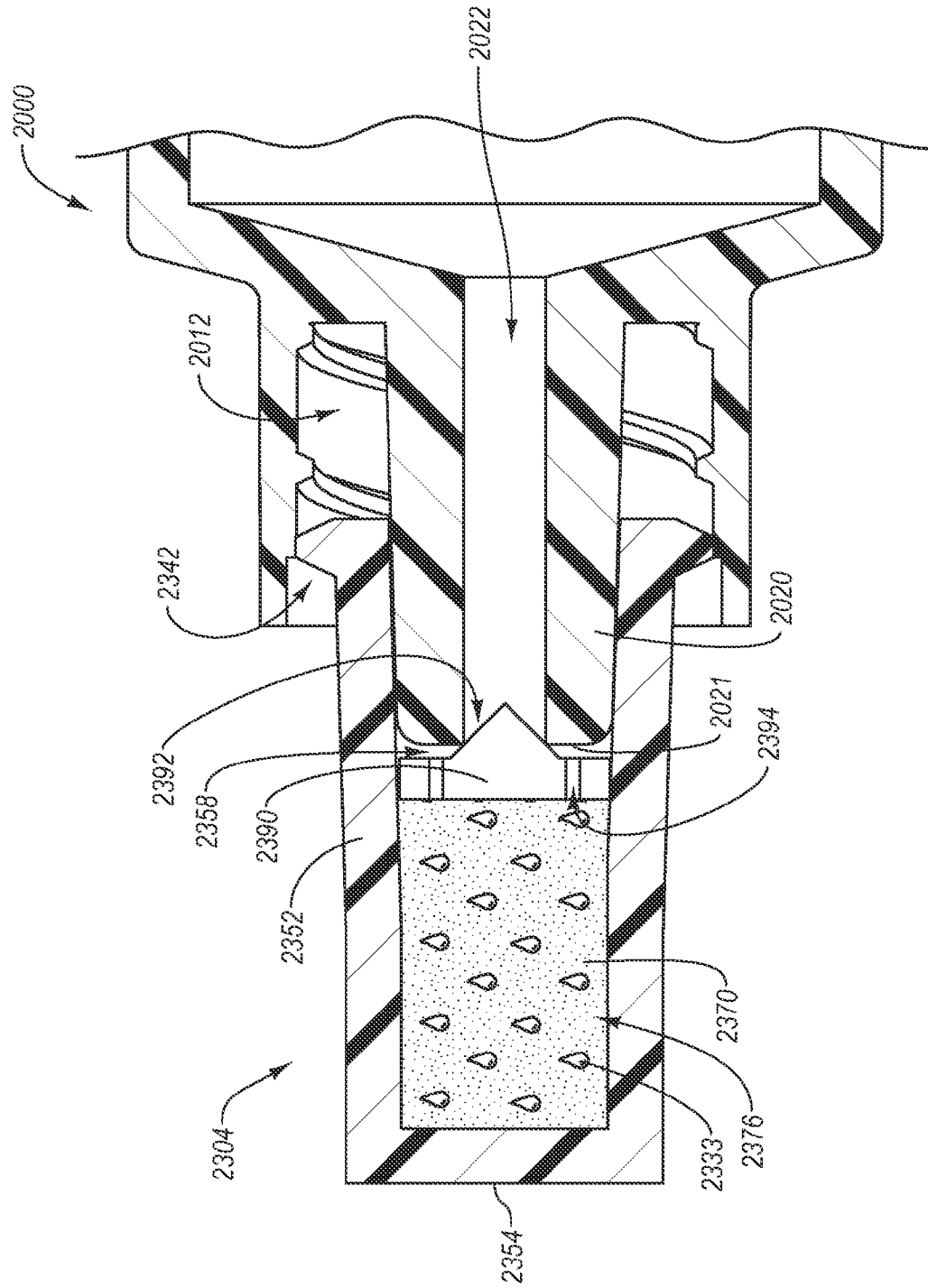


Fig. 42

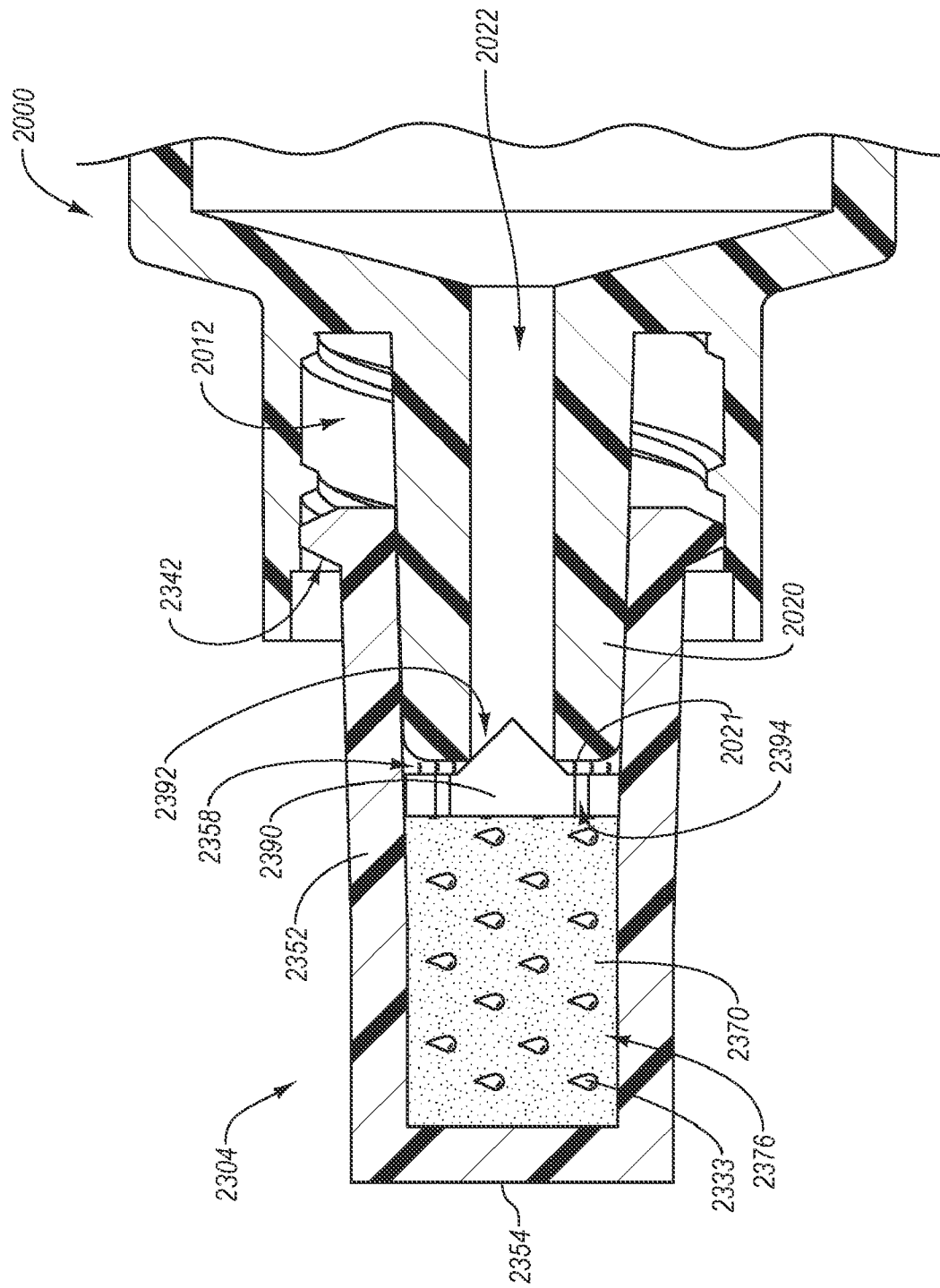


Fig. 43

Fig. 44

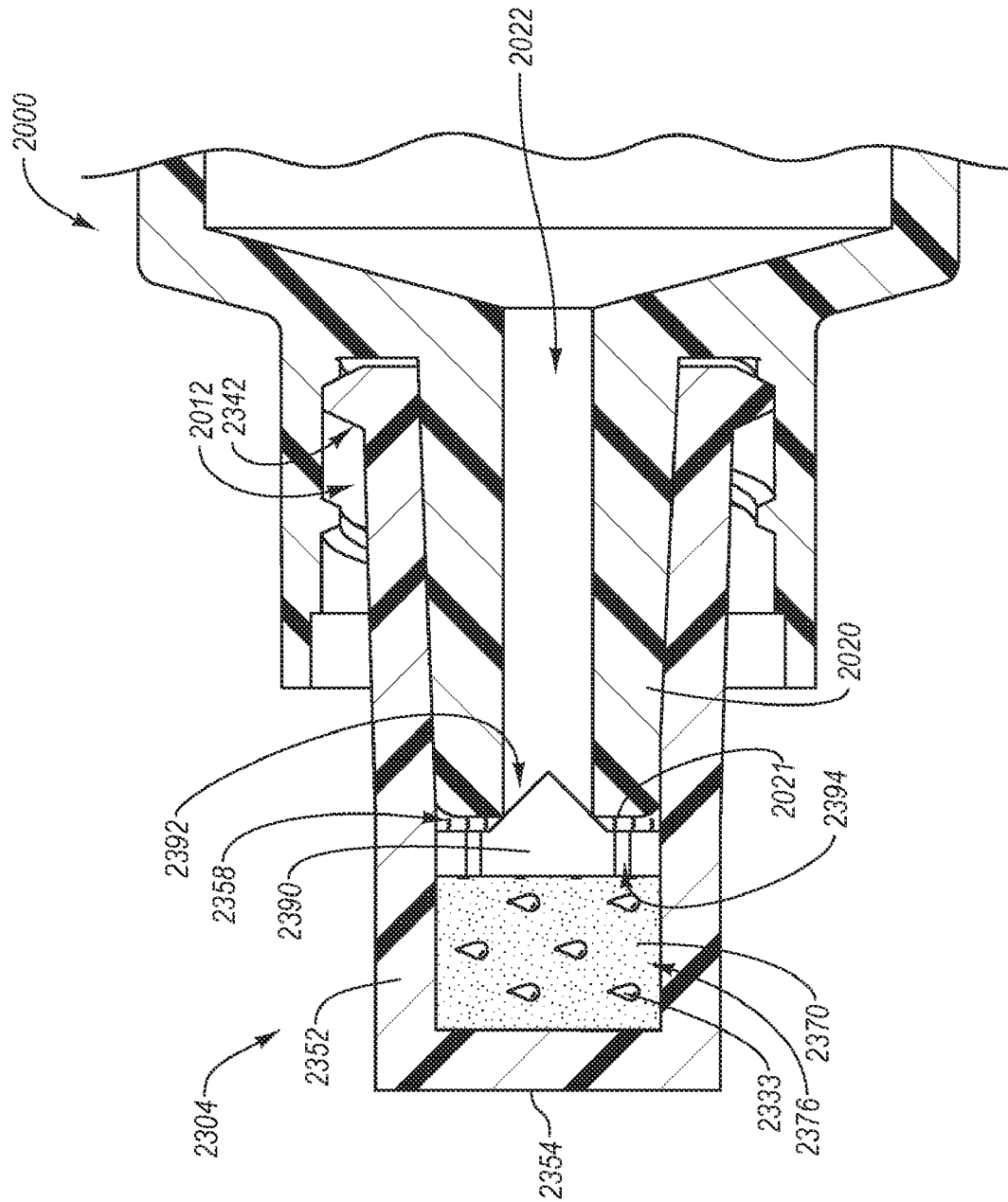


Fig. 45

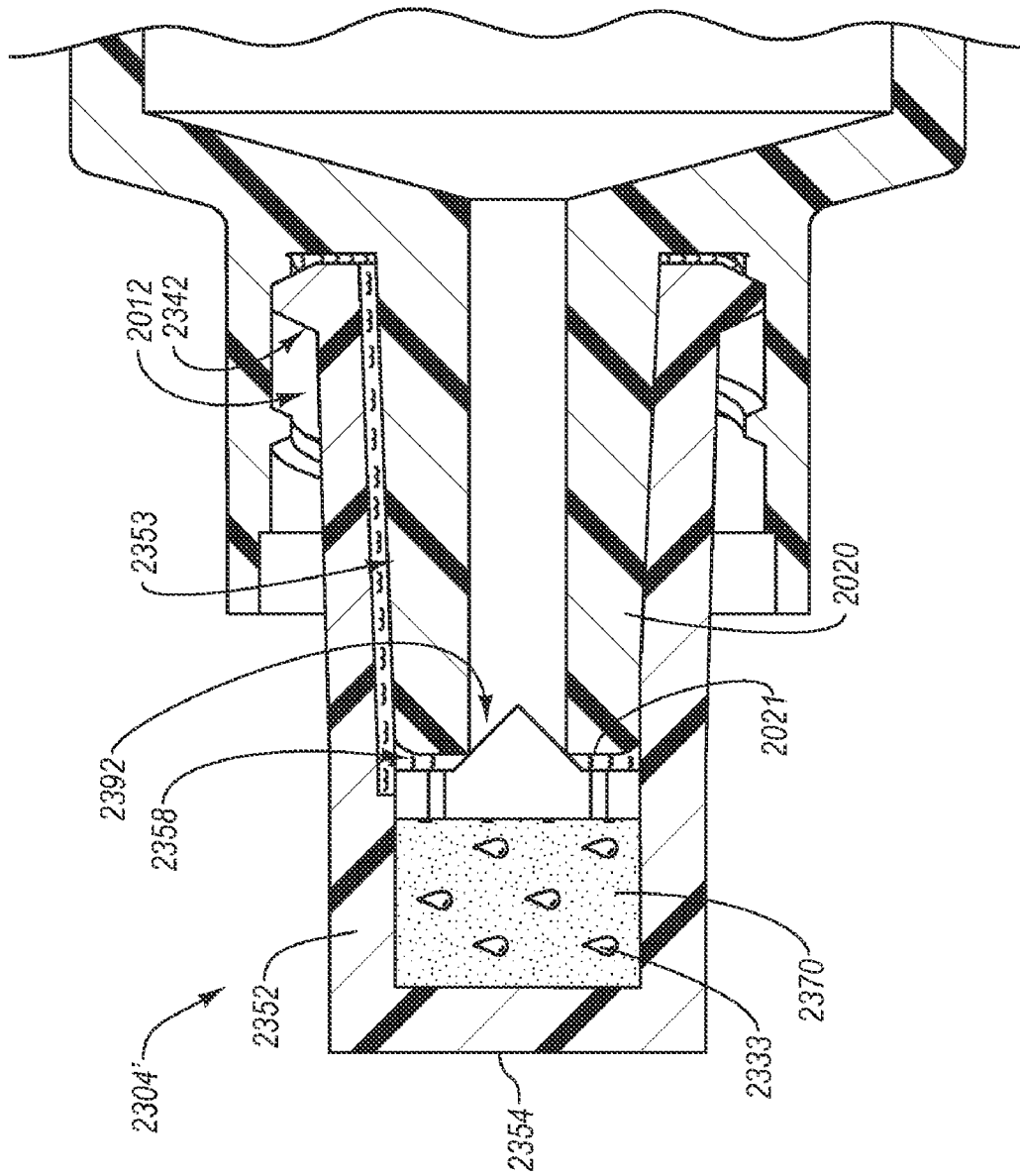


Fig. 46

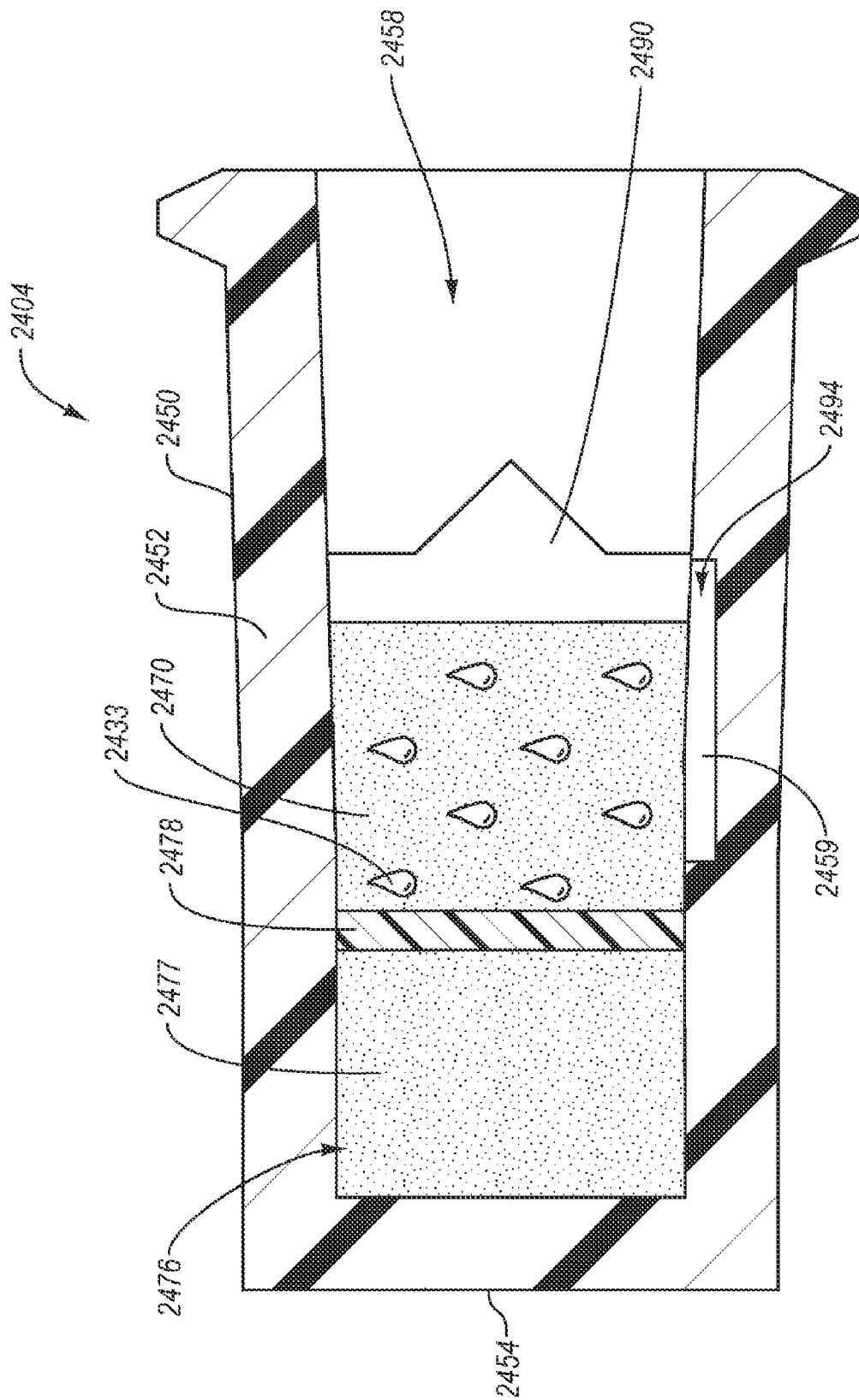


Fig. 47

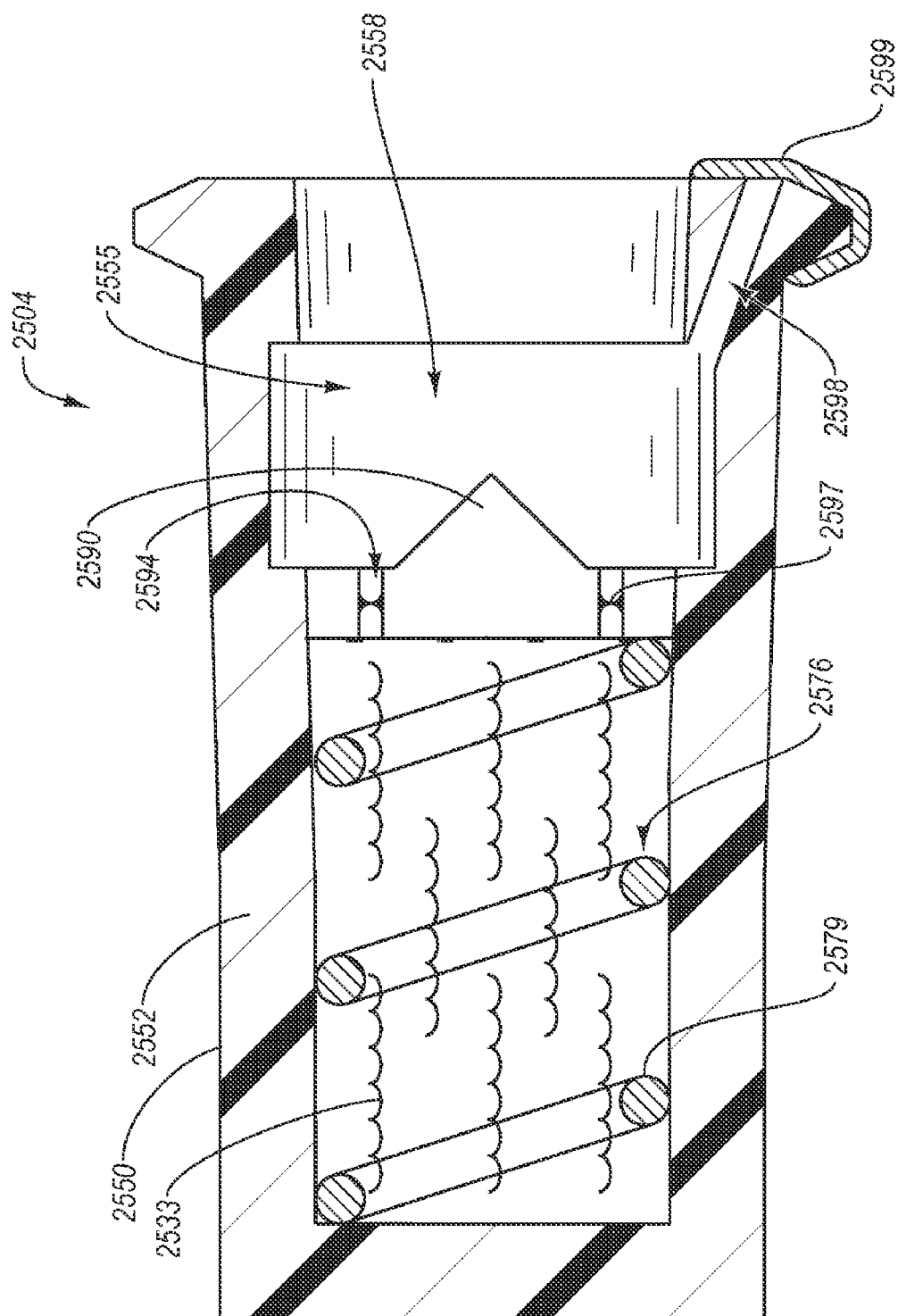


Fig. 48

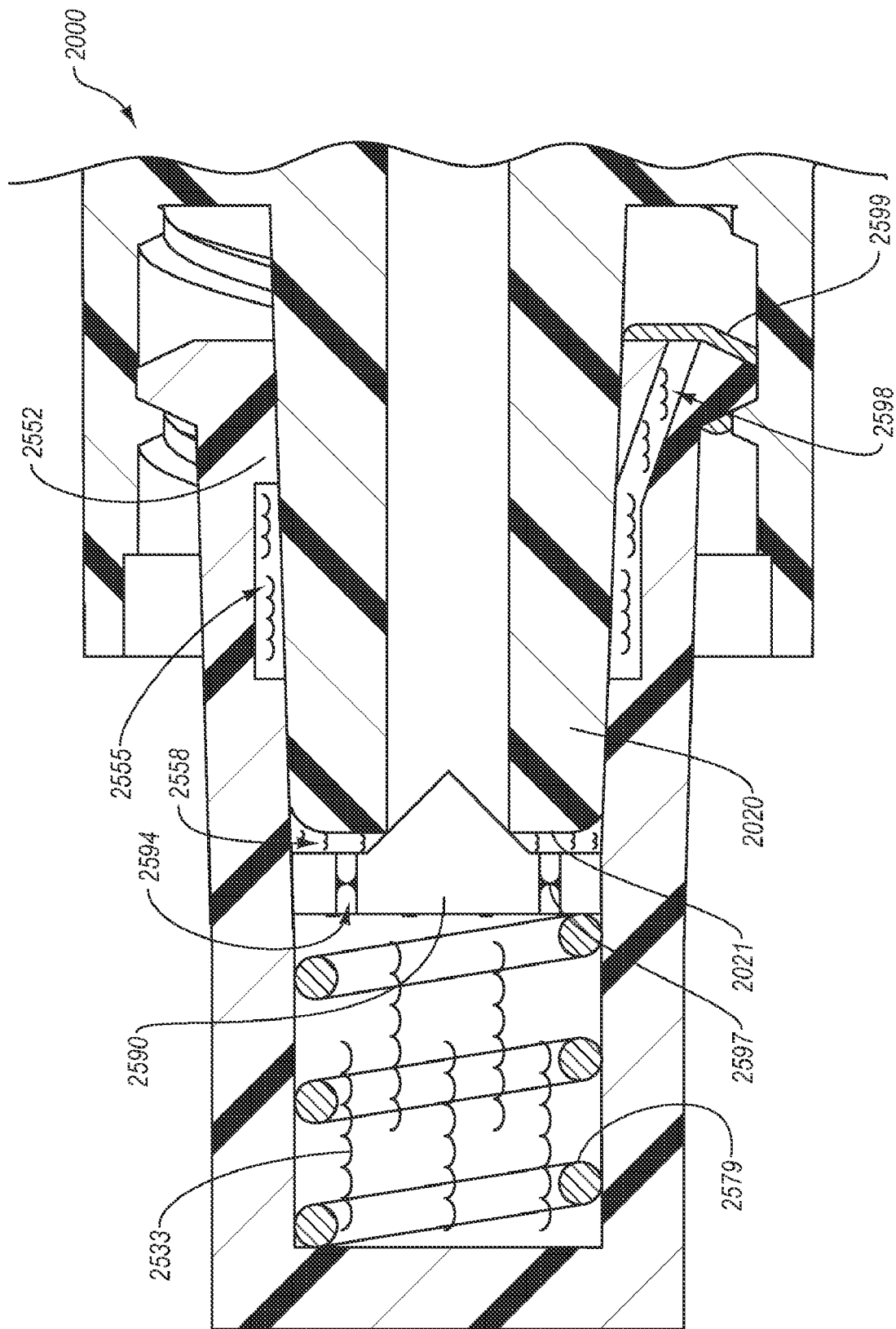


Fig. 49

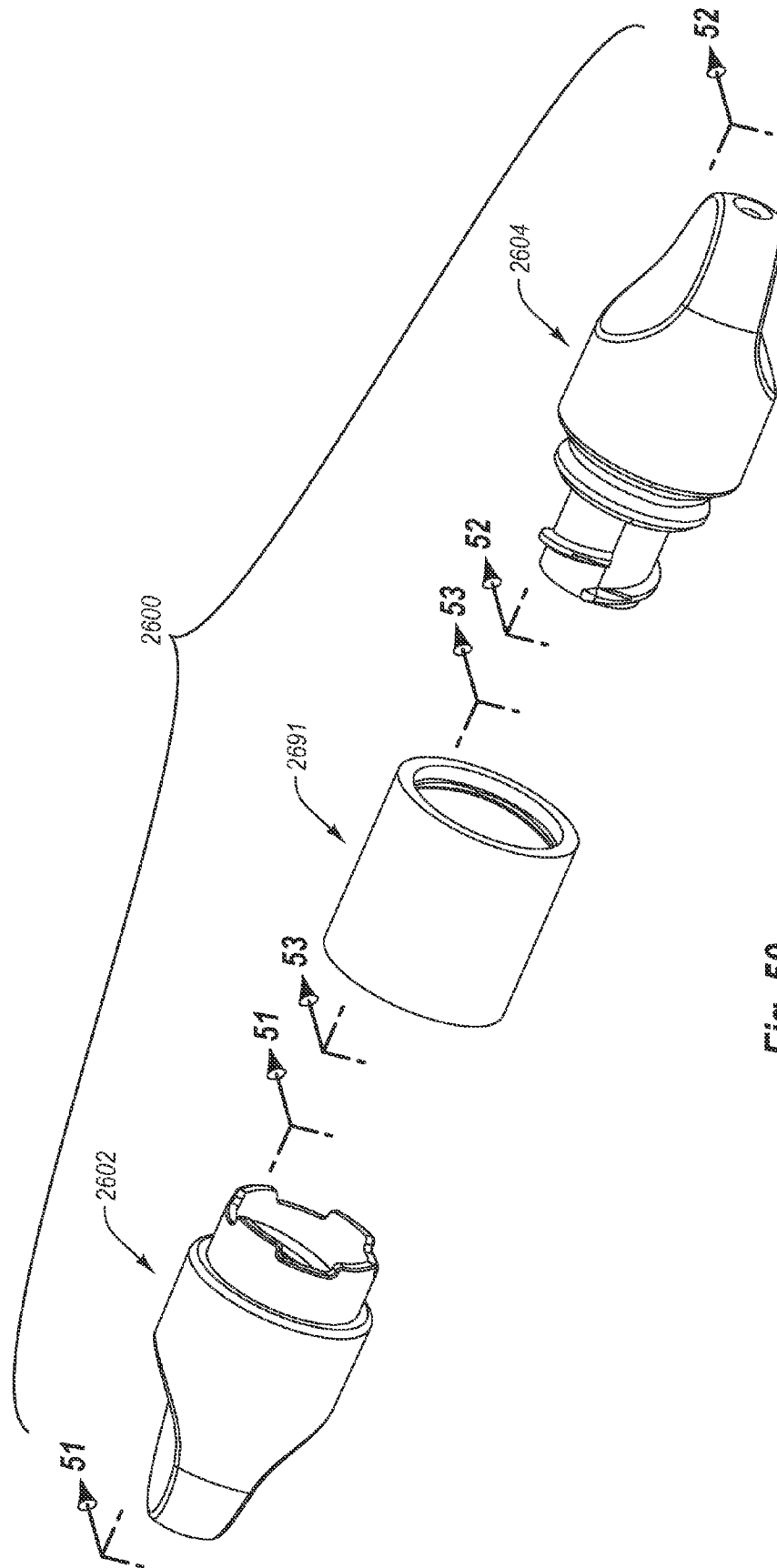


Fig. 50

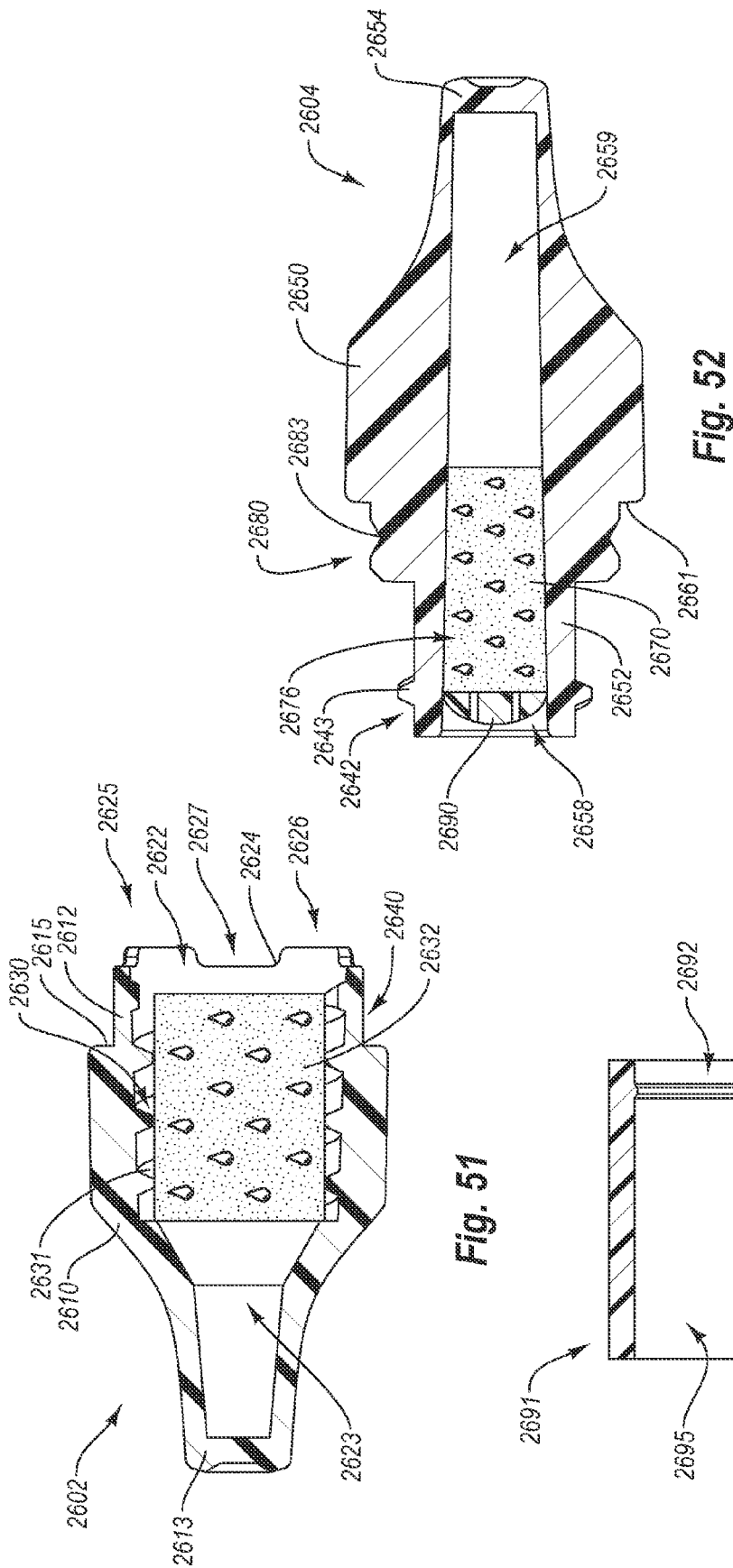


Fig. 51

Fig. 52

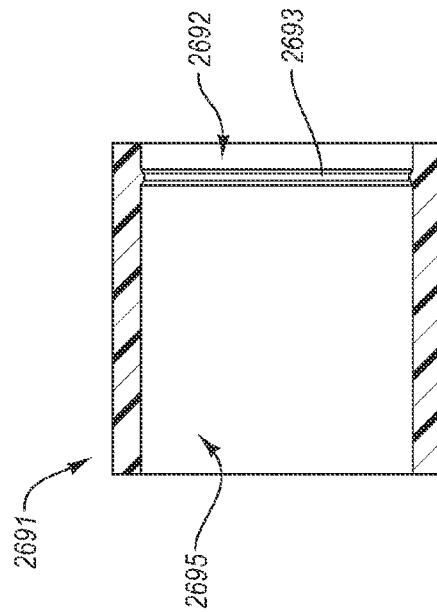


Fig. 53

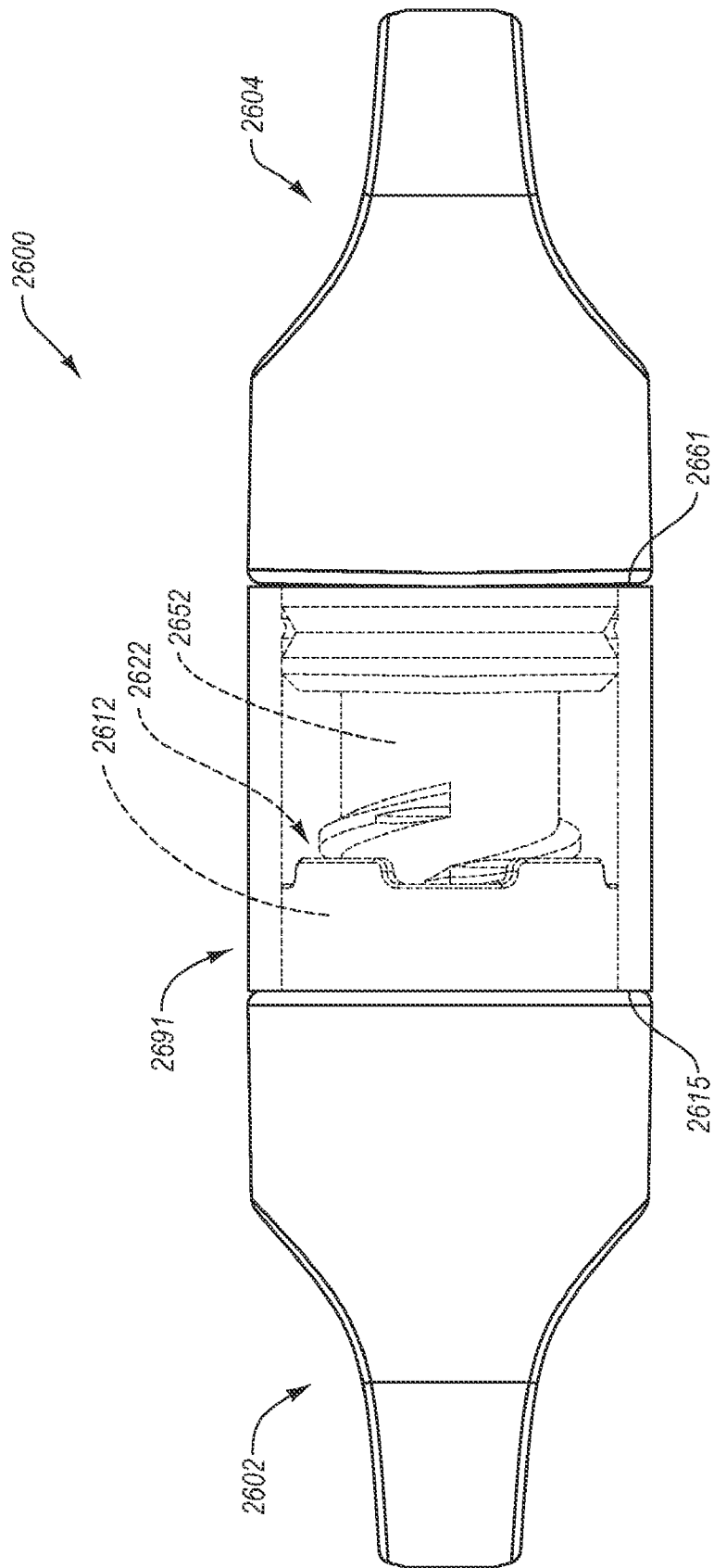


Fig. 54

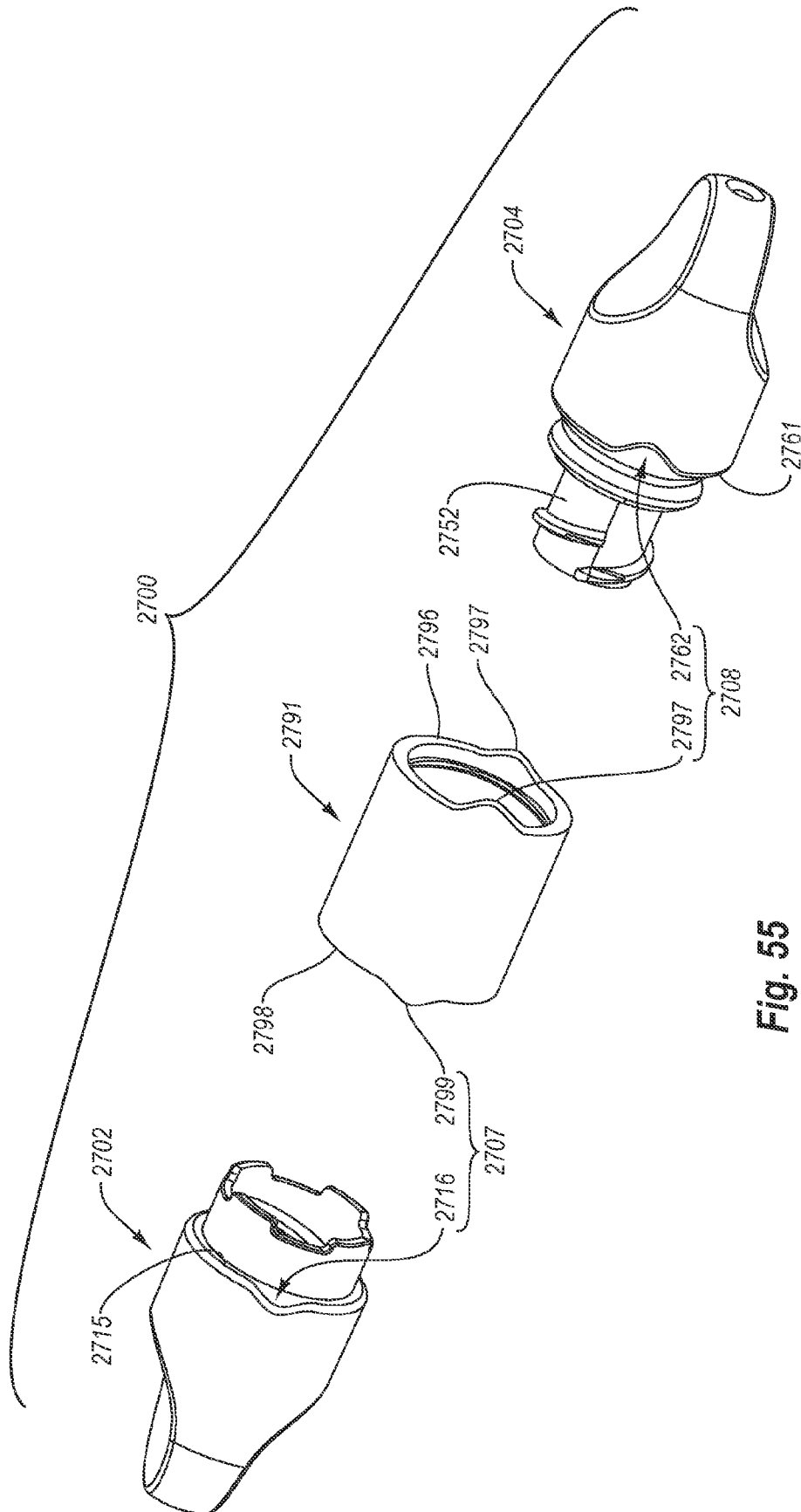
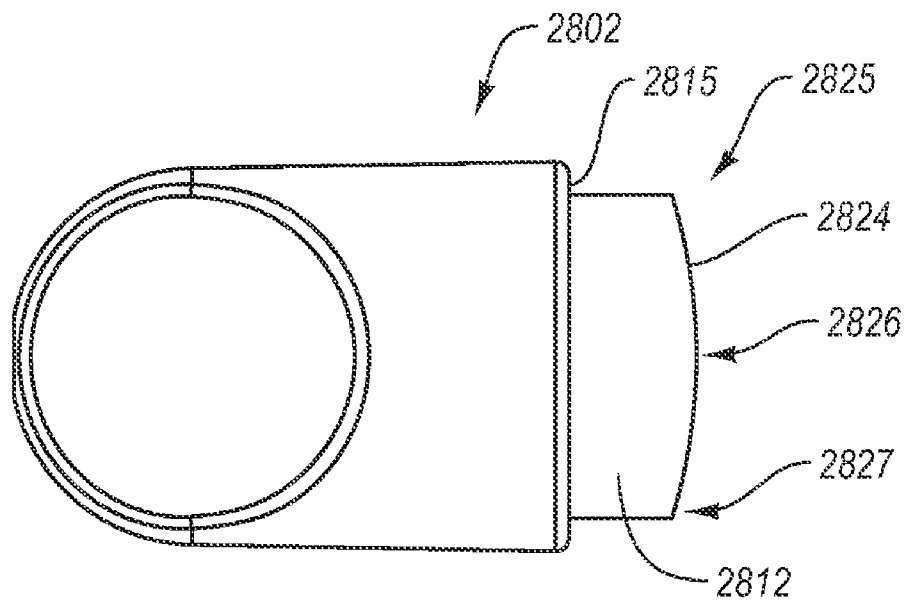
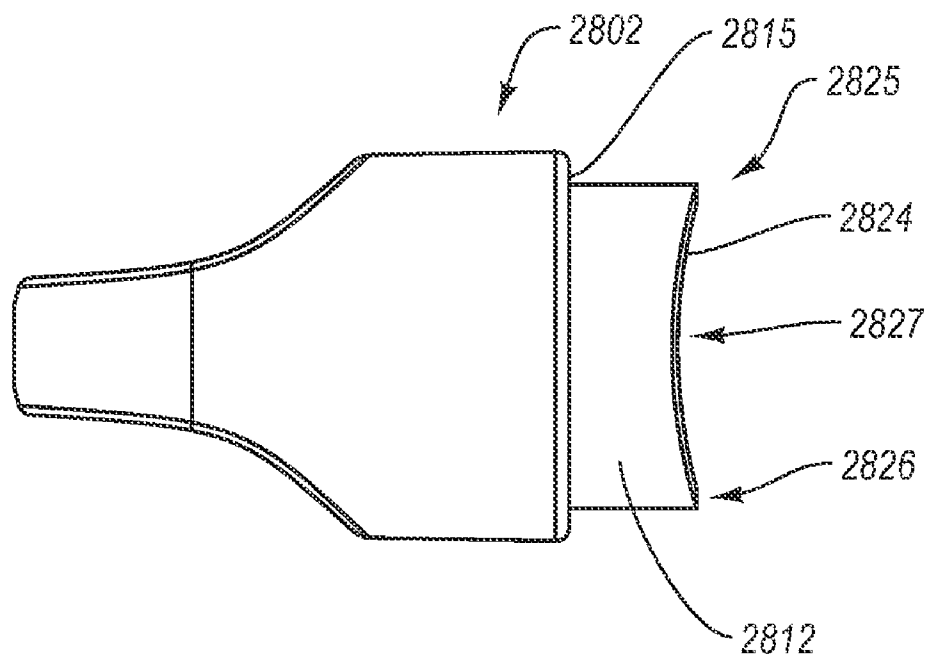
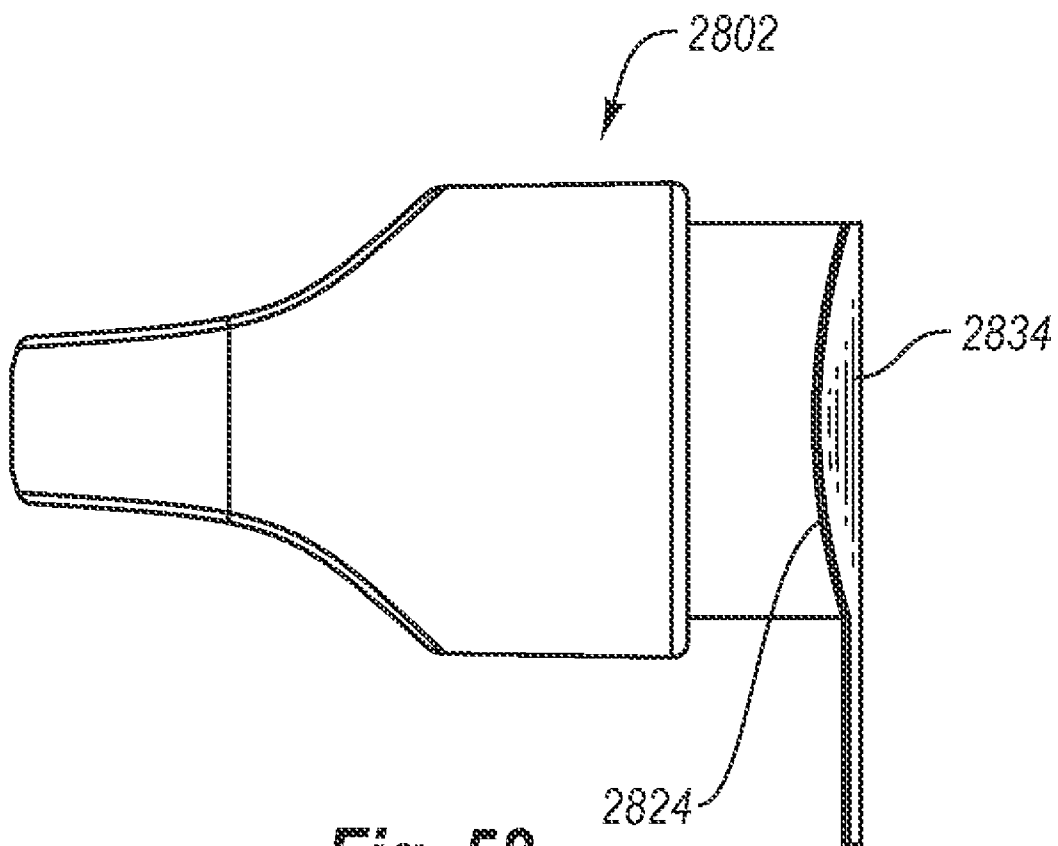


Fig. 55

**Fig. 56****Fig. 57**

***Fig. 58***

1

METHODS FOR DISINFECTING MEDICAL CONNECTORS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 12/171,997, titled STERILITY-PROTECTING CAPS WITH FLUID RESERVOIR FOR SEPARATED CONNECTORS, filed Jul. 11, 2008, which is a continuation-in-part of U.S. patent application Ser. No. 12/164,310, titled NESTABLE STERILITY-PROTECTING CAPS WITH FLUID RESERVOIR FOR SEPARATED CONNECTORS, filed Jun. 30, 2008, which is a continuation-in-part of U.S. patent application Ser. No. 12/014,388, titled NESTABLE STERILITY-PROTECTING CAPS FOR SEPARATED CONNECTORS, filed Jan. 15, 2008, which claims the benefit of U.S. Provisional Application No. 60/880,541, titled ANTISEPTIC PROTECTIVE CAP FOR MALE AND FEMALE SCREW-TOGETHER CONNECTORS, filed Jan. 16, 2007, the entire contents of each of which are hereby incorporated by reference herein.

BACKGROUND

1. Technical Field

The present disclosure generally relates to caps for medical connectors and more specifically relates to caps that can be used to protect the sterility of unconnected medical connectors, such as connectors that may be used for fluid flow or for fluid delivery systems.

2. Related Art

Bloodstream infections, such as may be caused by microorganisms that enter patients via intravascular catheters, are a significant cause of illness and excess medical costs. A substantial number of such infections occur in U.S. intensive care units annually. Additionally, a significant fraction of these infections result in death.

Guidelines from the Centers for Disease Control and Prevention describe various ways to limit bloodstream infections in hospital, outpatient, and home care settings. The guidelines address issues such as hand hygiene, catheter site care and admixture preparation. However, despite these guidelines, such infections continue to plague healthcare systems at relatively unchanged rates.

Impregnating catheters with various antimicrobial agents is one approach for reducing these infections. Impregnated catheters, however, provide less than satisfactory results. Additionally, some microbes have developed resistance to the various antimicrobial agents used in the catheters. Other systems and approaches have also been developed, but these likewise suffer from a variety of limitations and drawbacks.

SUMMARY

Disclosed herein are sterility caps, and related systems and methods, that can reduce the threat of microorganisms entering the bloodstream of a patient via fluid flow or fluid delivery systems, such as, for example, needleless injection sites and/or fluid transfer devices having a male luer. In some embodiments, a cap is configured to couple with and sterilize a medical connector having a male luer. In further embodiments, the cap can include an antiseptic, and can be configured to create a seal with the male luer so as prevent antiseptic from entering a lumen of the male luer. Other or further features of various embodiments are also disclosed and are set

2

forth in the appended claims, which are hereby incorporated by reference in this summary section.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevation view of an embodiment of an assembly that includes an attached pair of medical caps;

FIG. 1A is an end perspective view of the caps of FIG. 1;

FIG. 1B is an end perspective view of the caps of FIG. 1 shown from a vantage point opposite of that shown in FIG. 1A;

FIG. 2 is an exploded perspective view of the medical caps of FIG. 1;

FIG. 3 is a perspective view of a first of the medical caps of FIG. 1, which shows internal threads;

FIG. 4 is a perspective view of the cap of FIG. 3 and an associated medical connector about to be connected therewith;

FIG. 5 is a perspective view of a second of the caps of FIG. 1 and a luer lock connector to which the male cap may be affixed;

FIG. 6 is a side elevation view of an attached pair of medical caps, similar to the caps of FIG. 1, but having an embodiment of a sealing mechanism disposed about connecting edges of the caps;

FIG. 7 is an exploded side elevation view of the cap assembly of FIG. 6;

FIG. 7A is a perspective view of one of the caps of FIG. 7 with a sealing mechanism disposed thereon;

FIG. 7B is a perspective view of the other cap of FIG. 7 with a sealing mechanism disposed thereon;

FIG. 8A is a side elevation view of the interconnected cap assembly of FIG. 6 with an embodiment of a seal partially displaced about connecting edges of the cap assembly;

FIG. 8B is a side elevation view of the interconnected cap assembly of FIG. 8A with the seal fully in place;

FIG. 9A is a side elevation view of the cap portion of FIG. 3 and an absorbent pad positioned above the cap portion;

FIG. 9B is a side elevation view of the cap portion and pad of FIG. 9A schematically showing the absorbent pad disposed within the cap portion;

FIG. 9C is a side elevation view of the cap portion and pad of FIG. 9B with a quantity of antiseptic material being dispensed into the cap and pad;

FIG. 9D is a perspective view of the cap portion containing the pad of FIGS. 9B and 9C affixed to an associated complementary cap;

FIG. 9E is a side elevation view of the cap portion of FIG. 5 and an absorbent pad disposed therein;

FIG. 10 is a cross-sectional perspective view of another embodiment of an assembly that includes a pair of caps, which are attached to each other via a threaded interface;

FIG. 11 is an exploded perspective view of the assembly of FIG. 10 showing the caps detached from each other;

FIG. 12 is a cross-sectional perspective view of another embodiment of an assembly that includes a pair of caps, which are attached to each other via a snapping interface;

FIG. 13 is a cross-sectional perspective view of another embodiment of an assembly that includes a pair of caps, which are attached to each other via a friction-fit interface;

FIG. 14 is a cross-sectional perspective view of another embodiment of an assembly that includes a pair of caps, which are attached to each other via a press-fit interface;

FIG. 15 is a cross-sectional perspective view of the assembly of FIG. 14 showing the caps detached from each other;

3

FIG. 16 is a cross-sectional perspective view of another embodiment of an assembly that includes a pair of caps, which are attached to each other via a welded interface;

FIG. 17 is a cross-sectional perspective view of the assembly of FIG. 16 showing the caps detached from each other;

FIG. 18 is a perspective view of another embodiment of an assembly that includes a pair of caps, which are attached to each other at least partially via a snapping interface;

FIG. 19 is a perspective view of the assembly of FIG. 18 showing the caps detached from each other;

FIG. 20 is a perspective view from a different angle of one of the caps of FIG. 18;

FIG. 21 is a perspective view from a different angle of another of the caps of FIG. 18;

FIG. 22 is a perspective view of another embodiment of an assembly that includes a pair of caps, which are attached to each other via a snapping interface;

FIG. 23 is a side elevation view of an embodiment of a cap that is compatible with at least the assemblies of FIGS. 18 and 22;

FIG. 24 is a cross-sectional view of another embodiment of an assembly that includes a pair of caps, which are attached to each other via a sleeve;

FIG. 25 is a perspective view of another embodiment of an assembly that includes two cap portions integrally connected to each other;

FIG. 26 is an exploded perspective view of the assembly of FIG. 25;

FIG. 27 is a perspective view focusing on one cap portion of the assembly of FIG. 25, with covers removed from the assembly;

FIG. 28 is a perspective view focusing on the other cap portion of the assembly of FIG. 25, with covers removed from the assembly;

FIG. 29 is a cross-sectional view of the assembly of FIG. 28 taken along the view line 29-29;

FIG. 30 is a cross-sectional view of the assembly of FIG. 25 showing an early stage of coupling a cap portion of the assembly with a medical connector that has a male luer;

FIG. 31 is a cross-sectional view of the assembly of FIG. 25 showing a late stage of coupling the cap portion of the assembly with the medical connector that has a male luer;

FIG. 32 is a cross-sectional view of the assembly of FIG. 25 showing a late stage of coupling the other cap portion of the assembly with a first embodiment of a needleless injection site;

FIG. 33 is a cross-sectional view of the assembly of FIG. 25 showing a late stage of coupling the other cap portion of the assembly with a second embodiment of a needleless injection site;

FIG. 34 is a cross-sectional view of the assembly of FIG. 25 showing a late stage of coupling the other cap portion of the assembly with a third embodiment of a needleless injection site;

FIG. 35 is a cross-sectional view of another embodiment of an assembly that includes two cap portions integrally connected to each other, with covers removed from the assembly;

FIG. 36 is an exploded perspective view of another embodiment of an assembly that includes two cap portions integrally connected to each other;

FIG. 37 is a cross-sectional view of the assembly of FIG. 36 similar to the view shown in FIG. 29;

FIG. 38 is a cross-sectional view of the assembly of FIG. 36 showing an early stage of coupling a cap portion of the assembly with a medical connector that has a male luer;

4

FIG. 39 is a cross-sectional view of the assembly of FIG. 36 showing a late stage of coupling a cap portion of the assembly with a medical connector that has a male luer;

FIG. 40 is an exploded perspective view of another embodiment of a cap configured for coupling with a medical connector having a male luer;

FIG. 41 is a cross-sectional view of the assembled cap of FIG. 40 showing an early stage of coupling the cap with a medical connector that has a male luer in which the male luer has not yet contacted a sealing member of the cap;

FIG. 42 is a cross-sectional view such as that of FIG. 41 showing a later stage of coupling the cap with the medical connector in which the male luer forms a fluid-tight seal with the sealing member of the cap;

FIG. 43 is a cross-sectional view such as that of FIG. 41 showing a yet later stage of coupling the cap with the medical connector in which a pad is compressed so as to expel anti-septic therefrom through the sealing member and in which the male luer has not yet formed a fluid-tight seal with a sidewall of the medical connector;

FIG. 44 is a cross-sectional view such as that of FIG. 41 showing a yet later stage of coupling the cap with the medical connector in which the pad is compressed further so as to expel additional antiseptic therefrom through the sealing member and in which the male luer has not yet formed a fluid-tight seal with a sidewall of the medical connector;

FIG. 45 is a cross-sectional view such as that of FIG. 41 showing a yet later stage of coupling the cap with the medical connector in which that pad is compressed even further so as to expel additional antiseptic therefrom through the sealing member and in which the male luer forms a fluid-tight seal with a sidewall of the medical connector;

FIG. 46 is a cross-sectional view such as that of FIG. 41 showing another embodiment of cap coupled with a medical connector having a male luer;

FIG. 47 is a cross-sectional view of another embodiment of a cap configured for coupling with a medical connector having a male luer;

FIG. 48 is a cross-sectional view of yet another embodiment of a cap configured for coupling with a medical connector having a male luer;

FIG. 49 is a cross-sectional view of the cap of FIG. 48 coupled with a medical connector having a male luer;

FIG. 50 is an exploded perspective view of another embodiment of an assembly that includes a female cap and a male cap, which can be connected in a pre-use configuration via a sleeve;

FIG. 51 is a cross-sectional view of the female cap of FIG. 50 taken along the view line 51-51;

FIG. 52 is a cross-sectional view of the male cap of FIG. 49 taken along the view line 52-52;

FIG. 53 is a cross-sectional view of the sleeve of FIG. 49 taken along the view line 53-53;

FIG. 54 is an elevation view of the assembly of FIG. 50 shown in a pre-use configuration;

FIG. 55 is an exploded perspective view of another embodiment of an assembly that includes a female cap and a male cap, which can be connected in a pre-use configuration via a sleeve and that includes separation assists;

FIG. 56 is an elevation view of an embodiment of a cap that includes a seal inhibitor;

FIG. 57 is another elevation view of the cap of FIG. 56 showing a different face thereof; and

FIG. 58 is an elevation view of the cap of FIG. 56 coupled with a removable cover.

DETAILED DESCRIPTION

Disclosed herein are caps that can be used to protect and/or sterilize medical connectors. Systems and methods related to

such caps are also disclosed. An example of medical connectors for which caps disclosed herein may be used are intravascular connectors associated with a fluid pathway, such as an IV line. Commonly, a fluid pathway is used to intermittently administer medications to a patient. For example, a fluid pathway, which communicates fluids with a patient's blood stream, may have one or more connectors associated therewith. Each of the fluid pathway connectors can be connected to other connectors, such as a connector associated with a central line. In such a situation, the medical connectors, such as luer lock connectors, are connected and disconnected at various times, and may remain disconnected for several minutes or hours. Medical connector caps are used to cover and protect the various medical connectors while the connectors are separated from one another. When the medical connectors are separated from each other, there are two connectors that each can benefit from being covered by a cap. Therefore, in some cases, it can be advantageous to have a single connector set that can be used to provide protection for both ends of a separated connection. In other or further embodiments, a cap can include an antiseptic for sterilizing a medical connector. In some cases, it can be advantageous for the cap to form a seal with the medical connector to thereby prevent the antiseptic from exiting the cap into the fluid pathway.

Shown in FIGS. 1-1B, is a system, unit, or assembly 100 of a pair of separable caps 102 and 104, which are securely, but releasably, affixed one to the other across a common interface 106. Internal parts and surfaces of the assembly 100 are sterile and are able to reduce, prevent, or eliminate contamination of connectors with which caps 102, 104 can be coupled.

As further discussed below, in various embodiments, caps 102 and 104 can be distributed in a coupled state, such as that shown in FIGS. 1-1B, and may be decoupled by a user (e.g., a medical professional) and subsequently coupled with connectors. Caps 102 and 104 can include features to aid in such a decoupling action and/or in the coupling of caps 102, 104 with the respective connectors. For example, in the illustrated embodiment, each cap 102, 104 includes gripping features 103.

The gripping features 103 can comprise longitudinally extending lands or ridges 105 that taper from a relatively wide width near the interface 106 of the caps 102, 104 to a narrower width at or near an outer end of the cap 102, 104. The gripping features 103 can further include longitudinally extending depressions or grooves 107 between adjacent ridges 105. For example, as can be seen in FIGS. 1-8B, the grooves 107 can extend radially inwardly from an outer surface of the cap 102 that comprises the ridges 105, and the grooves 107 can also commence at a position near the interface 106 and can grow wider and deeper toward an outer end of the cap 102. The gripping features 103 can further include longitudinally extending bumps or protrusions 108 between adjacent ridges 105. As can be seen in FIGS. 1-8B, the protrusions 108 can extend radially outwardly from an outer surface of the cap 104 that comprises the ridges 105, and the protrusions 108 can also commence at a position near the interface 106 and can grow wider and taller toward an outer end of the cap 104. The uneven surfaces provided by the ridges 105 and the grooves 107 or protrusions 108 can facilitate rotational movement of the caps 102, 104 (e.g., rotational movement relative to each other), which can aid in decoupling the caps 102, 104 from each other and/or securing the caps 102, 104 to separated connectors. For example, the uneven surfaces may be easily gripped by the fingertips of a medical practitioner.

As can be seen, for example, in FIGS. 1A and 1B, the patterns of the ridges 105, grooves 107, and/or protrusions

108 can be different for the caps 102, 104. In the illustrated embodiment, cap 102 includes only ridges 105 and grooves 107, whereas cap 104 includes only ridges 105 and protrusions 108. Such differences can aid in distinguishing the caps 102, 104 from each other. Other features and methods for distinguishing the caps 102, 104 from each other are discussed further below.

Caps 102 and 104 are shown as separated from each other, or in a decoupled state, in FIG. 2, wherein cap 104 is shown as having an insertable or male section 108. Section 108 has an elongated portion 110 that ends at an exteriorly disposed threaded segment 112. Threaded segment 112 comprises threads 114 that are sized and shaped to be inserted and joined by threading into cap 102.

Cap 102, as shown in FIG. 3, has a closed, hollow interior 116, which may also be referred to as a sterilization cavity or chamber, which opens outwardly at a proximal end 118 to expose an interiorly disposed threaded segment 120 that includes threads 122. Threads 122 are of a size and pitch to complementarily engage threads 114 of cap 104 for a screw or push-on tight fit with cap 104.

As illustrated in FIG. 4, cap 102 has an interior surface 124, an opening edge 126 and an exterior surface 128, opening edge 126 being a common link between interior surface 124 and exterior surface 128. Further, threads 122 also have a size and pitch to engage a threadable segment 130 of a female connector, such as for example, female luer connector 132. Such connectors are generally and commonly used as catheter and other fluid-tight protective connectors in medical applications. As seen in FIG. 4, cap 102 provides a protective cover for connector 132 when encased about connector 132 (displaced in direction of arrow 134) whereupon threadable segment 130 engages and is drawn into a secure, but releasable connection with threads 122 of cap 102.

In some embodiments, the connector 132 comprises a needleless injection site, which may sometimes referred to as a needleless injection port, hub, valve, or device, or as a needleless access site, port, hub, valve, or device, and which can include such brands as, for example, Clave® (available from ICU Medical, Inc.), SmartSite® (available from Cardinal Health, Inc.), and Q-Syte™ (available from Becton, Dickinson and Company). Stated otherwise, in some embodiments, cap 102 can be suitably connected with any of a variety of different needleless injection sites, such as those previously listed. In certain embodiments, once cap 102 has been applied to or coupled with connector 132, it is unnecessary to disinfect (e.g. treat with an alcohol swab) the connector 132 prior to each reconnection of the connector 132 with another connector, as the connector 132 will be kept in an uncontaminated state while coupled with the cap 102. Use of the cap 102 thus can replace the standard swabbing protocol.

As seen in FIG. 5, threads 114 of cap 104 are of a size and pitch to engage threads 138 of a male luer-lock connector 136. For example, connector 136 can comprise the end of an IV tubing set that is disconnected from an IV catheter needleless injection site. Note that cap 104 has a medially disposed, elongated hole 140, which may also be referred to as a sterilization chamber, into which a frustoconical luer 142 of connector 136 may be facily and securely inserted when cap 104 is displaced in the direction of arrow 144 to engage connector 136.

Cap 104 also has a surface 146 which continues through to a circular edge 148. Further, distally displaced from circular edge 148, surface 146 abruptly ends at a circular ring shaped edge 150, which is therefrom joined to an outside surface 152. It may be noted that opening edge 126 (see FIG. 4) and ring shaped edge 150 combine to form common interface 106 (see

FIG. 1) when cap 102 is affixed to cap 104 to construct assembly 100. It should also be noted that, in certain embodiments, surfaces of assembly 100, which contact internal surfaces of a connector, such as connector 132 or connector 136, are sufficiently sterile to not contaminate the inner surfaces thereof.

Internal portions and associated edges of caps 102 and 104 can be pre-sterilized and so maintained until use. Caps 102 and 104 may be injection molded using polypropylene or other material that can be sterilized and which is impervious to contaminating agents while cap 102 is nested with cap 104, before being opened for use. Caps 102 and 104 can also be impregnated or coated with an antimicrobial substance. As an example, each cap 102 and cap 104 may be individually sterilized by ethylene oxide (ETO) before final assembly and aseptically paired, or assembly 100 may be finally consolidated as a single unit and then sterilized, such as by radiation (e.g. gamma). Even so, assembly 100 should be kept intact until time for use, with internal surfaces of nested parts 102 and 104 remaining clean and sterile until assembly 100 is opened for use.

Reference is now made to FIGS. 6 through 7B, wherein a seal, such as an "O" ring, is disposed between surfaces 126 and 150 to provide yet another barrier against internal surface contamination of caps 102 and 104. As seen in FIG. 6, an "O" ring 154 is disposed between surfaces 126 and 150 to provide a seal thereby. While "O" ring 154 can be displaced from caps 102 and 104 as illustrated in FIG. 7, it is anticipated that "O" ring 154 can be adapted to remain affixed to one of caps 102 and 104. For example, as illustrated in FIG. 7A, "O" ring 154 can remain positioned adjacent surface 150 on cap 104 when caps 102 and 104 are disconnected from one another, rather than being separated when cap 104 is displaced from cap 102, as seen in FIG. 7.

Alternatively, "O" ring 154 can be associated with cap 102, as seen in FIG. 7B. In particular, opening edge 126 of cap 102 can have an annular groove 156 for receiving "O" ring 154 therein. Annular groove 156 can be sized and shaped such that "O" ring 154 sealingly engages cap 104 or a medical connector when cap 102 is coupled thereto. It will be appreciated that annular groove 156 can be disposed in opening edge 126 toward the exterior of cap 102 as illustrated in FIG. 7B, or annular groove 126 can be disposed in opening edge 126 towards the interior of cap 102. In some exemplary embodiments, opening edge 126 of cap 102 does not have annular groove 126 therein. In such embodiments, "O" ring 154 can be mounted directly to opening edge 126. "O" ring 154 can be mounted on or to caps 102 or 104 in any suitable manner, including with the use of an adhesive, such as glue, a mechanical fastener, or a friction fitting.

While the seal between caps 102 and 104 has been described as being an "O" ring mounted on one of caps 102 or 104, it will be appreciated that other seals are contemplated. For example, each of caps 102 and 104 can have an "O" ring mounted thereon. In such a configuration, the two "O" rings abut each other when caps 102 and 104 are coupled together, thereby forming a seal to antiseptically partition the internal and external surfaces of caps 102 and 104. In an alternate embodiment, an "O" ring or other sealing mechanism can be mounted on surfaces 109a and 109b. Alternatively, one or both of caps 102 and 104 can be formed with a lip, bump, or groove that provides a sealing function when caps 102 and 104 are coupled to each other or to separated medical connectors. In one exemplary embodiment, one of caps 102 and 104 has a ridge extending around its interfacing surface, and the other cap has a corresponding groove in its interfacing surface into which the ridge is received to create the seal. In

yet another exemplary embodiment, one or both of caps 102 and 104 can be overmolded or comolded using any known and suitable overmolding or comolding process. For example, one or both of caps 102 and 104, and associated surfaces 126 and 150, can be overmolded or comolded. Thus, caps 102 and 104 can be formed of a polymer, and surfaces 126 and 150 can be formed of a softer polymer that is comolded or overmolded to the rest of caps 102 or 104. Surfaces 126 and 150, formed of the softer polymer, are thus able to be compressed or deformed sufficiently to create an impermeable seal when caps 102 and 104 are coupled together or coupled to separated medical connectors.

As noted elsewhere herein, a sealing mechanism, as described herein, can be used to limit or prevent evaporation or loss of an antiseptic agent disposed within caps 102 and 104 when caps 102 and 104 are coupled together. Additionally, a sealing mechanism, as described herein, can also limit or prevent evaporation or loss of an antiseptic agent disposed within caps 102 and 104 when caps 102 and 104 are coupled to separated medical connectors. Further, a sealing mechanism, as described herein, can also limit or prevent microbial ingress within caps 102 and 104 when they are coupled to each other, or within caps 102 and 104 when caps 102 and 104 are individually coupled to separated medical connectors. Moreover, a sealing mechanism, as described herein, can be adapted to maintain an antiseptic agent within caps 102 and 104 when caps 102 and 104 are either coupled to one another or to separated medical connectors for a predetermined amount of time. Thus, the seal may be adapted to limit or prevent microbial ingress, while also partially or completely preventing evaporation of an antiseptic agent disposed within caps 102 and 104 when caps 102 and 104 are coupled together or when caps 102 and 104 are coupled to separated medical connectors. Similarly, the seal may be adapted to limit or prevent microbial ingress while not preventing evaporation of an antiseptic agent disposed within caps 102 and 104. In yet other embodiments, no seal is provided between caps 102 and 104 when coupled together or between caps 102 and 104 when coupled to separated medical connectors.

Further safety in sealing against internal surface contamination may be provided by a sealing tape, or a planar or foil seal, such as tape 158 seen in FIG. 8A. Tape 158 is disposed to fully cover exposed edges of surfaces 126 and 150. Tape 158 may, for example, be of an impervious pliable material, such as a metallized-surface mylar. As seen in FIG. 8B, tape 158 is wrapped about surfaces 126 and 150 to provide a secure seal. It is preferred that tape 158 frangibly divides when cap 102 is separated from cap 104 to facilitate separation of caps 102 and 104 and provide a visible indication that the seal is broken. Thus tape 158 provides both a seal to prevent microbial ingress and a mechanism for maintaining the secure connection between caps 102 and 104 prior to use. It will be appreciated, however, that any suitable sealing mechanism can be used to maintain the secure connection between caps 102 and 104 prior to use. For example, any sealing mechanism can be used that securely and selectively couples caps 102 and 104 together, requires deliberate action to break the seal, and provides a visual indication of whether the seal has been broken. By way of example and not limitation, a suitable sealing mechanism may include a heat stake, a frictional seal, a barbed seal, a ratchet seal, and the like.

When capping disconnected medical connectors, it can be desirable to do more than merely cover the connectors. For example, an absorbent pad, such as pad 160, seen in FIG. 9A, may be included within cap 102 (e.g., within the sterilization chamber 116), such as by displacing pad 160 into cap 102 as indicated by arrow 162. Pad 160 is seen disposed in cap 102

in FIG. 9B. An antiseptic **164** can also be disposed within cap **102** as illustrated in FIG. 9C. Antiseptic **164** can be in liquid or solid form. For example, alcohol or another stable liquid antiseptic may be added from a container **166** to be received within, wet, soak, or saturate pad **160** to a predetermined concentration level. Note that once assembly **100** is fully assembled, pad **160** will substantially remain at the predetermined concentration level due to the exterior seals provided for assembly **100** as described herein. Alternatively, or additionally, pad **160** may receive or be impregnated with a dry antiseptic, such as, for example, chlorhexidine gluconate.

Further note that once cap **104** is securely affixed to cap **102**, as seen in FIG. 9D, pad **160** is disposed to contact at least circular edge **148** (see also FIG. 5). (In FIG. 9D, parts of cap **104** which are internal to assembly **100** are seen with hidden or dashed lines.) Such contact provides a wiping action preferred to make contact with a surface before contact is made with an associated connector. Note also that residual antiseptic on associated internal surfaces of cap **104** may be transferred to related parts of the associated connector for cleaning and/or disinfecting purposes.

Pad **160** can be formed of a deformable, resilient material such that when cap **104** is coupled to cap **102**, elongated portion **110** can compress pad **160** within cap **102**, as illustrated in FIG. 9D. Further, pad **160** can expand to its original shape when cap **104** is removed from cap **102**. Similarly, pad **160** can be compressed within cap **102** when cap **102** is coupled to a medical connector, such as medical connector **132**. More specifically, during the connection of cap **102** to a medical connector, cap **102** and pad **160** rotate relative to an opening edge of the medical connector, thereby drawing the medical connector into cap **102**. The rotation of cap **102** causes pad **160** to wipe or scrub the opening edge of the medical connector. Pad **160** and any antiseptic disposed within cap **102** can thus cleanse and disinfect the opening edges of the medical connector. Pad **160** can also be formed such that when a medical connector is coupled to cap **102**, pad **160** is deformed such that pad **160** extends around the opening edges and/or threads of the medical connector. For example, pad **160** can be formed such that as cap **102** is twisted onto medical connector **132**, pad **160** deforms around threads **130** and/or the opening edges of medical connector **132**, thereby scrubbing threads **130** and/or the opening edge of medical connector **132**.

Pad **160** can also provide additional functionality when a liquid antiseptic is disposed within cap **102**. In particular, pad **160** acts as a sponge to absorb or release the liquid antiseptic within cap **104**. More specifically, when pad **160** is compressed by elongate portion **110** of cap **104** (FIG. 9D; see also elongate portion **268** compressing pad **160** in FIG. 14) or the opening edges of a medical connector coupled to cap **102**, pad **160** releases at least a portion of the antiseptic so that the antiseptic can be transferred to elongate portion **110** or the opening edges of the medical connector. Conversely, when cap **102** or a medical connector is disconnected from cap **102**, pad **160** expands and absorbs excess antiseptic so that the antiseptic does not drip or spill out of cap **102**.

Similar to pad **160** and antiseptic **164** disposed within cap **102**, cap **104** may also have a pad and/or an antiseptic disposed therein. For example, as illustrated in FIG. 9E, a pad **170** may be disposed within elongate hole **140** of cap **104**. An antiseptic can also be disposed within cap **104** in a manner similar to antiseptic **164** in cap **102**. Antiseptic can be in liquid or solid form. For example, alcohol or another stable liquid antiseptic may be added from a container to saturate pad **170** to a predetermined level. Alternatively, or additionally, pad **170** may be impregnated with a dry antiseptic, such as chlo-

roxidine gluconate. Once assembly **100** is fully assembled, an antiseptically saturated pad **170** disposed within cap **104** will substantially remain at the predetermined saturation level due to the exterior seals for assembly **100** as described above.

Once caps **102** and **104** are disconnected from each other and connected to individual medical connectors, pad **170** disposed within cap **104** may scrub related parts of the associated connector for cleaning and/or disinfecting purposes. It will be appreciated, however, that in some embodiments, pad **170** may not contact a medical connector coupled to cap **104**. Additionally, the antiseptic disposed within cap **104** may be transferred to the related parts of the associated medical connector for cleaning and/or disinfecting purposes.

Additional embodiments of caps such as the caps **102**, **104** are provided in FIGS. 10-29 and the associated written description of U.S. patent application Ser. No. 12/171,997, titled STERILITY-PROTECTING CAPS WITH FLUID RESERVOIR FOR SEPARATED CONNECTORS, which was filed on Jul. 11, 2008 and was published as U.S. Patent Application Publication No. 2009/0062766 on Mar. 5, 2009 ("the Publication"), which is hereby incorporated by reference herein. As indicated in the Publication, any suitable feature of the illustrative embodiments of FIGS. 16-29 of the Publication, which are described with respect to a female-type cap similar to the cap **102**, may be applied to or incorporated within a male-type cap, similar to the cap **104**. Likewise, the female-type caps described with reference to FIGS. 16-29 of the Publication can be coupled to a male-type cap in a manner similar to that described with reference to caps **102** and **104**, in which the caps **102**, **104** are nested with each other. In other embodiments, any suitable feature of the caps described with respect to FIGS. 1-29 of the Publication, whether of a male or female variety, can be formed and/or employed without being nested or otherwise associated with a complementary cap.

Discussed hereafter are additional embodiments of caps, which can have coupling arrangements and/or other features that differ in certain respects from those of the caps **102**, **104** described above and other caps described in the Publication. Any suitable feature of such caps can be incorporated into the caps described hereafter, and vice versa.

FIGS. 10 and 11 depict a system or assembly **1000** that includes a first protective medical connector, shield, or cap **1002** and a second protective medical connector, shield, or cap **1004**. As shown in FIG. 10, the caps **1002**, **1004** are connected to each other when the assembly **1000** is in a shipping or pre-use state. As shown in FIG. 11, the caps **1002**, **1004** can be separated from each other such that each may be coupled with a corresponding or complementary medical connector. For example, as with the cap **102**, the cap **1002** can be configured to couple with a female connector, such as a female luer lock or a needleless injection site (see, e.g., FIG. 4). Accordingly, the cap **1002** may be referred to as a female cap. As with the cap **104**, the cap **1004** can be configured to couple with a male connector, such as a male luer lock (see, e.g., FIG. 5). Accordingly, the cap **1004** and may be referred to as a male cap.

With continued reference to FIGS. 10 and 11, the cap **1002** can comprise a housing **1010**. The housing **1010** can be elongated, and may define a cylinder or any other suitable shape. For example, in the illustrated embodiment, the housing **1010** includes a sidewall **1012** that defines a substantially cylindrical outer surface **1014**. The outer surface can be smooth, as shown, which can enhance comfort to a patient if the cap **1002** contacts the patient when coupled with a medical connector. In other embodiments, the outer surface can include gripping features, which can aid in rotating the cap **1002** relative to the

11

cap **1004** to permit separation of the caps **1002**, **1004** and/or aid in rotating the cap **1002** relative to a medical connector. Such gripping features can include, for example, ridges, grooves, an/or protrusions similar to the ridges **105**, grooves **107**, and protrusions **108** described above and/or an elastomeric or other coating or layer having a relatively high coefficient of friction. The sidewall **1012** can define a sealing surface **1016** at one end thereof and can define a terminal edge **1018** at an opposite end thereof.

The housing **1010** can further include a transverse wall or partition **1020**. In the illustrated embodiment, the partition **1020** defines a plane that is substantially perpendicular to a longitudinal axis of the sidewall **1012**. A first portion of the sidewall **1012** can cooperate with one side of the partition **1020** to define a sterilization chamber **1022**, which is closed at one end by the partition **1020** and open at an opposite end thereof (e.g., the sealing surface **1016** can define an open end of the sterilization chamber **1022**). Similarly, a second portion of the sidewall **1012** can cooperate with an opposite side of the partition **1020** to define a coupling chamber **1024**, which likewise is closed at one end by the partition **1020** and open at an opposite end thereof (e.g., the terminal edge **1018** can define an open end of the coupling chamber **1024**).

An interior surface the sidewall **1012** can include a connection interface **1030** in the region of the sterilization chamber **1022**. The connection interface **1030** can comprise inwardly projecting threads **1031** similar to the threads **122** described above, and can be configured to complementarily engage a connection interface of a medical connector, such as, for example, outwardly projecting threads of a needleless injection site. The threaded connection interface **1030** thus can allow for selective coupling of the cap **1002** to a medical connector in a secure, yet selectively removable fashion. Other configurations of the connection interface **1030** may permit the cap **1002** to be coupled with a medical connector in a secure, yet selectively removable fashion, such as friction-fit, snap-fit, or other suitable interfacing arrangements.

The sterilization chamber **1022** can include a pad **1032** therein. The pad **1032** can resemble the pads **160**, **170** described above. In various embodiments, the pad **1032** can be deformable, and can also be configured to retain an antiseptic **1033**, such as, for example, the antiseptic **164** described above. In further embodiments, the pad **1032** can be resiliently deformable. For example, the pad **1032** can comprise any suitable sponge-like material, such as an elastomeric foam, any open-cell foam, felt, or non-woven fiber matrix, and can be configured to conform to the contours of a portion of a medical connector that is introduced into the sterilization chamber **1022** (e.g., uneven surfaces of an end of a needleless injection site; see also FIGS. **32-34** and the associated written description herein). The pad **1032** can also comprise any closed-cell foam, as well as a solid elastomeric foam such as Silicon or the like.

The pad **1032** can have a series or network of openings or spaces therein that can retain the antiseptic **1033** when the pad **1032** is in an expanded state. For example, the antiseptic **1033** can be received within, occupy, fill (or partially fill), wet, soak, or saturate at least a fraction of the pad **1032**, or stated otherwise, can fill the pad **1032** to a given concentration level. Compression of the pad **1032** can cause antiseptic **1033** to egress from the pad **1032** so as to contact the medical connector. Resilient expansion of the foam upon removal of a compressive force can allow the pad **1032** to soak up or absorb at least some of the antiseptic **1033** that had previously been forced from the pad **1032**. In some embodiments, the antiseptic **1033** can comprise any liquid antiseptic, such as alcohol, Isopropyl alcohol at various concentrations ranging

12

from 50-90%, ethanol at various concentrations ranging from 50-95%, and combinations of any alcohols with any antiseptics, or a dry material, such as chlorhexidine, ethylenediaminetetraacetic acid (EDTA), Iodophors, or any combination thereof. Accordingly, although the antiseptic **1033** is schematically depicted in FIG. **10** as a series of droplets, the antiseptic **1033** is not necessarily liquid and may fill the pad **1032** to a greater or lesser extent. In the illustrated embodiment, when the sterilization chamber **1022** is in a sealed state (e.g., in its pre-use condition), the pad **1032** is in a relaxed, expanded, or uncompressed state in a longitudinal direction. It is noted that the pad **1032** may be uncompressed in one or more dimensions, yet compressed in one or more other dimensions, when the assembly **1000** is in the pre-use state. For example, the pad **1032** can be expanded or in a relaxed state in a longitudinal direction, yet compressed radially inwardly via the sidewall **1012**, when the assembly **1000** is in the pre-use state. Such a lack of compression of the pad **1032** in the longitudinal direction can result from the fact that the cap **1004** does not interact with the connection interface **1030** of the cap **1002** to seal the cap **1002**, and thus no portion of the cap **1004** contacts the pad **1032** when the caps **1002**, **1004** are in the pre-use configuration.

In the illustrated embodiment, the pad **1032** is substantially cylindrical and defines an outer diameter that is approximately the same size as an inner diameter of the threads **1031**. In other embodiments, the outer diameter of the pad **1032** can be larger than the inner diameter of the threads **1031** so as to be radially compressed and held tighter within the sterilization chamber **1022**. In further embodiments, the pad **1032** can include threading that projects radially inwardly and that is complementary to the threads **1031** to thereby secure the pad **1032** within the chamber **1022**.

The sterilization chamber **1022** can be sealed at the sealing surface **1016** via a cover **1034** that can span an open end of the sterilization chamber **1022**. The cover **1034** can be secured to the housing **1010** in any suitable manner, such as, for example, via an adhesive. Preferably, the cover **1034** can be readily removed by a practitioner. For example, in some embodiments, the cover **1034** can include a tab **1035** and a practitioner can readily remove the cover **1034** by holding the housing **1010** in one hand and pulling the tab **1035** away from the housing **1010** with the other hand. The removable cover **1034** can be formed of any suitable material, such as, for example, an impervious pliable material (e.g., foil, plastic, metallized-surface mylar, and the like). The cover **1034** can provide a hermetic seal that can assist in maintaining the sterility of the sterilization chamber **1022** prior to use of the cap **1002** and/or can prevent evaporative loss of antiseptic **1033** from the sterilization chamber **1022**.

When the cap **1002** is coupled with a medical connector, the coupling action can bring a portion of the medical connector into contact with the pad **1032** and can allow the pad **1032** to wipe or scrub the medical connector, as described above. Likewise, the antiseptic **1033** can be forced into contact with the medical connector during the coupling phase and can remain in contact with the medical connector, while the cap **1002** is coupled with the medical connector. The connection interface **1030** can cooperate with a connection interface of the medical connector to maintain the cap **1002** in an attached configuration relative to the connector. Moreover, the connection interface **1030** can couple with the medical connector, such as via complementary threading, so as to prevent antiseptic from leaking from the sterilization chamber **1022**.

In some embodiments, such as where the pad **1032** is formed of a material that is not fully elastically resilient or

13

that requires a relatively long relaxation time in which to transition from a compressed state to a relaxed or uncompressed state (e.g., in a longitudinal direction), pre-use storage in the relaxed or uncompressed state in at least one dimension can preserve or enhance the cleaning, scrubbing, or sterilization properties of the pad 1032. For example, as the cap 1002 is coupled with the medical connector (e.g., the medical connector 132 of FIG. 4), an end of the medical connector can come into contact with a proximal surface (e.g., the surface furthest from the partition 1020) of the pad 1032. Further advancement of the cap 1002 onto the medical connector can cause the pad 1032 to deform to complement a contour of the end of the medical connector as the pad 1032 is compressed, which can permit a relatively tight or continuous contact between the pad 1032 and the medical connector. In the illustrated embodiment, the cap 1002 is rotated relative to the medical connector, as it is advanced onto the medical connector. This rotational motion causes the contoured surface of the pad 1032 to rub the medical connector. In certain embodiments, increasingly greater compression of the pad 1032 yields increasingly stronger rubbing of the medical connector, coupled with greater amounts of the antiseptic 1033 being expelled from the pad 1032. Accordingly, when the pad 1032 is uncompressed in at least one dimension (e.g., in a longitudinal direction) in a pre-use state, and thus is not plastically deformed or is not subject to time-consuming elastic recovery from pre-compression, the pad 1032 can be in sanitizing contact with the medical connector for a relatively greater portion of the coupling procedure. In some embodiments, a practitioner can more quickly couple the cap 1002 to the medical connector, as there is no need to first wait for the pad 1032 to relax to an uncompressed or expanded state to achieve better sterilization of the medical connector.

Various parameters can be adjusted to determine the amount of antiseptic 1033 that is expelled from the pad 1032 when the cap 1002 is coupled with a medical connector. For example, the depth to which the medical connector is received within the sterilization chamber 1022, the concentration of antiseptic 1033 within the pad 1032, and/or other parameters can be altered. In various embodiments, no less than about $\frac{1}{4}$, no less than about $\frac{1}{3}$, no less than about $\frac{1}{2}$, no less than about $\frac{2}{3}$, or no less than about $\frac{3}{4}$ of the antiseptic 1033 is expelled from the pad 1032 when the cap 1002 is coupled with a medical connector. In some embodiments, all, or substantially all, of the antiseptic 1033 is expelled from the pad 1032.

With reference to FIG. 10, an interior surface the sidewall 1012 can include another connection interface 1040 in the region of the coupling chamber 1024. The connection interface 1040 can be configured to complementarily engage a connection interface 1042 of the cap 1004. For example, in the illustrated embodiment, the connection interface 1040 of the cap 1002 comprises inwardly projecting threads 1041, and the connection interface 1042 of the connector 1004 comprises outwardly projecting threads 1043 complementary thereto at an exterior surface of the cap 1004. The connection interfaces 1040, 1042 thus can allow the caps 1002, 1004 to be coupled to each other in a secure, yet selectively removable fashion. Other configurations of the connection interfaces 1040, 1042 may similarly permit the caps 1002, 1004 to be coupled with each other in a secure, yet selectively removable fashion, such as friction-fit, snap-fit, or other suitable interfacing arrangements. The coupling chamber 1024 can further include a sealing member 1044, such as an elastomeric gasket described further below.

With reference to FIGS. 10 and 11, the cap 1004 can comprise a housing 1050. The housing 1050 can be elongated, and may define a stepped, substantially cylindrical

14

shape, or may define any other suitable shape. For example, in the illustrated embodiment, the housing 1050 includes a sidewall 1052, which is substantially cylindrical, and a base wall 1054 at one end of the sidewall 1052. A sealing end 1056 of the sidewall 1052 can be located opposite the base wall 1054, and can define an opening into a sterilization chamber 1058. The sidewall 1052 and the base wall 1054 thus can cooperate to define the sterilization chamber 1058.

In some embodiments, the housing 1050 includes a skirt 1060, which can extend radially outwardly from the sidewall 1052. In some embodiments, the skirt 1060 provides a convenient surface for manipulation of the cap 1004. For example, in some embodiments, an outer diameter of the sidewall 1052 is smaller than an outer diameter of the sidewall 1012 of the cap 1002 such that the disparity between the outer diameters could complicate the gripping and rotation of the caps 1002, 1004 relative to each other. Moreover, in some embodiments, the sidewall 1052 defines a relatively small outer surface area, which could make it difficult to grip the cap 1004. The larger outer diameter and corresponding larger surface area of the skirt can facilitate gripping of the cap 1004. The outer surface of the skirt 1060 can be smooth, as shown, or may include gripping features, which can aid in rotating the cap 1004 relative to the cap 1002 to permit separation of the caps 1002, 1004 and/or aid in rotating the cap 1004 relative to a medical connector. Such gripping features can include, for example, ridges, grooves, and/or protrusions similar to the ridges 105, grooves 107, and protrusions 108 described above and/or an elastomeric or other coating having a relatively high coefficient of friction.

In some embodiments, a terminal edge 1062 of the skirt 1060 can be substantially coplanar with an outer surface of the base wall 1054. In certain of such embodiments, the skirt 1060 can increase the stability of the assembly 1000. For example, the assembly 1000 can stand uprightly on the base wall 1054, and the skirt 1060 can inhibit tipping of the assembly 1000.

With reference to FIG. 10, the sterilization chamber 1058 can include a pad 1070 such as the pad 1032. The pad 1070 can be deformable, so as to conform to the contours of a portion of a medical connector that is introduced into the sterilization chamber 1058 (e.g., an outer surface of a male luer). Compression and/or decompression of the pad 1070 can cause an antiseptic 1033 to exit from and/or be absorbed by the pad 1070, respectively, in a manner such as described above with respect to the pad 1032 (it is noted that the antiseptic 1033 used with the pad 1070 need not necessarily be the same antiseptic as that used with the pad 1032, although such is possible). Likewise, scrubbing or sanitization of a medical connector via the pad 1070 can proceed in a manner such as that described above with respect to the pad 1032. In the illustrated embodiment, the pad 1070 is in a relaxed or uncompressed state in at least a longitudinal direction when the sterilization chamber 1058 is in a sealed or pre-use configuration.

As previously discussed, the cap 1004 can include the connection interface 1042, which can interact with the connection interface 1040 of the cap 1002. The connection interfaces 1040, 1042 can cooperate to hold the cap 1004 tightly against the sealing member 1044. For example, where the connection interfaces 1040, 1042 comprise threading, appropriate rotation of the cap 1004 relative to the cap 1002 can draw the sealing end 1056 of the sidewall 1052 into abutment with the sealing member 1044, and additional rotation in the same direction may deform the sealing member 1044. The sealing end 1056 and the sealing member 1044 can form a hermetic seal that can assist in maintaining the sterility of the

15

sterilization chamber **1058** prior to use of the cap **1004**, and can prevent evaporative loss of an antiseptic from the sterilization chamber **1058**. In further embodiments, a sealing tape (not shown), such as the sealing tape **158** (see FIGS. **8A** and **8B**), can be positioned about the caps **1002**, **1004** so as to contact a lower edge of the housing **1010** (e.g., an outer surface of the portion of the sidewall **1012** that defines the coupling chamber **1058**) and an outer surface of the skirt **1060** of the housing **1050**. The tape can aid in preventing evaporative loss of the antiseptic and/or can indicate whether the caps **1002**, **1004** have been separated or otherwise moved from their initial or pre-use configuration. For example, in some embodiments, the tape can be frangible.

In the illustrated embodiment, the connection interface **1042** comprises outwardly projecting threads similar to the threads **114** described above, and can be configured to complementarily engage a connection interface of a medical connector, such as, for example, inwardly projecting threads of a skirt that surrounds a male luer. The threaded connection interface **1042** thus can allow for selective coupling of the cap **1004** to a medical connector in a secure, yet selectively removable fashion. Other configurations of the connection interface **1042** may permit the cap **1004** to be coupled with a medical connector in a secure, yet selectively removable fashion, such as friction-fit, snap-fit, or other suitable interfacing arrangements.

With continued reference to FIG. **10**, additional description of the illustrated embodiment of the assembly **1000** in the pre-use state will now be provided. As previously discussed, each sterilization chamber **1022**, **1058** can be defined by a separate housing **1012**, **1050**. The chambers **1022**, **1058** can be isolated from each other in the pre-use condition, or stated otherwise, no fluid communication may exist between the chambers **1022**, **1058**.

The caps **1002**, **1004** can cooperate to seal one of the chambers (e.g., the chamber **1058** in the illustrated embodiment) such that manipulation of the caps **1002**, **1004** away from their pre-use configuration can unseal the chamber **1058**, whereas the other chamber (e.g., the chamber **1022** in the illustrated embodiment) can remain in a sealed orientation independent of the relative orientations of the caps **1002**, **1004**. At least a portion of the housing **1050** of the cap **1004** can be received within, or can nest within, a portion of the housing **1010** of the cap **1002**. In the illustrated embodiment, the pad **1032** is free of any compression from the cap **1004** and the pad **1070** is free of any compression from the cap **1002** when the sterilization chambers **1022**, **1058**, in which the pads **1032**, **1070** are housed, are in a pre-use, sealed condition.

In the illustrated embodiment, the caps **1002**, **1004** are substantially coaxial with each other. As previously discussed, the sterilization chambers **1022**, **1058** defined by the caps **1002**, **1004** each can have an open end and a closed end, and in the pre-use configuration, the chambers **1022**, **1058** can be oriented such that their sealed open ends face in the same direction along the common axis of the caps **1002**, **1004**.

With reference to FIG. **11**, in order to prepare the cap **1004** for use with a medical connector (e.g., the connector **136** of FIG. **5**), the caps **1002**, **1004** are decoupled from each other. For example, in the illustrated embodiment, the caps **1002**, **1004** are rotated in opposite directions about a common longitudinal axis such that the connection interfaces **1040**, **1042** urge the caps **1002**, **1004** away from each other and are eventually released from each other. The cap **1004** can then be coupled with the medical connector via the connection interface **1042**, such as in a secure, yet selectively removable manner.

16

The cap **1002** can be prepared for use with a medical connector (e.g., the connector **132** of FIG. **4**) and connected to the medical connector independent of the coupling status of the caps **1002**, **1004** relative to each other. The cover **1034** can be removed from the cap **1002**, thereby permitting the cap **1002** to be coupled with the medical connector via the connection interface **1040**, such as in a secure, yet selectively removable manner.

The pre-use configuration of the system **1000**, in which the caps **1002**, **1004** are coupled with each other, can ease clinician handling of the system **1000**. As the caps **1002**, **1004** may be used to cover female and male connectors, respectively, immediately upon decoupling of the female and male connectors from each other, having the caps **1002**, **1004** available in a coupled yet easily separable configuration can be convenient and time saving. Moreover, the system **1000** can include relatively few parts, which can reduce manufacturing costs. In some embodiments, the pre-use coupled configuration of the caps **1002**, **1004** likewise can reduce packaging costs of the system **1000**.

FIG. **12** illustrates another embodiment of an assembly **1100**, which can resemble the assembly **1000** described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "11." Relevant disclosure set forth above regarding similarly identified features thus may not be repeated hereafter. Moreover, specific features of the assembly **1100** may not be identified by a reference numeral in the drawings or specifically discussed in the written description that follows. However, such features may clearly be the same, or substantially the same, as features depicted in other embodiments and described with respect to such embodiments. Accordingly, the relevant descriptions of such features apply equally to the features of the assembly **1100**. Any suitable combination of the features and variations of the same described with respect to the assembly **1000** and components thereof can be employed with the assembly **1100** and components thereof, and vice versa. This pattern of disclosure applies equally to further embodiments depicted in subsequent figures and described hereafter.

As with the assembly **1000**, the assembly **1100** can include a cap **1102** and a cap **1104** that are coupled with each other when in a pre-use state and that can be removed from each other. The cap **1102** can be configured to couple with a female connector, and the cap **1104** can be configured to couple with a male connector. The cap **1102** can include a housing **1110**, which can include a sidewall **1112** and a partition **1120**. A portion of the sidewall **1112** can cooperate with the partition **1120** to define a sterilization chamber **1122** such as the sterilization chamber **1022**. In the illustrated embodiment, the sterilization chamber **1122** is somewhat shorter than the sterilization chamber **1022** (see FIG. **10**). The sterilization chamber **1122** can include a connection interface **1130**, which, in the illustrated embodiment, includes threading **1131**. The sterilization chamber **1122** can include a pad **1132**, such as the pad **1032**, and can be sealed via a removable cover **1134**.

Another portion of the sidewall **1112** can cooperate with the partition **1120** to define a coupling chamber **1124** that extends in a direction opposite the sterilization chamber **1122**. A terminal edge **1118** of the sidewall **1112** can define an opening of the sterilization chamber **1122**. The sidewall **1112** can define a connection interface **1140** that is configured to aid in coupling the caps **1102**, **1104** with each other, as described further below.

With continued reference to FIG. **12**, the cap **1104** can include a housing **1150** that includes a sidewall **1152** and a base wall **1154**. The sidewall **1152** and the base wall **1154** can

17

cooperate to define a sterilization chamber **1158**, which can include a pad **1170** therein. The sterilization chamber **1158** can be sealed at a sealing end **1156** of the sidewall **1152** via a removable cover **1136**, which can resemble the cover **1134**. A portion of the sidewall **1152** can define a connection interface **1142**, which includes one or more threads **1143** in the illustrated embodiment.

The housing **1150** can define a skirt **1160** that projects radially outwardly from the sidewall **1152**. The skirt **1160** can terminate at a terminal edge **1162**. In the illustrated embodiment, the skirt **1160** is shorter than the skirt **1060** of the housing **1050** (see FIG. 10) and is spaced above a plane that is defined by an outer surface of the base wall **1154**. In some embodiments, the terminal edge **1162** contacts or is in close proximity to the terminal edge **1118** of the housing **1110** when the caps **1102**, **1104** are coupled with each other in a pre-use configuration, which can provide continuity to an outer surface of the assembly **1100** when it is in a pre-use configuration. The skirt **1160** can be rounded or beveled at the terminal edge **1162**, and an end of the sidewall **1112** can be rounded or beveled at the terminal edge **1118**, which can provide the system **1100** with an annular recess **1163** that can provide a visual and/or tactile indication of the transition from the skirt **1160** to the sidewall **1112**. The rounded ends can also enhance practitioner and/or patient comfort during use of the caps **1102**, **1104**.

In the illustrated embodiment, the sidewall **1152** of the housing **1150** defines a connection interface **1180** that is configured to couple with the connection interface **1140** of the housing **1110**. In particular, the connection interface **1180** includes an outward projection **1181** and the connection interface **1140** includes a recess **1144** that extends radially outwardly relative to the connection chamber **1124** and that is sized to receive the annular projection **1181** therein in a snap-fit engagement. In the illustrated embodiment, each of the projection **1181** and the recess **1144** is annular and extends about the cap **1104** and the cap **1102**, respectively, in its entirety. In other embodiments, the projection **1181** and/or the recess **1144** extend about only a portion of the caps **1102**, **1104**. In still other or further embodiments, the connection interface **1180** can include a recess in the sidewall **1152** and the connection interface **1140** can include an inward projection sized to fit within the recess in a snap-fit engagement. In still other or further embodiments, the connection interfaces **1140**, **1180** can include complementary threading, such as the connection interfaces **1040**, **1042** described above. Other coupling arrangements are also possible.

Features, usage, and operation of the assembly **1100** can resemble that of the assembly **1000** described above. For example, when the assembly **1100** is in the pre-use condition, each sterilization chamber **1122**, **1158** can be defined by a separate housing **1112**, **1150**, and the sterilization chambers **1122**, **1158** can be fluidly isolated from one another (e.g., no fluid communication may exist between the sterilization chambers **1122**, **1158**). Likewise, at least a portion of the housing **1150** of the cap **1104** can be received within, or can nest within, a portion of the housing **1110** of the cap **1102**. In the illustrated embodiment, each of the pads **1132**, **1170** is in an uncompressed or expanded state when each of the sterilization chambers **1122**, **1158** in which it is housed is in a pre-use, sealed condition.

However, certain differences can exist between the assembly **1100** and the assembly **1000**. For example, each of the sterilization chambers **1122**, **1158** can remain sealed independent of the coupling status of the caps **1102**, **1104**. Stated otherwise, the caps **1102**, **1104** do not cooperate to seal either of the chambers **1122**, **1158**. Accordingly, one or both of the

18

caps **1102**, **1104** can be unsealed (e.g., the covers **1134**, **1136** can be removed) and coupled with a separate medical connector (e.g., via the connection interfaces **1130**, **1142**) without detaching the caps **1102**, **1104** from each other. Stated in yet another manner, either of the caps **1102**, **1104** can be installed on a medical connector without being detached from and/or without unsealing the other cap **1102**, **1104**. Alternatively, the caps **1102**, **1104** can be detached from each other, one or both of the caps **1102**, **1104** each can be connected with a separate medical connector (i.e., via the connection interfaces **1130**, **1142**), and the caps **1102**, **1104** can be reattached to each other (i.e., via the connection interfaces **1140**, **1180**), while remaining connected to the one or more medical connectors.

Moreover, in the illustrated embodiment, the caps **1102**, **1104** are substantially coaxial with each other, thus resembling the caps **1002**, **1004**. However, the sterilization chambers **1122**, **1158** are oriented such that their sealed open ends face away from each other (e.g., outwardly in opposite directions) along the common axis of the caps **1102**, **1104**, when the assembly **1100** is in the pre-use configuration.

FIG. 13 illustrates another embodiment of an assembly **1200**, which can resemble one or more of the assemblies described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "12." As with the assembly **1100**, the assembly **1200** can include a cap **1202** and cap **1204** that are coupled with each other, when in a pre-use state, and that can be removed from each other.

The caps **1202**, **1204** can differ from the caps **1102**, **1104** in the manner by which they are coupled with each other. In particular, the cap **1202** includes a housing **1210** that defines a connection chamber **1224** configured to receive a portion of a housing **1250** of the cap **1204**. The housing **1210** defines a connection interface **1240**, and the housing **1250** defines a connection interface **1280**. Rather than cooperating in a snap-fit engagement, however, the connection interfaces **1240**, **1280** cooperate with each other in a friction-fit engagement to provide a secure attachment between the caps **1202**, **1204** and yet to permit the caps **1202**, **1204** to be selectively removable from each other and to permit selective reattachment of the caps **1202**, **1204** to each other. Features, usage, and operation of the assembly **1200** can otherwise resemble that of the assembly **1100** described above.

FIGS. 14 and 15 illustrate another embodiment of an assembly **1300**, which can resemble one or more of the assemblies described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "13." The assembly **1300** can include a cap **1302** and cap **1304** that are coupled with each other when in a pre-use state and that can be removed from each other. However, as discussed further below, the caps **1302**, **1304** can include connection interfaces **1340**, **1380**, respectively, that attach the caps **1302**, **1304** to each other in a pre-use configuration, and that permit ready detachment of the caps **1302**, **1304** one from another, but that do not themselves permit reattachment of the caps **1302**, **1304**.

The cap **1302** can include a housing **1310**, which can include a sidewall **1312** and a base wall **1313**. The sidewall **1312** and the base wall **1313** can cooperate to define a sterilization chamber **1322** that can include a pad **1332** therein and that can be sealed via a removable cover **1334**. The base wall **1313** can include a terminal surface **1318** and can define the connection interface **1340**. In the illustrated embodiment, the connection interface **1340** includes a depression or recess **1345** that bows the terminal surface **1318** inwardly, or toward

the sterilization chamber 1322. The connection interface 1340 further includes a pin 1346 that extends outwardly, or away from the sterilization chamber 1322.

With continued reference to FIGS. 14 and 15, the cap 1304 can include a housing 1350 that includes a sidewall 1352 and a base wall 1354. The sidewall 1352 and the base wall 1354 can cooperate to define a sterilization chamber 1358, which can include a pad 1370 therein. The sterilization chamber 1358 can be sealed via a removable cover 1336. A portion of the sidewall 1352 can define a connection interface 1342, which includes one or more threads 1343 in the illustrated embodiment.

The housing 1350 can define a skirt 1360 that projects radially outwardly from the sidewall 1352. The skirt 1360 can terminate at a terminal edge 1362. In the illustrated embodiment, the skirt 1360 extends past a plane that is defined by an outer surface of the base wall 1354 and is sufficiently long to permit the terminal edge 1362 thereof to contact the terminal surface 1318 of the housing 1310 when the caps 1302, 1304 are in a pre-use configuration. As with the skirt 1160 and the sidewall 1112, the skirt 1360 can be rounded or beveled at its terminal edge 1362, and the sidewall 1112 can be rounded or beveled at the terminal surface 1118, which can provide the system 1300 with an annular recess 1363.

The housing 1350 defines the connection interface 1380, which is configured to couple with the connection interface 1340 of the housing 1310. The connection interface 1380 includes a protrusion 1382 that extends from the base wall 1354 in a direction opposite the sterilization chamber 1358. The protrusion 1382 is sized and shaped to receive therein at least a portion of the pin 1346, and may be substantially annular. In various embodiments, the protrusion 1382 is joined to the pin in any suitable manner, such as, for example, press-fit or friction-fit engagement and/or any suitable adhesive.

In the illustrated embodiment, an additional protrusion 1384 is coaxial with and encircles the protrusion 1382, and may also be substantially annular. The protrusion 1384 can contact the terminal surface 1318 of the housing 1310 when the caps 1302, 1304 are in a pre-use configuration, and can provide stability to the connection interfaces 1340, 1380 and assist in preventing premature separation of the caps 1302, 1304. The protrusion 1384 can be said to define a connection chamber 1324 in which the connection interface 1380 is located.

As shown in FIG. 15, the caps 1302, 1304 can be separated from each other, which can facilitate coupling of the caps 1302, 1304 to separate medical connectors by removing a constraint on the range of motion of the caps 1302, 1304 relative to each other. In the illustrated embodiment, the pin 1346 can be sufficiently thin, sufficiently weak, or otherwise configured to break away from the housing 1310, and can remain attached to the protrusion 1382 of the housing 1350. In various embodiments, in order to break the pin 1346, a practitioner can rotate the caps 1302, 1304 relative to each other about their common longitudinal axis and/or can rotate one or more of the caps 1302, 1304 about an axis perpendicular to its longitudinal axis so as to move the longitudinal axes of the caps 1302, 1304 out of alignment with each other.

Breaking the pin 1346 can leave a nub 1347 on the housing 1310. In certain embodiments, the nub 1347 can be fully below the terminal surface 1318 of the housing 1310 due to the recess 1345, which can prevent or reduce contact with the nub 1347, such as by a patient or practitioner.

In certain embodiments, the connection interfaces 1340, 1380 are configured so as to not rejoin with each other once the caps 1302, 1304 have been separated from the pre-use

configuration. For example, once the pin 1346 has been broken, the caps 1302, 1304 cannot readily be rejoined to each other via the pin 1346. Accordingly, the caps 1302, 1304 can be configured to be attached with each other in a pre-use configuration and readily separated from each other as desired, but not readily rejoined with each other once separated.

Features, usage, and operation of the assembly 1300 can resemble those of one or more of the assemblies described above in other respects. For example, when the assembly 1300 is in the pre-use condition, each sterilization chamber 1322, 1358 can be defined by a separate housing 1312, 1350, and the sterilization chambers 1322, 1358 can be fluidly isolated from one another. Likewise, at least a portion of one of the housings 1310, 1350 can be received within, or can nest within, a portion of the other housing 1310, 1350. To this end, it is noted that in other embodiments of the assembly 1300, the housing 1350 of the cap 1304 may define the pin 1346 (or, more generally, the connection interface 1340), and the housing 1310 of the cap 1302 may define the annular extension 1382 (or, more generally, the connection interface 1380). In the illustrated embodiment, each of the pads 1332, 1370 is in an uncompressed or expanded state when the sterilization chamber 1322, 1358 in which it is housed is in a pre-use, sealed condition. Like the assemblies 1100, 1200, each of the sterilization chambers 1322, 1358 can remain sealed independent of the coupling status of the caps 1302, 1304. One or both of the sterilization chambers 1322, 1358 can be opened and used, while the caps 1302, 1304 are connected with each other, or the caps 1302, 1304 can be separated from each other and one or both of the sterilization chambers 1322, 1358 can then be opened and each used with a separate medical connector.

FIGS. 16 and 17 illustrate another embodiment of an assembly 1400, which can resemble the assembly 1300 described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "14." The assembly 1400 can include a cap 1402 and cap 1404 that are coupled with each other when in a pre-use state, and that can be removed from each other in a manner similar to the caps 1302, 1304. However, connection interfaces 1440, 1480 of the caps differ from the connection interfaces 1340, 1380 of the caps 1302, 1304.

The connection interface 1440 can be defined by a terminal surface 1418 of a housing 1410 of the cap 1402. The connection interface 1440 can include a depression or recess 1448 that bows the terminal surface 1418 inwardly, or toward a sterilization chamber 1422. The recess 1448 can be annular, although other shapes and configurations are possible.

A sidewall 1452 of the cap 1404 can be somewhat longer than the sidewall 1352 of the cap 1304, and a base wall 1454 of the cap 1404 can be in close proximity with or adjacent to the terminal surface 1418 of the cap 1402. A protrusion 1485 can extend outwardly from the base wall 1454, or in a direction away from a sterilization chamber 1458. The protrusion 1485 can be annular so as to be received within the annular recess 1448, although other shapes and configurations are possible. The protrusion 1485 can be joined to the recess 1448 in any suitable manner, such as via an adhesive or via welding (e.g., spin, ultra-sonic, laser, radio frequency, thermal, etc.).

In the illustrated embodiment, the protrusion 1485 is welded to the recess 1448, and the weld is configured to be broken to permit separation of the caps 1402, 1404. As shown in FIG. 17, a weld edge 1486 can remain within the recess 1448 when the caps 1402, 1404 are separated. In certain embodiments, the weld edge 1486 can be fully below the terminal surface 1418 of the housing 1410, which can prevent

or reduce contact with the weld edge 1486, such as by a patient or practitioner. In order to break the weld, a practitioner can rotate the caps 1402, 1404 relative to each other about their common longitudinal axis and/or can rotate one or more of the caps 1402, 1404 about an axis perpendicular to its longitudinal axis, so as to move the longitudinal axes of the caps 1402, 1404 out of alignment with each other. In other embodiments, the connection interfaces 1440, 1480 can be reversed such that the cap 1402 includes the protrusion 1485 and the cap 1404 can include the recess 1448.

FIGS. 18-21 illustrate another embodiment of an assembly 1500, which can resemble one or more of the assemblies described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "15." As can be seen in FIGS. 18 and 19, and as discussed hereafter, the assembly 1500 can include a cap 1502 and cap 1504 that are coupled with each other when in a pre-use state and that can be removed from each other. The cap 1502 can be configured to couple with a female connector, and the cap 1504 can be configured to couple with a male connector. The caps 1502, 1504 can be in a side-by-side arrangement when connected to each other in a pre-use configuration. In the illustrated embodiment, both caps 1502, 1504 can be sealed shut in the pre-use configuration via a common cover 1537.

The cap 1502 can include a housing 1510, which can include a sidewall 1512 and a base wall 1513. The sidewall 1512 can cooperate with the base wall 1513 to define a sterilization chamber 1522. The sterilization chamber 1522 can include a connection interface 1530, which, in the illustrated embodiment, includes threading 1531 disposed on an interior surface of the housing 1512. The connection interface 1530 can be configured to attach the cap 1502 to a medical connector in a secure yet selectively removable manner. The sterilization chamber 1522 can include a pad 1532.

The housing 1510 can further include a skirt 1561 that projects radially outwardly from the sidewall 1512 and that can also extend substantially parallel to the sidewall 1512. The skirt 1561 can include one or more spacers or supports 1564 that can provide structural rigidity to the skirt 1561. As shown in FIGS. 19 and 21, the housing 1510 can define a connection interface 1540 that is configured to aid in coupling the caps 1502, 1504 with each other in a pre-use configuration, as discussed further below. The connection interface 1540 can include a slot 1548 defined by the skirt 1561, which can extend in a direction substantially parallel to a longitudinal axis of the sterilization chamber 1522. The sidewall 1512 and the skirt 1561 can cooperate to define an open connection chamber 1524, which is also discussed below. The slot 1548 can define a side opening of the connection chamber 1524.

With reference to FIGS. 19 and 20, the cap 1504 can include a housing 1550 that includes a sidewall 1552 and a base wall 1554. The sidewall 1552 and the base wall 1554 can cooperate to define a sterilization chamber 1558, which can include a pad 1570 therein. A portion of the sidewall 1552 can define a connection interface 1542, which includes one or more threads 1543 in the illustrated embodiment. The connection interface 1542 can be configured to attach the cap 1504 to a medical connector in a secure yet selectively removable manner. The housing 1550 can define a skirt 1560 that projects radially outwardly from the sidewall 1552 and that can also extend substantially parallel to the sidewall 1552. In the illustrated embodiment, the skirt 1560 extends about only a portion of the cap 1504. The skirt 1560 can include one or more spacers or supports 1565 that can provide structural rigidity to the skirt 1560.

The housing 1550 can further define a connection interface 1580 that is configured to interact with the connection interface 1540 of the housing 1510 to couple the caps 1502, 1504. The connection interfaces 1540 can maintain the caps 1502, 1504 in a pre-use configuration, and can permit the caps 1502, 1504 to be selectively removed from this configuration. In the illustrated embodiment, the connection interfaces 1540, 1580 can further interact with each other to permit selective reattachment of the caps 1502, 1504 to each other.

In the illustrated embodiment, the connection interface 1580 includes a locking member, snapping member, or radial extension 1585. The extension 1585 projects radially from the sidewall 1552 and includes an enlarged region at its outermost end. The extension 1585 is configured to be received within the slot 1548 and the connection chamber 1524 of the cap 1502. The enlarged portion of the extension 1585 can prevent the extension 1585 from moving out of the slot 1548 in a lateral direction. Although not shown, in some embodiments, the slot 1548 and the extension 1585 can include keying, such as a protrusion and recess that cooperate in a snapping fashion, which can selectively prevent the extension 1585 from moving out of the slot 1548 in a longitudinal direction in the absence of application of sufficient force by a practitioner. In other embodiments, the connection interfaces 1540, 1580 can be reversed such that the cap 1402 includes the extension 1585 and the cap 1504 includes the slot 1548.

In the illustrated embodiment, a terminal surface 1518 of the cap 1502 and a terminal surface 1562 of the cap 1504 are substantially coplanar when the system 1500 is in the pre-use configuration. This can contribute to the stability of the pre-use system 1500, as the connected system 1500 can be set on a planar surface without a predisposition to tipping. Likewise, in the illustrated embodiment, a sealing end 1516 of the cap 1502 and a sealing end 1556 of the cap 1504 are substantially coplanar when the system 1500 is in the pre-use configuration. Each sealing end 1516, 1556 can be sealed closed via a single or common removable cover 1537. In the illustrated embodiment, the cover 1537 includes two tabs 1538 that can permit selective opening of just one of the caps 1502, 1504, or the opening both of the caps 1502, 1504 by beginning with opening one of the caps 1502, 1504 by removing a portion of the cover 1537 from that cap 1502, 1504 and then continuing to remove the cover 1537 from the remaining cap 1502, 1504. Other arrangements are also possible.

The cover 1537 can assist in maintaining the caps 1502, 1504 coupled with each other in the pre-use configuration, as it can be sufficiently tight to resist longitudinal movement of the caps 1502, 1504 relative to each other. In various embodiments, the cover 1537 is removed from one or both of the caps 1502, 1504 prior to removing the caps 1502, 1504 from each other, as shown in FIG. 19. In other embodiments, the connection interfaces 1540, 1580 of the caps 1502, 1504 can be decoupled from each other prior to removing the cover 1537.

Features, usage, and operation of the assembly 1500 can resemble that of one or more of the assemblies described above. For example, when the assembly 1500 is in the pre-use condition, each sterilization chamber 1522, 1558 can be defined by a separate housing 1512, 1550, and the sterilization chambers 1522, 1558 can be fluidly isolated from one another. Likewise, at least a portion of the housing 1550 of the cap 1504 can be received within, or can nest within, a portion of the housing 1510 of the cap 1502. In the illustrated embodiment, each of the pads 1532, 1570 is in an uncompressed or expanded state when the sterilization chamber 1522, 1558 in which it is housed is in a pre-use, sealed condition.

However, certain differences can exist. For example, in the illustrated embodiment, the caps 1502, 1504 are side-by-side,

23

rather than coaxial, when in the pre-use configuration. Stated otherwise, each cap **1502**, **1504** can define a longitudinal axis, and the longitudinal axes can be substantially parallel with each other or non-collinear relative to each other when the caps **1502**, **1504** are in the pre-use configuration. In the illustrated embodiment, the sterilization chambers **1522**, **1558** are oriented such that their sealed open ends face in substantially the same direction when the assembly **1500** is in the pre-use configuration.

FIG. 22 illustrates another embodiment of an assembly **1600**, which can resemble one or more of the assemblies described above, particularly the assembly **1500**, in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "16." The assembly **1600** can include caps **1602**, **1604** such as the caps **1502**, **1504**. Rather than including a single cover **1537**, however, an individual cover **1634**, **1636** is provided to each of the caps **1602**, **1604**. Such an arrangement can, in some instances, facilitate removal of the caps **1602**, **1604** from each other while the caps **1602**, **1604** are maintained in a sealed configuration.

FIG. 23 illustrates an embodiment of a cap **1702** that can be used in the place of the caps **1502**, **1602** in the systems **1500**, **1600**. The cap **1702** can include a housing **1710** that includes a sidewall **1712** and a skirt **1761**. The sidewall **1712** can taper radially outwardly with increasing distance from the skirt **1761**. Moreover, the housing **1710** can include an extension region **1717** that projects in an opposite direction from the skirt **1761**. The extension region **1717** can include a rounded terminal surface **1718**. The cap **1702** thus can more closely resemble the cap **102** described above. For example, the extension region **1717** can include gripping features **1703**, such as ridges **1705** and grooves **1707**. Similar alterations can be made to the caps **1504**, **1604**.

FIG. 24 illustrates another embodiment of an assembly **1800**, which can resemble one or more of the assemblies described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "18." The assembly **1800** can include a cap **1802** and cap **1804** that are coupled with each other when in a pre-use state and that can be removed from each other. In particular, the caps **1802**, **1804** can be coupled with each other via a sealing mechanism. In the illustrated embodiment, the caps **1802**, **1804** are coupled with each other via a sealing sleeve **1890**. The caps **1802**, **1804** can have open ends facing one another, and sterilization chambers **1822**, **1858** of the caps **1802**, **1804** can be in fluid communication with each other, when in the pre-use configuration.

The cap **1802** can include a housing **1810**, which can include a sidewall **1812** and a base wall **1813**. The sidewall **1812** can cooperate with the base wall **1813** to define the sterilization chamber **1822**. The sterilization chamber **1822** can include a connection interface **1830**, which, in the illustrated embodiment, includes threading **1831** disposed on an interior surface of the housing **1812**. The connection interface **1830** can be configured to attach the cap **1802** to a medical connector in a secure yet selectively removable manner. The sterilization chamber **1822** can include a pad **1832**.

An exterior surface of the sidewall **1812** can define a connection interface **1840** that is configured to couple the cap **1802** with a connection interface **1891** of the sleeve **1890**. In the illustrated embodiment, the connection interfaces **1840**, **1891** couple with each other via a friction-fit engagement. The friction fit can be sufficiently strong to provide a fluid-tight seal between the cap **1802** and the sleeve **1890**, yet can allow the cap **1802** to be removed from the sleeve **1890** via mere manipulation by a medical practitioner (e.g., without the

24

use of ancillary tools). The fluid-tight seal can prevent evaporative loss of antiseptic from the pad **1832** and/or can maintain the sterility of the sterilization chamber **1822**. In other or further embodiments, the connection interfaces **1840**, **1891** can include threading or other suitable attachment features.

In the illustrated embodiment, the base wall **1813** protrudes slightly beyond an end of the sleeve **1890**, which can aid in manipulating the cap **1802** away from the sleeve **1890**. In other embodiments, the base wall **1813** can protrude even further, or can include one or more protrusions or gripping features, that can aid in removing the cap **1802** from the sleeve **1890**.

The cap **1802** can include a flange **1815** having an outer diameter larger than an inner diameter of the end of the sleeve **1890** that connects with the cap **1802**. The flange **1815** can prevent the cap **1802** from being inserted into the sleeve **1890** too deeply. In other or further embodiments, the flange **1815** can cooperate with an end surface of the sleeve **1890** to create a liquid-tight seal. For example, in some embodiments, a sealing member, such as an "O" ring, is included between the flange **1815** and the end of the sleeve **1890** to provide the liquid-tight seal.

The cap **1804** can include a housing **1850** that includes a sidewall **1852** and a base wall **1854**. The sidewall **1852** and the base wall **1854** can cooperate to define a sterilization chamber **1858**, which can include a pad **1870** therein. A portion of the sidewall **1852** can define a connection interface **1842**, which includes one or more threads **1843** in the illustrated embodiment. The connection interface **1842** can be configured to attach the cap **1804** to a medical connector in a secure yet selectively removable manner. Additionally, the connection interface **1842** can cooperate with a connection interface **1892** defined by the sleeve **1890** to couple the cap **1804** with the cap **1802**. The connection interface **1892** can include threading **1893** that is complementary to the threading **1843**. The interfaces **1842**, **1892**, when coupled with each other, can provide a fluid-tight seal between the cap **1804** and the sleeve **1890**. In other embodiments, the connection interfaces **1842**, **1890** can instead define a friction-fit seal, such as that provided by the illustrated embodiment of the connection interfaces **1840**, **1891** described above. In still other or further embodiments, a flange **1859** defined by the housing **1850** can cooperate with an end surface of the sleeve **1890** to create a liquid-tight seal, which can prevent evaporative loss of antiseptic from the pad **1870** and/or maintain the sterility of the sterilization chamber **1858**. For example, in some embodiments, a sealing member, such as an "O" ring, is included between the flange **1859** and the end of the sleeve **1890** to provide the liquid-tight seal.

Features, usage, and operation of the assembly **1800** can resemble that of one or more of the assemblies described above. For example, when the assembly **1800** is in the pre-use condition, each sterilization chamber **1822**, **1858** can be defined by a separate housing **1812**, **1850**. Likewise, the caps **1802**, **1804** can be coaxial with each other, and the open ends of the caps **1802**, **1804** can face in opposite directions (e.g., towards each other). In the illustrated embodiment, each of the pads **1832**, **1870** is in an uncompressed or expanded state when the sterilization chamber **1822**, **1858** in which it is housed is in a pre-use, sealed condition.

However, certain differences can exist. For example, in the illustrated embodiment, the sterilization chambers **1822**, **1858** are in fluid communication with each other when the caps **1802**, **1804** are in the pre-use state. Moreover, in the illustrated embodiment, no portion of the housing **1850** of the cap **1804** is received within, or nested within, any portion of the housing **1810** of the cap **1802**.

FIGS. 25-29 illustrate another embodiment of an assembly 1900, which can resemble one or more of the assemblies described above in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "19." As shown, for example, FIGS. 25 and 26, the assembly 1900 can include a male cap portion or cap 1902 and a female cap portion or cap 1904 that are integrally formed or otherwise permanently attached with each other. For example, the caps 1902, 1904 can include a single, integrally molded housing 1910. The cap 1902 can be configured to couple with a female connector, and the cap 1904 can be configured to couple with a male connector. In the illustrated embodiment, the caps 1902, 1904 are in a coaxial arrangement. As shown, for example, in FIGS. 26 and 28, the assembly 1900 can include a pad 1970 that is received within one or more of the caps 1902, 1904. As shown, for example, in FIGS. 25 and 26, each cap 1902, 1904 can be sealed shut in the pre-use configuration via a separate cover 1934, 1938, respectively. Each cover 1934, 1938 can include a tab 1935, 1939, respectively, that can aid in removal of the cover.

With continued reference to FIGS. 25-29, the housing 1910 can define at least a portion of each of the caps 1902, 1904. The housing 1910 includes a first sidewall 1912 that defines a first sterilization chamber 1922 and includes a second sidewall 1952 that defines a second sterilization chamber 1958. As shown in FIG. 29, the first sidewall 1912 can define larger inner and outer diameters than those defined by the second sidewall 1952. The housing 1910 can transition from the first sidewall 1912 and the first sterilization chamber 1922 to the second sidewall 1952 and the second sterilization chamber 1958 at a constriction or abutment 1920. The housing 1910 can be substantially hollow such that the first and second sterilization chambers 1922, 1958 are in fluid communication with each other. The housing 1910 can define another abutment 1921, which is discussed further below.

As shown in FIGS. 26, 28, and 29, the male cap 1902 can include a connection interface 1930 that is configured to couple with a connection interface of a medical connector, such as a needleless injection site. The connection interface 1930 can include threading 1931, which can be disposed at an interior of the sidewall 1912. In some embodiments, the male cap 1902 includes one or more gripping features 1903 at an exterior surface of the sidewall 1912. In the illustrated embodiment, the gripping features 1903 are raised areas. In other embodiments, the gripping features 1903 can include depressed areas. The gripping features 1903 can be formed in the shape of a company logo or any other suitable shape.

As shown in FIGS. 26, 27, and 29, the female cap 1904 can include a connection interface 1942 that is configured to couple with a connection interface of a medical connector, such as a medical attachment having a male luer. The connection interface 1942 can include threading 1943, which can be disposed at an exterior surface of the sidewall 1952. The cap 1904 can include one or more vents 1959, which can be located at an end of the sidewall 1952. The one or more vents can also extend along the length of sidewall 1952. In the illustrated embodiment, a constriction, rim, or lip 1953 projects radially inwardly at the end of the sidewall 1952, which can aid in maintaining the pad 1970 within the cap 1904. In particular, the lip 1953 can define a smaller inner diameter than an outer diameter of the pad 1970 (see FIG. 29). The vents 1959 can comprise notches in the lip 1953. The illustrated embodiment includes four vents 1959, although more or fewer vents are possible.

With reference to FIG. 26, the pad 1970 can define a shape generally resembling a series of tiered cylinders. A rim 1971

can extend transversely, or radially outwardly, from a cylinder that has the smallest diameter. Another rim 1972 can extend transversely from a cylinder having an intermediate diameter. The largest cylinder can have a recess 1973 disposed therein. In certain embodiments, such as the illustrated embodiment, one or more extensions 1974 protrude from an end of the pad 1970 in a longitudinal direction. Each extension 1974 can include a groove 1975 therein, as discussed further below. In other embodiments, the one or more extensions 1974 are omitted.

With reference to FIG. 29, the pad 1970 can be secured within the housing 1910 in any suitable manner, and thus can resist translational movement in either direction that would cause the pad 1970 to exit the housing 1910 from either open end of the housing. For example, in the illustrated embodiment, interaction of the threads 1931 with a left end of the pad 1970 can prevent the pad 1970 from moving out of the housing 1910 in a leftward direction as a portion of a medical connector (e.g., a male luer connector) is inserted into the housing 1910 from the right. As shown in FIG. 29, some portions of the pad 1970 can be compressed by the threads 1931, whereas the grooves 1975 of the extensions 1974 can accommodate the threads 1931. The enlarged tiered sections of the pad 1970, and the resultant interaction of the rims 1971, 1972 with the abutments 1920, 1921, respectively, can prevent the pad 1970 from moving out of the housing 1910 in the rightward direction as a portion of a medical connector (e.g., a needleless injection site) is advanced into the housing 1920 from the left. In other or further embodiments, the pad 1970 can be adhered to the housing 1910.

With reference to FIGS. 26 and 27, the cover 1938 can be secured to the housing 1910 in any suitable manner. For example, in some embodiments, an end of the cover 1938 is adhered or otherwise sealed to a sealing surface 1956 at an end of the sidewall 1952 so as to provide a hermetic seal. A side portion of the cover 1938 thus can cover the connection interface 1942 of the cap 1904. In other or further embodiments, a lower circumferential edge of the cover 1938 can be adhered or otherwise sealed to a sealing surface 1957 at a base end of the sidewall 1952 so as to provide a hermetic seal. With reference to FIGS. 26 and 28, the cover 1934 can be adhered or otherwise sealed to a sealing surface 1916 at an end of the sidewall 1912 of the housing 1910.

FIG. 30 illustrates an early stage of the coupling of a medical connector 2000 with the cap 1904. The medical connector 2000 can include a housing 2005 that complies with ISO standards (e.g., ISO 594-1:1986 and ISO 594-2:1998). The housing 2005 can include a skirt 2010 that defines a connection interface 2012, which itself can include threading 2014. The housing 2005 can also include a male luer 2020, which can define a fluid passageway 2022.

In the illustrated embodiment, a tip of the male luer 2020 can contact an end surface of the pad 1970 prior to engagement of the connection interfaces 1942, 2012 (e.g., the threadings 1943, 2014) with each other. Accordingly, some compression of the pad 1970 may occur without assistance from the connection interfaces 1942, 2012. In other embodiments, the connection interfaces 1942, 2012 may engage one another prior to contact being made between the tip of the male luer 2020 and the end surface of the pad 1970, such as may occur when the pad 1970 is more recessed within the housing 1910 and/or the skirt 2010 and its connection interface 2012 are longer. In either case, in some embodiments, the connection interfaces 1942, 2012 can assist in the compression of the pad 1970. The desired antiseptic concentration level of the pad 1970 is determined by the volume required to fully coat and

27

sterilize the medical connector **2000**, while taking into consideration the evaporative loss that may occur during the shelf life of cap **1904**.

FIG. **31** illustrates a later stage of the coupling of the medical connector **2000** with the cap **1904**. As the male luer **2020** is advanced into the sterilization chamber **1958** of the cap **1904**, it compresses the pad **1970** and causes antiseptic **1933** to egress therefrom. The pad **1970** can remain relatively fixed, rotationally, while the male luer **2020** is rotated and advanced further into the chamber **1958**, which can effect a rubbing or scrubbing of the tip of the luer **2020**, particularly as increased compression of the pad **1970** provides an increased force of the pad **1970** against the tip. The released antiseptic can fill an opening or volume of space between the sidewall **1952** of the housing **1910** and an outer surface of the male luer **2020**, and can thereby sterilize the outer surface of the male luer **2020**. Additionally, in the illustrated embodiment, the fluid passageway **2022** of the male luer **2020** is open such that antiseptic fluid **1933** may enter into it.

In certain embodiments, a seal can form between the lip **1953** and the male luer **2020** when the luer **2020** is advanced sufficiently far into the chamber **1958**. The seal thus formed can be an interrupted seal, such that the seal is formed only at those regions where the luer **2020** and the lip **1953** are in contact with each other. Antiseptic **1933** can be permitted to exit from the chamber **1958** via the vents **1959**. In some embodiments, the vents **1959** are sufficiently large to permit antiseptic **1933** to exit from the chamber **1958** freely once the antiseptic **1933** has been expelled from the pad **1970**. Antiseptic **1933** that exits from the chamber **1958** through the vents **1959** can sterilize portions of the male luer **2020** that are proximal of the lip **1953**.

In other embodiments, the vents **1959** are sufficiently small to prevent antiseptic **1933** from exiting from the chamber **1958** when a pressure within the chamber **1958** is the same or approximately the same as a pressure outside of the chamber **1958** (e.g., atmospheric pressure), and yet are sufficiently large to permit antiseptic **1933** to exit the chamber **1958** when the pressure within the chamber **1958** is significantly greater than the pressure outside of the chamber **1958**, such as may result when the luer **2020** is being advanced deeper within the chamber **1958**. The vents **1959** thus can permit selective egress of the antiseptic **1933** to aid in achieving the desired positioning of the male luer **2020**, yet can maintain the antiseptic **1933** within the chamber **1958** in order to bathe a portion of the male luer **2020** once the male luer **2020** is positioned as desired. In still other embodiments, a fluid-tight seal is formed between the lip **1953** and the male luer **2020**.

In certain embodiments, the pad **1970** may be recessed within the chamber **1958** to a greater degree when in the uncompressed state (e.g., when in the state shown in FIG. **30**). Moreover, the threads **2014** of the connection interface **2012** and the threads **1943** of the connection interface **1942** can permit the antiseptic **1933** to pass through them, so as to provide additional venting of the chamber **1958**. For example, threaded connection interfaces **2012**, **1942** can permit antiseptic **1933** that has exited from the chamber **1958** to spiral about an outer surface of the second sidewall **1952** in a distal direction.

Each of FIGS. **32-34** illustrates the cap **1902** coupled with a separate needleless injection site **2040**, **2060**, **2080**. As with other caps disclosed herein, the cap **1902** can be versatile so as to couple with a variety of different types of medical connectors in a secure fashion that sterilizes each type of medical connector. As can be seen in each of FIGS. **32-34**, coupling of the needleless injection sites **2040**, **2060**, **2080** with the cap **1902** can effect compression of one end of the

28

pad **1970** in a manner similar to that described above with respect to compression of the other end of the pad **1970**. Compression of the pad **1970** and rotation of the needleless injection site **2040**, **2060**, **2080** can effect rubbing, swabbing, or scrubbing of the needleless injection site and sterilization thereof via the antiseptic **1933**.

With reference to FIG. **32**, the needleless injection site **2040** can comprise a Clave® port available from ICU Medical, Inc. The needleless injection site **2040** can include a housing **2042** that defines a connection interface **2044**. The needleless injection site **2040** can further include an elastomeric seal **2046**, which is shown in a closed configuration in which fluid access is not permitted into a fluid passageway **2048**. Small crevices can exist between the housing **2042** and the elastomeric seal **2046** at an end of the needleless injection site **2040** that is inserted into sterilization chamber **1922**. As the connection interface **2044** cooperates with the connection interface **1930** defined by the sidewall **1912** to draw the tip of the needleless injection site **2040** into the sterilization chamber **1922**, the pad **1970** can be compressed so as to generally conform to the crevices. Compression of the pad **1970** likewise can expel antiseptic **1933**, which, in some instances, can fill in portions of the crevices that the pad **1970** may not be able to contact directly. As the pad **1970** is compressed, the seal **2046** can remain closed so as to prevent antiseptic **1933** from entering the fluid passageway **2048**. With reference again to FIG. **29**, if present, the one or more extensions **1974**, due to their positioning over the threads **1031**, additionally can rub or scrub the side surfaces of the needleless injection site **2040**. Thus, a thorough rubbing and sterilization of the needleless injection site **2040** can be accomplished via the cap **1902**, and the performance of the cap **1902** in this regard can exceed that achieved via standard swabbing protocols and can be less susceptible to human error.

With reference to FIG. **33**, the needleless injection site **2060** can comprise a Q-Syte® port available from Becton, Dickinson and Company. The needleless injection site **2060** can include a housing **2062** and an elastomeric seal **2066**, which is shown in a closed configuration in which fluid access is not permitted into a fluid passageway **2068**. As with the needleless injection site **2040**, small crevices can exist between the housing **2062** and the elastomeric seal **2066**. However, the crevices can exist at a side portion of the needleless injection site **2060**, rather than at its tip. Nevertheless, as the needleless injection site **2060** is advanced into the cap **1902**, the pad **1970** can be compressed so as to generally conform to these differently shaped crevices. Compression of the pad **1970** likewise can expel antiseptic **1933**, which, in some instances, can fill in portions of the crevices that the pad **1970** may not be able to contact directly. The seal **2066** can be maintained in the closed position during the coupling procedure, so as to prevent any of the antiseptic **1933** from entering the fluid passageway **2068**.

With reference to FIG. **34**, the needleless injection site **2080** can comprise a SmartSite® port available from Cardinal Health, Inc. The needleless injection site **2080** can include a housing **2082** and an elastomeric seal **2086**, which is shown in a closed configuration in which fluid access is not permitted into a fluid passageway **2088**. As with the needleless injection sites **2040**, **2060**, small crevices can exist between the housing **2082** and the elastomeric seal **2086**. However, these crevices can be in yet different positions than those of the needleless injection sites **2040**, **2060**. Nevertheless, as the needleless injection site **2080** is advanced into the cap **1902**, the pad **1970** can be compressed so as to generally conform to these differently shaped crevices. Compression of the pad **1970** likewise can expel antiseptic **1933**, which, in some

29

instances, can fill in portions of the crevices that the pad 1970 may not be able to contact directly. The seal 2086 can be maintained in the closed position during the coupling procedure so as to prevent any of the antiseptic 1933 from entering the fluid passageway 2088. Additionally, each of the needleless injection sites 2040, 2060, 2080 may advance into the cap 1902 by different amounts. The cap 1902 thus can be adaptable and versatile. Additional, non-limiting examples of needleless injection sites with which the cap 1902 can selectively couple include the Clearlink® Site available from Baxter and the InVision-Plus® available from Rymed.

Features, usage, and operation of the assembly 1900 can resemble that of one or more of the assemblies described above. For example, in the illustrated embodiment, the pad 1970 is in an uncompressed or expanded state when the sterilization chambers 1922, 1958 in which it is housed are in a pre-use, sealed condition. Additionally, the caps 1902, 1904 are coaxial with each other with open ends that face in opposite directions. Likewise, the caps 1902, 1904 are connected to each other when the assembly 1900 is in a pre-use state.

However, certain differences can exist. For example, in the illustrated embodiment, the caps 1902, 1904 cannot be removed from each other. Moreover, the assembly 1900 includes a single pad 1970 that is used in both caps 1902, 1904. Although not shown in the drawings, it is understood that each cap 1902, 1904 can be coupled with a separate medical connector such that the pad 1970 is compressed from both ends when the caps 1902, 1904 are in a coupled state.

FIG. 35 illustrates another embodiment of an assembly 2100, which can resemble one or more of the assemblies described above, particularly the assembly 1900, in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "21." The assembly 2100 can include caps 2102, 2104, such as the caps 1902, 1904, that are fixedly, permanently, or integrally connected with each other. Covers such as the covers 1934, 1938, which are not shown in FIG. 35, can be used with the caps 2102, 2104. The assembly 2100 can include a single housing 2110 that defines two sterilization chambers 2122, 2158. The housing 2110 can include a partition 2120 that separates the sterilization chambers 2122, 2158 from each other such that the chambers 2122, 2158 are fluidly separated from one another. Each chamber 2122, 2158 can include a separate pad 2132, 2170 therein.

FIGS. 36 and 37 illustrate another embodiment of an assembly 2200, which can resemble one or more of the assemblies described above, particularly the assemblies 1900 and 2100, in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "22." The assembly 2200 can include a female cap 2202 and a male cap 2204 that are fixedly, permanently, or integrally connected with each other. The assembly can include a housing 2210, which can include a sidewall 2252 that defines a sterilization chamber 2258 and a connection interface 2242. Covers 2234, 2238, such as the covers 1934, 1938, can be used with the caps 2202, 2204.

The female cap 2202 can be substantially the same as the female cap 1902. However, the male cap 2204 can differ from the male cap 1904 in certain respects. For example, the cap 2204 can include a sealing member 2290. In the illustrated embodiment, the sealing member 2290 is shaped substantially as a conical disk. The sealing member 2290 can include a seal region 2292 which, in the illustrated embodiment, is rounded and projects toward an open end of the sterilization chamber 2258 when situated therein. Alternatively, the sealing member 2290 may be in the form of other shapes such as, for example, a square shape or other non-circular shapes.

30

Further, the sealing member 2290 and the seal region 2292 may be a separate components that are integrally connected. The sealing member 2290 can include one or more ports 2294, which can define openings or channels 2293 that extend between opposing faces of the sealing member 2290. Other configurations of the ports 2294 are also contemplated, such as, for example, self-sealing slits. In other configurations wherein the sealing member 2290 is a non-circular shape, the ports can be eliminated since the antiseptic can flow around the sides of the sealing member 2290. In some embodiments, the sealing member 2290 can be relatively rigid so as to maintain a pre-formed shape, but may be configured to readily form a liquid-tight seal with a male luer of a medical connector. The sealing member 2290 can be formed of any suitable material, such as an elastomer or any thermoplastic such as polypropylene, polycarbonate, acrylonitrile butadiene styrene (ABS), polyvinyl chloride (PVC), or rigid or semi-rigid thermoset plastic. The sealing member 2290 can be formed in any suitable fashion, such as via molding or die cutting.

The sealing member 2290 can be coupled with a biasing element 2276, which can be configured to resist or oppose movement of the sealing member 2290. Stated otherwise, the biasing element 2276 can provide a bias to the sealing member 2290 in a direction of an initial position of the sealing member 2290, such as that shown in FIG. 37, once the sealing member 2290 has been displaced from that initial position. Accordingly, in the embodiment depicted in FIG. 37, the biasing element 2276 biases the sealing member 2290 in a proximal direction when the sealing member 2290 is displaced distally. The terms "proximal" and "distal," when used herein relative to a cap, are such that a medical device is inserted into a proximal end of the cap and advanced toward a distal end of the cap. Accordingly, in the illustrated embodiment, the proximal ends of the caps 2202, 2204 are at opposite ends of the assembly 2200 and the distal ends of the caps 2202, 2204 are fixedly joined with each other.

The male cap 2204 can include a rim 2253, similar to the lip 1953, which can include one or more vents 2259. However, in the illustrated embodiment, the rim 2253 is more recessed from a proximal end of the cap 2204 (e.g., deeper within the cavity 2258). A portion of a pad 2270 that is positioned within the sterilization chamber 2258 can be shorter than a corresponding portion of the pad 1970, so as to more readily fit below the more recessed rim 2253. As shown in FIG. 37, the pad 2270 can be seated beneath the sealing member 2290, and the sealing member 2290 can be seated beneath the rim 2253 when the male cap is in the pre-use configuration. In some embodiments, the pad 2270 is in an uncompressed state (e.g., a longitudinally uncompressed state) when situated as shown in FIG. 37. The pad 2270 can include an antiseptic 2233 therein.

In the illustrated embodiment, the pad 2270 is resiliently compressible such that the biasing element 2276 comprises the pad 2270. Stated otherwise, compression of the pad 2270 gives rise to a biasing force that tends to restore the pad 2270 to its uncompressed state. The biasing force may increase with greater compression of the pad 2270. In some embodiments, the pad 2270 is fixedly secured to the sealing member 2290, such as by an adhesive or any suitable lamination technique. In other embodiments, the sealing member 2290 is not secured to the pad 2270, but movement of the sealing member 2290 within the sterilization chamber 2258 can nevertheless be constrained by a proximal end of the pad 2270 and a distal edge of the rim 2253.

The sealing member 2290 can aid in maintaining the antiseptic 2233 within the pad 2270 when the cap 2204 is in a

31

pre-use condition. For example, in some embodiments, only a small surface area of the proximal end of the pad 2270 that is directly beneath the ports 2294 of the sealing member 2290 is directly exposed to air when the proximal end of the cap 2204 is uncovered. Accordingly, evaporative loss of the antiseptic 2233 can be slowed. Moreover, in other or further embodiments, the ports 2294 may be defined by channels that are sufficiently small to prevent liquid antiseptic 2233 from passing through them when the pressure on both sides of the sealing member 2290 is balanced. However, the ports 2294 may permit liquid antiseptic 2233 to pass through them when the pressure on one side of the sealing member 2290 is greater than the pressure on the other side of the sealing member 2290, as discussed further below. The pad 2270 itself can also be configured to retain the antiseptic 2233 until it is compressed.

In some embodiments, an outer edge of the sealing member 2290 can form a liquid-tight seal with an inner surface of the sidewall 2252 when the cap 2204 is in the pre-use state. In further embodiments, the seal can be maintained as the sealing member 2290 is moved distally within the sterilization chamber 2258 such that liquid antiseptic 2233 is only permitted to bypass the sealing member 2290 through the ports 2294. In other embodiments, an outer edge of the sealing member 2290 may not form a liquid-tight seal with the sidewall 2252, whether initially or after having been moved from the pre-use condition, such that antiseptic 2233 can bypass the sealing member 2290 around its outer edge.

FIG. 38 illustrates an early stage of coupling a medical connector 2000 with the cap 2204. A tip 2021 of a male luer 2020 contacts the seal region 2292 of the sealing member 2290. In the illustrated embodiment, a portion of the sealing member 2290 extends into a lumen 2022 of the connector 2000 such that the contact is primarily between an inner edge of the tip 2021 and a thin band of the sealing member 2290. Such an arrangement can assist in forming a liquid-tight seal due to a relatively higher pressure that results between the tip 2021 and the sealing member 2290 when forces (e.g., an insertion force on the tip and an oppositely directed biasing force on the sealing member) are distributed over relatively smaller areas. Such an arrangement likewise can allow antiseptic to contact much or all of an external surface of the luer 2020, including a distal surface of the tip 2021.

In the illustrated embodiment, contact between the tip 2021 and the sealing member 2290 occurs just prior to engagement of a connection 2012 of the connector 2000 with the connection interface 2242. In other embodiments, the connection interfaces 2012, 2242 can engage each other prior to contact between the tip 2021 and the sealing member 2290. In either case, as the connection interfaces 2012, 2242 cooperate with each other to connect the cap 2204 to the medical connector 2000 (e.g., as the cap 2204 is threaded onto the connector 2000), a liquid-tight seal is formed or maintained between the seal region 2292 of the sealing member 2290 and the tip 2021 of the male luer 2020.

FIG. 39 illustrates a late or final stage of coupling the medical connector 2000 with the cap 2204. To arrive at this stage, cap 2204 is advanced over the male luer 2020 to a greater extent. As a result, the luer 2020 is advanced further into the sterilization chamber 2258, thereby moving the sealing member 2290 distally and compressing the pad 2270. Compression of the pad 2270 forces antiseptic 2233 out of the pad 2270. Moreover, as the pad 2270 is compressed, the volume of the portion of the sterilization chamber 2258 that is on the distal side of the sealing member 2290 is reduced, thereby increasing the pressure in that portion of the sterilization chamber 2258. As a result, the antiseptic 2233 is

32

forced through the ports 2294 into the portion of the sterilization chamber 2258 on the proximal side of the sealing member 2290. Due to the seal between the sealing member 2290 and the luer 2020, the antiseptic 2233 is prevented from entering the lumen 2022 of the luer 2020, and thus is prevented from contacting or mixing with medical fluid that may be within the lumen 2022 when the cap 2204 is coupled with the medical connector 2000 and/or that may flow through the lumen 2022 after the cap 2204 has been removed from the connector 2000. The antiseptic 2233 can fill the open region of the sterilization chamber 2258 on the proximal side of the sealing member 2290.

As the luer 2020 is advanced distally in the sterilization chamber 2258, another seal, or partial seal, can be formed between an outer surface of the luer 2020 and an inner surface of the rim 2253. Where present, the seal can be substantially liquid-tight. However, the vents 2259 can interrupt the seal so as to permit antiseptic 2233 to exit from the chamber 2258. In further embodiments, a proximal or distal surface of the rim 2253 can be covered with a covering, such as, for example, Tyvek® or other nonwoven material, which can filter microbes from the air entering the sterilization chamber 2258 via the vents 2259, yet can permit antiseptic 2233 to pass through it so as to exit from the sterilization chamber 2258. In other embodiments, the rim 2253 is uninterrupted (e.g., is free of vents 2259) such that an uninterrupted seal can be formed between the rim 2253 and the male luer 2020.

With continued reference to FIG. 39, when the cap 2204 is connected to the medical device 2000, antiseptic 2233 can fill the sterilization chamber 2258 between the seals formed by contact between the luer 2020 and the sealing member 2290 and between the luer 2020 and the rim 2253. An outer surface of the luer 2020 between these two sealed regions of the luer 2020 thus can be bathed in the antiseptic 2233 and sterilized thereby. As mentioned with respect to the assembly 1900, the rim 2253 can be positioned at a deeper or a more shallow position relative to the housing 2252, which can result in sterilization of a smaller or greater surface area of the luer 2020, respectively. In certain embodiments in which the proximal seal between the rim 2253 and the male luer 2020 is interrupted (e.g., where the rim 2253 includes vents 2259), antiseptic 2233 can be permitted to exit from the chamber 2258. In some embodiments, the vents 2259 are sufficiently large to permit antiseptic 2233 to exit from the chamber 2258 freely once the antiseptic 2233 has been expelled from the pad 2270. Antiseptic 2233 that exits from the chamber 2258 through the vents 2259 can sterilize portions of the male luer 2020 that are proximal of the rim 2253.

When the cap 2204 is removed from the medical device 2000, it can naturally or automatically return to the orientation shown in FIG. 37. In particular, the resiliently compressible pad 2270 can move the sealing member 2290 distally to its pre-use position. In so doing, the expanding portion of the sterilization chamber 2258 that is distal of the sealing member 2290 can have a decreased pressure such that antiseptic 2233 is forced back through the ports 2294 of the sealing member 2290 in a distal direction. The expanding pad 2270 can soak up or absorb the returned antiseptic 2233.

In other embodiments, the caps 2202, 2204 can more closely resemble the caps 2102, 2104 described above. For example, the cap 2202 can have a separate pad, which is separated from the pad 2270 by a partition. In still other embodiments, the caps 2202, 2204 can be readily disconnected from each other, and in further embodiments, may be configured for selective reconnection with each other in manners such as those described with respect to other caps herein.

FIGS. 40-45 illustrate another embodiment of a cap 2304, which can resemble one or more of the caps described above in certain respects. For example, the cap 2304 can replace or readily be altered to replace any of the caps 1004, 1104, 1204, 1304, 1404, 1504, 1604, 1804, 1904, 2104, 2204 in the systems 1000, 1100, 1200, 1300, 1400, 1500, 1600, 1800, 1900, 2100, 2200 described above. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "23."

The cap 2304 can include a housing 2350 having a sidewall 2352 and a base wall 2354 that define a sterilization chamber 2358. The housing 2350 can further include a coupling interface 2342. The cap 2304 can include a biasing member 2376, which can comprise a resiliently compressible pad 2370, which can in turn include an antiseptic 2333 therein. The cap 2304 can further include a sealing member 2390, which includes a sealing region 2392 and one or more ports 2394, which include channels 2393 that extend through the sealing member 2390.

The sidewall 2352 of the housing 2350 can be different from that of the illustrated embodiment of the cap 2204. In particular, at least a portion of an inner surface of the sidewall 2352 (e.g., a proximal region thereof) can be tapered so as to form a liquid-tight seal with a male luer. For example, at least a portion of the inner surface of the sidewall 2352 can comply with ISO standards (e.g., ISO 594-1:1986 and ISO 594-2:1998) for forming a seal with a male luer. In the illustrated embodiment, the sidewall 2352 is devoid of any inwardly projecting rims that could interrupt complementarities between the sidewall 2352 and a male luer.

FIGS. 41-45 illustrate consecutive stages of the cap 2304 being coupled with a medical device 2000. As shown in FIG. 41, a tip 2021 of a male luer 2020 can be received within the sterilization chamber 2358 prior to contacting the sealing member 2390. Stated otherwise, the sealing member 2390 can be recessed relative to a proximal end of the sidewall 2352 by a distance that is sufficiently great to permit at least a portion of the male luer 2020 to be received within the sidewall 2352 before the male luer contacts the sealing member 2390.

In FIG. 42, the luer 2020 has been advanced further within the sterilization chamber 2358 so as to contact the seal region 2392 of the sealing member 2390. In the illustrated embodiment, the connection interface 2342 of the cap 2304 engages a connection interface 2012 of the medical connector 2000 just prior to contact being made between the tip 2021 of the luer 2020 and the seal region 2392. The connection interfaces 2342, 2012 thus can assist in the creation of a fluid-tight seal between the luer 2020 and the sealing member 2390.

The sealing member 2390 can remain in the initial or pre-use position that is shown in both FIGS. 41 and 42 until the seal has been formed between the luer 2020 and the sealing member 2390. Further advancement of the luer 2020 into the sterilization chamber 2358 can strengthen the seal due to the spring force that arises as the pad 2370 is compressed. When the sealing member 2390 is in the initial orientation, the ports 2394 can prevent antiseptic 2333 from passing through them. Also, the composition of the pad 2370 or the affinity of the pad 2370 to absorb antiseptic 2333 will determine the retention of the antiseptic 2333 in the pad 2370.

In FIG. 43, the luer 2020 has been advanced slightly further into the sterilization chamber 2358, thereby compressing the pad 2370 somewhat and forcing antiseptic 2333 through the ports 2394. As schematically shown by wavy lines, the antiseptic 2333 begins to fill the space between the sealing member 2390 and the tip 2021 of the luer 2020. The antiseptic

2333 does not, however, enter into a lumen of the luer 2020 due to the seal between the luer 2020 and the sealing member 2390.

In FIG. 44, the luer 2020 has been advanced even further into the sterilization chamber 2358, thereby compressing the pad 2370 to a greater extent and forcing additional antiseptic 2333 through the ports 2394. Although the outer surface of the luer 2020 appears to be nearly parallel to and in contact with an inner surface of the tapered portion of the sidewall 2352, a seal has not yet been formed in this area. Accordingly, the antiseptic 2333 can fill not only the space between the sealing member 2390 and the tip 2021 of the luer 2020, but also the small amount of space between the luer 2020 and the sidewall 2352. The luer 2020 thus can be covered in antiseptic 2333 and sterilized thereby. In some embodiments, the antiseptic 2333 remains within portions of the space between the luer 2020 and the sidewall 2352 only temporarily, as additional advancement of the luer 2020 can close this space to form a seal.

FIG. 45 illustrates a final or fully coupled stage, or an end-of-stroke orientation, in which the luer 2020 has been advanced even further into the sterilization chamber 2358 such that the luer 2020 forms a seal with the sidewall 2352. Antiseptic 2333 can be retained in all open portions of the sterilization chamber 2358 that are between the seal formed by the luer 2020 and the sealing member 2390 and the seal formed by the luer 2020 and the sidewall 2352. In the illustrated embodiment, only a small portion of the luer 2020, which includes the tip 2021, is in continual contact with the portion of the antiseptic 2333 thus retained. This portion of the luer 2020 can be bathed by the antiseptic 2333 and sterilized thereby. In other embodiments, larger portions of the luer 2020 can be bathed.

The seal formed by the luer 2020 and the sealing member 2390 and the seal formed by the luer 2020 and the sidewall 2352 is accomplished by appropriate sizing of the individual components. The sizing is subject to and based upon the ISO luer taper specification, which implies a range of axial engagement of 2 millimeters. All manufactured components can vary with tolerance limits between a maximum and minimum material condition. The maximum material condition and minimum material condition indicate large and small components, respectively. When all combinations of maximum and minimum material condition parts are considered, the variation in mating depth in the axial direction is 2 millimeters. The minimum material condition in this case is also the case of maximum mating depth (or stroke). In other words, the minimum material condition is the loosest fit, and the maximum material condition is the tightest fit of the taper. A minimum dispense stroke of 1 millimeter indicates that the components have been dimensioned such that for the tightest fitting luer 2020 (i.e., maximum material condition), a minimum of 1 millimeter dispense stroke will exist. Hence, a minimum of 1 millimeter of seal movement will exist prior to luer engagement.

FIG. 46 illustrates another embodiment of a cap 2304' in an end-of-stroke orientation. The cap 2304' is substantially the same as the cap 2304 just discussed. For example, a substantial portion of an interior surface of the sidewall 2352 is tapered so as to be complementary to the male luer 2020. However, the sidewall 2352 includes one or more venting channels or vents 2353 therein that prevent the sidewall 2352 from sealing with the male luer 2020. The illustrated vent 2352 extends from a proximal end of the sidewall 2352 in a longitudinal direction to a position just beyond (or distal of) an end-of-stroke position of the tip 2021 of the male luer 2020. Accordingly, after liquid-impervious contact is estab-

lished between the male luer 2020 and those portions of the sidewall 2352 having a taper complementary to the male luer 2020, antiseptic 2333 can still exit the chamber 2358 via the vent 2353. In certain embodiments, the coupled connection interfaces 2012, 2342 can permit the antiseptic 2333 to pass through them so as to provide additional venting of the chamber 2358. For example, threaded connection interfaces 2012, 2342 can permit antiseptic 2333 that has exited from the chamber 2358 to spiral about an outer surface of the sidewall 2352 and/or otherwise seep in a distal direction.

In various embodiments, the cap 2304' comprises one or more, two or more, three or more, or four or more vents 2353. One or more of the vents 2353 can be substantially linear in a longitudinal direction (as shown) and/or can define alternate orientations. For example in some embodiments, one or more vents 2353 can be angled relative to a longitudinal axis of the cap 2304' (e.g., can be helical), or can include a portion that is so angled. One or more of the vents 2353 can extend any suitable distance between the proximal end of the sidewall 2352 and the base wall 2354. For example, in various embodiments, the vents 2353 extend no less than about 1/4, no less than about 1/3, no less than about 1/2, no less than about 2/3, or no less than about 3/4 the distance between the proximal end of the sidewall 2352 and the base wall 2354. Where suitable, one or more vents 2353 can be incorporated into embodiments of the caps described above, as well as those described hereafter.

FIG. 47 illustrates another embodiment of a cap 2404, which can resemble one or more of the caps described above, particularly the caps 2304, 2304', in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "24." The cap can include a housing 2450, a biasing member 2476, and a sealing member 2490. The housing 2450 can have a sidewall 2452 and a base wall 2454 that define a sterilization chamber 2458. The housing 2450 can further define one or more ports 2494. In the illustrated embodiment, the port 2494 comprises a longitudinal groove 2459 extending a distance along the sidewall 2452. The longitudinal distance which the groove 2459 extends can be varied as desired. In some embodiments, the longitudinal distance is greater than or equal to a stroke length through which the sealing member 2490 is displaced when the cap 2404 is connected to a medical connector for reasons discussed hereafter, although such is not required.

The sealing member 2490 can be devoid of channels, and may act in a plunger-like fashion. The sealing member 2490 can form a liquid-impermeable seal with the sidewall 2452 when in the pre-use configuration shown in FIG. 47. However, distal displacement of the sealing member 2490 can move a proximal end of the sealing member 2490 past a proximal end of the channel 2494, thereby opening the channel 2494. This can permit an antiseptic 2433 to be forced from a pad 2470 by the displaced sealing member 2494 and moved through the channel 2494, thereby entering the portion of the sterilization chamber 2458 which is proximal to the sealing member 2490. In embodiments where the longitudinal length of a channel 2459 is greater than or equal to a stroke length through which the sealing member 2490 is displaced, antiseptic 2433 can be permitted to pass through the channel 2494 during all stages of the displacement.

In the illustrated embodiment, the biasing member 2476 includes a resiliently compressible pad 2477, although additional or other components are possible (e.g., a compressible spring). The pad 2477 is separated from the pad 2470 by a barrier 2478, which can comprise any suitable material capable of preventing passage of the antiseptic 2433. For example, in some embodiments, the barrier 2478 comprises a plastic film or disk. The barrier 2478 thus can restrain the

antiseptic 2433 to a predetermined portion of the sterilization chamber 2458 that is closest to the sealing member 2490. Such an arrangement can permit the usage of less antiseptic 2433, as a greater portion of the antiseptic 2433 can be expelled from the pad 2470.

In some embodiments, both of the pads 2470, 2477 comprise the same material, while in other embodiments different materials may be selected for desired properties. For example, the pad 2470 may comprise a more absorbent foam while the pad 2477 may comprise a springier foam. In some embodiments, both pads 2470, 2477 can provide a bias to the sealing member 2490 when they are compressed such that the biasing member 2476 can be said to include both pads 2470, 2477. In still other or further embodiments, the biasing member 2476 can comprise a spring or other at least somewhat resiliently deformable element in place of the pad 2477.

Although in the illustrated embodiment, the sealing member 2490 is devoid of ports, other embodiments can include ports in addition to or instead of the channels 2494 in the sidewall 2452. Likewise, it is understood that channels 2494 could be included in other embodiments of caps described herein in addition to or in place of ports through sealing members. Similar substitutions and rearrangements are possible with respect to other features of the cap 2404, such as the two-part biasing member 2476 and the barrier 2478.

FIGS. 48 and 49 illustrate another embodiment of a cap 2504, which can resemble one or more of the caps described above, particularly the caps 2304, 2304', 2404, in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "25." The cap can include a housing 2550, a biasing member 2576, and a sealing member 2590. The housing 2550 can have a sidewall 2552 that defines a sterilization chamber 2558. The housing 2550 can further define a bathing recess 2555 within the sterilization chamber 2558, which can be included in a tapered region at a proximal end of the sidewall 2552. As shown in FIG. 49, antiseptic 2533 can be retained within the bathing recess 2555 and maintained in contact with an outer surface of a male luer 2020. Accordingly, a greater portion of the luer 2020 than just a tip 2021 thereof can be maintained in contact with the antiseptic 2533 when the luer 2020 is in an end-of-stroke position.

The housing 2550 can further define a vent 2598 having a cover 2599. The vent 2598 can be defined by a channel that extends from an interior of the sidewall 2552 to an exterior thereof. A distal end of the vent 2598 can open into the bathing recess 2555, and a proximal end of the vent 2598 can be at a proximal end of the sidewall 2552. The vent 2598 can function in manners such as those described above with respect to other vents.

In some embodiments, the cover 2599 can comprise a material, such as, for example, Tyvek® or other nonwoven material, which can filter microbes from the air entering the sterilization chamber 2558 via the vent 2598 and can permit antiseptic 2533 to exit from the sterilization chamber 2558.

With continued reference to FIGS. 48 and 49, the antiseptic 2533 can be held within the sterilization chamber 2533 without pads. A biasing member 2576 can include a compression spring 2579. A sealing member 2590 can form a fluid-tight seal with the sidewall 2552 to retain the antiseptic 2533 within a reservoir portion of the chamber 2533. While the sealing member 2590 can resemble any of the sealing members discussed above, the illustrated embodiment includes ports 2594 that have two-way valves 2597 therein. In various embodiments, the two-way valves 2597 are formed of self-sealing slits and/or the two-way valves 2597 can be disposed within channels through the sealing member 2590.

FIG. 50 illustrates another embodiment of an assembly 2600, which can resemble one or more of the assemblies described above, particularly the assembly 1800, in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "26." The assembly 2600 can include a cap 2602 and cap 2604 that are coupled with each other when in a pre-use state and that can be removed from each other. In particular, the caps 2602, 2604 can be coupled with each other via a sealing mechanism. In the illustrated embodiment, the caps 2602, 2604 are coupled with each other via a sealing sleeve 2691.

With reference to FIG. 51, the cap 2602 can include a housing 2610, which can include a sidewall 2612 and a base wall 2613. The housing 2610 can include a substantially cylindrical region toward a proximal end thereof, which can be flattened and taper toward the narrower base wall 2613. Such a shape can provide a convenient handle at a distal end of the cap 2602. A cavity 2623 can be formed at an interior of the sidewall 2612 and the base wall 2613, which can reduce material costs for the cap 2602.

The sidewall 2612 can define a sterilization chamber 2622, which can include a connection interface 2630 that includes threads 2631. The connection interface 2630 can be configured to attach the cap 2602 to a medical connector in a secure yet selectively removable manner. The sterilization chamber 2622 can further include a pad 2632.

A proximal surface 2624 of the sidewall 2612 can define a seal inhibitor 2625 that is configured to prevent the cap 2602 from forming a fluid-tight seal with a medical connector, such as a needleless injection site, when it is coupled therewith. For example, in the illustrated embodiment, the proximal surface 2624 of the sidewall 2612 is substantially castellated such that it defines a series of offset contact regions 2626 and venting regions 2627. In the illustrated embodiment, each of the contact regions 2626 and venting regions 2627 includes a planar surface that is substantially perpendicular to a longitudinal axis of the cap 2602. The contact regions 2626 are at a more proximal position than are the venting regions 2627. Accordingly, when the cap 2602 is coupled with certain embodiments of needleless injection sites, the contact regions 2626 can come into contact with surfaces of the needleless injection sites that project outwardly, whereas the venting regions 2627 can avoid making any such contact.

For example, in arrangements such as those depicted in FIGS. 32 and 33, the cap 2602 can be advanced onto a needleless injection site 2040, 2060 sufficiently to bring the planar surfaces of the contact regions 2626 into contact with a radially outwardly projecting planar surfaces of the needleless injection site 2040, 2060. However, in such a configuration, the venting regions 2627 would be spaced from the outwardly projecting planar surface of the needleless injection site 2040, 2060 so as not to form a seal therewith. The cap 2602 thus would be permitted to vent via the venting regions 2627. As further discussed below, other configurations of the seal inhibitor 2625 are also possible. Moreover, in some embodiments, the cap 2625 is devoid of a seal inhibitor 2625.

With reference to FIGS. 51 and 53, an exterior surface of the sidewall 2612 can define another connection interface 2640 that is configured to couple the cap 2602 with a connection interface 2695 of the sleeve 2691. In the illustrated embodiment, the connection interfaces 2640, 2695 couple with each other via a friction-fit engagement. The friction fit can be sufficiently strong to provide a fluid-tight seal between the cap 2602 and the sleeve 2691, yet can allow the cap 2602 to be removed from the sleeve 2691 via mere manipulation by a medical practitioner (e.g., without the use of ancillary tools). The fluid-tight seal can prevent evaporative loss of

antiseptic from the pad 2632 and/or can maintain the sterility of the sterilization chamber 2622. In other or further embodiments, the connection interfaces 2640, 2695 can include threads or other suitable attachment features.

The cap 2602 can include a flange 2615 having an outer diameter larger than an inner diameter of the end of the sleeve 2691 that connects with the cap 2602. The flange 2615 can prevent the cap 2602 from being inserted into the sleeve 2690 too deeply. In other or further embodiments, the flange 2615 can cooperate with an end surface of the sleeve 2690 to create a liquid-tight seal (see FIG. 54). For example, in some embodiments, a sealing member, such as an "O" ring, is included between the flange 2615 and the end of the sleeve 2690 to provide the liquid-tight seal.

With reference to FIG. 52, the cap 2604 can include a housing 2650 that includes a sidewall 2652 and a base wall 2654, which can cooperate to define a cavity 2659 similar to the cavity 2623 described above. Likewise, the housing 2650 can define a substantially cylindrical shape at a proximal end of the cap 2604, which flattens and tapers toward the base wall 2654.

The sidewall 2652 can define a sterilization chamber 2658, which can include a sealing member 2690 and a biasing member 2676. The sealing member 2690 and the biasing member 2676 can resemble any suitable combination of these components, and features thereof, described above. In the illustrated embodiment, the biasing member 2676 comprises a pad 2670.

A portion of the sidewall 2652 can define a connection interface 2642, which includes one or more threads 2643 in the illustrated embodiment. The connection interface 2642 can be configured to attach the cap 2604 to a medical connector in a secure yet selectively removable manner.

With reference to FIGS. 52 and 53, the sidewall 2652 can define an additional connection interface 2680, which can cooperate with a connection interface 2692 defined by the sleeve 2691 to couple the cap 2604 with the cap 2602. The connection interface 2680 of the cap 2604 can include a groove 2683, which may be substantially annular and extend about a periphery of the cap 2604. The connection interface 2692 of the sleeve 2691 can include a complementary inward projection 2693, which likewise can be substantially annular. The interfaces 2680, 2692, when coupled with each other, can provide a fluid-tight seal between the cap 2604 and the sleeve 2690. In other embodiments, the connection interfaces 2680, 2690 can instead define a friction-fit seal, such as that provided by the illustrated embodiment of the connection interfaces 2640, 2695 described above. In still other or further embodiments, a flange 2661 defined by the housing 2650 can cooperate with an end surface of the sleeve 2691 to create a liquid-tight seal (see FIG. 54), which can prevent evaporative loss of antiseptic from the pad 2670 and/or maintain the sterility of the sterilization chamber 2658. For example, in some embodiments, a sealing member, such as an "O" ring, is included between the flange 2659 and the end of the sleeve 2691 to provide the liquid-tight seal.

With reference to FIG. 54, when the assembly 2600 is in a fully coupled or pre-use state, a proximal end of the sidewall 2652 of the cap 2604 is received within the cavity 2622 defined by the sidewall 2612 of the cap 2602. In some embodiments, the sidewall 2652 of the cap 2604 does not contact any portion of the sidewall 2612 of the cap 2602 in this pre-use configuration, nor does the sidewall 2652 contact the pad 2632 that is within the cap 2602. Such a configuration can result in a relatively compact assembly 2600 in which each cap 2602, 2604 can be quickly prepared for use. In other embodiments, the sidewalls 2652, 2612 may contact or

couple with each other (e.g., via the connection interfaces **2642**, **2630**) and/or the sidewall **2652** may contact the pad **2632** in the pre-use configuration. In still other embodiments, the sidewalls **2652**, **2612** may be spaced from each other such that the sidewall **2652** is not received within the cavity **2622**.

FIG. **55** illustrates another embodiment of an assembly **2700**, which can resemble one or more of the assemblies described above, particularly the assemblies **1800**, **2600**, in certain respects. Accordingly, like features are designated with like reference numerals, with the leading digits incremented to "27." The assembly **2700** can include a cap **2702** and cap **2704** that are coupled with each other when in a pre-use state via a sealing sleeve **2791**.

The assembly **2700** can include one or more separation assists **2707**, **2708**, which can aid in removal of the cap **2702** and/or the cap **2704** from the sleeve **2791**. In the illustrated embodiment, the separation assists **2707**, **2708** each includes a complementary recess/protrusion pair. In particular, a flange **2715** of the cap **2702** defines a recess **2716** that is sized and dimensioned to receive therein a protrusion **2799** that is defined by an edge **2798** of the sleeve **2791**. The recess **2716** and the protrusion **2799** cooperate with each other as a separation assist **2707**. Similarly, a flange **2761** of the cap **2704** defines a recess **2762** that is sized and dimensioned to receive therein a protrusion **2797** that is defined by an edge **2796** of the sleeve **2791**. The recess **2762** and the protrusion **2797** cooperate with each other as a separation assist **2708**.

Focusing now on the separation assist **2707**, the recess **2716** can include two substantially planar surfaces that meet at a rounded base. The planar surfaces can be at an angle relative to a plane that is perpendicular to a longitudinal axis (or central axis) of the cap **2702** (e.g., a plane defined by portion of the flange **2715** that does not include the recess **2716**, in the illustrated embodiment). For example, in the illustrated embodiment, each of the planar surfaces of the recess **2716** defines an angle of about 20 degrees relative to the perpendicular plane. Similarly, the protrusion **2799** can include two substantially planar surfaces that meet at a rounded apex. The planar surfaces can be at the same angle relative to the perpendicular plane as are the planar surfaces of the recess **2716**. For example, in the illustrated embodiment, each of the planar surfaces of the protrusion **2799** defines an angle of about 20 degrees relative to a plane defined by the portion of the edge **2798** of the sleeve **2791** that does not include the protrusion **2799**.

When the cap **2702** is joined with the sleeve **2791** in a pre-use configuration (similar to that shown in FIG. **54**), the planar portions of the recess **2716** and of the protrusion **2799** can be in close proximity to each other or can contact each other. In order to separate the cap **2702** from the sleeve **2791**, the cap **2702** can be rotated relative to the sleeve **2791**, which can cause opposing planar surfaces of the recess **2716** and the protrusion **2799** to contact each other and slide past each other. This interaction can convert the rotational movement of the cap **2702** about a common axis of the cap **2702** and the sleeve **2791** into translational movement of the cap **2702** away from the sleeve **2791** along the common axis. Due to the symmetry of the planar surfaces of each of the recess **2716** and the protrusion **2799** of the illustrated embodiment, the cap **2702** can be rotated in either direction to achieve the same lifting action via the separation assist **2707** that tends to move the cap **2702** away from the sleeve **2791**.

In other embodiments, the separation assist **2707** can be configured to aid in separating the cap **2702** from the sleeve **2791** only when the cap **2702** is rotated in one predetermined direction (e.g., either clockwise or counterclockwise). For example, one planar surface may be at about 20 degrees

relative to the perpendicular plane, whereas the other planar surface may be at a about 90 degrees relative to the perpendicular plane (i.e., approximately parallel to or extending through a central axis of the cap **2702**). In other embodiments, one or more of the planar surfaces of the recess **2716** and/or the protrusion **2799** may be at larger or smaller angles relative to the perpendicular plane. For example, in various embodiments, a set of complementary planes may be at an angle of no more than about 15 degrees, no more than about 20 degrees, no more than about 30 degrees, no more than about 45 degrees, no more than about 60 degrees, or no more than about 75 degrees. Other configurations of the separation assist **2707** are also possible. For example, in some embodiments, the complementary surfaces of the recess **2716** and the protrusion **2799** can define angles as just described, but the surfaces may be rounded or otherwise non-planar.

The foregoing discussion regarding the separation assist **2707** applies equally to the separation assist **2708**. In the illustrated embodiment, the separation assist **2707** and the separation assist **2708** are substantially identical, such that the recess **2762** and the protrusion **2797** likewise include complementary planar surfaces that are at an angle of about 20 degrees relative to a plane oriented perpendicularly through a central axis of the cap **2704** and the sleeve **2791**. In other embodiments, the arrangements of the separation assists **2707**, **2708** may be different from each other. For example, the planar surfaces of the separation assist **2707** may be at a larger or smaller angle than those of the separation assist **2708** so as to provide a different amount of separation force. Moreover, in some embodiments, the assembly **2700** includes a number of separation assists **2707** equal to the number of separation assists **2708**, whereas in other embodiments, the assembly **2700** may include more or fewer separation assists **2707** as compared with the number of separation assists **2708**. For example, in the illustrated embodiment, the assembly **2700** includes one separation assist **2707** and two separation assists **2708**.

In the illustrated embodiment, the two separation assists **2708** are at diametrically opposite positions. Such an orientation can aid in maintaining the cap **2704** and the sleeve **2791** in a substantially coaxial orientation as the cap **2704** is being removed, which can prevent an elongated sidewall **2752** from contacting an inner surface of the sleeve **2791** and thereby potentially complicating removal of the cap **2704**. In other arrangements, additional separation assists **2708** may be used, and the separation assists **2708** may be equally spaced from each other about a perimeter of the sleeve **2791**.

Other arrangements of the separation assists **2707**, **2708** are contemplated. For example, in some embodiments, the caps **2702**, **2704** include one or more of the protrusions **2799**, **2797**, respectively, whereas the sleeve **2791** includes one or more of the recesses **2716**, **2762**.

FIGS. **56** and **57** illustrate another embodiment of a cap **2802**, which in some embodiments can be used in place of the cap **2602** in the assembly **2600**. In other embodiments, the cap **2802** can be modified so as to be used in place of the cap **2702** in the assembly **2700**, such as by altering a flange **2815** of the cap **2802** to include a recess.

The cap **2802** can include a seal inhibitor **2825** having a different arrangement from that shown with respect to the caps **2602**, **2702**. In the illustrated embodiment, the seal inhibitor **2825** is defined by a proximal surface **2824** of a sidewall **2812** of the cap **2802**, which defines a rounded, sinusoidal contour. In particular, the proximal surface **2824** can define two contact regions **2826** and two venting regions **2827**. In the illustrated embodiment, the contact regions **2826** are at diametrically opposite positions and the venting regions

2827 likewise are at diametrically opposite positions. The contact regions 2626 are at a more proximal position than are the venting regions 2627. As discussed above with respect to the cap 2602, the venting regions 2827 can prevent the cap 2802 from forming a seal with a medical connector, and can permit venting of the cap 2802 when it is coupled with the medical connector.

As shown in FIG. 58, the proximal surface 2824 of the cap 2802 can be well-suited for coupling with a removable cover 2834 such as the removable covers discussed above. Accordingly, various embodiments of the cap 2802 either can be readily fitted with a cover 2834 and distributed for individual use, or can be incorporated into an assembly, such as the assemblies 2600, 2700 described above, and distributed for use in a dual-cap system. Such versatility can reduce manufacturing costs, such as by eliminating tooling costs.

The caps described herein can be formed of, or coated with various colored materials or coatings. In some embodiments, the caps each include the same color. In other embodiments, the caps include different colors. Coloring the caps can, in some instances, provide advantages, such as ready identification of the type of cap, ready matching of a particularly colored cap with a particular type of medical connector, and the like.

The foregoing disclosure recites various embodiments that include systems configured for use with a pair of separated medical connectors. Examples of first means for coupling a male cap with a first medical connector include the connection interfaces 1042, 1142, 1342, 1542, 1842, 1942, 2242, 2342, 2642 of the caps 1004, 1104, 1304, 1504, 1804, 1904, 2204, 2304, 2304', 2604. Examples of first means for sterilizing a male luer of a first medical connector include the pads 1070, 1170, 1370, 1570, 1870, 2170, 2270, 2370, 2470, 2670. Examples of second means for coupling the female cap with a second medical connector include the connection interfaces 1030, 1130, 1530, 1830, 1930, 2230, 2630 of the caps 1002, 1102, 1502, 1802, 1902, 2202, 2602. Examples of second means for sterilizing at least a portion of a second medical connector include the pads 1032, 1132, 1332, 1532, 1832, 2132, 2632. Examples of means for coupling the male and female caps in a pre-use configuration include the connection interfaces 1040 and 1042; 1140 and 1180; 1240 and 1280; 1340 and 1380; 1440 and 1480; 1540 and 1580; 1840, 1891, 1842, and 1892; and 2640, 2695, 2680, and 2692. Examples of means for sealing a lumen of a male luer include the sealing members 2290, 2390, 2490, 2590, and 2690. Examples of means for biasing a means for sealing a lumen of a male luer include the biasing members 2276, 2376, 2476, 2576, and 2676.

It will be understood by those having skill in the art that many changes may be made to the details of the above-described embodiments without departing from the underlying principles presented herein. For example, any suitable combination of features of the various embodiments of assemblies described above is contemplated.

Any methods disclosed herein comprise one or more steps or actions for performing the described method. The method steps and/or actions may be interchanged with one another. In other words, unless a specific order of steps or actions is required for proper operation of the embodiment, the order and/or use of specific steps and/or actions may be modified.

It should be appreciated that in the above description of embodiments, various features are sometimes grouped

together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure. This method of disclosure, however, is not to be interpreted as reflecting an intention that any claim require more features than those expressly recited in that claim. Rather, as the following claims reflect, inventive aspects lie in a combination of fewer than all features of any single foregoing disclosed embodiment. Thus, the claims following this Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment. This disclosure includes all permutations of the independent claims with their dependent claims.

Recitation in the claims of the term "first" with respect to a feature or element does not necessarily imply the existence of a second or additional such feature or element. Elements recited in means-plus-function format are intended to be construed in accordance with 35 U.S.C. §112 ¶6. It will be apparent to those having skill in the art that changes may be made to the details of the above-described embodiments without departing from the underlying principles of the invention.

What is claimed is:

1. A method of disinfecting a male luer connector of the type including a post having a lumen through which fluid flows, the method comprising:

providing a male-disinfecting cap including

a receiving portion having a sidewall defining a chamber into which the post of the male luer connector can be received;

a biasing member disposed in the chamber;

a sealing member disposed in the chamber; and

an antiseptic agent disposed in the chamber; and

moving the cap in relation to the male luer connector so that (i) the post is received into the chamber, (ii) the biasing member urges the sealing member toward the post to cover the lumen and maintain the sealing member against the lumen, and, (iii) while the sealing member covers the lumen so as to inhibit at least the antiseptic agent from entering the lumen, at least a portion of the antiseptic agent is caused to come into contact with the post.

2. A method according to claim 1, wherein the sealing member is configured to permit the flow of the antiseptic agent past the sealing member to the post.

3. A method according to claim 2, wherein the sealing member includes at least one channel near its periphery.

4. A method according to claim 1, further comprising providing a pad disposed in the chamber abutting the sealing member, the pad containing the antiseptic.

5. A method according to claim 1, further comprising providing a cover disposed over an opening of the chamber.

6. A method according to claim 5, wherein the cover comprises an impervious pliable material.

7. A method according to claim 6, wherein the impervious pliable material is a foil.

8. A method according to claim 1, wherein a portion of the sidewall of the receiving portion has a taper that narrows toward an interior of the chamber.

9. A method according to claim 8, wherein the taper is near an opening of the chamber.

10. A method according to claim 8, further comprising engaging the post against the taper of the sidewall.