



US008647326B2

(12) **United States Patent**
Solomon et al.

(10) **Patent No.:** **US 8,647,326 B2**
(45) **Date of Patent:** **Feb. 11, 2014**

(54) **SYSTEM FOR CLEANING LUER CONNECTORS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 762 days.

(21) Appl. No.: **12/610,033**

(22) Filed: **Oct. 30, 2009**

(65) **Prior Publication Data**

US 2010/0047123 A1 Feb. 25, 2010

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/171,997, filed on Jul. 11, 2008, now Pat. No. 8,197,749, which is a continuation-in-part of application No. 12/164,310, filed on Jun. 30, 2008, now Pat. No. 8,177,761, which is a continuation-in-part of application No. 12/014,388, filed on Jan. 15, 2008, now abandoned.

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

(51) **Int. Cl.**
A61M 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/533**; 604/535; 604/256; 604/265;
422/28; 422/292

(58) **Field of Classification Search**

USPC 422/28, 292; 604/29, 256, 265, 533,
604/539, 905

See application file for complete search history.

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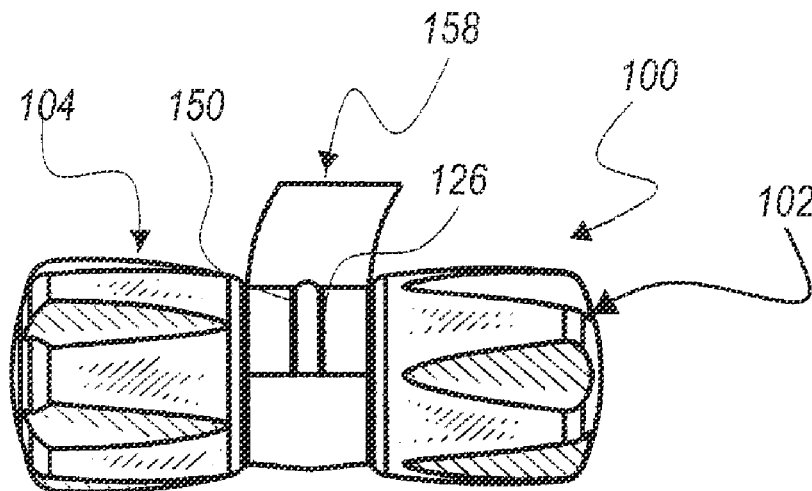
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(57) **ABSTRACT**

One or more caps can be used to cover and sterilize one or more separated medical connectors. A pair of caps can be connected to each other and sealed when in a pre-use state. The paired caps can be unsealed so as to permit connection to the medical connectors.

16 Claims, 24 Drawing Sheets



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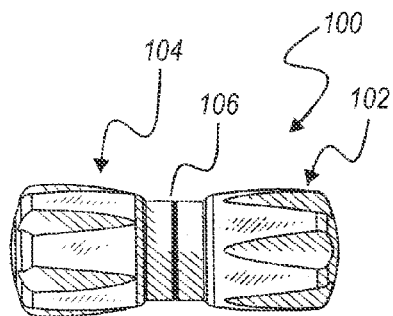


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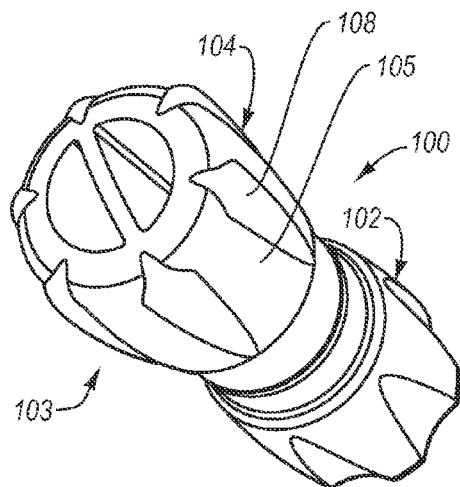


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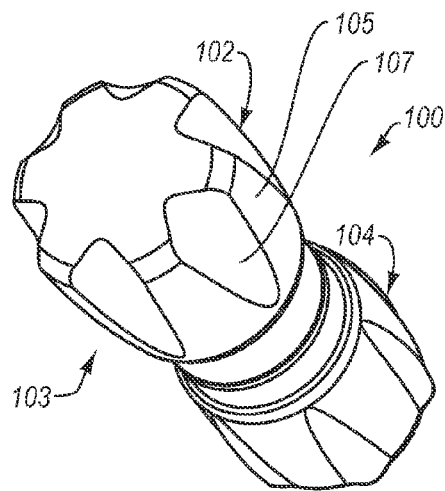


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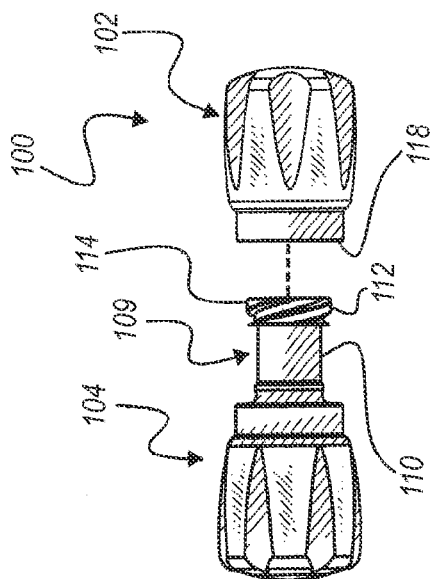


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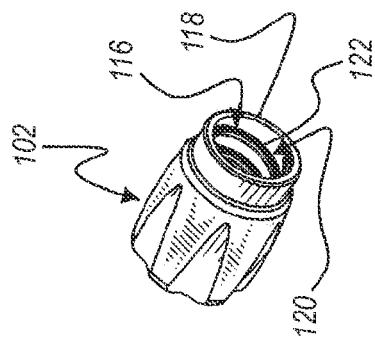


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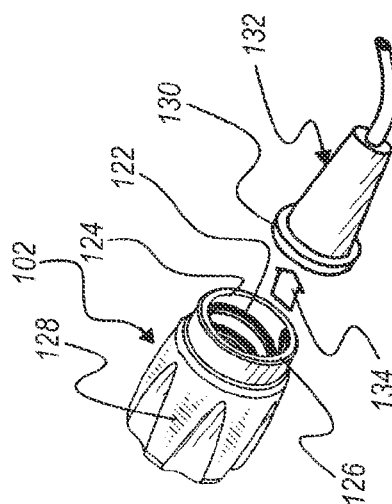


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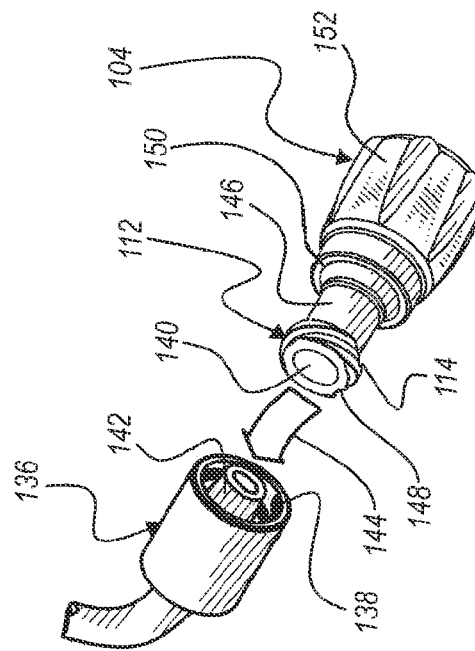


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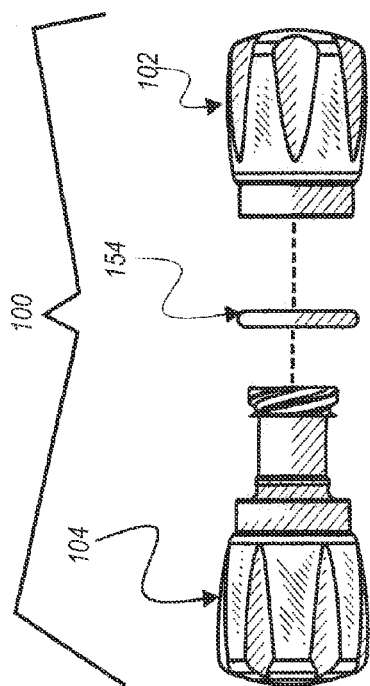


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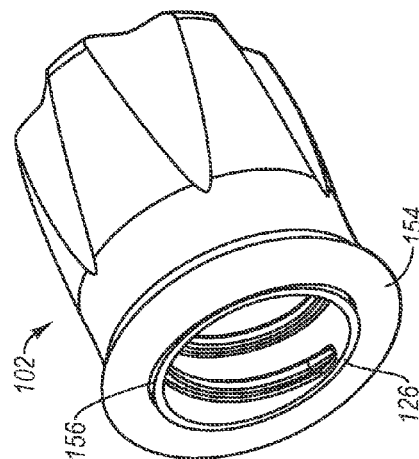


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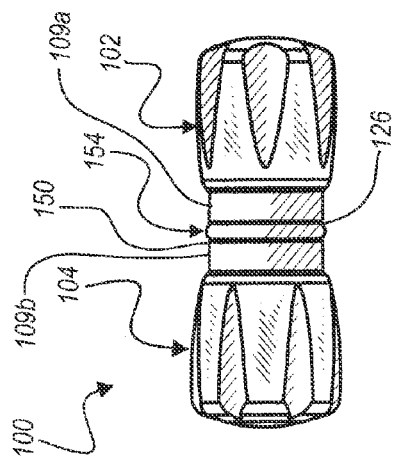


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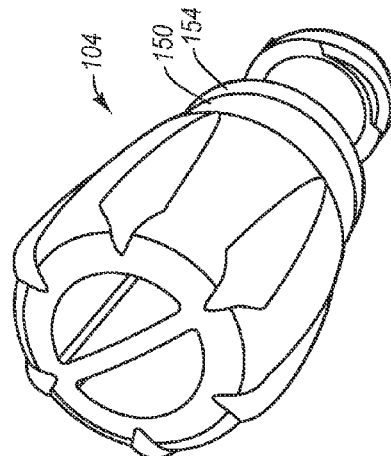


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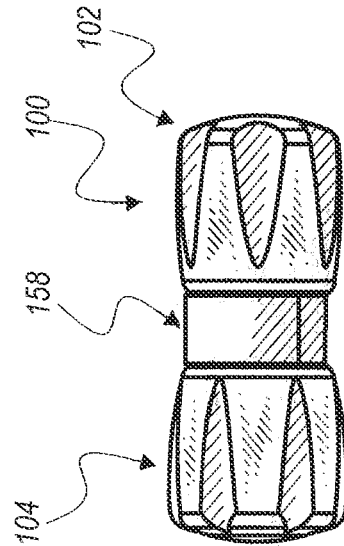


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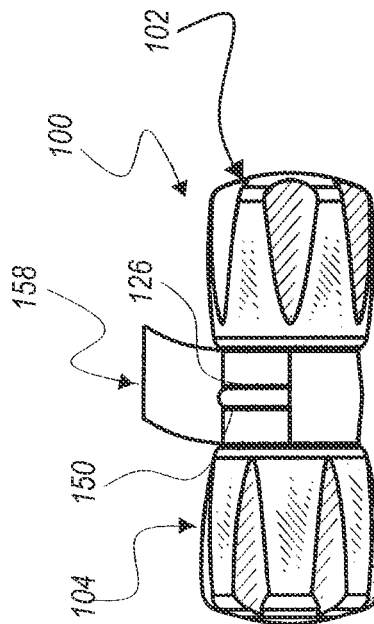


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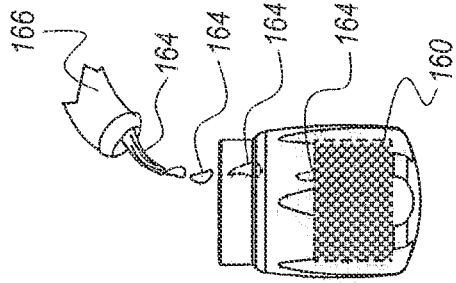


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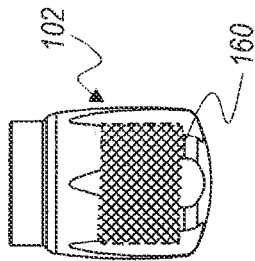


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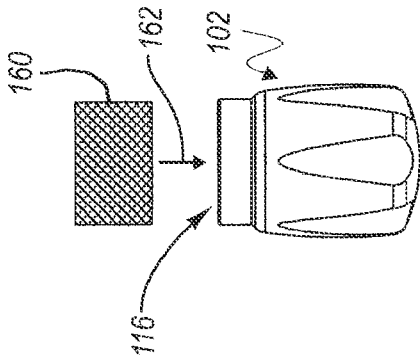


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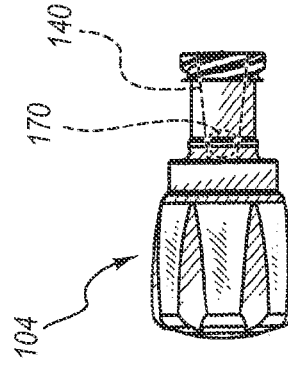


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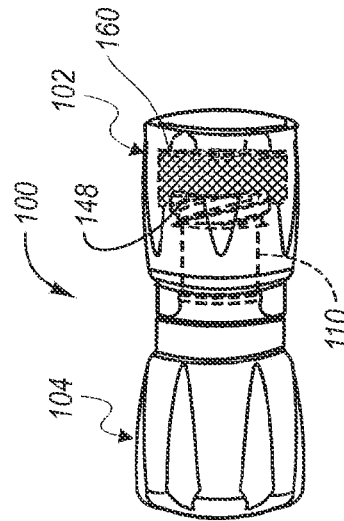


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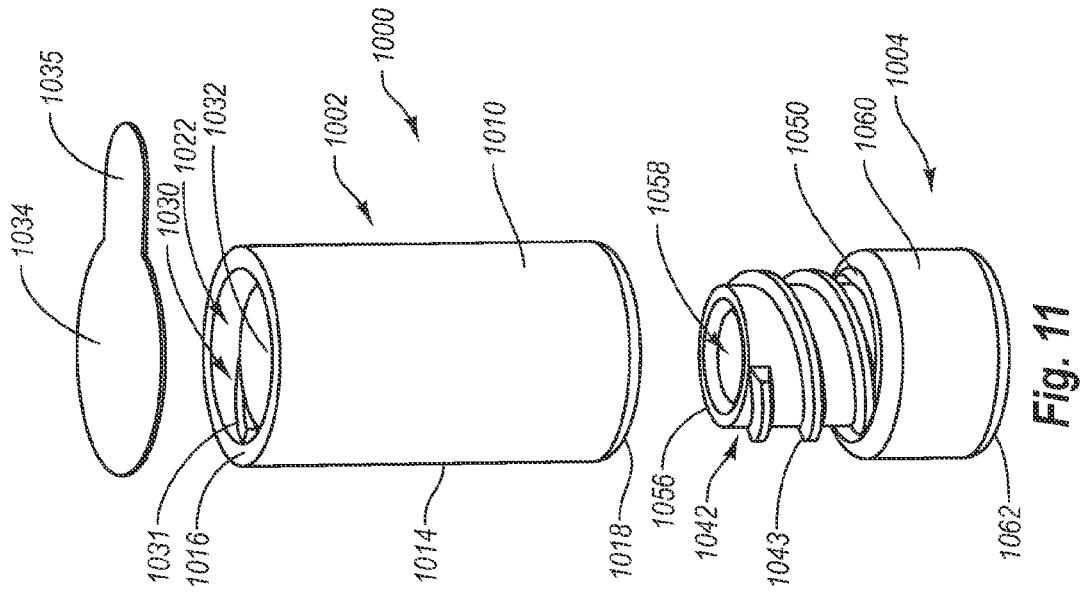


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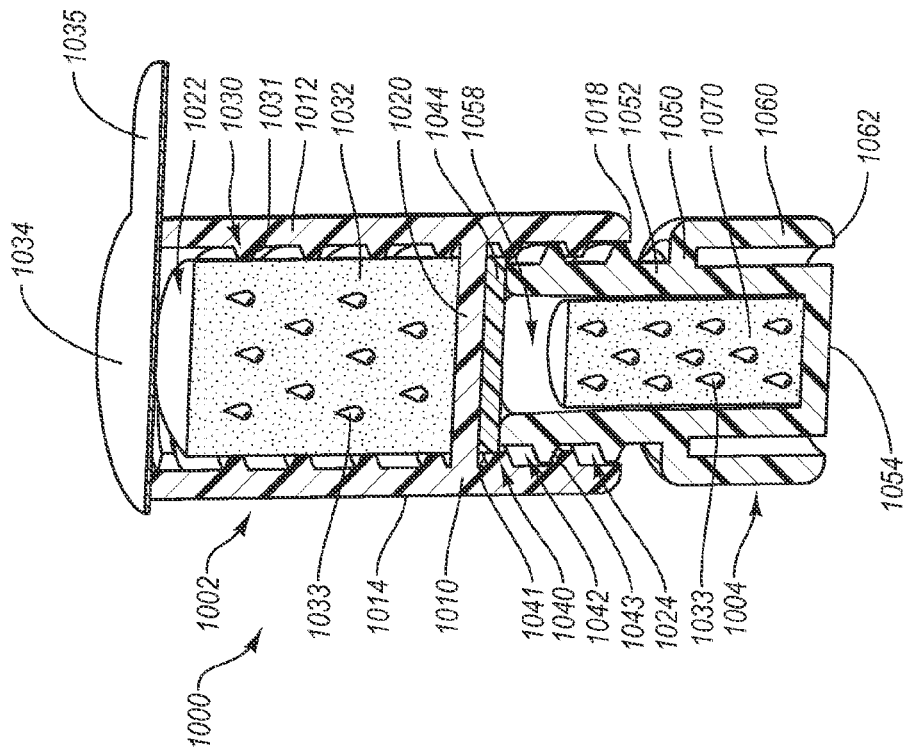


Fig. 10

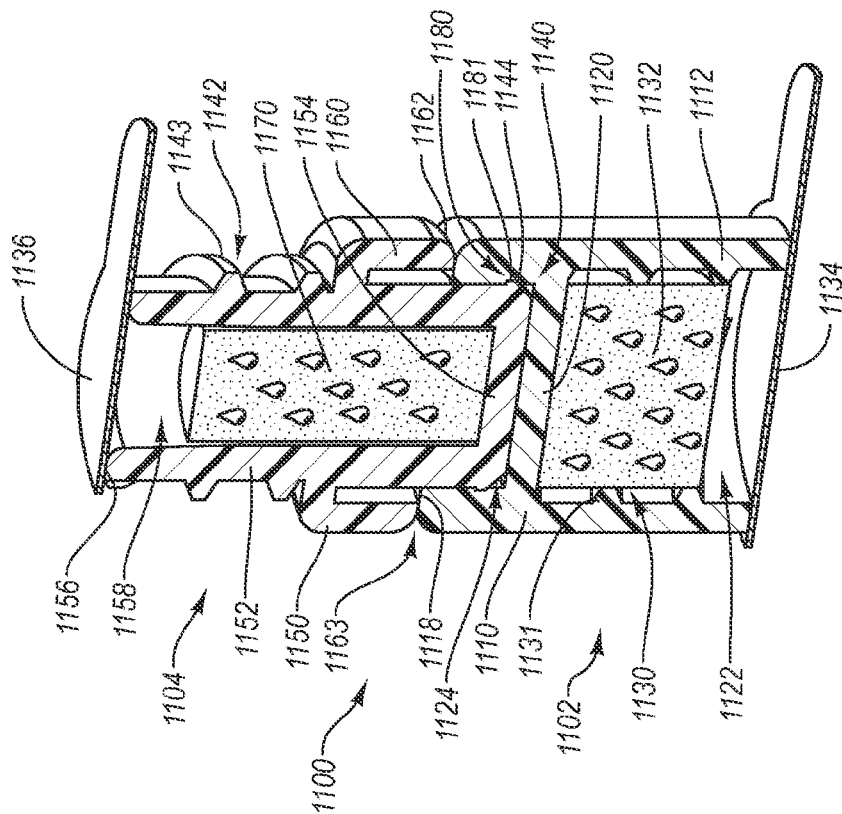


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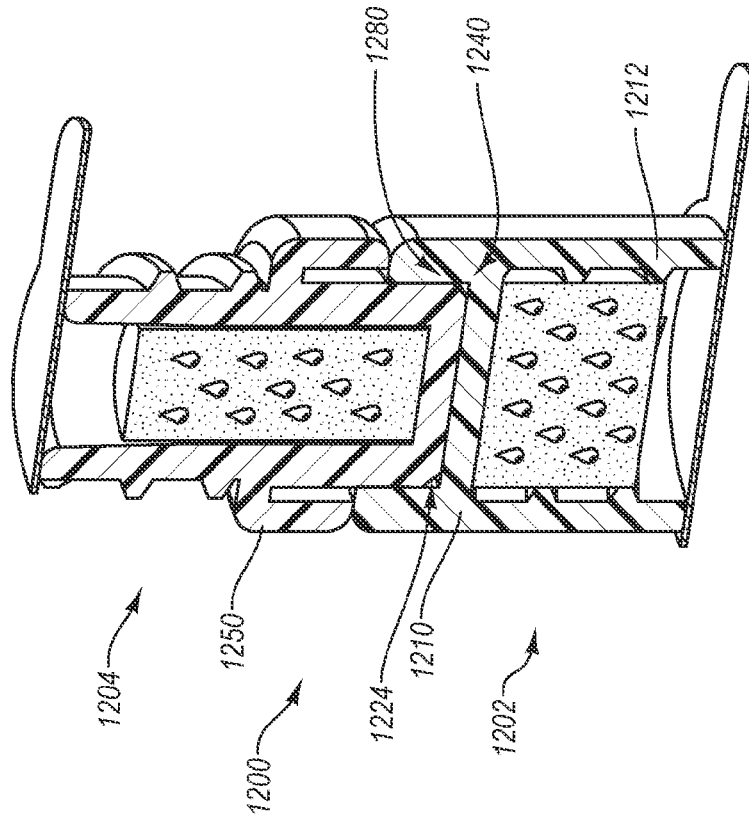


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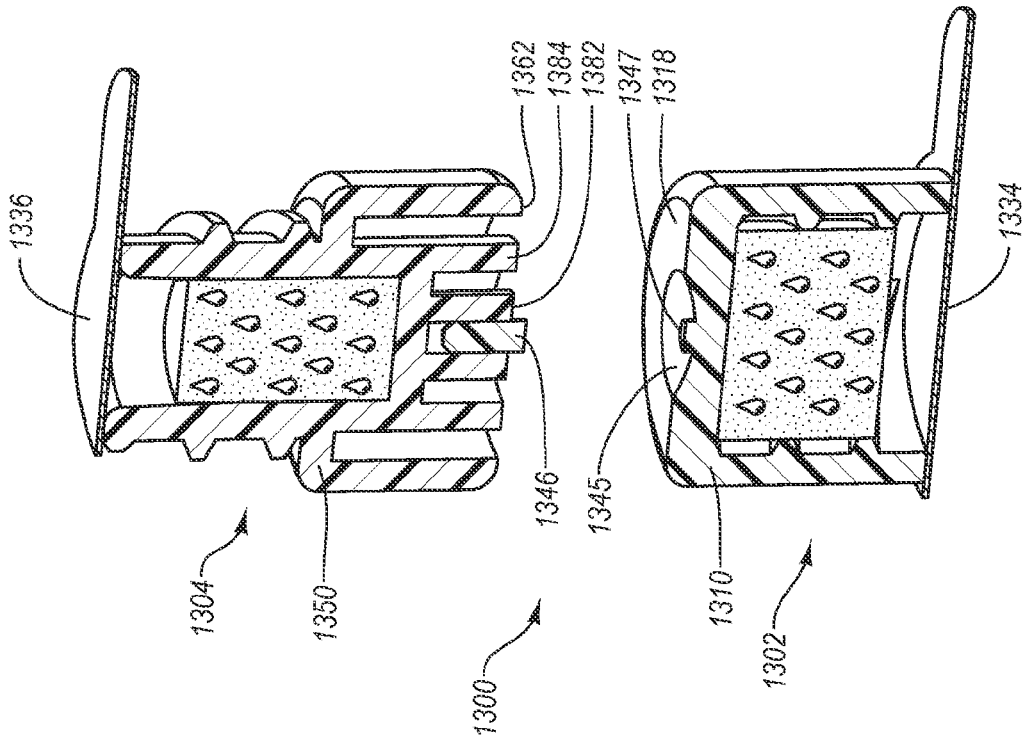


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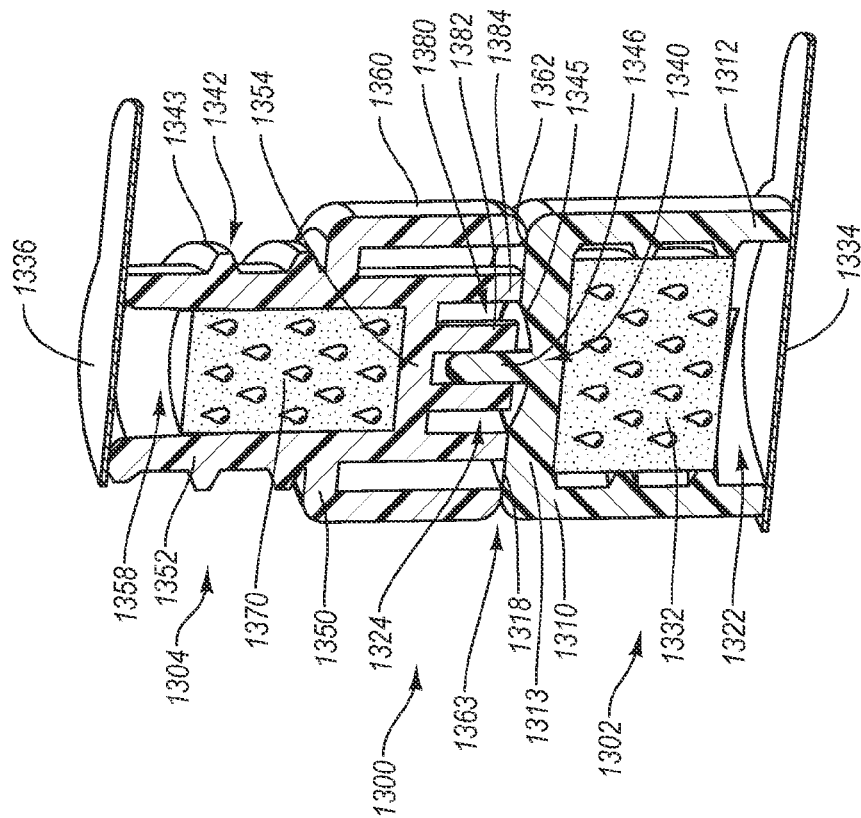


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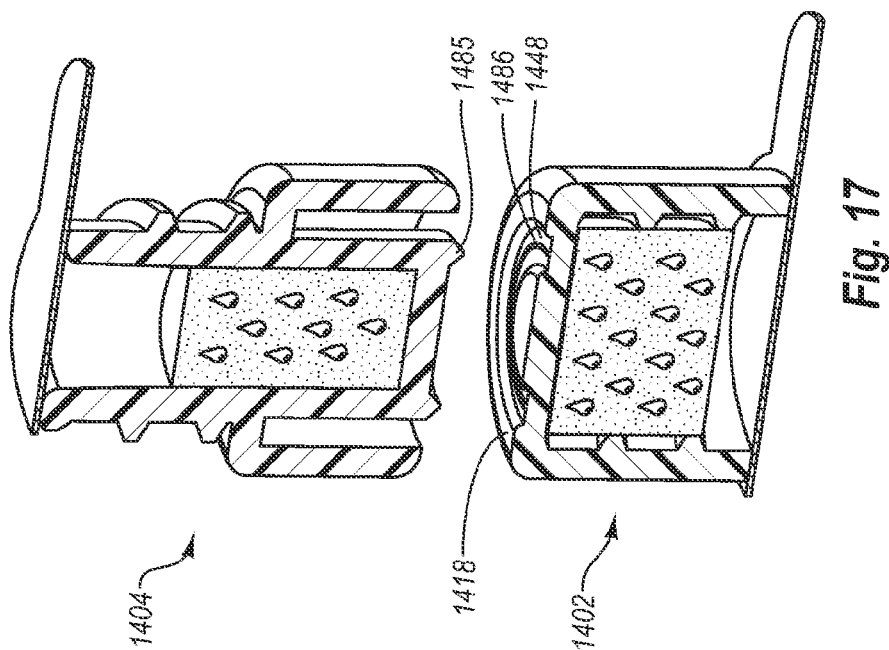


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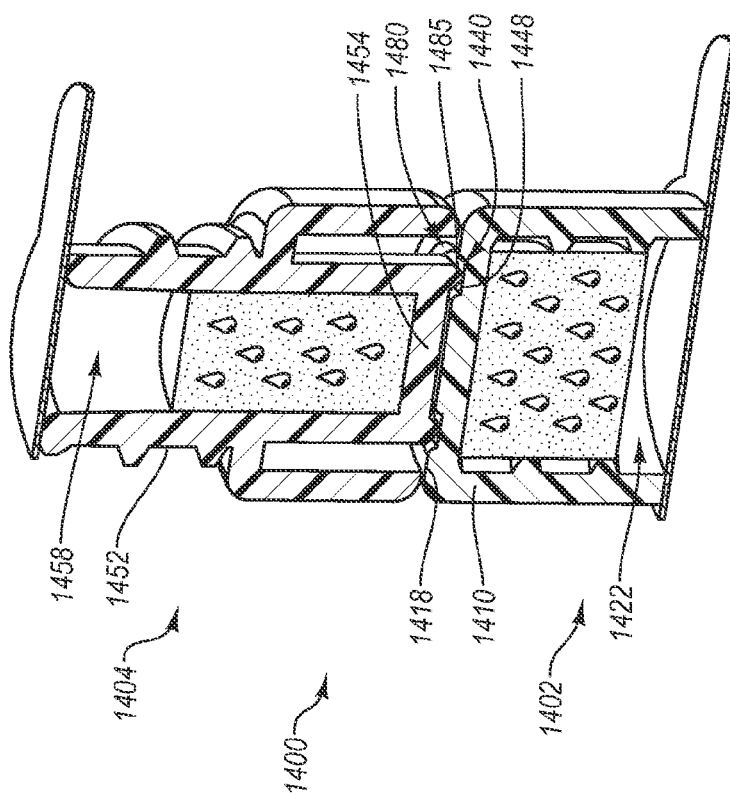
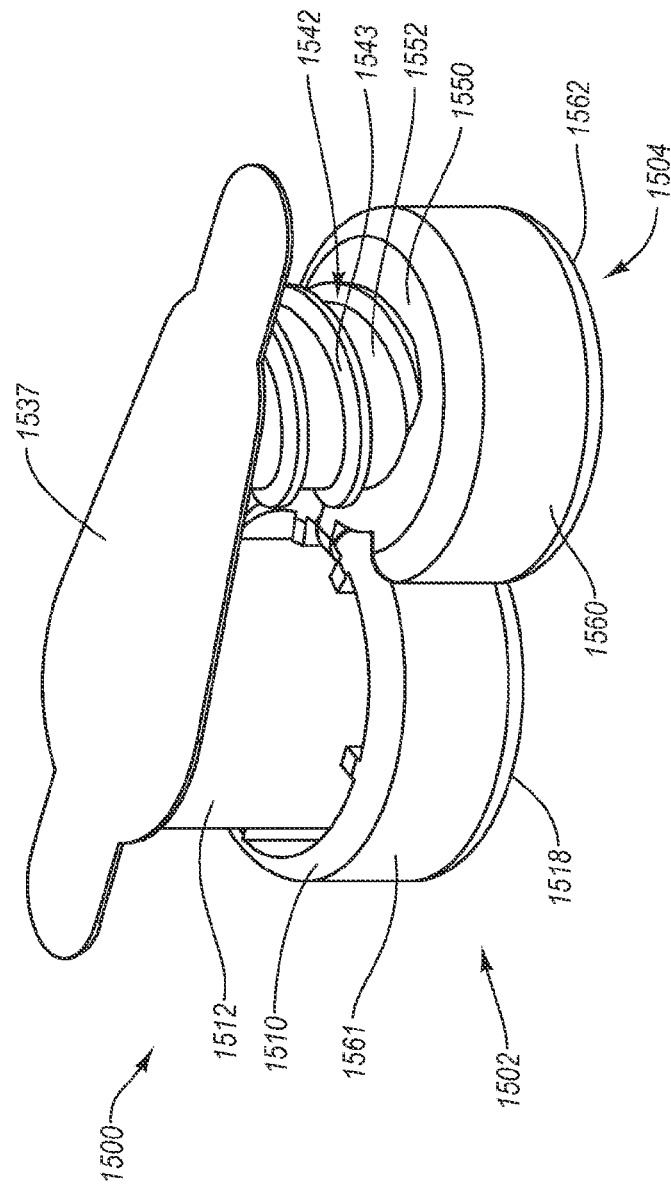


Fig. 16



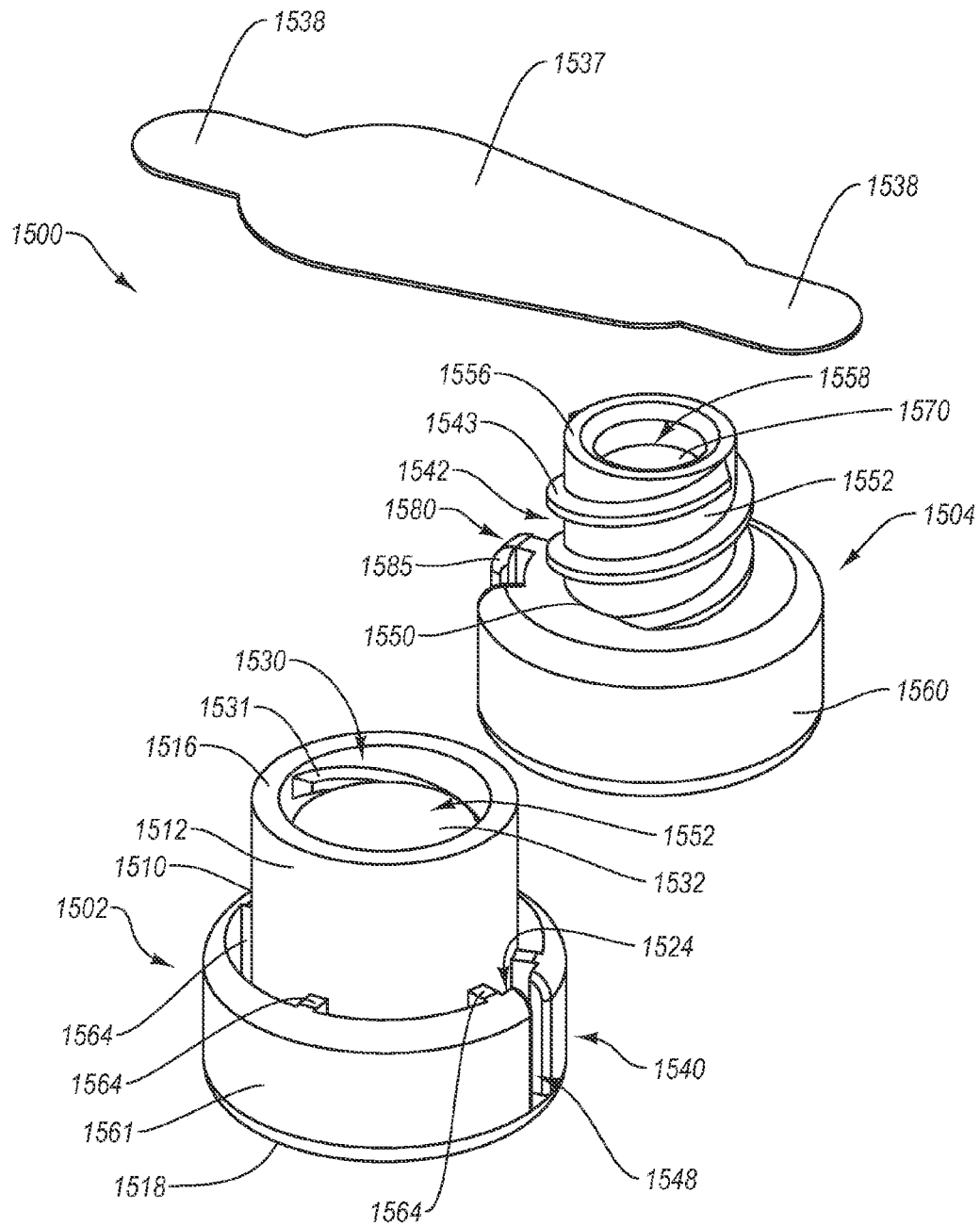


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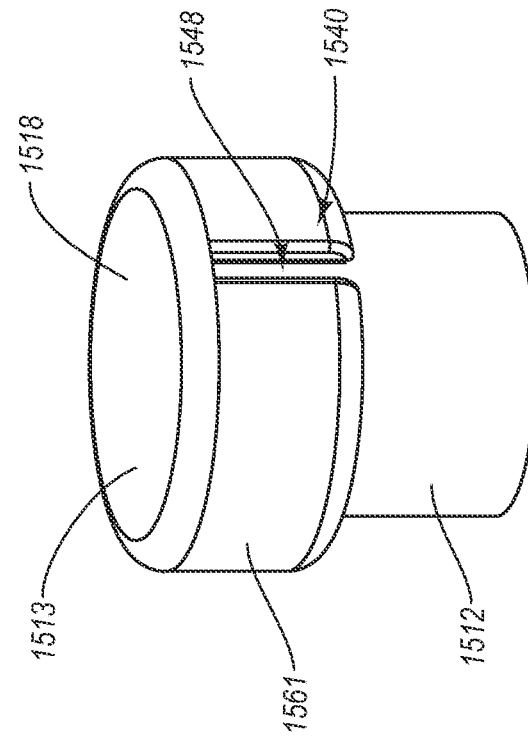


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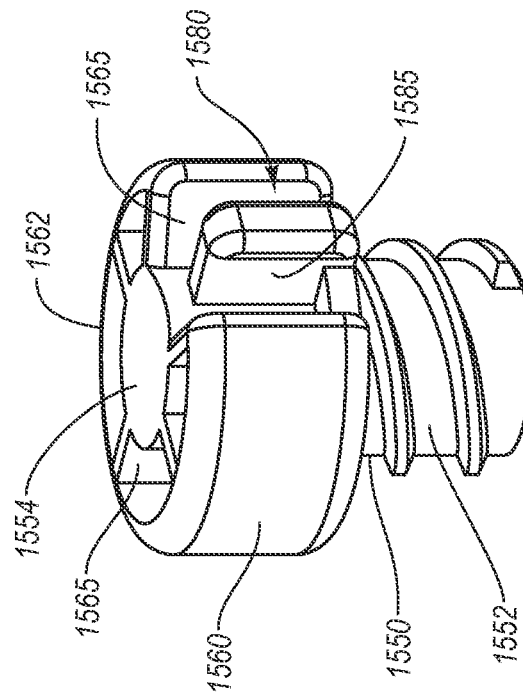


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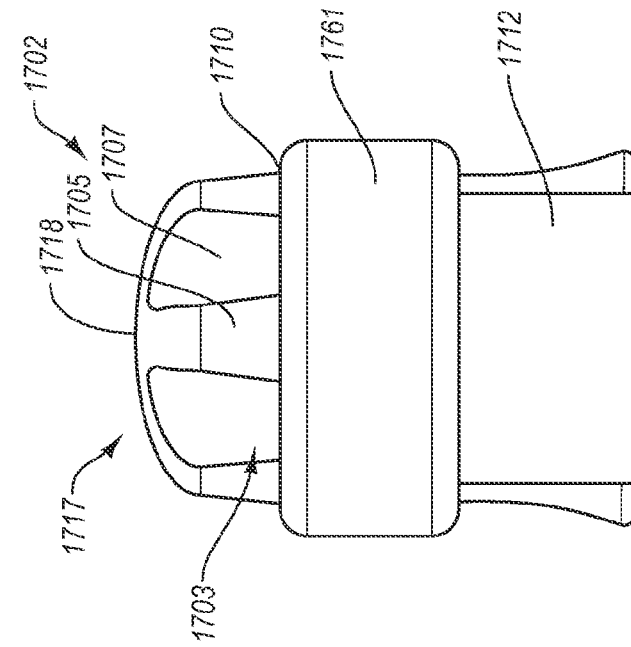


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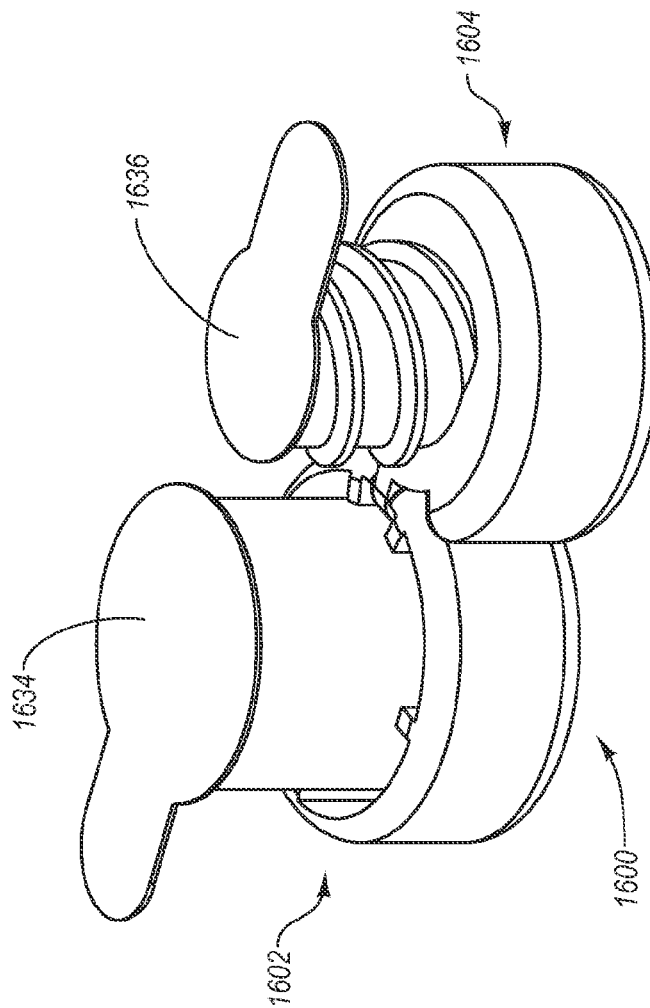


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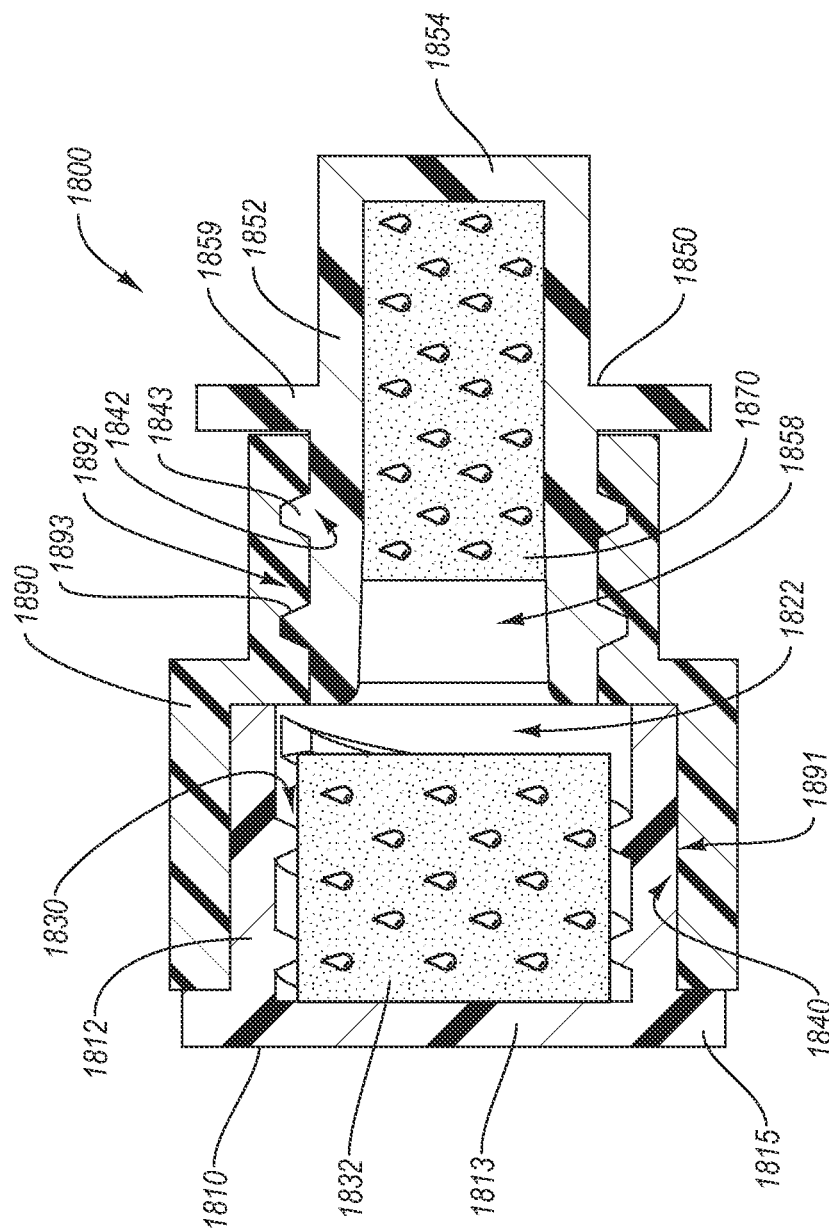


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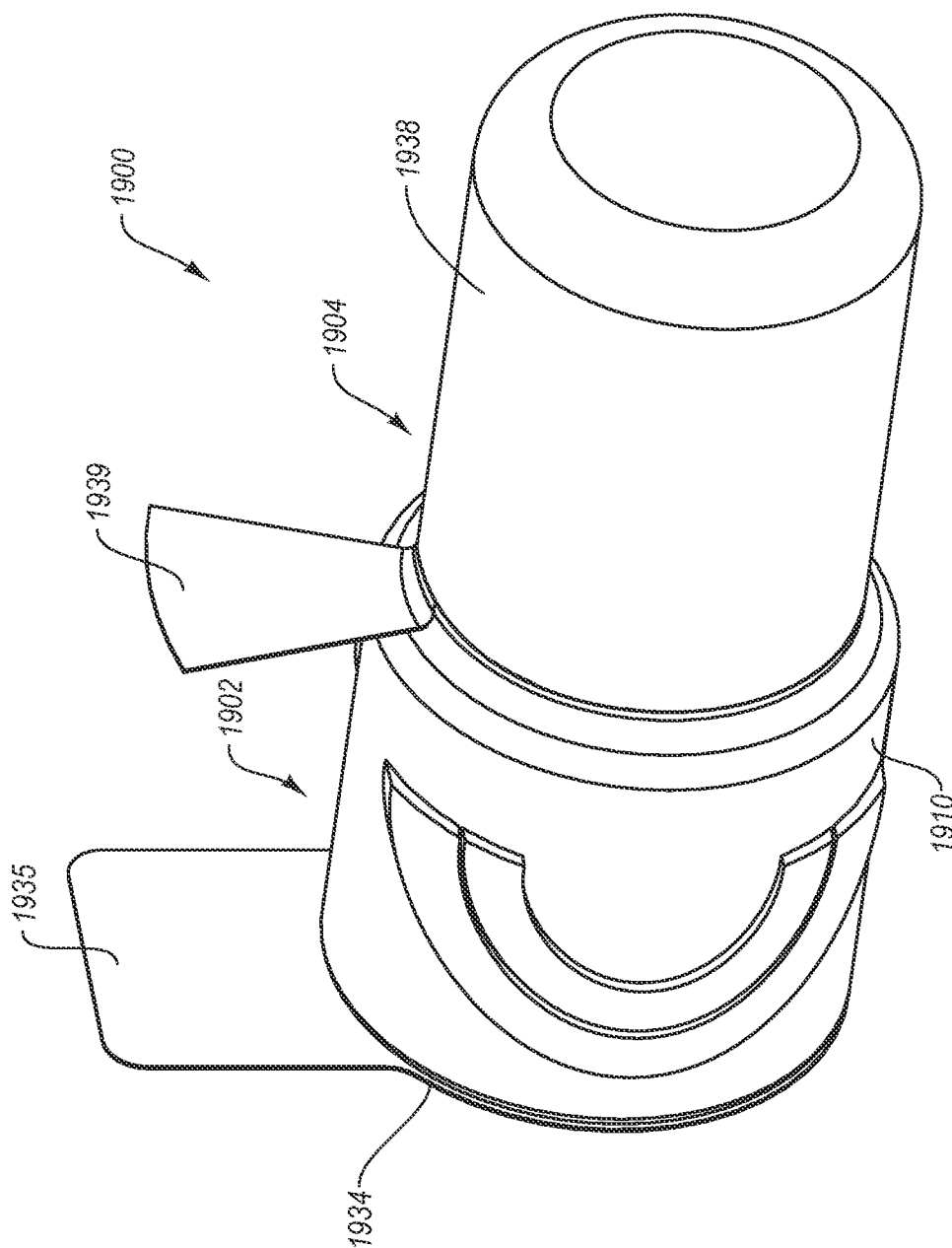
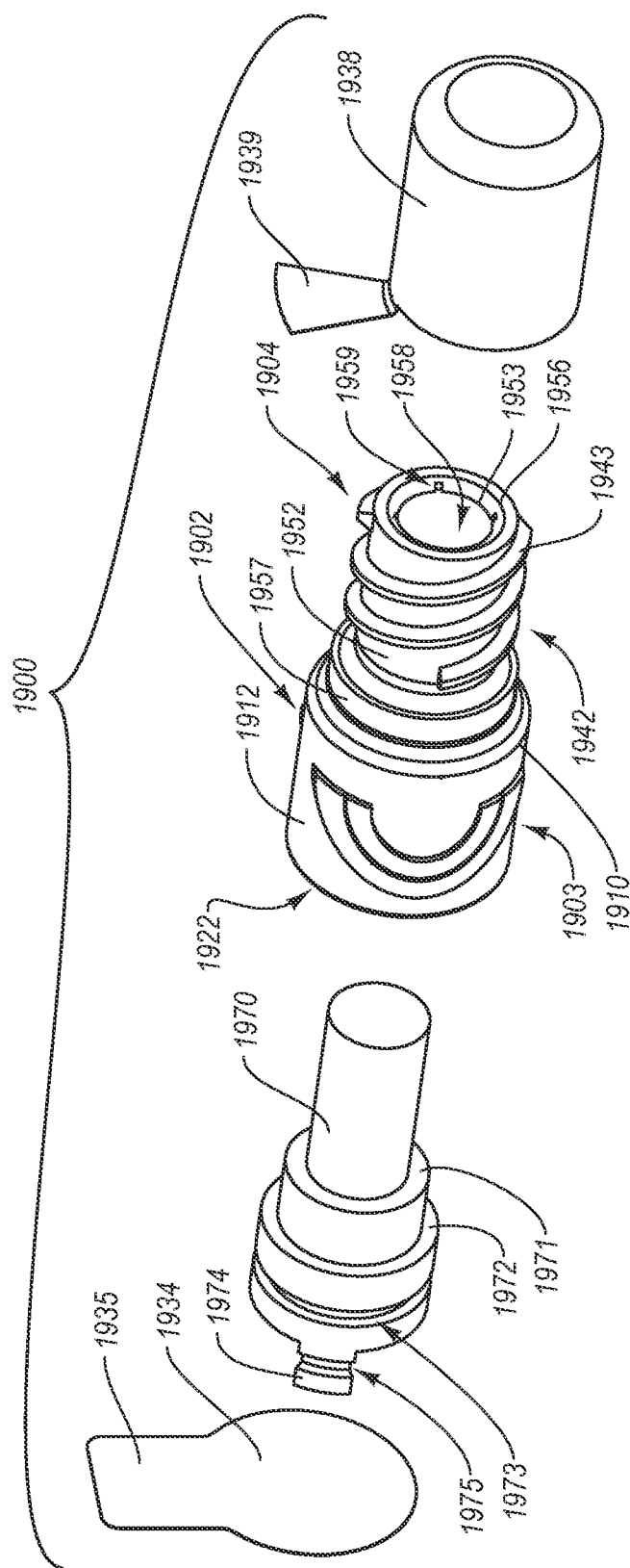


Fig. 25



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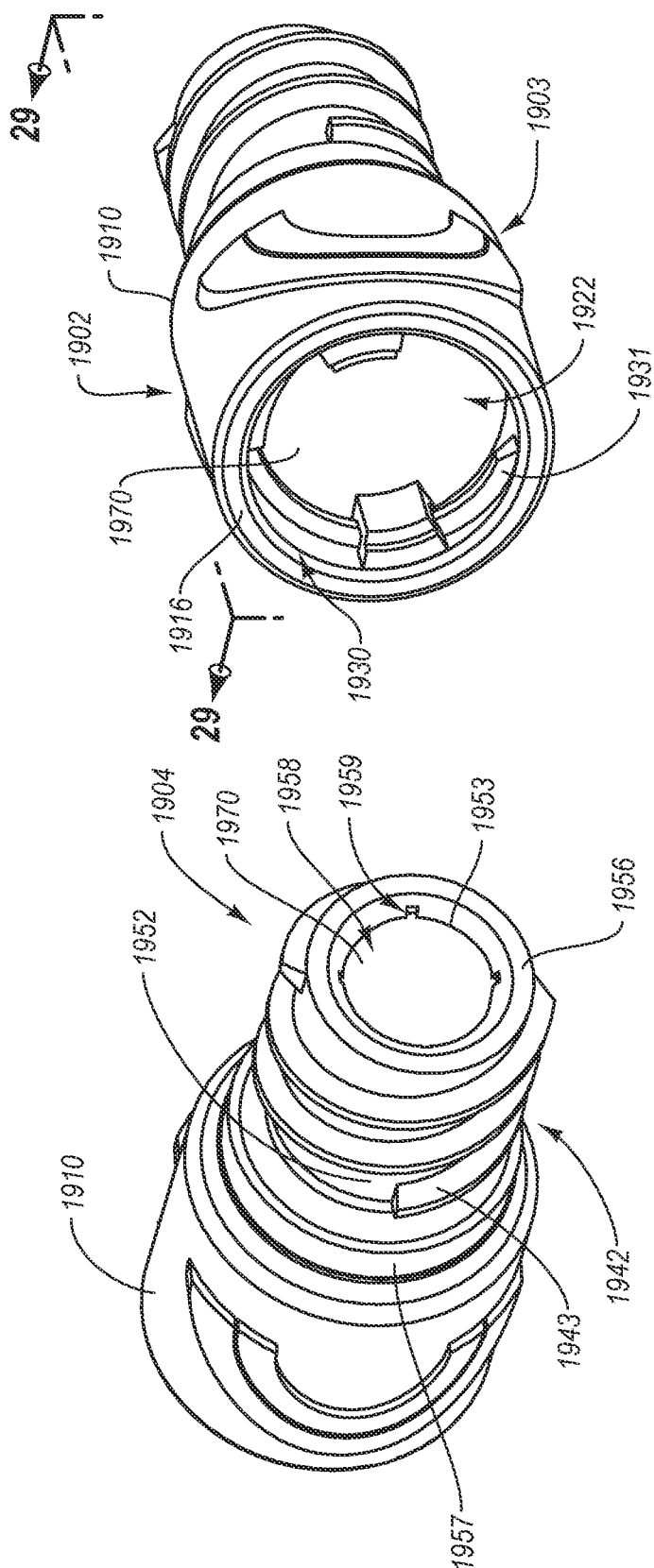


Fig. 28

Fig. 27

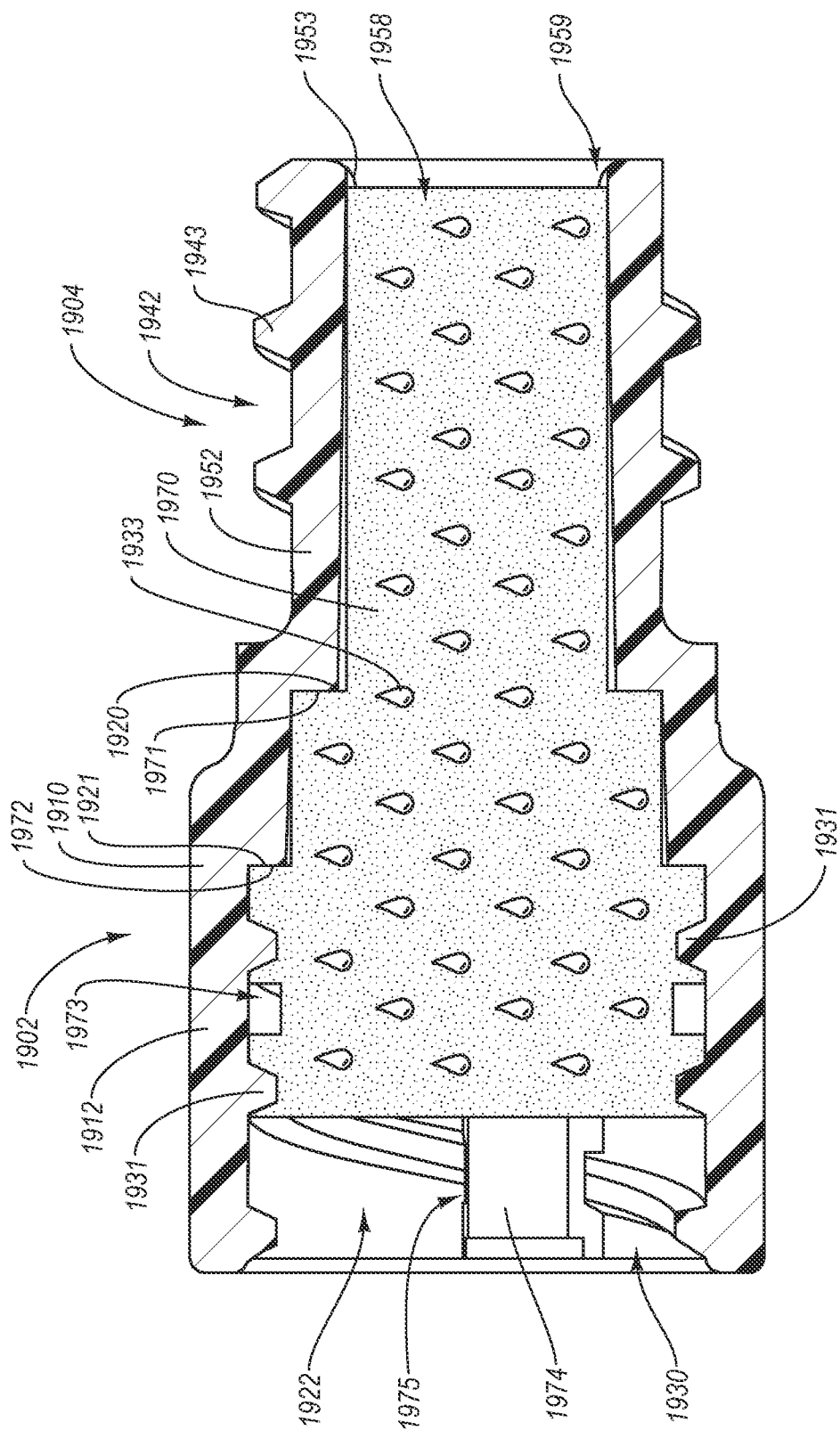


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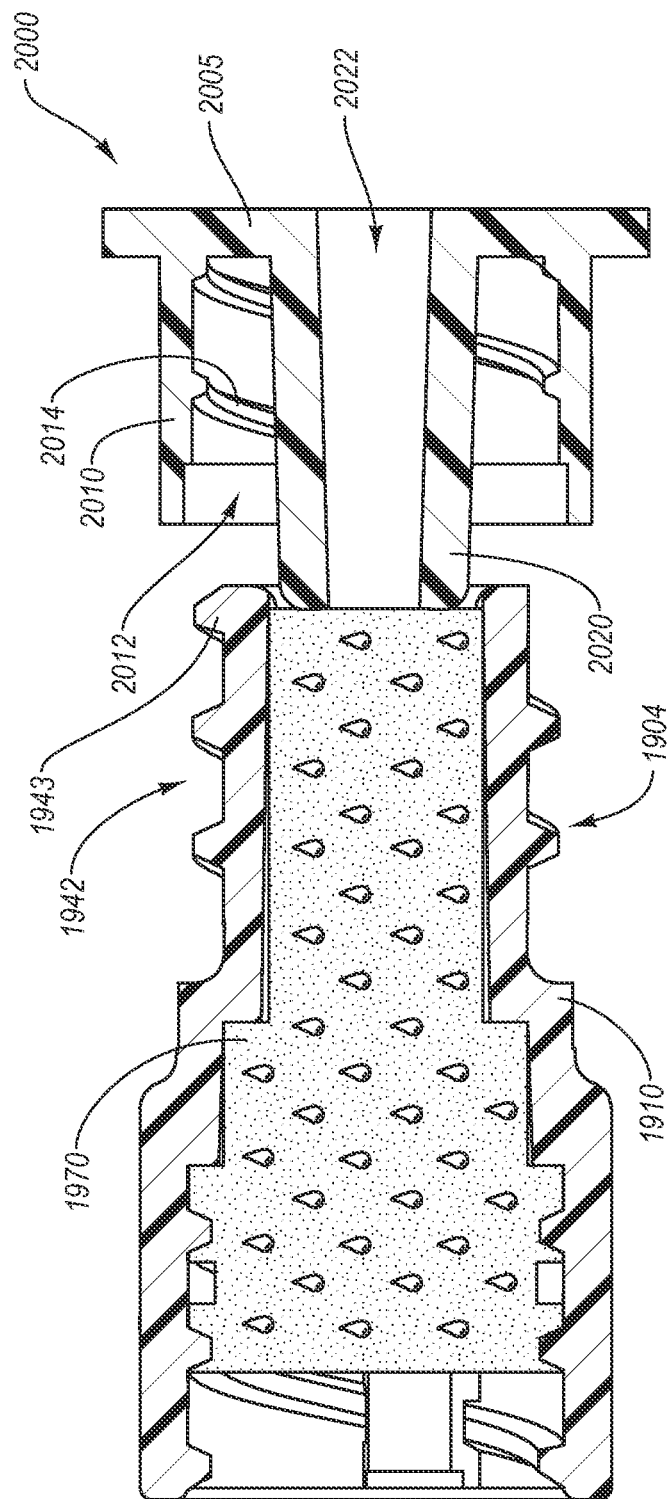


Fig. 30

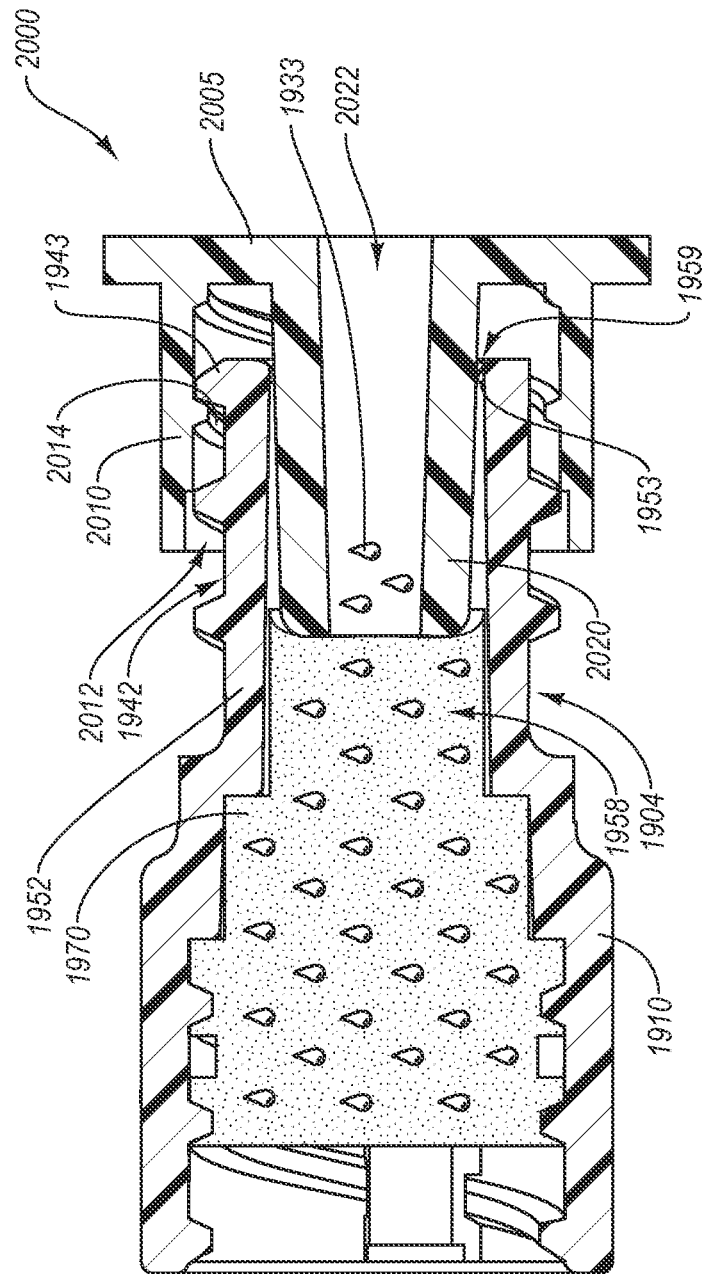


Fig. 31

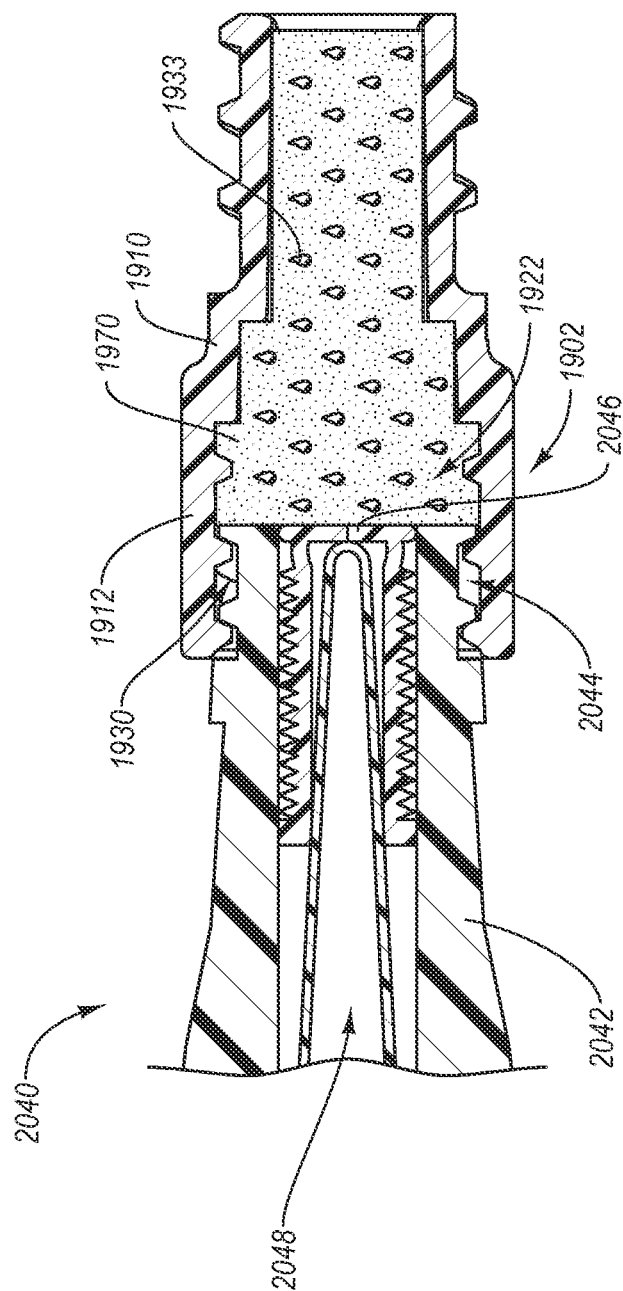


Fig. 32

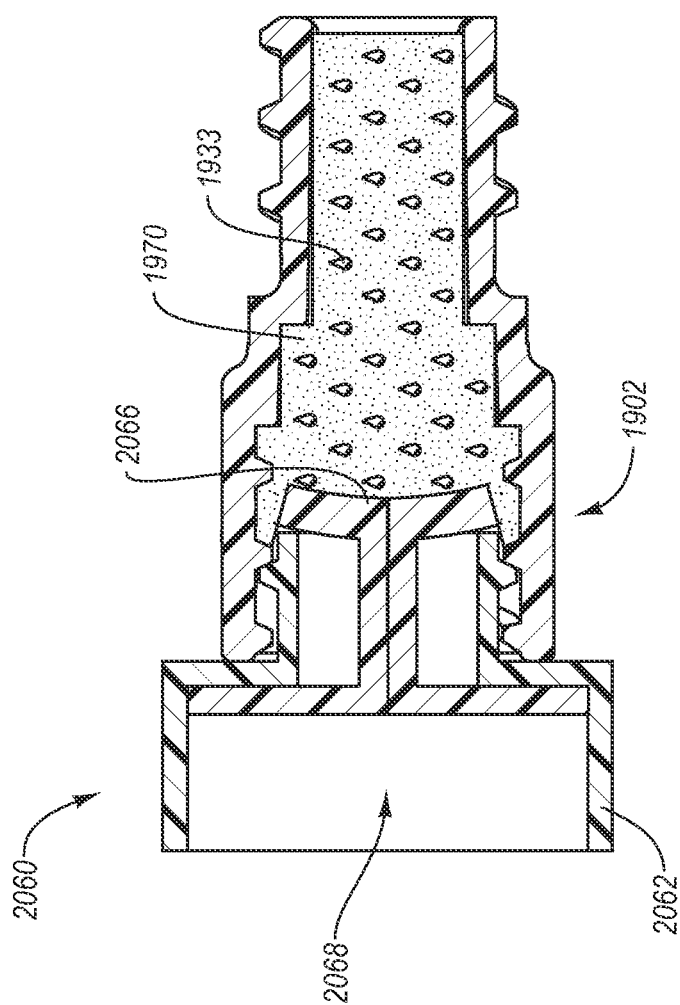


Fig. 33

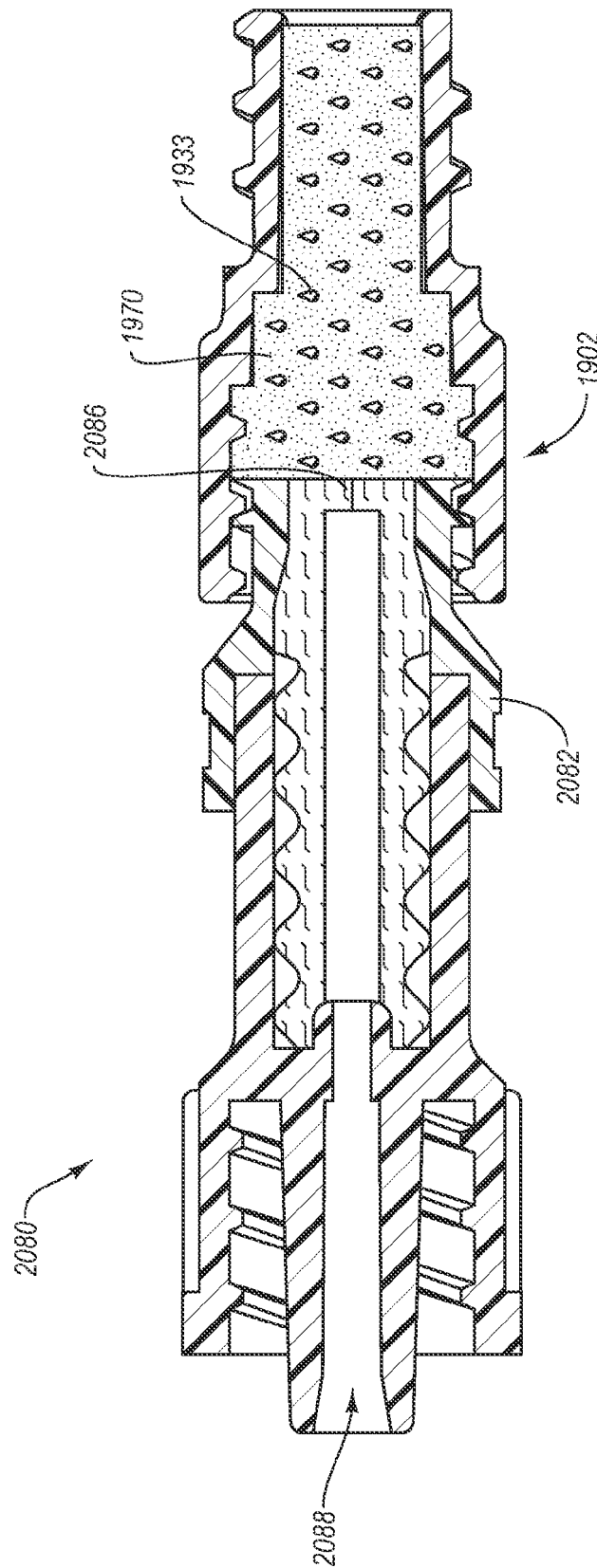


Fig. 34

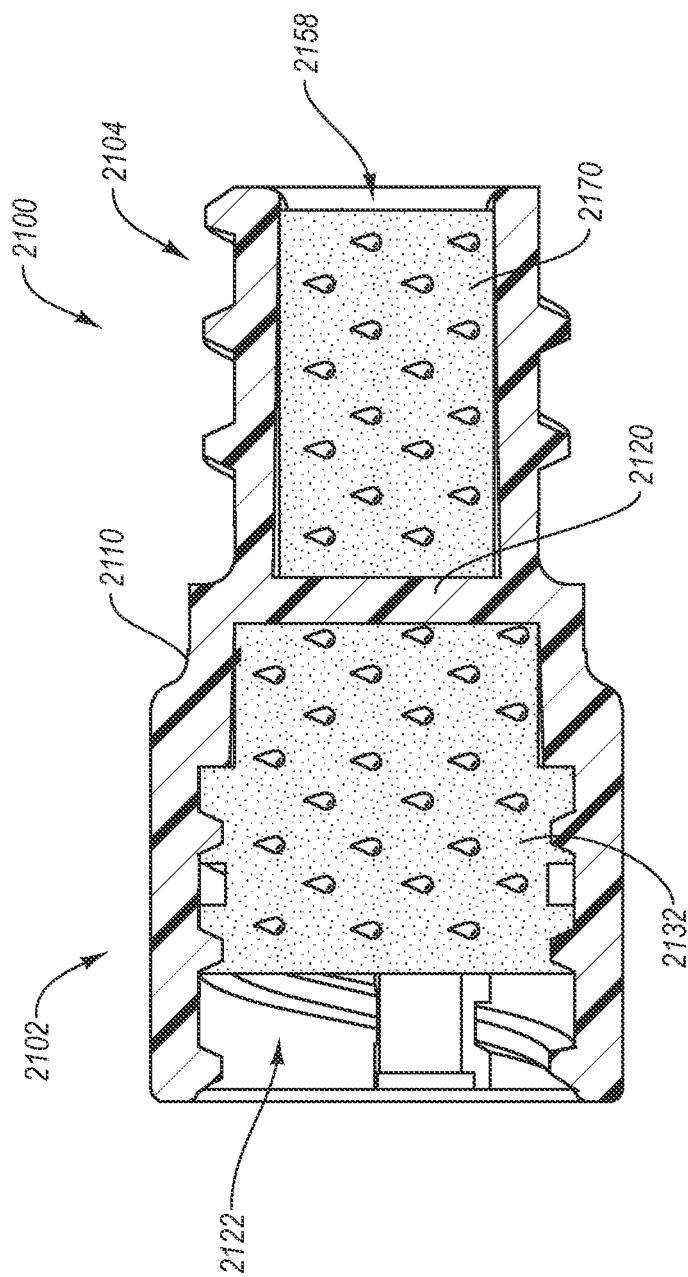


Fig. 35

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SYSTEM FOR CLEANING LUER 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 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 some embodiments, a pair of caps are attached to each other when in a pre-use state, and each cap can be coupled with a separate medical connector. In further embodiments, the caps can be separated from each other and individually secured to complementary components of a medical fluid flow or fluid delivery system.

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Other or further features of various embodiments are also disclosed and are set 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;

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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; and

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.

DETAILED DESCRIPTION

Disclosed herein are caps that can be used to protect and/or sterilize medical connectors when the connectors are separated (e.g., temporarily separated) from each other. 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 a central line. Commonly, a fluid

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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 an IV bag. 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.

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

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having an insertable or male section 109. Section 109 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

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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 addi-

tionally, 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 chlorhexidine 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 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, and/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 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 gluconate, 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

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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 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

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(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 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 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 pads 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 is 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.

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.

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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 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.

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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 the sterilization chamber **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 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**. Alterna-

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tively, 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

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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.

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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

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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, 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 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.

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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 anti-septic 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

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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

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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 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

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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 so as 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 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 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.

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 of the caps 1004, 1104, 1304, 1504, 1804, and 1904. Examples of first means for sterilizing a male luer of a first medical connector include the pads 1070, 1170, 1370, 1570, 1870, 2170. Examples of second means for coupling the female cap with a second medical connector include the connection interfaces 1030, 1130, 1530, 1830, 1930 of the caps 1002, 1102, 1502, 1802, 1902. Examples of second means for sterilizing at least a portion of a second medical connector include the pads 1032, 1132, 1332, 1532, 1832, 2132. 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; and 1840, 1891, 1842, and 1892.

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

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ing 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 system of medical luer connector caps comprising:
at least two disinfecting caps, each including a receiving portion having (i) a chamber defining an opening in which a medical tubing connector can be received, (ii) an exterior surface extending around the opening for receiving a cover, (iii) a means for engaging threads of luer connectors; and
a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps.
2. A system according to claim 1, wherein the means for engaging threads of at least one of the disinfecting caps is disposed on an exterior wall of the cap so as to engage a male luer connector.

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3. A system according to claim 2, wherein the means for engaging threads includes a helical thread.

4. A system according to claim 1, wherein the means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a female luer connector.

5. A system according to claim 4, wherein the means for engaging threads includes a helical thread.

6. A system according to claim 1 wherein the cover comprises an adhesive.

7. A system according to claim 1 wherein the cover comprises an impervious pliable material.

8. A system according to claim 7 wherein the material is a foil or a plastic.

9. A system according to claim 1 wherein each of the at least two caps further comprises a connection interface.

10. A system according to claim 1 wherein the at least two caps are connected to one-another by an interlocking means.

11. A system according to claim 1 wherein at least one of the cap comprises a slot for engaging a protrusion of another of the at least two caps.

12. A system according to claim 1 wherein each of the caps further comprise a gripping portion.

13. A system according to claim 12 wherein each of the caps are connected to one-another at their respective gripping portion.

14. A system according to claim 1 wherein the system further comprise an antiseptic agent.

15. A system according to claim 14 wherein the system further comprise an absorbent pad.

16. A system of medical luer connector caps comprising:
a first disinfecting cap, including a first receiving portion having (i) a first chamber defining a first opening in which a medical tubing connector can be received, (ii) a first exterior surface extending around the first opening for receiving a cover, (iii) first means for engaging threads of luer connectors;
a second disinfecting cap, including a second receiving portion having (i) a second chamber defining a second opening in which a medical tubing connector can be received, (ii) a second exterior surface extending around the second opening for receiving a cover, (iii) second means for engaging threads of luer connectors;
and
a cover extending over and solely in contact with the first and second exterior surfaces, so as to seal the first and second chambers.

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