

DISINFECTION CAP

TECHNICAL FIELD

[0001] The present disclosure relates to disinfection cap devices for disinfecting
5 corresponding medical connectors. The present disclosure generally relates to a device for
disinfecting and sterilizing access ports of medical connectors having a fitting. Generally,
exemplary embodiments of the present disclosure relate to the fields of threaded or
interlocking fittings, including medical caps and medical disinfection caps, and in particular
caps and/or disinfection caps for uses with threaded fluid connectors. One or more exemplary
10 embodiments of the present disclosure relate to male disinfection cap devices for disinfecting
male threaded luer connectors.

BACKGROUND

[0002] Vascular access devices (VAD's) are commonly used therapeutic devices and
15 include intravenous (IV) catheters. There are two general classifications of VAD's: peripheral
catheters and central venous catheters. Bacteria and other microorganisms may gain entry into
a patient's vascular system from access hub, port, or valve upon connection to the VAD to
deliver the fluid or pharmaceutical. Each access hub, port, valve or connection is associated
with some risk of transmitting a catheter related bloodstream infection (CRBSI), which can be
20 costly and potentially lethal. In order to decrease CRBSI cases and to ensure VAD's are used
and maintained correctly, standards of practice have been developed, which include
disinfecting and cleaning procedures. Disinfection caps have been added to the Society for
Healthcare Epidemiology of America (SHEA) guidelines and the Infusion Nurses Standards
(INS) guidelines.

25 **[0003]** In developed markets, when utilizing an IV catheter, a needleless connector will
typically be used to close off the system and then subsequently accessed to administer
medication or other necessary fluids via the catheter to the patient. INS Standards of Practice
recommend the use of a needleless connector and state that it should be "consistently and
thoroughly disinfected using alcohol, tincture of iodine or chlorhexidine gluconate/alcohol
30 combination prior to each access." The disinfection of the needleless connector is ultimately
intended to aid in the reduction of bacteria that could be living on the surface and possibly lead

to a variety of catheter related complications including CRBSI. Nurses will typically utilize a 70% isopropyl alcohol (IPA) pad to complete this disinfection task by doing what is known as "scrubbing the hub." However, compliance to this practice is typically very low. In addition to a lack of compliance to "scrubbing the hub", it has also been noted through clinician interviews
5 that there is often a variation in scrub time, dry time and the number of times the needleless connector is scrubbed.

[0004] The need to protect female and male luer connectors to reduce central line-associated bloodstream infections (CLABSI) and peripheral line-associated bloodstream infection (PLABSI) has been rising. Intravenous gravity sets and threaded male luer
10 connections on syringes are subject to contamination when not protected properly. Currently when IV connectors are disconnected from central lines or peripheral lines to temporarily discontinue infusion, nurses often loop the male luer connector to a Y-site needle-free connector or wrap the male luer connector in a piece of Isopropyl Alcohol ("IPA") impregnated wipe or cloth. However such protection is very weak and does not protect the luer
15 from touch contamination properly. Male disinfection caps have become the state of art disinfection and protection device to disinfect and create a physical barrier on male luer connector to prevent microbial growth.

[0005] Throughout the sequence of procedures associated with the transmission of a microorganism that can cause a CRBSI, there are many risks of contact or contamination. By
20 way of example, contamination can occur during drug mixing, attachment of a cannula, and insertion into the access hub. Furthermore, threaded male luer connectors have an open luer with an exposed lumen. Because the procedure to connect to a VAD is so common and simple, the risk associated with entry into a patient's vascular system has often been overlooked. Presently, the risk to hospitals and patients is a substantial function of the diligence of the
25 clinician performing the connection, and this diligence is largely uncontrollable.

[0006] Disinfectants typically have a threshold limit for systemic exposure for infusion into blood stream due to biotoxicity of the disinfectants at high dosage. Thus, there is a need for a disinfection device capable of blocking the lumen of open luers to facilitate the mitigation of such disinfectant ingress into connectors, thereby reducing risk of the disinfectant entering
30 the blood stream. There is a need for a mechanism to prevent disinfectant from entering the lumen and fluid path while providing effective disinfection of the surrounding connector or fitting.

SUMMARY

[0007] A first aspect of the present disclosure relates to a disinfection cap having a housing comprising a top wall, a cylindrical sidewall, and an open bottom formed by the cylindrical sidewall. The cylindrical sidewall has an inner surface defining a cavity. The open
5 bottom has an opening to the cavity for receiving a hub of a luer connector.

[0008] A blockage feature is disposed within the cavity. The blockage feature is configured as a cylindrical protrusion being disposed on the top wall of the housing. The cylindrical protrusion fluidly blocks the hub of the luer connector. A fluid releasably retained within a depressible open cell foam structure is disposed within the cavity. The hub of said
10 luer connector is received within said inner surface of said cavity.

[0009] In one or more embodiments, the cavity extends essentially from an inner surface of said top wall toward said open bottom of said housing.

[0010] In one or more embodiments, the cylindrical protrusion is non-removably disposed on the top wall of the housing.

[0011] In one or more embodiments the open cell foam structure is disposed against the top wall. In one or more embodiments, the open cell foam structure has a hollow cylindrical shape configured to fit around the cylindrical protrusion.

[0012] In one or more embodiments, the cylindrical protrusion further includes an upper portion and a lower portion, the upper portion having a diameter equal to the top wall, the lower portion having a diameter smaller than the upper portion, the lower portion
20 configured to fluidly block the hub of the luer connector.

[0013] In one or more embodiments, the open cell foam structure is disposed against a bottom surface of the upper portion of the cylindrical protrusion. The open cell foam structure has a hollow cylindrical shape configured to fit around the lower portion of the cylindrical
25 protrusion.

[0014] In one or more embodiments, the second depressible open cell foam is disposed between the upper portion of the cylindrical protrusion and the top wall of the cavity. The second open cell foam structure releasably retains a fluid.

[0015] In one or more embodiments, the disinfection cap further includes at least one thread on the outer surface of the housing. The at least one thread being sufficient to interlock
30 with a mating feature of the luer connector.

[0016] In one or more embodiments, the hub is secured within the inner surface of the cavity by interlocking at least a portion of the at least one thread with a mating feature on the hub of the luer connector.

[0017] In one or more embodiments, the inner surface of the cavity is secured by an interference fit with the hub of the luer connector.

[0018] In one or more embodiments the fluid is selected from a group consisting essentially of isopropyl alcohol, ethanol, 2-propanol, butanol, methylparaben, ethylparaben, propylparaben, propyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene, t-butyl-hydroquinone, chloroxylenol, chlorhexidine, chlorhexidine diacetate, chlorhexidine gluconate, povidone iodine, alcohol, dichlorobenzyl alcohol, dehydroacetic acid, hexetidine, triclosan, hydrogen peroxide, colloidal silver, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, and mixtures thereof.

[0019] A second aspect of the present disclosure relates to a disinfection cap having a housing comprising a top wall having an aperture extending partially into the housing, a cylindrical sidewall having an inner surface defining a cavity, an open bottom formed by the cylindrical sidewall with an opening to the cavity within the housing for receiving a hub of a luer connector. An umbrella stopper includes a stem, the stem at least partially disposed into the aperture of the top wall. The umbrella stopper further includes a fanned barrier configured as a blockage feature for fluidly blocking a hub of a medical device. The fanned barrier creates a liquid tight seal with the inner surface of the sidewall. A fluid is releasably retained within the cavity and the fanned barrier of the umbrella stopper. The hub of the luer connector is received within the inner surface of the cavity. When the fanned barrier deforms when moved against the hub, fluid is released.

[0020] In one or more embodiments, the umbrella stopper further includes a rounded or chamfered end, the rounded or chamfered end is configured to fluidly block the hub of the luer connector. In one or more embodiments the fanned barrier is at a right angle to the stem. In one or more embodiments the fanned barrier is at an obtuse angle to the stem.

[0021] A third aspect of the present disclosure relates to a disinfection cap having a housing comprising top wall, a cylindrical sidewall having an inner surface defining a cavity, an open bottom formed by a cylindrical sidewall with an opening to the cavity within said housing for receiving a hub of a luer connector. A blockage feature is disposed within the cavity, the blockage feature being configured as a plurality of hydrophilic bristles. The

hydrophilic bristles are disposed on the top wall of the housing, the hydrophilic bristles fluidly blocking the hub of the luer connector; and a fluid releasably retained within the hydrophilic bristles. The hub of said luer connector is received within said inner surface of said cavity.

[0022] In one or more embodiments the disinfection cap further includes a movable
5 conical stopper, the conical stopper comprising a top portion and a bottom portion, the top portion including a flange having a diameter less than the diameter of the cavity. The top portion further includes a lumen extending therethrough. The cavity includes a protrusion configured as a secondary blockage feature by which the protrusion blocks the hub of the luer connector.

10 **[0023]** A fourth aspect of the present disclosure relates to a disinfection cap having a housing comprising a top portion including a set of winged protrusions configured to receive a membrane or pouch, the membrane or pouching including a bulbous cavity for retaining a fluid and a fluid path fluidly connecting the bulbous cavity to a drain. The drain is disposed on a top surface of the top portion, the drain includes a conical cavity having a lumen disposed on a
15 bottom surface of the conical cavity. The lumen is in fluid communication with a cavity defined by an inner sidewall of a bottom portion of the housing. At least two spines extend from the top surface into a center of the conical cavity, the at least two spines structurally securing a protrusion disposed within the cavity, the protrusion extending through the lumen. The protrusion is configured as blockage feature by which the lower portion has a diameter
20 equal to or greater than the diameter of a hub of a medical device. An open bottom is formed by a cylindrical sidewall of the cavity with an opening to the cavity within said housing for receiving a hub of a luer connector.

[0024] In one or more embodiments, the hub of the luer connector is received within the inner surface of said cavity.

25 **[0025]** A fifth aspect of the present disclosure relates to a disinfection cap having a housing comprising an upper portion and an open bottom. The upper portion has an engagement surface disposed around a circumference of a top surface of the upper portion. The engagement surface is configured to receive a membrane or pouch, the membrane or pouch having a dome shape defining a bulbous cavity for retaining fluid. The open bottom is formed
30 by a cylindrical sidewall of the cavity with an opening to the cavity for receiving a hub of a luer connector. At least two vents or slits are disposed through the top surface of the upper portion, the at least two vents or slits are in fluid communication with the bulbous cavity of the

upper portion and the cavity. The hub of the luer connector is received within an inner surface of the cavity. The bulbous cavity may be depressed or collapsed onto the top surface of the upper portion, thereby releasing fluid into the at least two vents or slits.

[0026] In one or more embodiments the hub of the luer connector abuts a top wall of
5 the cavity, the top wall fluidly sealing the hub of the luer connector.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Figure 1 illustrates a perspective view of a disinfection cap according to an exemplary first embodiment of the disclosure;

10 [0028] Figure 2 illustrates a cross sectional view of the disinfection cap along the axis X-X' in accordance with a first embodiment of the present disclosure;

[0029] Figure 3A illustrates a perspective view of a threaded connection in accordance with a first embodiment of the present disclosure;

15 [0030] Figure 3B illustrates a perspective view of the threaded connection along the axis Y-Y' in accordance with a first embodiment of the present disclosure;

[0031] Figure 4A illustrates a perspective view of the disinfection cap in accordance with the first embodiment of the present disclosure;

[0032] Figure 4B illustrates a perspective view of the disinfection cap along the axis Z-Z' in accordance with the first embodiment of the present disclosure;

20 [0033] Figure 5A illustrates a cross-sectional view of the disinfection cap in accordance with a second embodiment of the present disclosure;

[0034] Figure 5B illustrates an exploded cross-sectional view of the disinfection cap in accordance with a second embodiment of the present disclosure;

25 [0035] Figure 6 illustrates a cross-sectional view of a disinfection cap in accordance with a third embodiment of the present disclosure;

[0036] Figure 7A illustrates a cross-sectional view of a disinfection cap in accordance with a fourth embodiment of the present disclosure;

[0037] Figure 7B illustrates a cross-sectional view of a disinfection cap in accordance with the fourth embodiment of the present disclosure;

[0038] Figure 8A illustrates a cross-sectional view of a disinfection cap in accordance with a fifth embodiment of the present disclosure;

[0039] Figure 8B illustrates a cross-sectional view of a disinfection cap in accordance with the fifth embodiment of the present disclosure;

5 [0040] Figure 9 illustrates a cross-sectional view of a disinfection cap in accordance with a sixth embodiment of the present disclosure;

[0041] Figure 10A illustrates a cross-sectional view of a disinfection cap in accordance with a sixth embodiment of the present disclosure;

10 [0042] Figure 10B illustrates a cross-sectional view of a disinfection cap in accordance with the sixth embodiment of the present disclosure; and,

[0043] Figure 11 illustrates a cross-sectional view of a disinfection cap in accordance with a seventh embodiment of the present disclosure.

DETAILED DESCRIPTION

15 [0044] Embodiments of the disclosure pertain to a disinfection cap for connection to and disinfection of a medical connector, including threaded connections. In one or more embodiments, the medical connector is a needless connector or a luer connector. The disclosure aims to provide a mechanism to prevent disinfectant from entering the fluid path of the medical connector while providing for effective disinfection for the hub and surrounding
20 periphery of the medical connector.

[0045] Before describing several exemplary embodiments of the disclosure, it is to be understood that the disclosure is not limited to the details of construction or process steps set forth in the following description. The disclosure is capable of other embodiments and of being practiced or being carried out in various ways.

25 [0046] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the disclosure as it is oriented in the drawing figures. However, it is to be understood that the disclosure may assume alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices
30 and processes illustrated in the attached drawings, and described in the following specification,

are simply exemplary embodiments of the disclosure. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0047] As used herein, the use of "a," "an," and "the" includes the singular and plural.

5 **[0048]** As used herein, the term "catheter related bloodstream infection" or "CRBSI" refers to any infection resulting from the presence of a catheter or IV line.

[0049] As used herein, the term "Luer connector" refers to a connection collar that is the standard way of attaching syringes, catheters, hubbed needles, IV tubes, etc. to each other. The Luer connector consists of and interlocking tubes, slightly tapered to hold together with
10 just a simple pressure/twist fit. Luer connectors can optionally include an additional outer rim of threading, allowing them to be more secure. The Luer connector end is generally associated with a flush syringe and can interlock and connect to the end located on the vascular access device (VAD). A Luer connector comprises a distal end, a proximal end, an irregularly shaped outer wall, a profiled center passageway for fluid communication from the chamber of the
15 barrel of a syringe to the hub of a VAD. A Luer connector also has a distal end channel that releasably attaches the Luer connector to the hub of a VAD, and a proximal end channel that releasably attaches the Luer connector to the barrel of a syringe. As used herein, the term "Luer connector" refers to a luer connector or a fe luer connector.

[0050] As used herein, the term "medical device" refers to common medical devices
20 having threaded or interlocking connections, the connections having corresponding mating elements. By way of example but not limitation, a syringe may have a threaded connection which releasably interlocks with a secondary medical device such as a luer connection of a catheter, an IV line and the like. The threaded connection may include a lumen defining a fluid path surrounded by a protruding wall having the threaded means for attaching to the secondary
25 medical device.

[0051] As would be readily appreciated by skilled artisans in the relevant art, while descriptive terms such as "thread", "taper", "tab", "wall", "top", "side", "bottom" and others are used throughout this specification to facilitate understanding, it is not intended to limit any components that can be used in combinations or individually to implement various aspects of
30 the embodiments of the present disclosure.

[0052] Embodiments of the disinfection cap of the present disclosure comprise a housing having a top wall defining a closed end, a substantially cylindrical sidewall having an

inner surface defining a cavity, an open end formed by said cylindrical sidewall with an opening to the cavity within said housing for receiving a hub of a threaded connection, an at least one thread on an exterior surface of the cylindrical sidewall that is sufficient to interlock with a mating feature of said threaded connection, a blockage feature disposed within the cavity, and a disinfectant or antimicrobial agent retained within the cavity. Embodiments of the disinfection cap disclose the at least one thread of the disinfection cap engaging the mating feature of the threaded connection, and more specifically a luer connection. The blockage feature is configured to prevent disinfectant ingress into a fluid path of the hub of the luer connection. In one or more embodiments, the exterior surface of the housing at the open end of the disinfection cap includes a peripheral ledge extending radially outward from the open end defining an end face and an engagement surface for a peelable seal and/or septum for maintaining sterility of the cavity. The peelable seal reduces or prevents contamination of the cavity during shipping and storage of the disinfection cap. The peelable seal is generally kept in the closed position until just prior to an injection and/or aspiration procedure, at which time the peelable seal is removed. The removable seal minimizes entry of potential particulate hazard and also provides a substantially impermeable enclosure for the cavity prior to use of the disinfection cap. The removable seal provides a sufficient seal at a range of temperatures, pressures, and humidity levels.

[0053] The disinfection cap provides a mechanical barrier for connectors and contains a disinfectant fluid or an antimicrobial agent (hereinafter "fluid"). The disinfection cap of the present disclosure allows the practitioner to streamline the disinfecting process. The matters exemplified in this description are provided to assist in a comprehensive understanding of exemplary embodiments of the disclosure. Accordingly, those of ordinary skill in the art will recognize that various changes and modifications of the embodiments described herein can be made without departing from the scope and spirit of the disclosure. Also, descriptions of well-known functions and constructions are omitted for clarity and conciseness.

[0054] In particular, the practitioner may disinfect the luer connector in a single motion by inserting or threading the disinfection cap onto the luer connector of the medical device which causes the blockage feature to prevent fluid ingress into the fluid path of the luer connector, while the hub of the luer connector simultaneously causes the release of the fluid allowing for disinfection of the luer connector hub and its periphery. The disinfection cap may then be removed by removing or unthreading the disinfection cap from the luer connector of

the medical device and inserting or threading onto the luer connector, by way of example, a Y-site connection or a luer connector.

[0055] In an exemplary implementation of the embodiments of present disclosure, the disinfection cap includes integrated threads or tabs, and other features in any and all combinations allowing it to interface with a threaded fitting of a medical device. In preferred embodiments, the disinfection cap interfaces with a Luer fitting. Exemplary configurations for couplers, fittings, ports and adapters may include commercially available luer locks, luer slip ports, locking ports, threaded connections, interlocking connection or generally other common medical device fitting known in the art.

[0056] Referring now to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views, embodiments of the present disclosure are described as follows.

[0057] As depicted in Figures 1 and 2, a first aspect of the present disclosure relates to a disinfection cap **100** including a housing **110** having an upper portion **110A** and a lower portion **110B**. In one or more embodiments, the lower portion **110B** is substantially cylindrical having a cylindrical housing **112**. In further embodiments, the lower portion **110B** may have tapered lower portion. The upper portion **110A** of the housing has an inwardly tapered sidewall. In further embodiments, the upper portion **110A** and lower portion **110B** have a substantially cylindrical sidewall. In one or more embodiments, an inner surface **126** of the lower portion **110B** of the housing **110** defines a cavity **130** having open bottom **116** for receiving a hub of a luer connector. In one embodiment, upper portion **110A** is integrally formed with the lower portion **110B** while further embodiments are non-removably or removably assembled with a threaded connection, press-fit connection, adhesive connection or a combination thereof.

[0058] In one or more embodiments, the cavity **130** can be configured to facilitate a loose fit between the cavity **130** and the hub of the luer connector, wherein the disinfection cap **100** is secured by an at least one thread **122** or set of tabs included on the outer surface of the cylindrical housing **112**. The at least one thread **122** disposed on the outer surface of the cylindrical housing **112** is sized and have a thread pattern that will engage with a standard ISO-2 type of fitting. The loose fit allows for fluid to flow around the hub of the luer connector. In further embodiments, the cavity **130** can be configured in a Luer Slip fitting to facilitate an interference fit between the cavity **130** and the hub of the luer connector. The interference fit

can be configured to be sufficiently strong enough to not require a threaded connection or the at least one thread **122** in removably securing the cavity **130** to the luer connector.

[0059] In one or more embodiments, when the hub of the luer connector is received within the inner surface **126** of the cavity **130**, the hub is secured within the cavity **130** of the disinfection cap **100** by interlocking at least a portion of the at least one thread **122** with a mating feature on the hub of the luer connector. In one or more embodiments, the at least one thread **122** can include an inclined thread pattern. In one or more embodiments, the at least one thread **122** can include a helical-shaped thread pattern. Such connectors are generally and commonly used as catheter and other fluid-tight protective connectors in medical applications.

10 In some embodiments, the disinfectant cap **100** provides a protective cover for a luer connector when engaged with the connector when threads from the luer connector engage and form a releasable connection with at least one thread **122** of disinfection cap **100**.

[0060] Figure 2 depicts a cross-sectional view of the disinfection cap **100** along an X-X' plane as shown in Figure 1. As depicted in Figure 2, cavity **130** of the housing **110** extends a length **L_C** of the total length of the housing **110** from the open bottom **116** to a top wall **114**, the cavity **130** having a substantially cylindrical shape. From the top wall **114** extends a protrusion **118** configured as a blockage feature for a lumen extending through the hub of the luer connector of the medical device. The protrusion **118** in the preferred embodiment has a substantially cylindrical shape and is uniformly connected to the top wall **114**. The diameter of protrusion **118** is sized and configured to fluidly block the lumen of the luer connector. In one or more embodiments, the protrusion **118** has a substantially conical shape. In one or more embodiments, the end 124 of the protrusion **118** is rounded or chamfered to aid in inserting the protrusion **118** into the lumen of the luer connector.

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[0061] An open cell foam structure **120** for absorbing and retaining fluid can be disposed against the top wall **114**. In the preferred embodiment, the open cell foam structure **120** having a hollow cylindrical shape, configured to fit around the protrusion **118**, not extending beyond the protrusion **118**. The open cell foam structure **120** is compressible in both horizontal and vertical directions, allowing the open cell foam structure **120** to create an interference fit with the inner surface **126** of the cavity **130**. The open cell foam allows for fluid to be excreted as the open cell foam structure **120** is compressed. As the disinfection cap **100** is threaded or pushed against the luer connector, the lumen of the luer connector is fluidly sealed and blocked by the protrusion **118** while the hub of the luer connector compresses the

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open cell foam structure **120**, releasing the fluid which disinfects the hub and the periphery of the luer connector. In the preferred embodiment, the open cell foam structure **120** can be neoprene, polyurethane, natural rubber, or medical-grade open cell foam having low or zero cytotoxicity ratings suitable for sterilization.

5 **[0062]** An exemplary luer connector **170** is depicted in Figures 3A and 3B, with Figure 3A illustrating a cross-section along plane Y-Y'. The luer connector **170** includes a lumen **172** disposed through a hub **174** having a conical surface, a mating feature having at least one thread **176**, and a mating surface **178** disposed at the bottom of the hub **174**. Figures 4A and 4B depict the disinfection cap **100** fully inserted into the luer connector **170**, with
10 Figure 4B illustrating a cross-section along plane Z-Z'. As depicted, the at least one thread **122** of the disinfection cap **100** has fully engaged and releasably secured to the at least one thread **176** of the luer connector **170**. In this position, an engagement surface of the disinfection cap **100** abuts the mating surface **178** of the luer connector **170**. In this position, the hub **174** has fully depressed the open cell foam structure **120**, thereby releasing the fluid contained within
15 and disinfecting the hub **174** and the periphery of the luer connector **170** while the protrusion **118** of the disinfection cap **100** fluidly seals the lumen **172** of the luer connector **170**, preventing fluid from entering the fluid path of the lumen **172** of the luer connector **170**.

[0063] Further embodiments of the disinfection cap are contemplated having alternative blockage features. Exemplary disinfection caps include a housing having an upper
20 portion and a lower portion. In one or more embodiments, the lower portion of the sidewall is substantially cylindrical having a cylindrical housing, while further embodiments may have tapered housing. The upper portion of the housing has an inwardly tapered sidewall, while further embodiments have a substantially cylindrical sidewall. In one or more embodiments, the inner surface of the lower portion of the housing defines a cavity having open bottom for
25 receiving a hub of a luer connector.

[0064] In one or more embodiments, exemplary cavities can be configured to facilitate a loose fit between the cavity and the hub of the luer connector, wherein the exemplary disinfection cap is secured by an at least one thread or set of tabs included on the outer surface of the cylindrical housing. The loose fit allows for fluid to flow around the hub of the luer
30 connector. In further embodiments, the exemplary cavity can be configured in a Luer Slip connection to facilitate an interference fit between the cavity and the hub of the luer connector. The interference fit can be configured to be sufficiently strong enough to not require

a threaded connection or the at least one thread in removably securing the cavity to the luer connector.

[0065] In one or more embodiments, when the hub of the luer connector is received within the inner surface of the cavity, the hub is secured within the cavity of the disinfection cap by interlocking at least a portion of the at least one thread with a mating feature on the hub of the luer connector. In one or more embodiments, the at least one thread can include an inclined thread pattern. In one or more embodiments, the at least one thread can include a helical-shaped thread pattern. Such connectors are generally and commonly used as catheter and other fluid-tight protective connectors in medical applications. In some embodiments, the disinfectant cap provides a protective cover for a luer connector when engaged with the connector when threads from the luer connector engage and form a releasable connection with at least one thread of the disinfection cap.

[0066] Figures 5A and 5B depict an exemplary disinfection cap **200** in accordance with a second embodiment of the present disclosure, with Figure 5B depicting an exploded view of the exemplary disinfection cap **200** and Figures 5A and 5B depicting cross sections. The disinfection cap **200** includes a housing **210** having a lower portion with an inner surface **226** of the lower portion of the housing **210** defining a cavity **230** having open bottom **216** for receiving a hub of a luer connector.

[0067] The cavity **230** of the housing **210** extends a length L_C of the total length of the housing **210** from the open bottom **216** to a top wall **214**, the cavity **230** having a substantially cylindrical shape. A stopper **218** abuts the top wall **214**, the stopper **218** being configured as a blockage feature for a lumen extending through the hub of the luer connector of the medical device.

[0068] The stopper **218** in the preferred embodiment has a substantially cylindrical shape, having an upper portion **228** and a lower portion **223**, the upper portion **228** and the lower portion **223** being integrally formed. The upper portion **228** has a diameter equal to or greater than the top wall **214**, creating an interference fit which removably retains the stopper within the cavity **230**. The diameter of the lower portion **223** of the stopper **218** is sized and configured to fluidly block the lumen of the luer connector. In one or more embodiments, the lower portion **223** has a substantially conical shape. In one or more embodiments, the end **224** of the lower portion **223** is rounded or chamfered to aid in inserting the lower portion **223** into the lumen of the luer connector. The diameter of the upper portion **228** is greater than the

diameter of the lower portion **223**. In the preferred embodiment, the stopper **218** is bonded to the top wall **214** of the cavity **230** of the disinfection cap **200** by an interference connection, medical grade adhesive connection or a combination thereof. The stopper **218** may be rubber, TPE or plastic.

5 **[0069]** An open cell foam structure **220** for absorbing and retaining fluid can be disposed against a bottom surface of the upper portion **228** of the stopper **218**. In the preferred embodiment, the open cell foam structure **220** has a hollow cylindrical shape, configured to fit around the lower portion **223** of the stopper **218**, not extending beyond the lower portion **223**. The open cell foam structure **220** is compressible in both horizontal and vertical directions,
10 allowing the open cell foam structure **220** to create an interference fit with the inner surface **226** of the cavity **230**. The open cell foam structure **220** allows for fluid to be excreted as the open cell foam structure **220** is compressed. As the disinfection cap **200** is threaded or pushed against the luer connector, the lumen of the luer connector is fluidly sealed and blocked by the stopper **218** while the hub of the luer connector compresses the open cell foam structure
15 **220**, releasing the fluid which disinfects the hub and the periphery of the luer connector. In the preferred embodiment, the open cell foam structure **220** can be neoprene, polyurethane, natural rubber, or medical-grade open cell foam having low or zero cytotoxicity ratings suitable for sterilization.

[0070] Figure 6 depicts an exemplary disinfection cap **300** in accordance with a third
20 embodiment of the present disclosure. The disinfection cap **300** includes a housing **310** having an upper portion **304**, a lower portion **306** and an inner surface **326** of the lower portion of the housing **310** defining a cavity **330** having open bottom **316** for receiving a hub of a luer connector. The upper portion **304** of the disinfection cap **300** has a larger diameter than the lower portion **306**, the upper portion **304** serving as a gripping surface for a practitioner to
25 manipulate the disinfection cap **300**. In one embodiment, the upper portion **304** is integrally formed with the lower portion **306** while further embodiments is non-removably or removably assembled with a threaded connection, press-fit connection, adhesive connection or a combination thereof.

[0071] The cavity **330** of the housing **310** extends a length L_c of the total length of the
30 housing **310** from the open bottom **316** to a top wall **314**, the cavity **330** having a substantially cylindrical shape. A first open cell foam structure **319** for absorbing and retaining fluid has a substantially cylindrical shape abutting the top wall **314**.

[0072] A stopper **318** abuts a bottom surface of the first open cell foam structure **319**, the stopper **318** being configured as a blockage feature for a lumen **372** extending through the hub **374** of the luer connector **370** of the medical device. The stopper **318** in the preferred embodiment has a substantially cylindrical shape, having an upper portion **328** and a lower portion **323**, the upper portion **328** and the lower portion **323** being integrally formed. The upper portion **328** has a diameter equal to or greater than the top wall **314**, creating an interference fit which removably retains the stopper within the cavity **330**. The diameter of the lower portion **323** of the stopper **318** is sized and configured to fluidly block the lumen of the luer connector. In one or more embodiments the lower portion **323** can have a substantially conical shape. In one or more embodiments the end **324** of the lower portion **323** can be rounded or chamfered to aid in inserting the lower portion **323** into the lumen of the luer connector. The diameter of the upper portion **328** is greater than the diameter of the lower portion **323**, and the diameter of the upper portion **328** is less than the diameter of the first open cell foam structure **319**.

[0073] A second open cell foam structure **320** for absorbing and retaining fluid can abut the bottom surface of the first open cell foam structure **319**. In the preferred embodiment, the open cell foam structure **220** has a hollow cylindrical shape, configured to fit around the lower portion **323** of the stopper **318**, not extending beyond the lower portion **323**. The first open cell foam structure **319** and the second open cell foam structure **320** have substantially the same outer diameters.

[0074] The first open cell foam structure **319** and the second open cell foam structure **320** are compressible in both horizontal and vertical directions, allowing the first open cell foam structure **319** and the second open cell foam structure **320** to create an interference fit with the inner surface **326** of the cavity **330**. The first open cell foam structure **319** and the second open cell foam structure **320** allow for fluid to be excreted as the first open cell foam structure **319** and the second open cell foam structure **320** are compressed. As the disinfection cap **300** is threaded or pushed against the luer connector, the lumen of the luer connector is fluidly sealed and blocked by the stopper **318** while the hub of the luer connector compresses the first open cell foam structure **319** and the second open cell foam structure **320** releasing the fluid which disinfects the hub and the periphery of the luer connector. In the preferred embodiment, the first open cell foam structure **319** and the second open cell foam structure **320**

can be neoprene, EPDM, Viton, polyurethane, natural rubber, or medical-grade open cell foam having low or zero cytotoxicity ratings suitable for sterilization.

[0075] Figure 7A and 7B depict an exemplary disinfection cap **400** in accordance with a fourth embodiment of the present disclosure. The disinfection cap **400** includes a housing **410** having an upper portion **404**, a lower portion **406** and an inner surface **426** of the lower portion of the housing **410** defining a cavity **430** having open bottom **416** for receiving a hub of a luer connector. The upper portion **404** of the disinfection cap **400** has a larger diameter than the lower portion **406**, the upper portion **404** serving as a gripping surface for a practitioner to manipulate the disinfection cap **400**. In one embodiment, the upper portion **404** is integrally formed with the lower portion **406** while further embodiments are non-removably or removably assembled with a threaded connection, press-fit connection, adhesive connection or a combination thereof.

[0076] The cavity **430** of the housing **410** extends a length L_C of the total length of the housing **410** from the open bottom **416** to a top wall **414**, the cavity **430** having a substantially cylindrical shape. The top wall **414** further includes an aperture **415** extending a length L_A into the housing **410**. The aperture **415** extends towards the upper portion **404**.

[0077] A stem **428** of an umbrella stopper **418** is at least partially disposed into the aperture **415**. The stem **428** may be integrally formed into the aperture **415**. In one or more embodiments, the stem **428** may be non-removably or removably assembled with a threaded connection, press-fit connection, adhesive connection or a combination thereof. The umbrella stopper **418** further includes a fanned barrier **427**, wherein the umbrella stopper **418** and more specifically the fanned barrier **427** are configured as a blockage feature for a lumen **472** extending through the hub **474** of the luer connector **470** of the medical device. The fanned barrier **427** of the umbrella stopper **418** creates a liquid tight seal with the inner surface **426** of the cavity **430**. The diameter of the fanned barrier **427** being essentially equal to the diameter of the cavity **430**. In one or more embodiments an end **424** of the stem **428** can be rounded or chamfered to aid in inserting the stem **428** into the lumen **472** of the luer connector **470**.

[0078] A fluid is disposed within a chamber defined by the fanned barrier **427** and an upper portion of the cavity **430**. As the disinfection cap **400** is threaded or pushed against the luer connector, the fanned barrier **427** elastically deforms into the lumen **472**, creating a liquid tight seal while the elastic deformation of the fanned barrier **427** interrupts the liquid tight seal of the fanned barrier **427** and the cavity **430**, releasing the fluid which disinfects the hub and

the periphery of the luer connector. In the preferred embodiment, the fanned barrier **427** can be made of a deformable elastomeric material such as rubber or TPE.

[0079] Figure 8A and 8B depict an exemplary disinfection cap **500** in accordance with a fifth embodiment of the present disclosure. The disinfection cap **500** includes a housing **510** having an upper portion **504**, a lower portion **506** and an inner surface **526** of the lower portion **506** of the housing **510** defining a cavity **530** having open bottom **516** for receiving a hub of a luer connector. The upper portion **504** of the disinfection cap **500** has a larger diameter than the lower portion **506**, the upper portion **504** serving as a gripping surface for a practitioner to manipulate the disinfection cap **500**. In one embodiment, the upper portion **504** is integrally formed with the lower portion **506** while further embodiments may be non-removably or removably assembled with a threaded connection, press-fit connection, adhesive connection or a combination thereof.

[0080] The cavity **530** of the housing **510** extends a length L_C of the total length of the housing **510** from the open bottom **516** to a top wall **514**, the cavity **530** having a substantially cylindrical shape. The top wall **514** further includes an aperture **515** extending a length L_A into the housing **510**. A stem **528** of an umbrella stopper **518** is at least partially disposed into the aperture **515**. The stem **528** may be integrally formed into the aperture **515**, while in further embodiments the stem **528** may be non-removably or removably assembled with a threaded connection, press-fit connection, adhesive connection or a combination thereof.

[0081] The umbrella stopper **518** further includes a fanned barrier **527**, the umbrella stopper **518** and more specifically the fanned barrier **527** being configured as a blockage feature for a lumen **572** extending through the hub **574** of the luer connector **570** of the medical device. In an initial position as shown in Figure 8A, the fanned barrier **527** of the umbrella stopper **518** creates a liquid tight seal with the inner surface **526** of the cavity **530**. The fanned barrier **527** barrier has a substantially conical shape, the edges of the fanned barrier **527** being configured to envelop a portion of the hub **574**. The fanned barrier **527** includes a plurality of spines **529** disposed radially from the stem **528**, the spines **529** aiding in retaining the conical structure of the fanned barrier **527**.

[0082] A fluid is disposed within a chamber defined by the fanned barrier **527** and an upper portion of the cavity **530**. As shown in figure 8B, as the disinfection cap **500** is threaded or pushed against the luer connector to a final position, the fanned barrier **527** elastically deforms into the lumen **572**, creating a liquid tight seal while the elastic deformation of the

fanned barrier **527** interrupts the liquid tight seal of the fanned barrier **527** and the cavity **530**, releasing the fluid which disinfects the hub and the periphery of the luer connector. In the preferred embodiment, the fanned barrier **527** can be made of a deformable elastomeric material such as rubber or TPE.

5 [0083] Figure 9 depicts an exemplary disinfection cap **600** in accordance with a sixth embodiment of the present disclosure. The disinfection cap **600** includes a housing **610** having an upper portion, a lower portion and an inner surface **626** of the lower portion of the housing **610** defining a cavity **630** having open bottom **616** for receiving a hub of a luer connector. The upper portion of the disinfection cap **600** has a larger diameter than the lower portion, the
10 upper portion serving as a gripping surface for a practitioner to manipulate the disinfection cap **600**. In one embodiment, the upper portion is integrally formed with the lower portion while further embodiments are non-removably or removably assembled with a threaded connection, press-fit connection, adhesive connection or a combination thereof.

[0084] The cavity **630** of the housing **610** extends a length L_C of the total length of the
15 housing **610** from the open bottom **616** to a top wall **614**, the cavity **630** having a substantially cylindrical shape. From the top wall **614** extend a plurality of hydrophilic bristles **618**, the hydrophilic bristles **618** extending a distance less than the total length of the cavity **630**. The hydrophilic bristles **618** retain a fluid. The hydrophilic bristles act as a blockage feature by preventing the fluid from flowing into a lumen **672** extending through the hub **674** of the luer
20 connector **670** of the medical device. As the disinfection cap **600** is threaded or pushed against the luer connector, the hydrophilic bristles **618** elastically deform, blocking the lumen **672**. The hydrophilic bristles **618** are initially bundled upon initial engagement and upon advancement of the hub **674** are compressed into the lumen **672** opening to prevent additional disinfectant inflow. The disinfectant adsorbed to that portion of the bristles is squeezed to the
25 surrounding bristle space to be dispensed to the external lumen surface.

[0085] Figure 10A and 10B depict an exemplary disinfection cap **600** in accordance with a sixth embodiment of the present disclosure. The disinfection cap **600** includes a housing **610** having an upper portion, a lower portion and an inner surface **626** of the lower portion of the housing **610** defining a cavity **630** having open bottom **616** for receiving a hub of a luer
30 connector. The upper portion of the disinfection cap **600** includes a set of winged protrusions **640** configured to receive a membrane or pouch **642**. The membrane or pouch **642** is secured to the winged protrusions **640** with medical grade adhesive. The set of winged protrusions **640**

may serve as a gripping feature, aiding a practitioner in twisting or inserting the disinfection cap **600** onto the luer connector. The membrane or pouch **642** includes a bulbous cavity **644** for retaining fluid **602**. The bulbous cavity **644** may be depressed or collapsed onto itself by a practitioner, thereby releasing the fluid **602** through a fluid path **646** into a drain **648** of the disinfection cap **600**. The drain **648** is disposed on a top surface **650** of the top portion of the disinfection cap **600**. A cavity **630** of the housing **610** extends a length L_c of the total length of the housing **610** from the open bottom **616** to a top wall **614**, the cavity **630** having a substantially cylindrical shape.

[0086] As shown in Figure 10B, the drain **648** includes a conical cavity **652** in fluid communication with a lumen **654** disposed on a bottom of the conical cavity **652**, the lumen **654** being in fluid communication with the cavity **630** of the housing **610**. From the top surface **650** extend at least two spines **656**, the at least two spines **656** extending into the center of the conical cavity **652**. The at least two spines **656** are configured to structurally secure a protrusion **658**, the protrusion **658** extending into the conical cavity **652** and lumen **654**. The protrusion **658** includes a top portion and a lower portion, the top portion having a smaller diameter than the lower portion. The diameter of the top portion being less than a diameter of the lumen **654** of the drain **648**. The lower portion of the protrusion **658** being configured as a blockage feature by which the lower portion has a diameter equal to or greater than the diameter of a hub of the luer connector of the medical device. The lower portion of the protrusion **658** fluidly seals a lumen of the hub of the luer connector when the disinfection cap **600** is threaded or pushed against the luer connector, allowing for the bulbous cavity **644** to be depressed or collapsed, thereby releasing fluid **602**. The fluid **602** disinfects the hub and a periphery of the luer connector.

[0087] Figure 11 depicts an exemplary disinfection cap **700** in accordance with a seventh embodiment of the present disclosure. The disinfection cap **700** includes a substantially cylindrical housing **710** having an upper portion, a lower portion and an inner surface **726** of the lower portion of the housing **710** defining a cavity **730** having open bottom **716** for receiving a hub of a luer connector. The upper portion of the disinfection cap **700** includes an engagement surface **740** disposed around a circumference of a top surface **750** of the upper portion of the cylindrical housing **710**. The engagement surface **740** is configured to receive a membrane or pouch **742**, the membrane or pouch **742** having a dome shape defining a bulbous cavity **744** for retaining fluid **702**. The membrane or pouch **742** is secured onto the

engagement surface **740** with medical grade adhesive. The bulbous cavity **744** may be depressed or collapsed onto the top surface **850** of the upper portion of the cylindrical housing **710** by a practitioner, thereby releasing the fluid **702** through a fluid path into the cavity **730** of the lower portion of the housing **710**. The fluid path is defined by at least two vents or slits **748** disposed through the top surface **750** of the upper portion of the cylindrical housing **710**. The slits facilitating fluid communication between the bulbous cavity **744** and the cavity **730** of the lower portion of the housing **710**.

[0088] The cavity **730** of the housing **710** extends a length L_c of the total length of the housing **710** from the open bottom **716** to a top wall **714**, the cavity **730** having a substantially cylindrical shape. The length L_c of the total length of the housing **710** is substantially equal to the length of a hub **774** of a luer connector **770**, wherein the top wall **714** is configured to act as a blockage feature for a lumen **772** of the luer connector **770**. Abutting the hub **774**, the top wall **714** fluidly seals the lumen **772** of the luer connector **770**, preventing ingress of fluid **702** from entering the lumen **772** as the fluid **702** is ejected from the at least two slits **748**. Likewise, the at least two slits **748** are positioned a distance D_s from one another whereby the at least two slits **748** eject fluid **702**, disinfecting the hub and a periphery of the luer connector.

[0089] The disinfection cap (**100, 200, 300, 400, 500, 600, 700**) can achieve disinfection when used on luer connectors by integrating fluid (**102, 202, 302, 402, 502, 602, 702**) in the cavity (**130, 230, 330, 430, 530, 630, 730**) of the disinfection cap (**100, 200, 300, 400, 500, 600, 700**). The fluid (**102, 202, 302, 402, 502, 602, 702**) can be directly included in the cavity (**130, 230, 330, 430, 530, 630, 730**). Disinfection cap (**100, 200, 300, 400, 500, 600, 700**) is designed to be compatible in interacting with various disinfectant or antimicrobial agents or fluid (**102, 202, 302, 402, 502, 602, 702**). In one or more embodiments, the disinfectant or antimicrobial agent or fluid (**102, 202, 302, 402, 502, 602, 702**) may include variations of alcohol or chlorhexidine. In one or more embodiments, the disinfectant or antimicrobial agent or fluid (**102, 202, 302**) may include variations of alcohol or chlorhexidine.

[0090] In one or more embodiments, the fluid (**102, 202, 302, 402, 502, 602, 702**) is selected from the group consisting essentially of isopropyl alcohol, ethanol, 2-propanol, butanol, methylparaben, ethylparaben, propylparaben, propyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene, t-butyl-hydroquinone, chloroxylonol, chlorohexidine, chlorhexidine diacetate, chlorohexidine gluconate, povidone iodine, alcohol, dichlorobenzyl

alcohol, dehydroacetic acid, hexetidine, triclosan, hydrogen peroxide, colloidal silver, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, and mixtures thereof. In a specific embodiment, the disinfectant or antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate. In one or more embodiments, the
5 disinfectant or antimicrobial agent (**102, 202, 302, 402, 502, 602, 702**) is a fluid or a gel.

[0091] In one or more embodiments, the disinfection cap (**100, 200, 300, 400, 500, 600, 700**) can include a removable peel seal covering the opening to the cavity (**130, 230, 330, 430, 530, 630, 730**). In one or more embodiments, the peelable seal comprises an aluminum or multi-layer polymer film peel back top. In a specific embodiment, the peelable is heat-sealed or
10 induction sealed to the open end of the disinfection cap (**100, 200, 300, 400, 500, 600, 700**). In one or more embodiments, the peelable seal comprises a moisture barrier.

[0092] The disinfection cap (**100, 200, 300, 400, 500, 600, 700**) is made from any of a number of types of plastic materials such as polycarbonate, polypropylene, polyethylene, polyethylene terephthalate, polylactide, acrylonitrile butadiene styrene or any other moldable
15 plastic material used in medical devices. In one or more embodiments, the disinfection cap (**100, 200, 300, 400, 500, 600, 700**) comprises a polypropylene or polyethylene material.

[0093] In one or more embodiments, the connector of the medical device may be selected from the group consisting essentially of needle-free connectors, catheter luer connectors, stopcocks, and hemodialysis connectors on primary IV gravity sets, secondary IV
20 gravity sets, extension sets, and infusion or syringe pump sets. In some embodiments, the disinfection cap can be connected with any of a variety of different needleless injection sites. In one or more embodiments, after the disinfection cap has been coupled with connector, it is unnecessary to disinfect (e.g., treat with an alcohol swab) the connector prior to each reconnection of the connector with another connector, as the connector will be kept in an
25 uncontaminated state while coupled with the disinfection cap. Use of the disinfection cap (**100, 200, 300, 400, 500, 600, 700**) replaces the standard swabbing protocol for cleaning connectors.

[0094] Yet another aspect of the present disclosure pertains to a method of disinfecting a medical connector. The method comprises connecting the disinfection cap (**100, 200, 300, 400, 500, 600, 700**) of one or more embodiments to a medical connector, wherein connecting
30 includes engaging the threads of the medical connector onto the threads on the outer surface of the sidewall of the housing (**110, 210, 310, 410, 510, 610, 710**) of the disinfection cap upon

insertion of the medical connector into the disinfection cap (100, 200, 300, 400, 500, 600, 700) such that the medical connector contacts the blockage feature.

[0095] A further aspect of the present disclosure pertains to an assembly. The assembly comprises the disinfection cap (100, 200, 300, 400, 500, 600, 700) of one or more
5 embodiments connected to a medical connector. In one or more embodiments, the medical connector is selected from a luer connector, or other needleless connector having a fitting. In one or more embodiments, the luer connector may be selected from the group consisting essentially of needle-free connectors, catheter luer connectors, stopcocks, and hemodialysis connectors.

10 [0096] A further aspect of the present disclosure pertains to packaging. In one or more embodiments, disinfection cap (100, 200, 300, 400, 500, 600, 700) can be packaged into a strip configuration. The strip configuration may comprise a single-piece top web on which multiple caps (100, 200, 300, 400, 500, 600, 700) are attached through a sealing layer. The strip configuration may also comprise individually sealed caps with individual top web foil, and
15 then a series of individually sealed caps are attached to a piece of strip composed of materials such as plastic in an arrayed fashion. The individual top web foil can have a tab that is attached to the strip material through adhesive or through sealant.

[0097] It is contemplated that the disinfection cap (100, 200, 300, 400, 500, 600, 700) disclosed herein and shown in the Figures may also be utilized with fe luer connectors,
20 including fe luer connectors, wherein the blockage feature can be used to block the lumen of open luers to facilitate the mitigation of such disinfectant ingress into connectors, thereby reducing risk of the disinfectant entering the blood stream. It is therefore contemplated that the disinfection cap (100, 200, 300, 400, 500, 600, 700) disclosed herein and shown in the Figures may be utilized with both and fe luer connectors.

25 [0098] While the present disclosure has been shown and described with reference to certain exemplary embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the embodiments of the present disclosure. Also, the inner and/or the outer housing of the disinfection cap can be single shot molded, or made by other suitable process.
30 Furthermore, any of the features or elements of any exemplary implementations of the embodiments of the present disclosure as described above and illustrated in the drawing figures can be implemented individually or in any combination(s) as would be readily appreciated by

skilled artisans without departing from the spirit and scope of the embodiments of the present disclosure.

[0099] In addition, the included drawing figures further describe non-limiting examples of implementations of certain exemplary embodiments of the present disclosure and aid in the description of technology associated therewith. Any specific or relative dimensions or measurements provided in the drawings other as noted above are exemplary and not intended to limit the scope or content of the claims.

[00100] Reference throughout this specification to "one embodiment," "certain embodiments," "one or more embodiments" or "an embodiment" means that a particular feature, structure, material, or characteristic described in connection with the embodiment is included in at least one embodiment of the disclosure. Thus, the appearances of the phrases such as "in one or more embodiments," "in certain embodiments," "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily referring to the same embodiment of the disclosure. Furthermore, the particular features, structures, materials, or characteristics may be combined in any suitable manner in one or more embodiments.

[00101] Although the disclosure herein has provided a description with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present disclosure. It will be apparent to those skilled in the art that various modifications and variations can be made to the method and apparatus of the present disclosure without departing from the spirit and scope of the disclosure. Thus, it is intended that the present disclosure include modifications and variations that are within the scope of the appended claims and their equivalents.

WHAT IS CLAIMED IS:

1. A disinfection cap having a housing comprising:
 - a top wall,
 - a cylindrical sidewall having an inner surface defining a cavity,
 - 5 an open bottom formed by the cylindrical sidewall with an opening to the cavity within said housing for receiving a hub of a luer connector;
 - a blockage feature disposed within the cavity, the blockage feature configured as a cylindrical protrusion, the cylindrical protrusion being disposed on the top wall of the housing, the cylindrical protrusion fluidly blocking the hub of the luer connector;
 - 10 and,
 - a fluid releasably retained within a depressible open cell foam structure disposed within the cavity, wherein when the hub of said luer connector is received within said inner surface of said cavity.
- 15 2. The disinfection cap of claim 1, wherein said cavity extends essentially from an inner surface of said top wall toward said open bottom of said housing.
3. The disinfection cap of claim 1, wherein the cylindrical protrusion is non-removably disposed on the top wall of the housing.
- 20 4. The disinfection cap of claim 1, wherein the depressible open cell foam structure is disposed against the top wall, the depressible open cell foam structure having a hollow cylindrical shape configured to fit around the cylindrical protrusion.
- 25 5. The disinfection cap of claim 1, wherein the cylindrical protrusion further includes an upper portion and a lower portion, the upper portion having a diameter equal to the top wall, the lower portion having a diameter smaller than the upper portion, the lower portion configured to fluidly block the hub of the luer connector.

6. The disinfection cap of claim 5, wherein the depressible open cell foam structure is disposed against a bottom surface of the upper portion of the cylindrical protrusion, the depressible open cell foam structure having a hollow cylindrical shape configured to fit around the lower portion of the cylindrical protrusion.

5

7. The disinfection cap of claim 5, wherein a second depressible open cell foam is disposed between the upper portion of the cylindrical protrusion and the top wall of the cavity, the second depressible open cell foam structure releasably retaining a fluid.

10 8. The disinfection cap of claim 1, further including an at least one thread on an outer surface of the housing, said at least one thread being sufficient to interlock with a mating feature of said luer connector.

9. The disinfection cap of claim 8, wherein said hub is secured within said inner surface of
15 said cavity by interlocking at least a portion of said at least one thread with a mating feature on said hub of said luer connector.

10. The disinfection cap of claim 1, wherein the inner surface of the cavity is secured by an interference fit with the hub of the luer connector.

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11. The disinfection cap of claim 1, wherein the fluid is selected from a group consisting essentially of isopropyl alcohol, ethanol, 2-propanol, butanol, methylparaben, ethylparaben, propylparaben, propyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene, t-butyl-hydroquinone, chloroxylenol, chlorhexidine, chlorhexidine diacetate, chlorhexidine
25 gluconate, povidone iodine, alcohol, dichlorobenzyl alcohol, dehydroacetic acid, hexetidine, triclosan, hydrogen peroxide, colloidal silver, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, and mixtures thereof.

12. A disinfection cap having a housing comprising:
- a top wall having an aperture extending partially into the housing,
 - a cylindrical sidewall having an inner surface defining a cavity,
 - an open bottom formed by the cylindrical sidewall with an opening to the cavity
- 5 within said housing for receiving a hub of a luer connector;
- an umbrella stopper including a stem at least partially disposed into the aperture of the top wall, the umbrella stopper further including a fanned barrier configured as a blockage feature for fluidly blocking a hub of a medical device, the fanned barrier creating a liquid tight seal with the inner surface of the cylindrical sidewall; and,
- 10 a fluid releasably retained within between the cavity and the fanned barrier of the umbrella stopper, wherein the hub of said luer connector is received within said inner surface of said cavity and wherein when the fanned barrier deforms when moved against the hub, thereby releasing the fluid.
- 15 13. The disinfection cap of claim 12, wherein the umbrella stopper further includes a rounded or chamfered end, the rounded or chamfered end configured to fluidly block the hub of the luer connector.
- 20 14. The disinfection cap of claim 12, wherein the fanned barrier is at a right angle to the stem.
15. The disinfection cap of claim 12, wherein the fanned barrier is at an obtuse angle to the stem.
- 25 16. A disinfection cap having a housing comprising:
- a top wall,
 - a cylindrical sidewall having an inner surface defining a cavity,

an open bottom formed by a cylindrical sidewall with an opening to the cavity within said housing for receiving a hub of a luer connector;

5 a blockage feature disposed within the cavity, the blockage feature configured as a plurality of hydrophilic bristles, the hydrophilic bristles being disposed on the top wall of the housing, the hydrophilic bristles fluidly blocking the hub of the luer connector; and

a fluid releasably retained within the hydrophilic bristles, wherein when the hub of said luer connector is received within said inner surface of said cavity.

10 17. The disinfection cap of claim 16, further including a movable conical stopper, the movable conical stopper comprising a top portion and a bottom portion, the top portion including a flange having a diameter less than the diameter of the cavity, the top portion including a lumen extending therethrough, the cavity including a protrusion configured as a secondary blockage feature by which the protrusion blocks the hub of the luer connector.

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18. A disinfection cap having a housing comprising:

a top portion including a set of winged protrusions configured to receive a membrane or pouch, the membrane or pouching including a bulbous cavity for retaining a fluid and a fluid path fluidly connecting the bulbous cavity to a drain;

20 a drain disposed on a top surface of the top portion, the drain including a conical cavity having a lumen disposed on a bottom surface of the conical cavity, the lumen being in fluid communication with a cavity defined by an inner sidewall of a bottom portion of the housing;

25 at least two spines extending from the top surface into a center of the conical cavity, the at least two spines structurally securing a protrusion disposed within the cavity, the protrusion extending through the lumen, the protrusion configured as blockage feature by which a lower portion of the disinfection cap has a diameter equal to or greater than the diameter of a hub of a medical device; and

an open bottom formed by a cylindrical sidewall of the cavity with an opening to the cavity within said housing for receiving a hub of a luer connector, wherein when the hub of said luer connector is received within an inner surface of said cavity.

5 19. A disinfection cap having a housing comprising:

an upper portion having an engagement surface disposed around a circumference of a top surface of the upper portion of a cylindrical housing, the engagement surface configured to receive a membrane or pouch, the membrane or pouch having a dome shape defining a bulbous cavity for retaining fluid;

10 an open bottom formed by a cylindrical sidewall of the bulbous cavity with an opening to the bulbous cavity within said housing for receiving a hub of a luer connector; and

at least two vents or slits disposed through the top surface of the upper portion, the at least two vents or slits in fluid communication with the bulbous cavity of the upper portion and the bulbous cavity, the at least two vents being disposed a distance from one another, the distance being greater than a length of the hub of said luer connector,

15 wherein when the hub of said luer connector is received within an inner surface of the bulbous cavity and wherein the bulbous cavity may be depressed or collapsed onto the top surface of the upper portion, thereby releasing fluid into the at least two vents or slits.

20 20. The disinfection cap of claim 19, wherein the hub of the luer connector abuts a top wall of the bulbous cavity, the top wall fluidly sealing the hub of the luer connector.

25