US Patent & Trademark Office
Patent Public Search | Text View

United States Patent	12383720
Kind Code	B2
Date of Patent	August 12, 2025
Inventor(s)	Kumar; Manish et al.

Universal disinfecting cap with expandable slitted opening

Abstract

A cap is described for connection to a needleless connector having an open lumen, the cap includes a housing having a top wall and sidewall forming a first cavity, a flexible container, an porous absorbent material and a sealing rubber. The flexible container includes an inner thread on an inner surface, the inner thread being sufficient to interlock with a mating feature of a female needleless connector. The inner surface of the flexible container defines a second cavity. The sidewall of the housing having a split-thread protrusion integrally formed with the distal wall, an outer thread disposed on an outer surface of the split-thread protrusion, the outer thread being sufficient to interlock with a mating feature of a male needleless connector. The second cavity configured to define a chamber to contain an absorbent reservoir material, a sealing rubber and disinfectant or antimicrobial agent.

Inventors: **Kumar; Manish (Arrah, IN), Nalawade; Praveen (Karnataka, IN), Jain; Shashwat (Indore, IN), Gupta; Kadamb (Uttar Pradesh, IN)**

Applicant: **Becton, Dickinson and Company** (Franklin Lakes, NJ)

Family ID: **1000008748001**

Assignee: **Becton, Dickinson and Company (Franklin Lakes, NJ)**

Appl. No.: **17/722053**

Filed: **April 15, 2022**

Prior Publication Data

Document Identifier	Publication Date
US 20230330407 A1	Oct. 19, 2023

Publication Classification

Int. Cl.: **A61M39/16** (20060101); **A61L2/18** (20060101); **A61L2/26** (20060101); **A61M39/20** (20060101); A61L101/34 (20060101)

U.S. Cl.:

CPC **A61M39/162** (20130101); **A61L2/18** (20130101); **A61L2/26** (20130101); **A61M39/20** (20130101); A61L2101/34 (20200801); A61L2202/24 (20130101)

Field of Classification Search

CPC: A61L (29/00); A61L (2202/24); A61M (2205/0205); A61M (39/162); A61M (39/20)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
8197749	12/2011	Howlett et al.	N/A	N/A
10871246	12/2019	Marici et al.	N/A	N/A
2019/0234540	12/2018	Marici et al.	N/A	N/A

FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
2019199750	12/2018	WO	N/A
2020160064	12/2019	WO	N/A

OTHER PUBLICATIONS

“PCT International Search Report and Written Opinion in PCT/US2023/018488 dated Aug. 7, 2023, 13 pages”. cited by applicant

---

Primary Examiner: Hall; Deanna K

Attorney, Agent or Firm: SERVILLA WHITNEY LLC

Background/Summary

TECHNICAL FIELD

(1) The present disclosure generally relates to a device for disinfecting and sterilizing multiple types of connectors including both male luer connectors and female luer connectors. Generally, exemplary embodiments of the present disclosure relate to the fields of medical caps and medical disinfection caps, and in particular caps and/or disinfection caps for uses with fluid luer connectors.

BACKGROUND

(2) Vascular access devices (VAD's) are commonly used therapeutic devices and 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 hubs, ports and valves 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 costly and potentially lethal.

(3) In order to decrease catheter-related bloodstream infection (CRBSI) cases and to ensure VAD's are used and maintained correctly, standards of practice have been developed, which include disinfecting and cleaning procedures.
(4) Disinfection caps have been added to the Society for Healthcare Epidemiology of America (SHEA) guidelines and caps are also incorporated into the Infusion Nurses Standards (INS) guidelines.
(5) 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 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 the 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 that there is often a variation in scrub time, dry time and the number of times the needleless connector is scrubbed.
(6) 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. Contamination can occur during drug mixing, attachment of a cannula, and insertion into the access hub. 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 clinician performing the connection, and this diligence is largely uncontrollable.
(7) Currently, caps for male needleless connectors, female needleless connectors, intravenous (IV), and hemodialysis lines use different designs and are therefore limited to the types of connectors to which the cap can be attached. Currently, there are female disinfecting cap devices for disinfecting ISO594-2 type of female threaded fluid luer connectors and there are male disinfecting cap devices for disinfecting ISO594-2 type of male threaded fluid luer connectors. However, there is not a singular universal disinfecting cap device with features allowing it to interface with both a male and female type of threaded connectors. Prior disinfecting caps were designed to fit one type of connector only, and were specific to one particular size and/or shape of connector. Thus, there is a need for a disinfecting device capable of accommodating multiple types of connectors to streamline the disinfecting process.

SUMMARY

(8) One aspect of the present disclosure pertains to a cap having a housing including a top wall, an essentially cylindrical sidewall forming a first cavity, the sidewall having a split-thread integrally formed with the distal wall and an open bottom formed by the cylindrical sidewall with an opening to the first cavity within the housing for receiving a flexible container; the split-thread protrusion of the sidewall having an inner surface and an outer surface and an flexible container disposed within the first cavity, the flexible container having closed distal end comprising a distal wall, an open proximal end, a sidewall extending proximally from the distal wall toward the open proximal end,, the inner surface of the flexible container defining a second cavity to receive a needleless connector having an closed lumen, an inner thread on the inner surface of the flexible container, the inner thread being sufficient to interlock with a mating feature of the female needleless connector, an outer thread on the outer surface of the split-thread protrusion, the outer thread being sufficient to interlock with a mating feature of the male needleless connector; a sealing rubber/foam; absorbent material configured within the second cavity; a disinfectant or an antimicrobial agent; and a cover for maintaining sterility and forming a seal at the open proximal end of the housing and flexible

container for maintaining the disinfectant or an antimicrobial agent within the second cavity prior to use of the cap.

(9) In one or more embodiments, the housing extends essentially from an inner surface of the top wall toward the open bottom of the housing. In one or more embodiments, the exterior wall surface of the sidewall of the housing includes an outer thread. In one or more embodiments, the outer thread has an inclined thread pattern. In one or more embodiments, the outer thread has a helical-shaped thread pattern. In one or more embodiments, the exterior wall surface of the sidewall of the housing includes a plurality of grip members. In one or more embodiments, the housing is made of a high density polyethylene or polypropylene material.

(10) In one or more embodiments, the flexible container extends essentially from an inner surface of the top wall toward the open bottom of the housing. In one or more embodiments, the flexible container extends essentially parallel to the sidewall of the housing. In one or more embodiments, the inner thread has an inclined thread pattern. In one or more embodiments, the inner thread have a helical-shaped thread pattern.

(11) The flexible container is disposed in the housing and positioned within the first cavity. The flexible container has an inner surface and an outer surface, the inner surface of the flexible container defining a second cavity. The flexible container has an inner thread on the inner surface of the flexible container.

(12) The cap also includes a porous absorbent material held by the inner wall below the thread or lug using radial compression. The cap also includes a sealing rubber disposed onto the absorbent reservoir material. In one or more embodiments, the porous absorbent material includes a centrally disposed through hole extending from a distal end to a proximal end of the absorbent reservoir material. In one or more embodiments, the sealing rubber is disposed within the centrally disposed through hole of the absorbent reservoir material. In one or more embodiments, the sealing rubber is stacked on top of the absorbent reservoir material using adhesive. In one or more embodiments, the sealing rubber is bonded to the absorbent material with a biocompatible adhesive.

(13) In one or more embodiments, the sealing rubber is in the form of an elongate shaft. In one or more embodiments, the elongate shaft of the sealing rubber is disposed into the though hole of the absorbent reservoir material.

(14) In one or more embodiments, the porous absorbent material surrounds an elongate shaft of the sealing rubber.

(15) In one or more embodiments, the porous absorbent material is a nonwoven material, foam, or a sponge. In one or more embodiments, the porous absorbent material is soaked with a disinfectant or an antimicrobial agent.

(16) In one or more embodiments, the sealing rubber is made of a closed cell foam, a polyethylene foam, a thermoplastic elastomer, a rubber or rubber like foams. In one or more specific embodiments, the sealing rubber is an EPDM sponges, EVA, Buna-N, silicone, vinyl, neoprene, fluoroelastomers, gum rubber.

(17) In one or more embodiments, the cap further includes a disinfectant or the antimicrobial agent.

(18) In one or more embodiments, the disinfectant or the antimicrobial agent 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, chloroxylenol, 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.

(19) In one or more embodiments, as shown in FIG. **3**, the cap includes a cover **60**. In one or more embodiments, as shown in FIG. **2**, the cap may also include a peel seal **80**. In one or more embodiments, the peel seal comprises an aluminum or multi-layer polymer film. In one or more embodiments, the peel seal further comprises a moisture barrier.

(20) This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.
(21) Additional features and advantages of the disclosure will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the disclosure. The features and advantages of the disclosure may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. These and other features of the present disclosure will become more fully apparent from the following description and appended claims, or may be learned by the practice of the disclosure as set forth hereinafter.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) FIG. **1** illustrates an exploded view of an exemplary cap according to an exemplary embodiment of the disclosure;
(2) FIG. **2** illustrates a perspective top view of a cap according to an exemplary embodiment of the disclosure;
(3) FIG. **3** illustrates a perspective top view of a cover and a cap according to an exemplary embodiment of the disclosure as shown in FIG. **1**;
(4) FIG. **4** illustrates a perspective side view of an exemplary split thread protrusion and chamfered entry of the housing shown in FIGS. **1** and **2**;
(5) FIG. **5** illustrates a perspective side view of an exemplary split thread protrusion of the housing and a flexible container having an chamfered entry and lug in the inner surface of the flexible container shown in FIGS. **1** and **2**;
(6) FIG. **6** illustrates a cross-sectional view of an exemplary assembled cap with a female connector;
(7) FIG. **7** illustrates a cross-sectional view of an exemplary assembled cap in connection with a female connector of various types superimposed on each other, as shown in FIG. **6**;
(8) FIG. **8** illustrates a cross-sectional view of an exemplary assembled cap with a male connector; and
(9) FIG. **9** illustrates a cross-sectional view of an exemplary assembled cap in connection with a male connector of various types superimposed on each other, as shown in FIG. **8**.
DETAILED DESCRIPTION
(10) Embodiments of the disclosure pertain to a sterile, universal cap for connection to and disinfection of a medical connector having an open or closed lumen, including male connectors and female connectors. The male connectors and female connectors can be male luer connectors and closed female luer connectors used in vascular access procedures. Embodiments of the cap comprise a housing, a flexible container, an absorbent material, a sealing rubber and a cover. Embodiments of the disclosure fit both a male Luer and a closed female Luer connectors with interchangeability. The cap may further comprise a disinfectant or the antimicrobial agent and a cover. The cap provides a mechanical barrier for connectors and contains an antimicrobial agent for disinfection. The cap of the present disclosure also allows the practitioner to streamline the disinfecting process while blocking the lumen of open luer to facilitate the mitigation of the ingress of contaminants and disinfectant into the open lumens of the connectors, thereby reducing risk of the contaminants and disinfectant entering the blood stream.
(11) With respect to terms used in this disclosure, the following definitions are provided.
(12) As used herein, the use of “a,” “an,” and “the” includes the singular and plural.
(13) 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.
(14) 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 male and female interlocking tubes, slightly tapered to hold together better with even 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 male end is generally associated with a flush syringe and can interlock and connect to the female 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 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.
(15) As would be readily appreciated by skilled artisans in the relevant art, while descriptive terms such as “lock”, “interlock”, “hole”, “tip”, “hub”, “thread”, “sponge”, “prong”, “protrusion”, “flexible container”, “lug”, “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 the embodiments of the present disclosure.
(16) 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.
(17) In an exemplary implementation of the embodiments of present disclosure, a cap, connector cap or disinfecting cap includes integrated thread, or threads, and other features in any and all combinations allowing it to interface with both male and female threaded fittings.
(18) According to further exemplary implementations of the embodiments of the present disclosure, configuration of structural elements making up the flexible container include an inner lug or thread to connect to female medical connectors. Configuration of structural elements making up the housing include one or more split thread protrusions comprising an outer thread to connect to male medical connectors, to facilitate securing of the cap onto a male fitting.
(19) According to still further exemplary implementations of the embodiments of the present disclosure, the split thread sidewall of the housing includes a plurality of cantilevered prongs in which the plurality of cantilevered prongs of the housing may bend in order to allow better interference fit compliance with the fittings.
(20) According to still further exemplary implementations of the embodiments of the present disclosure, female threads are sized and have a thread pattern that will engage with a standard ISO594-2 type of male fitting and/or a male threads that are sized and have a thread pattern that will engage with a standard ISO594-2 type of female fitting.
(21) In one or more embodiments, the female connector may be selected from the group consisting essentially of closed female luer connectors, needle-free connectors, catheter luer connectors, stopcocks, and hemodialysis connectors.
(22) In one or more embodiments, the male connector may be a male luer connector, male lock connector on IV line, intravenous tubing end, a stopcock, male lock luer or any male connectors following ISO-80369-7 dimensions.
(23) 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.
(24) 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.

(25) An exploded view of a cap of the present disclosure, as shown in FIG. **1**, relates to a cap **10** including a housing **20**, a flexible container **30** disposed within a first cavity of the housing, an absorbent material **40** disposed within a chamber of the flexible container, a sealing rubber **50** and a cover **60**. Embodiments of the present disclosure fit both a closed female Luer connectors **90** or male Luer connector **92** with interchangeability.

(26) As shown in FIG. **2**, housing **20** is a rigid cap having an expandable slitted opening having with slits or cutouts on its lateral surface for flexibility to allow the opening of housing to expand radially outwards based on the diameter of the engaging connector to accommodate different diameters of connectors (NFCs and IV male luers). The housing **20** comprises an integral body having a sidewall **21**, closed end **22** having a distal wall **23**, and an open end **24**. The sidewall **21**, closed end **22**, distal wall **23**, and the open end **24** defining a first chamber **25**. In one or more embodiments, the sidewall **21** of housing **20** is essentially cylindrical. The sidewall **21** of housing **20** of the sidewall having an inner surface **211** and an exterior wall surface **21**E. The sidewall of the housing having a length LC extending from the closed end **22** to an open end **24** and defining a first chamber **25**. A portion of the sidewall **21** of the housing **20** having a length LT extending from the open end **24** toward the closed end **22** includes a split-thread protrusion **26** integrally formed with the sidewall **21** extending from the distal wall **23**. A portion of the sidewall of the housing having a length LT includes a split-thread integrally formed with the distal wall. The inner surface of the split-thread protrusion of the sidewall having the flexible container disposed within the first cavity. The open end **24** formed by the cylindrical sidewall **21** having an opening to the first chamber **25** for receiving a flexible container **30** within the housing **20**. In one or more embodiments, as shown in FIG. **4**, the split-thread protrusion **26** are configured as one or more cantilevered prongs separated by one or more respective gaps or cutouts **27**. In an exemplary implementation, at least a portion of one or more of the two or more cantilevered prongs of split-thread protrusion **26** may bend in order to allow better interference fit compliance with the fitting such as at least one of male connector or female connector. In one or more embodiments, at least one of the cantilevered prongs of split-thread protrusion **26** can be configured to bend to facilitate interference fit between the housing **20** and the mating feature of the female needleless connector. The split-thread protrusion **26** of the sidewall having an inner surface **26**I and an exterior wall surface **26**E. The exterior wall surface **26**E of the split-thread protrusion **26** of the sidewall of the housing having one or more threads **29** that are sized and adapted to interlock with a mating feature of the male luer connector. As shown in FIGS. **1** and **4**, outer threads **29** of the split-thread protrusion **26** of sidewall of housing **20** extends in a helical pattern. In one or more embodiments, full length or partial length of the prongs on exterior wall surface **26**E may be threaded to control how deep the connectors can be threaded into the cavity. This may also facilitate the volume of compression on disinfectant impregnated sponges to control the disinfectant volume that's dispensed upon engagement to connectors.

(27) In an exemplary implementation of FIGS. **3** and **4**, housing is illustrated as comprising a plurality of prongs spaced by cutouts **27** and extending essentially from the closed end **22** of housing **20**. Referring to FIGS. **1** and **2**, in one or more embodiments, the exterior wall surface **21**E comprises a plurality of grip members **28**.

(28) In one or more embodiments, the flexible container **30** extends essentially parallel to the cylindrical sidewall **21** of the housing **20**. In one or more embodiments, flexible container **30** can extend essentially from the distal wall **23** toward the open end **24** of the housing **20**.

(29) As shown in FIGS. **2** and **5**, the flexible container **30** includes a sidewall **31** defining an inner surface **311** and an outer surface **310**, the inner surface **311** of flexible container **30** defining a second cavity **32**. The inner surface **311** of flexible container **30** has a pair of lugs **34** on diametrically opposite sides that has a size and pitch configured to engage a threadable segment of

a female connector, such as for example, a female luer connector. In some embodiments, cap **10** provides a protective cover for a female luer connector when engaged with the connector. Specifically, the cap **10** provides a protective cover when threads from the female luer connector engage and form a releasable connection with the lug **34** of flexible container **30**. In one or more embodiments, the lug **34** is included on the inner surface **311** of flexible container **30**, the lug **34** being sufficient to interlock with a mating feature of the female needleless connector.

(30) Referring to FIG. **1**, the flexible container **30** is disposed within first chamber **25** of the housing **20**. The flexible container **30** can be essentially cylindrical and coaxial with sidewall **21** of the housing **20**. The flexible container **30** has a closed bottom end made of an elastomeric material which can expand along with housing **20**. This is bonded to the housing with the lip towards the distal end and near the opening of the housing **20**. The elastomeric flexible container creates a better seal on the connectors compared to similar containers currently known in the prior art. The flexible container **30** is disposed within the first chamber **25** of the housing includes an inner surface **31**I defining an inner portion of second cavity **32**, and an outer surface **33** defined by the outer sidewall of the flexible container **30**. In one or more embodiments, the closed end **37** of the flexible container **30** is abutted against the distal wall **23** of the housing **20** when the flexible container **30** is disposed in the first chamber **25** of the housing **20**. Flexible container **30** comprises an inner thread or lug **34** disposed on the inner surface **31**I for engaging a male connector.

(31) The open end of the flexible container has an entry chamfer **35** on the flexible container **30** that supports entry of the female connector to enable ease in engagement.

(32) A porous absorbent material **40** is assembled into the flexible container **30**. In one or more embodiments, the porous absorbent material is a soft sponge. The porous absorbent material **40** retains disinfectant (e.g. isopropyl alcohol (IPA)) in its structure and releases the disinfectant when compressed with an engaging connector. Referring to FIG. **3**, in one or more embodiments, a porous absorbent material **40** is disposed within the second cavity **32** of the flexible container. In one or more embodiments, the porous absorbent material **40** is under radial compression by the inner surface **311** of the wall of flexible container **30** to retain the porous absorbent material **40** within the second cavity **32** of the flexible container. In one or more embodiments, the porous absorbent material **40** is a nonwoven material, foam, or a sponge. In a specific embodiment, the foam is a polyurethane foam.

(33) The porous absorbent material **40** comprises an integral body **41**, an annular wall **42**, a bottom surface **43** and a distal face **44**. In one or more embodiments, the foam of the porous absorbent material **40** is saturated or soaked with a disinfectant or an antimicrobial agent. In one or more embodiments, the porous absorbent material **40** is a nonwoven material, foam, or a sponge. In a specific embodiment, the porous absorbent material **40** is polyethylene foam. The foam may be open celled, semi-opened or closed celled. In one or more embodiments, the porous absorbent material **40** is molded, extruded or die cut from sheeting to form a cylindrical block shape. The cap of the present disclosure includes a slitted housing with flexible container with the composite sponge. The absorbent material may include a composite foam with seal rubber at the top and soft sponge underneath to minimize IPA Ingress and retain the disinfectant, respectively.

(34) The cap of the present disclosure provides long-lasting disinfection and prevents microbial entry (has a physical barrier, and ability to retain antimicrobial reagent/‘leak proof’ connection).

(35) In one or more embodiments, the porous absorbent material **40** also comprises of a centrally disposed opening **45** that is positioned concentrically relative to the annular wall **42** and completely extends from the bottom surface **43** to the distal face **44** of the porous absorbent material **40**. In one or more embodiments, as shown in FIGS. **5** through **8**, sealing rubber **50** is disposed onto porous absorbent material **40**. As shown in FIG. **1**, the sealing rubber **50** comprises of an integral body **56**, an annular wall **52**, a bonded surface **58** and a sealing surface **59**. In one or more embodiments, the annular wall **52** of the sealing rubber **50** is disposed into the opening **45** of the porous absorbent material **40**. In one or more embodiments, the sealing rubber is stacked on top of the absorbent

reservoir material using adhesive. In one or more embodiments, the sealing rubber is bonded to the absorbent material with a biocompatible adhesive.
(36) The sealing rubber **50** is a non-porous sponge bonded to the porous absorbent material **40**. The sealing rubber **50** seals the lumen of a male IV luers once engagement with the universal cap begins to prevent or minimize disinfectant (e.g. IPA) ingress into the fluid path of the connector. The possibility of IPA ingress is lower with the use of cap specifically in male luer connectors when compared to ingress in currently available disinfecting caps due to presence of a sealing rubber **50** which seals the lumen of a male IV luers upon engagement. In a specific embodiment, the sealing rubber **50** is in the form of a plug disposed in the center of the porous absorbent material **40**. The cap **10** of the present disclosure mitigates ingress of antimicrobial reagent specifically in Male Luer Connectors. The cap of the present disclosure mitigates particulate hazard which occurs when material with tendency to disintegrate can potentially enter the fluid path which constitutes a potential hazard to a patient.
(37) In a specific embodiment, the sealing rubber **50** is closed cell foam. In one or more embodiments, the sealing rubber **50** may comprise of closed cell foams such as PE foams or thermoplastic elastomers (TPE) foams. In one or more embodiment, the sealing rubber **50** may also comprise of rubber or rubber-like foams including: (ethylene propylene diene monomer) EPDM sponges, ethylene-vinyl acetate (EVA), Buna-N, polyethylene sponges, silicone, vinyl, neoprene, fluoroelastomers, gum rubber, or TPE materials. In one or more embodiments, the sealing rubber **50** is molded, extruded or die cut from sheeting to form a cylindrical block shape.
(38) The bonded surface **58** of the sealing rubber **50** is secured to the bottom surface **43** of the porous absorbent material **40**. When secured, the annular wall **52** of both the sealing rubber **50** and the porous absorbent material **40** are concentric and coincident. The methods of which the bonded surface **58** and the bottom surface **43** of the porous absorbent material **40** are secured include using adhesives and other appropriate bonding methods. The coincident annular wall **52** of the sealing rubber **50** and the annular wall **42** of the porous absorbent material **40** is appropriately sized to fit into the second cavity **32** of the flexible container **30** having a sdefined by inner surface **31**. When assembled, the sealing rubber and the reservoir foam completely fill the inner surface **311** of flexible container **30** defining a second cavity **32**. The assembly of the porous absorbent material **40** and the sealing rubber **50** are frictionally fitted into the second cavity **32** formed by the inner surface **311** of flexible container **30**.
(39) As the lug **34** of the flexible container **30** is threadably secured to a female luer connector, the luer connector compresses the sealing surface **59** of the sealing rubber **50** towards the closed end **37** of the flexible container **30**. Compression of the sealing rubber **50** causes the bonded surface **58** of the sealing rubber **50** to compress the porous absorbent material **40** further into the closed end **37** of the flexible container **30**. As a needless connector is threadably secured to the inner threads or lug **34** or outer threads **29**, the sealing rubber **50** applies pressure to the lumen of a luer connector. The pressure applied to the lumen of the connector by the sealing rubber **50** blocks the lumen and mitigates the potential of disinfectant ingress into the luer connectors. In one or more embodiments, the sealing rubber **50** is elastic. The pressure applied by the sealing rubber **50** to the connector can range from less than one psi and up to tens of psi. Additionally, the pressure applied by the sealing rubber **50** to the lumen of the luer connector sustains the fluid pressure in the lines of the luer connector to prevent fluid leakage and also prevents ingress of disinfectant into the lumen of the connector.
(40) The cap may further comprise a disinfectant or the antimicrobial agent **70**. The cap **10** can achieve disinfection when used on luer connectors by integrating disinfectant or antimicrobial agent in the second cavity **32** of flexible container **30**. The disinfectant or antimicrobial agent can be directly included in the second cavity **32** of flexible container **30** such that the disinfectant or antimicrobial agent can be absorbed into sponges or foam material that fills the second cavity **32** of flexible container **30**, specifically the porous absorbent material **40**. Cap **10** is designed to be

compatible in interacting with various disinfectants. In one or more embodiments, the disinfectant or antimicrobial agent may include variations of alcohol or chlorhexidine. In one or more embodiments, the disinfectant or antimicrobial agent 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, chloroxylenol, 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 a preferred embodiment, the disinfectant or antimicrobial agent comprises isopropyl alcohol (IPA). In one or more embodiments, the disinfectant or antimicrobial agent is a fluid or a gel. In a preferred implementation, porous absorbent material **40** is a sponge soaked with isopropyl alcohol (IPA).

(41) Compression of the porous absorbent material **40** and sealing rubber **50** toward the distal wall **23** of housing **20** upon connection to the female luer connector or the male luer connector allows the connector to contact the disinfectant or antimicrobial agent to disinfect the female luer connector or the male luer connector. Compression of the porous absorbent material **40** causes the antimicrobial or disinfectant to be excreted from the porous absorbent material **40**, thereby disinfecting the female luer connector or the male luer connector. The cap **10** of the present disclosure maximizes disinfecting area (e.g., threads, luer top surface, lumen external surface) and minimizes the entry of antimicrobial reagent to enter fluid path.

(42) In one or more embodiments, as shown in FIG. **3**, the cap includes a cover **60**.

(43) Cover **60** seals the internal contents of the cap **10** after assembly and maintains the sterility of the device. The cover **60** minimizes entry of potential particulate hazard and also provides a substantially impermeable enclosure for the cap **10**. In one or more embodiments, the cover **60** may be disposed on and sealed with the lip of flexible container **30**. Referring to FIG. **2**, in one or more embodiments, the cover **60** is disposed on the concentric non-slitted sidewall of housing **20** via friction fit to prevent the disinfectant or the antimicrobial agent from exiting the second cavity **32**. The cover **60** further ensures sterility of the housing **20**. The cover **60** provides a leak prevention and protection enclosure, protects the contents of porous absorbent material **40** contained within the first chamber **25**, and/or maintains a sealed, sterilized environment. The cover **60** provides a sufficient seal at a range of temperatures, pressures, and humidity levels.

(44) In one or more embodiments, as shown in FIG. **1**, the cap may also include a peel seal **80**. The peel seal reduces spillage or evaporation of the disinfectant. In one or more exemplary implementation, in addition to cover, a peel seal **80** can also be provided to a surface of a rim of the open end of the flexible container **30** to seal the opening prior to use of cap **10**. In one or more embodiments, the peel seal comprises an aluminum or multi-layer polymer film. In one or more embodiments, the peel seal further comprises a moisture barrier. Referring to back to FIG. **1**, rim of an open end of flexible container **30** defines an engagement surface where a cover **60** or peel seal **80** may be secured. Peel seal **80** may be attached to the flexible container **30** by heat seal.

(45) In one or more embodiments, the peel seal **80** as shown in FIG. **1** comprises an aluminum or multi-layer polymer film peel back top. In a specific embodiment, the peel seal **80** is heat-sealed or induction sealed to the open end of the flexible container **30**. In one or more embodiments, the cover **60** and or peel seal **80** comprise a moisture barrier.

(46) Referring to FIGS. **1** through **9**, according to exemplary embodiments of the disclosure, cap **10** can receive a tip or hub of a male connector **92** or female needleless connector **90**, for example after the cover **60** is removed or when peel seal **80** sealing second cavity **32** of the flexible container is pierced or removed, within second cavity **32** and secure, for example, threadedly via lug **34** or outer thread **29** as described above. One or more lugs or threads can be sufficient to interlock with a hub or tip of needleless connector.

(47) The cap **10** is made from any of several types of plastic materials such as polycarbonate, polypropylene, polyethylene, polyethylene terephthalate, polylactide, acrylonitrile butadiene styrene or any other moldable plastic material used in medical devices. In one or more embodiments, the cap **10** comprises a polypropylene or polyethylene material. In one or more embodiments, the cover or cap may be made of a high density polyethylene (HDPE) or polypropylene (PP) material.
(48) As shown in FIGS. **1** and **4**, the housing **20** comprises a proximal portion having a uniform non-slitted cylindrical sidewall and a distal portion having a slitted sidewall, the distal portion is bounded by a rim and end face located at an open proximal end **24** of the housing. The first chamber **25** within the housing **20** is configured for receiving a flexible container **30** and the second cavity **32** of the flexible container **30** is configured for receiving a needleless connector or a male needleless connector. Opposite to the open end of the first chamber **25** is a distal wall **23**.
(49) In one or more embodiments, an outer thread **29** can be included on the exterior wall surface **21**E of the split-thread sidewall of the housing **20**, the outer thread **29** being sufficient to interlock with a mating feature of the male connector.
(50) As shown in FIG. **4**, the sidewall of the split-thread at the distal end of the housing tapers outwardly to create an entry chamfer angle (ECA) and extends to a radius R**2** which is larger than the radius R**1** of the split-thread housing. The radius R**2** corresponds substantially to the largest radius of the split-thread housing.
(51) In one or more embodiments, prior to connection with a connector, the minimum diameter of the NFC thread is 6.73 mm, the Lug diameter is 4.9 mm and the amount of expansion is about ˜1 mm radially. In one or more embodiments, the maximum diameter of a needle-free connector thread is 7.6 mm and the maximum diameter of the Universal Disinfecting Cap (UDC)=5.9 mm and the amount of expansion is ˜0.75 mm radially.
(52) As shown in FIG. **5**, inner threads or lug **34** on the inner sidewall of the flexible container **30** may be tapered and may extends in a helical pattern.
(53) In one or more embodiments, the flexible container **30** and the housing **20** can be bonded together with solvent resistant biocompatible adhesive.
(54) The porous absorbent material **40** surrounds the sealing rubber **50**. The nonporous sealing rubber **50** and the porous absorbent material **40** are positioned within the inner surface **311** of flexible container **30** defining a second cavity **32** where the sealing surface **59** will be in contact with the lumen of open luer connectors. In one or more embodiments, the sealing rubber is stacked on top of the absorbent reservoir material using adhesive. In one or more embodiments, the sealing rubber is bonded to the absorbent material with a biocompatible adhesive.
(55) In some embodiments, the connector comprises a needleless injection site, which may sometimes be referred to as a needleless injection port, hub, valve, or device, or as a needleless access site, port, hub, valve, or device. In some embodiments, the cap can be connected with any of a variety of different needleless injection sites. In one or more embodiments, after the 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 uncontaminated state while coupled with the cap. Use of the cap replaces the standard swabbing protocol for cleaning connectors.
(56) Another aspect of the present disclosure pertains to a method of disinfecting a medical connector. The method comprises connecting the cap of one or more embodiments to a medical connector, wherein connecting includes engaging the threads of the medical connector onto the threads on the inner or outer surface of the flexible container of the present disclosure upon insertion of the medical connector into the cap such that the medical connector contacts the absorbent material and the disinfectant or antimicrobial agent.
(57) FIGS. **6** and **7** illustrates a cross-sectional view of an exemplary assembled cap with a female connector **90**. FIG. **7** illustrates a cross-sectional view of an exemplary assembled cap in

connection with a female connector of various types superimposed on each other, as shown in FIG. **6**. To connect the cap of the present disclosure with a female connector or needle free connector (NFC), the user removes cover on the cap and engages the outer thread of the female connector or needle free connector (NFC) which interacts with the Entry chamfer on the flexible container **30**. Axial movement of the female connector into the Cap flares out the housing and opens space for the NFC. To accommodate the engaging needle free connector (NFC), the slits in the housing expand. Since the flexible container is also bonded to the housing, the flexible container also expands radially outwards. Due to this expansion, the female luer connector or needle free connector (NFC) enters deeper into the cap and encounters a pair of diametrically opposite lugs (portion of threads). NFC threads initially overrides the lugs and then engages with lugs for further movement. Lugs present on the inner surface then engage with the threads of the female luer connector or needle free connector (NFC) and a secure connection is established. The lugs are disposed slightly away from the entry point which enables easy entry into the cap. Due to axial movement of female luer connector or needle free connector (NFC) into the cap, sealing rubber and in turn absorbent material get compressed and disinfectant or antimicrobial agent is released which wets and disinfects the septum and threads of female luer connector or needle free connector (NFC). The sealing rubber, which is wetted with disinfectant, contacts the septum of female luer connector or needle free connector (NFC). The sealing rubber seals the face of female luer connector or needle free connector (NFC) and forms a physical barrier to prevent ingress disinfectant or antimicrobial agent into the lumen of the luer.

(58) FIGS. **8** and **9** illustrates a cross-sectional view of an exemplary assembled cap with a male connector **92**. FIG. **9** illustrates a cross-sectional view of an exemplary assembled cap in connection with a male connector of various types superimposed on each other, as shown in FIG. **8**. To connect the cap **10** of the present disclosure with a male connector, such as a male luer on an IV line, the user removes the cover **60** on the cap **10** and engages the threads in the connector with the inner threads or lug **34** or outer threads **29** on the housing **20**. Outer collar of the connector engages with the threads present on the housing. Outer threads **29** engage with the inner threads of the male collar. The housing **20** is extracted from the male connector collar. The part connects nominally with the male connector. No expansion or compression of the slitted opening of the housing takes place since the threads are complementary to each other. When the male luer enters into the cap **10**, the face of male luer lumen first contacts the sealing rubber **50** wetted with disinfectant, which upon further compression creates a seal at the interface. The sealing rubber **50** seals the face of male luer and forms a physical barrier and stops disinfectant or antimicrobial agent ingress into the fluid path. This does not allow disinfectant or antimicrobial agent in the cap to ingress into the lumen of the luer. The absorbent material gets compressed during engagement and disinfectant or antimicrobial agent stored in its structure is released. This disinfects the luer outer surface of the male connector.

(59) The universal cap of the present disclosure allows for disinfection of all clinically relevant areas including threads, luer top surface, and the lumen external surface.

(60) The exemplary caps of the present disclosure are capable of capable of blocking the lumens of open luers to minimize ingress of disinfectant and microbial agents into connectors for both female luer connector and male luer connector, thereby reducing risk of the disinfectant and microbial agents entering the blood stream of a patient.

(61) 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. For example, a absorbent material can comprise any suitable disinfecting or other application-specific substance, and can be made of any suitable material. Also, the housing of the cap can be single shot molded, or made by other suitable process. 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.
(62) 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 inventive design or methodology as understood by artisans skilled in the relevant field of invention.
(63) Other objects, advantages and salient features of the disclosure will become apparent to those skilled in the art from the details provided, which, taken in conjunction with the annexed drawing figures, disclose exemplary embodiments of the disclosure.
(64) 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.
(65) 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.

Claims

1. A cap comprising: a housing having closed distal end comprising a distal wall, an open proximal end, a cylindrical sidewall extending proximally from the distal wall toward the open proximal end, a cylindrical sidewall forming a first cavity, the cylindrical sidewall having a split-thread protrusion integrally formed with the distal wall, the split-thread protrusion having an inner surface and an outer surface, the inner surface of the split-thread protrusion defining a first cavity, a flexible container disposed in the housing and positioned within the first cavity, the flexible container having a closed distal end comprising a distal wall, an open proximal end, a sidewall extending proximally from the distal wall toward the open proximal end, the sidewall integrally formed with the distal wall, the sidewall having an inner surface and an outer surface, the inner surface of the flexible container defining a second cavity, an outer thread on the outer surface of the split-thread protrusion of the housing, the outer thread being sufficient to interlock with a mating feature of a male connector; an open bottom formed by the cylindrical sidewall with an opening to the first cavity within the housing for receiving a needleless connector having an open lumen; an inner thread or a lug on the inner surface of the flexible container, the inner thread being sufficient to interlock with a mating feature of a female needleless connector, a porous absorbent material disposed within the second cavity under radial compression by the inner thread on the inner surface of the flexible container; and a sealing rubber is disposed on the porous absorbent material; a disinfectant or an antimicrobial agent; and a cover disposed over the proximal open end of the housing.
2. The cap of claim 1, wherein the porous absorbent material is a nonwoven material, foam, or a

sponge.
3. The cap of claim 1, wherein the porous absorbent material is soaked with a disinfectant or an antimicrobial agent.
4. The cap of claim 1, wherein the sealing rubber is made of a closed cell foam.
5. The cap of claim 4, wherein the sealing rubber is made of a polyethylene foam.
6. The cap of claim 4, wherein the sealing rubber is made of a thermoplastic elastomer.
7. The cap of claim 4, wherein the sealing rubber is made of a rubber or rubber like foams.
8. The cap of claim 7, wherein the sealing rubber is an EPDM sponges, EVA, Buna-N, silicone, vinyl, neoprene, fluoroelastomers, gum rubber.
9. The cap of claim 1, wherein the flexible container extends essentially from an inner surface of the distal wall toward the open proximal end of the housing.
10. The cap of claim 1, wherein the flexible container extends essentially parallel to the sidewall of the housing.
11. The cap of claim 1, wherein the inner thread and the outer thread have an inclined thread pattern.
12. The cap of claim 1, wherein the inner thread and outer thread have a helical-shaped thread pattern.
13. The cap of claim 1, wherein an exterior wall surface of the sidewall of the housing includes a plurality of grip members.
14. The cap of claim 1, further comprising a disinfectant or an antimicrobial agent.
15. The cap of claim 14, wherein the disinfectant or the antimicrobial agent is selected from isopropyl alcohol, ethanol, 2-propanol, butanol, methylparaben, ethylparaben, propylparaben, propyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene, t-butyl-hydroquinone, chloroxylenol, chlorohexidine, chlorhexidine diacetate, chlorohexidine gluconate, povidone iodine, alcohol, dichlorobenzyl alcohol, dehydroacetic acid, hexetidine, triclosan, hydrogen peroxide, colloidal silver, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, or mixtures thereof.
16. The cap of claim 1, wherein the housing is made of a high density polyethylene or polypropylene material.
17. The cap of claim 1, further comprising a peel seal.
18. The cap of claim 17, wherein the peel seal includes an aluminum or multi-layer polymer film.
19. The cap of claim 1, wherein the porous absorbent material comprises a centrally disposed through hole extending from a distal end to a proximal end of the porous absorbent material.
20. The cap of claim 19, wherein the sealing rubber is disposed in the through hole of the porous absorbent material.
21. The cap of claim 20, wherein the porous absorbent material surrounds the sealing rubber.
22. The cap of claim 19, wherein the sealing rubber is bonded to the absorbent material with a biocompatible adhesive.