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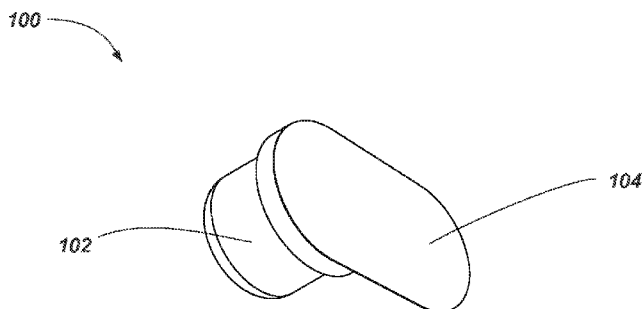


FIG. 1

(57) Abstract: Antimicrobial devices for use with or use with at least a portion of a medical device include a housing and a flexible member configured to secure the housing to the at least a portion of the medical device. Medical device assemblies include an access port configured to at least one of sample fluid from a subject and deliver fluid to a subject and an antimicrobial device adapted to disinfect at least a portion of the access port. Methods of disinfecting a portion of a device include coupling an antimicrobial device to the portion of the device with a flexible member.

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ANTIMICROBIAL DEVICES FOR USE WITH MEDICAL DEVICES AND RELATED ASSEMBLIES AND METHODS

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PRIORITY CLAIM

This application claims the benefit of the filing dates of United States Provisional Patent Application Serial No. 61/663,287, filed June 22, 2012, for “ANTIMICROBIAL DEVICES FOR USE WITH MEDICAL DEVICES AND RELATED ASSEMBLIES AND METHODS” and United States Provisional Patent Application Serial
10 No. 61/663,272, filed June 22, 2012, for “ANTIMICROBIAL DEVICES FOR USE WITH MEDICAL DEVICES AND RELATED ASSEMBLIES AND METHODS,” the disclosure of each of which is hereby incorporated herein in its entirety by this reference.

TECHNICAL FIELD

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The disclosure generally relates to antimicrobial devices for use with medical devices and related assemblies and methods. In particular, embodiments of the disclosure relate to antimicrobial devices for use in disinfecting at least a portion of a medical device, such as, one or more portions of a medical device for delivering fluid to and/or sampling fluid from a subject.

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BACKGROUND

In the medical field and, in particular, within the area of delivery of fluids to a subject and removal of fluids from a subject, a need exists to prevent the transmission of pathogens into or onto a subject from a potentially contaminated
25 surface of a medical device. Such pathogens include microorganisms such as bacteria and viruses. For example, bloodstream infections, which may be caused by microorganisms that enter patients via intravascular catheters, are a significant cause of illness and excess medical costs and may result in serious infections or death.

Traditionally, cleaning a potentially contaminated surface of a medical
30 device includes treating the surface with an alcohol swab. Such alcohol swabs include cotton gauze soaked in, *e.g.*, isopropyl alcohol or ethanol. The swab is applied by a healthcare provider and wiped across surface of the medical device. As the alcohol applied by the pad evaporates, it destroys microorganisms. Impregnating

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medical devices, such as catheters, with various antimicrobial agents is another approach for reducing the chances of contamination of the medical device.

Other devices comprising a cap for cleaning a medical device include United States Patent Application Publication No. US 2007/0112333 to Hoang et al.,
5 published May 17, 2007; United States Patent 7,780,794 to Rogers et al., issued August 24, 2010; United States Patent Application Publication No. US 2011/0044850 to Solomon et al., published February 24, 2011; United States Patent Application Publication No. US 2011/0217212 to Solomon et al., published September 8, 2011; and United States Patent Application Publication No. US
10 2011/0232020 to Rogers et al., published September 29, 2011, the disclosure of each of which is hereby incorporated herein in its entirety by this reference.

DISCLOSURE

Described are antimicrobial devices and related assemblies and methods for
15 disinfecting at least a portion of a medical device, such as, one or more portions of a medical device for at least one of delivering fluid to and sampling fluid from a subject (*e.g.*, an intravenous (IV) device).

Disclosed is an antimicrobial device for use with at least a portion of a medical device. The antimicrobial device may include a housing having a cavity
20 formed therein and an amount of antimicrobial substance disposed within the cavity. The antimicrobial device may further include a flexible membrane comprising a lateral portion extending at least partially across the cavity of the housing to form an opening into the cavity of the housing, wherein only the flexible membrane is configured to secure the housing to a portion of the medical device.

25 Also disclosed is an antimicrobial device for use with at least a portion of a medical device. The antimicrobial device will typically include a housing comprising a volume of antimicrobial substance and a smooth inner surface extending in a direction along at least a portion of a longitudinal axis of the housing. The antimicrobial device may further include a flexible member configured to
30 secure the housing to the at least a portion of the medical device.

Also disclosed is an antimicrobial device including a housing having a cavity formed therein and a volume of antimicrobial substance disposed within the cavity.

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The antimicrobial device further includes a flexible member configured to secure the housing to the at least a portion of the medical device. Such a flexible member comprises a lateral portion extending at least partially across the cavity of the housing to form an opening into the cavity of the housing and a throat portion
5 extending from the lateral portion of the flexible member along the longitudinal axis of the housing into the cavity of the housing.

Also disclosed is an antimicrobial device for use in conjunction with at least a portion of a medical device. The antimicrobial device includes a housing comprising a volume of antimicrobial substance and a flexible member configured
10 to secure the housing to a non-threaded portion of the medical device (*e.g.*, a portion having a substantially smooth surface), configured to secure the housing to a threaded portion of the medical device, or both.

Further disclosed is an antimicrobial device for use with at least a portion of a medical device. The antimicrobial device comprises a housing comprising an
15 amount of antimicrobial substance and a flexible member configured to secure the housing to the portion of the medical device, wherein a proximal end of the housing is oriented to angularly correspond with an end of a y-site medical device proximate a needle access valve of the y-site medical device.

Also disclosed is a medical device assembly including an access port
20 configured to sample fluid from a subject and/or deliver fluid to a subject and an antimicrobial device adapted to disinfect at least a portion of the access port.

Further disclosed is a method of disinfecting a portion of a device with an antiseptic and/or disinfectant solution such as alcohol and/or ethanol. The method includes coupling an antimicrobial device to the portion of the device, retaining the
25 antimicrobial device on the portion of the device with a flexible member for a selected period of time, and removing the antimicrobial device from the portion of the device.

Further disclosed is a method of disinfecting a portion of a device with an antiseptic and/or disinfectant solution such as alcohol and/or ethanol. The method
30 includes coupling an antimicrobial device to the portion of the device and engaging the portion of the device with a throat portion of a flexible member of the antimicrobial device.

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Further disclosed is another method of disinfecting a portion of a device. The method includes coupling an antimicrobial device to the portion of the device and engaging a threaded portion of the device with a flexible member of the antimicrobial device.

5 Yet further disclosed are methods of forming such antimicrobial devices.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a perspective view of an antimicrobial device in accordance with an embodiment of the disclosure.

10 FIG. 2 illustrates a cross-sectional side view of the antimicrobial device shown in FIG. 1.

FIG. 3 illustrates an exploded side view of the antimicrobial device shown in FIG. 1.

15 FIG. 4 illustrates a perspective view of the antimicrobial device shown in FIG. 1 with the foil seal removed.

FIG. 5 illustrates a cross-sectional side view of an antimicrobial device in accordance with another embodiment of the disclosure.

FIG. 6 illustrates an exploded side view of the antimicrobial device shown in FIG. 5.

20 FIG. 7 illustrates a cross-sectional side view of an antimicrobial device in accordance with yet another embodiment of the disclosure.

FIG. 8 illustrates an exploded side view of the antimicrobial device shown in FIG. 7.

25 FIG. 9 illustrates a partial cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device shown in FIGS. 1 through 4 received on a portion of a medical device.

FIG. 10 illustrates a partial cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device shown in FIGS. 1 through 4 received on a portion of another medical device including a threaded portion.

30 FIG. 11 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device shown in FIGS. 5 and 6 received on a portion of a medical device.

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FIG. 12 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device shown in FIGS. 5 and 6 received on a portion of another medical device including a threaded portion.

FIG. 13 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device shown in FIGS. 7 and 8 received on a portion of a medical device.

FIG. 14 illustrates a cross-sectional side view of an antimicrobial device in accordance with yet another embodiment of the disclosure.

FIG. 15 illustrates an exploded side view of the antimicrobial device shown in FIG. 13.

FIG. 16 illustrates a perspective view of the antimicrobial device shown in FIG. 13 with the foil seal removed.

FIG. 17 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device shown in FIGS. 14 through 16 received on a portion of a medical device.

FIG. 18 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device shown in FIGS. 14 through 16 received on a portion of another medical device including a threaded portion.

MODE(S) FOR CARRYING OUT THE INVENTION

In the following detailed description, reference is made to the accompanying drawings that depict, by way of illustration, specific embodiments in which the disclosure may be practiced. However, other embodiments may be utilized, and structural, logical, and configurational changes may be made without departing from the scope of the disclosure. The illustrations presented herein are not meant to be actual views of any particular material, apparatus, assembly, system, or method, but are merely idealized representations that are employed to describe embodiments of the disclosure. The drawings presented herein are not necessarily drawn to scale. Additionally, elements common between drawings may retain the same numerical designation.

Generally, antimicrobial devices as described herein may be utilized to disinfect potentially contaminated surfaces of various devices (*e.g.*, medical

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devices). Related assemblies and methods are also disclosed herein. Such antimicrobial devices may be configured as a cap having a volume of antimicrobial substance therein. For example, the volume of antimicrobial substance may comprise a disinfectant and/or antiseptic (*e.g.*, a disinfectant and/or antiseptic in a fluid state) such as, for example, alcohol (*e.g.*, isopropyl alcohol) at various concentrations (*e.g.*, 50 to 90%), ethanol at various concentrations (*e.g.*, ranging from 50 to 95%), and combinations of these and any other suitable disinfectant and/or antiseptics. The cap may be coupled to and used to protect (*e.g.*, by covering a portion of the medical device) and/or disinfect a portion of medical device by receiving the portion of the medical device (*e.g.*, at least temporarily) within the cap.

In some embodiments, such antimicrobial devices reduce the likelihood of microorganisms entering the bloodstream of a subject via a medical device or assembly configured to deliver fluid to a subject and/or remove a fluid from a subject. For example, the antimicrobial device may be utilized with one or more portions of fluid flow or fluid delivery systems such as, for example, an intravenous (IV) device that delivers substances (*e.g.*, fluid) to and from one or more veins of a subject. Such IV devices may include a peripheral IV line having a cannula in communication with the vasculature of a subject. The IV device may include one or more connections, valves, and access ports for delivering fluids to and from the subject that may become contaminated while the IV device is connected to the subject (*e.g.*, in fluid communication with one or more portions of subject's internal systems). For example, the peripheral IV line may include one or more of needle injection sites (*e.g.*, y-sites), needleless injection sites (*e.g.*, a luer-activated valve (LAV)), and other fluid transfer devices. Accordingly, antimicrobial devices as disclosed herein may be utilized with any such connectors, valves, and access ports in such fluid flow or fluid delivery systems.

The antimicrobial devices disclosed herein may be particularly useful in at least temporarily (*e.g.*, transiently, for a selected period a time) connecting to (*e.g.*, coupling and retaining) to one or more portions of a medical device, such as, the various portions of fluid systems discussed above in order to disinfect and/or protect portions of the medical device that are exposed to potential contamination during use (*e.g.*, during use with a subject). For example, the antimicrobial device may

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disinfect and protect a portion of the medical device from further contamination as the antimicrobial device remains secured to the medical device in disinfecting contact with the portion of the medical device.

Such antimicrobial devices are typically configured to connect and secure to
5 both a portion of a medical device lacking a threaded connection and/or a portion of a medical including threaded connection (*e.g.*, threads of a Luer connection). In other words, the antimicrobial device may be configured to connect and secure to a portion of medical device with or without a threaded connection. For example, as discussed below in greater detail, the antimicrobial device includes a flexible
10 member (*e.g.*, a membrane) configured to engage with a portion of a non-threaded (*e.g.*, having a smooth surface, a flat surface, an uneven non-threaded surface, or combinations thereof) access port of a medical device (*e.g.*, a needle injection site of an IV device). The flexible membrane of the antimicrobial device may also engage with a portion of a threaded portion (*e.g.*, threads of Luer connection) of an access
15 port of a medical device (*e.g.*, a needleless injection site of an IV device). In other words, the flexible member alone may engage and secure the threaded portion (*e.g.*, the threads) of the medical device to retain the portion of the medical device within a housing of the antimicrobial device without the need for a set of complementary threads on the housing.

20 In some embodiments, the flexible member or membrane of the antimicrobial device is flexible in the sense that the membrane is easily deformable by a medical practitioner as the practitioner installs and removes the antimicrobial device from the portion of the medical by hand. The stiffness of the flexible member may be selected based on the configuration of the flexible member of the
25 antimicrobial device. For example, a flexible member such as that shown in FIG. 10, which has a relatively small contact surface with the medical device, may have a relatively greater stiffness in order to retain the medical device. A flexible member such as that shown in FIG. 12, which has a relatively larger contact surface with the medical device, may have a relatively lower stiffness in order to retain the medical
30 device.

Such antimicrobial devices including a flexible member may be relatively more robust than a threaded cap having a disinfectant therein as such threaded caps

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are generally limited to connecting only with one particular type of a complementary threaded portion of a medical device. Further, the threading protruding from an inner surface within the threaded cap limits the size (*e.g.*, diameter) of the portions of the medical device that may be received within the threaded cap.

5 FIG. 1 illustrates a perspective view of an antimicrobial device 100. As shown in FIG. 1, the antimicrobial device 100 includes a housing 102 formed as cap and a sealing member 104. The sealing member 104 may comprise any suitable nonporous material configured to at least partially seal a volume of fluid within the housing 102 of the antimicrobial device 100. For example, the sealing member 104
10 may have a pull-tab configuration (*e.g.*, a metal tab formed from a foil, polymer tab, *etc.*) having a first portion sealed about the housing 102 and a second portion for a practitioner to grab in order to remove the sealing member 104.

 FIGS. 2 and 3 illustrate a cross-sectional side view of the antimicrobial device 100 and an exploded view of the antimicrobial device 100, respectively. As
15 shown in FIGS. 2 and 3, the antimicrobial device 100 includes a volume of antimicrobial substance 106 within the housing 102. As discussed above, the antimicrobial substance 106 may comprise at least one of a disinfectant and antiseptic in a fluid state at various concentrations. The volume of antimicrobial substance 106 will typically include a pad (*e.g.*, sponge material, such as an open-
20 cell foam, felt, fiber matrix, combinations thereof, *etc.*) configured to retain the antimicrobial substance within the housing 102. The pad of the volume of antimicrobial substance 106 may be at least partially compressible such that the volume of antimicrobial substance 106 may fit within the housing 102 (*e.g.*, positioned proximate a distal end 122 of the housing 102) and may at least partially
25 surround a portion of a medical device when received within the housing 102. For example, the pad of the volume of antimicrobial substance 106 may at least partially deform to receive the portion of the medical device inserted into the housing 102 (*see, e.g.*, FIG. 9).

 The antimicrobial device 100 may include a membrane 108 (*e.g.*, a flexible
30 membrane) configured to at least partially yield (*e.g.*, elastically yield) about a portion of a medical device when inserted within the housing 102. For example, the membrane 108 of the antimicrobial device 100 may be positioned proximate to (*e.g.*,

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at) a proximal end 120 of the housing 102. The membrane 108 may be secured to the proximal end 120 of the housing 102. In some embodiments, the antimicrobial device 100 includes a retaining ring 110 extending around an outer surface of the housing 102 for securing (*e.g.*, via an interference or friction fit) at least a portion of the membrane 108 (*e.g.*, a longitudinal portion 109 of the membrane 108 extending along a longitudinal axis 124 of the housing 102) to a portion of the housing 102 (*e.g.*, a reduced diameter portion 114). For example, the retaining ring 110 may be sized to have a diameter substantially equal to or slightly smaller than the diameter of housing 102 or the combined diameter of the housing 102 and the longitudinal portion 109 of the membrane 108. The retaining ring 110 may be forced over the housing 102 and the longitudinal portion 109 of the membrane 108 to secure the membrane 108 to the housing 102. In other embodiments, one or more portions of the membrane 108 (*e.g.*, the longitudinal portion 109) may be secured to the housing 102 by any other suitable process (*e.g.*, by adhesion, welding, overmolding, or combinations thereof).

The membrane 108 will typically extend across the proximal end 120 of the housing 102 at least partially enclosing the housing 102. For example, the membrane 108 may include a lateral portion 111 extending in a direction transverse to (*e.g.*, perpendicular to) the longitudinal axis 124 of the housing 102.

Referring still to FIGS. 2 and 3, the housing 102 of the antimicrobial device 100 may be configured as a cap for receiving at least a portion of one or more medical devices. For example, the housing 102 of the antimicrobial device 100 may have a substantially smooth inner surface 126 (*e.g.*, a substantially flat surface, a substantially even surface, a substantially continuous surface). In other words, the housing 102 of the antimicrobial device 100 may lack threads such that the inner surface 126 extending along the longitudinal axis 124 (*e.g.*, centerline) of the housing 102 is substantially smooth and unencumbered for receiving one or more portions of a medical device (*e.g.*, portions of varying sizes, portion lacking threading, or combinations thereof). That is, the lack of protrusions such as threads within the housing 102 enable the inner volume or diameter of the housing 102 to be maximized for receiving one or more portions of a medical device therein.

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The sealing member 104 may be secured to (*e.g.*, adhered to) a portion of the antimicrobial device 100 (*e.g.*, the housing 102, the membrane 108, the retaining ring 110, or combinations thereof) to seal the volume of antimicrobial substance 106 within the housing 102.

5 FIG. 4 illustrates a perspective view of the antimicrobial device 100 with the sealing member 104 removed. Referring to FIG. 4, the membrane 108 includes an opening 112 for receiving a portion of a medical device. In some embodiments, the opening 112 may be a circular opening positioned at the center of the membrane 108. In other embodiments, the opening 112 is formed as any suitable
10 shape or as one or more slits in the membrane 108 suitable for enabling a portion of a medical device to pass therethrough. In some embodiments, the membrane 108 is formed to initially seal the housing 102 (*e.g.*, the membrane is initially without opening 112) and at least a portion of the membrane 108 may be formed to fail (*e.g.*, tear) under a force applied to the membrane 108 (*e.g.*, by a portion of the medical
15 device) in order to form the opening 112. In other words, at least a portion of the membrane 108 (*e.g.*, one or more slits) may be formed as a relatively weaker portion of the membrane 108 configured to fail under a force applied thereto in order to form the opening 112.

FIGS. 5 and 6 illustrate a cross-sectional side view of an antimicrobial
20 device 200 and an exploded view of the antimicrobial device 200, respectively, that may be the same or somewhat similar to and may include one or more features of the antimicrobial device 100 discussed above with regard to FIGS. 1 through 4. For example, the antimicrobial device 200 includes a housing 102, a sealing member 104, and a volume of antimicrobial substance 106. As shown in FIGS. 5
25 and 6, the antimicrobial device 200 includes a membrane 208, which may be somewhat similar to membrane 108 (FIG. 2), and may include a throat portion 216. For example, the membrane 208 may include the throat portion 216 extending along a longitudinal axis 124 of the housing 104. In some embodiments, the throat portion 216 is formed to have a substantially cylindrical shape (*e.g.*, a cylinder being
30 coaxial with the housing 104) and may extend from a portion of the membrane 208 (*e.g.*, a lateral portion 211) into the housing 102 (*e.g.*, toward the volume of antimicrobial substance 106 within the housing 102). The throat portion 216 may

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extend around a portion of the medical device received within the housing and act to enhance the coupling (and retaining) of the portion of the medical device in the housing 102 by the membrane 208.

FIGS. 7 and 8 illustrate a cross-sectional side view of an antimicrobial device 300 and an exploded view of the antimicrobial device 300, respectively, that may be the same or somewhat similar to and may include one or more features of the antimicrobial devices 100, 200 discussed above with regard to FIGS. 1 through 6. The depicted antimicrobial device 300 includes a housing 302, a sealing member 104, and an amount of antimicrobial substance 106. As shown in FIGS. 7 and 8, the housing 302 may have a proximal end 320 that is oriented to angularly correspond with an end of a y-site medical device (*e.g.*, an end of a y-site medical device including a needle access valve (*see, e.g.*, FIG. 13)). For example, the housing 302 may have a proximal end 320 that is angularly offset from a distal end 322. The end surface 303 of the housing 302 and a longitudinal axis 324 of the housing 302 are positioned at an oblique angle relative to each other. In other words, the end surface 303 is formed within a plane that is not perpendicular to (*e.g.*, does not form a right angle with) the longitudinal axis 324 of the housing 302. In some embodiments, the housing 302 may have a substantially trapezoidal shape (*e.g.*, a right trapezoidal shape).

The antimicrobial device 300 may include a membrane 308, which may be somewhat similar to membranes 108, 208 (FIGS. 2 and 5) (*e.g.*, membrane 308 may include a throat portion). The membrane 308 be secured (*e.g.*, adhered) to the housing 302. The angularly offset end surface 303 of the housing 302 may also angularly offset the membrane 308 (and an opening 312 formed therein) from the longitudinal axis 324 of the housing 302 (*e.g.*, the membrane 302 and the longitudinal axis 324 of the housing 302 are positioned at an oblique angle relative to each other). The membrane 308 may be elliptical in shape rather than the circular shape of membrane 108 in order to correspond with to the end surface 303 of the housing 302. The antimicrobial device 300 including the offset end surface 303 may enhance the coupling (and retaining) of a portion of the medical device such as a y-site as the housing 102 and the membrane 208 correspond with the shape of the y-site at an end thereof (*see, e.g.*, FIG. 13).

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FIG. 9 illustrates a partial cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device 100 shown in FIGS. 1 through 4 received on a portion of a medical device 10. As shown in FIG. 9, the portion of the medical device 10 (*e.g.*, a non-threaded portion of a needle access site) may be inserted through the opening 112 in the membrane 108. For example, the portion of the medical device 10 may be forced through the opening 112 to elastically deform at least a portion of the membrane 108.

The portion of the medical device 10 may be inserted into the housing 102 in order to at least partially disinfect the portion of the medical device 10 with the volume of antimicrobial substance 106. In some embodiments, the portion of the medical device 10 at least partially deforms the volume of antimicrobial substance 106 (*e.g.*, the pad holding the volume of antimicrobial substance 106).

In some embodiments, an inner portion of the membrane 108 will act to secure the portion of the medical device 10 within the housing 102. For example, the opening 112 may be sized such that the membrane 108 is elastically deformed in order to insert or remove the portion of the medical device 10. Accordingly, the portion of the medical device 10 may be retained in the housing 102 until enough force is applied to remove the portion of the medical device 10 from the housing 102 by pulling the portion of the medical device 10 back through the opening 112 in the membrane 108. In some embodiments, the membrane 108 may be sized such that the inner portion of the membrane 108 surrounding and forming the opening 112 may contact a portion of the medical device 10 such that friction between the portion of the medical device 10 and the inner portion of the membrane 108 acts to retain the portion of the medical device 10 within the housing 102. In some embodiments, the membrane 108 is sized such that the inner portion of the membrane 108 is deformed (*e.g.*, elastically deformed) to extend in direction along the longitudinal axis 124 of the housing 102 to increase the contact surface area between the membrane 108 and the portion of the medical device 10 (*see, e.g.*, FIG. 10).

FIG. 10 illustrates a partial cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device 100 shown in FIGS. 1 through 4 received on a threaded portion 22 of a medical device 20. As shown in FIG. 10, the threaded portion 22 of the medical device 20 (*e.g.*, a threaded Luer connection of

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a needleless access site) may be inserted through the opening 112 in the membrane 108. For example, the threaded portion 22 of the medical device 20 may be forced through the opening 112 to elastically deform at least a portion of the membrane 108.

5 The portion of the medical device 20 may be inserted into the housing 102 in order to at least partially disinfect the portion of the medical device 20 with the volume of antimicrobial substance 106. In some embodiments, the portion of the medical device 20 at least partially deforms the volume of antimicrobial substance 106 (*e.g.*, the pad holding the volume of antimicrobial substance 106).

10 In some embodiments, an inner portion of the membrane 108 acts to secure the threaded portion 22 of the medical device 20 within the housing 102 through interference between the threaded portion 22 of the medical device 20. For example, the opening 112 may be sized such that the membrane 108 must be elastically deformed in order to insert or remove the threaded portion 22 of the medical device
15 20. By way of further example, the opening 112 may be sized such that the diameter of the opening 112 is substantially equal to or less than one of the diameter of the surface 26 of the medical device on which the threads 24 are formed and protrude or the outer diameter of the threads 24. Accordingly, the threaded portion 22 of the medical device 20 may be retained in the housing 102 until enough force is applied
20 to remove the threaded portion 22 of the medical device 20 from the housing 102 by pulling the threaded portion 22 of the medical device 20 back through the opening 112 in the membrane 108. In some embodiments, the inner portion of the membrane 108 surrounding and forming the opening 112 contacts a portion (*e.g.*, the threads 24 of the threaded portion 22) of the medical device 20 such that friction between the
25 threaded portion 22 of the medical device 20 and the inner portion of the membrane 108 acts to retain the threaded portion 22 of the medical device 20 within the housing 102.

FIG. 11 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device 200 shown in FIGS. 5 and 6 received on a
30 portion of the medical device 10 (*e.g.*, a needle access valve) in a manner similar to that discussed above with reference to FIG. 9. As shown in FIG. 11, the portion of the medical device 10 (*e.g.*, a non-threaded portion of a needle access site) may be

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inserted through the opening 212 in the membrane 208 and at least partially into the throat portion 216 of the membrane 208. The throat portion 216 of membrane 208 may provide a greater contact surface area between the portion of the medical device 10 and the membrane 208 to retain the portion of the medical device 10 in the housing 102.

FIG. 12 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device 200 shown in FIGS. 5 and 6 received on a portion of the medical device 20 including the threaded portion 22 (*e.g.*, a needleless access valve) in a manner similar to that discussed above with reference to FIG. 10. As shown in FIG. 12, the portion of the medical device 20 (*e.g.*, the threaded portion 22 of a needleless access site) may be inserted through the opening 212 in the membrane 208 and at least partially into the throat portion 216 of the membrane 208. The throat portion 216 of membrane 208 may provide a greater contact surface area between the threaded portion 22 of the medical device 20 and the membrane 208 to retain the threaded portion 22 of the medical device 20 in the housing 102. For example, the throat portion 216 may be sized and configured to extend along a majority (*e.g.*, an entirety) of the threaded portion 22 and engage the threads 24 of the threaded portion 22 of the medical device 20.

FIG. 13 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device 300 shown in FIGS. 7 and 8 received on a portion of the medical device 10 (*e.g.*, a y-site needle access valve) in a manner similar to that discussed above with reference to FIG. 9. As shown in FIG. 13, the portion of the medical device 10 (*e.g.*, a non-threaded portion of a needle access site) may be inserted through the opening 312 in the membrane 308. The angular offset or angle of the end surface 303 of the housing 302 and the membrane 308 mimic the angle of the second valve or passageway 14 enabling a greater portion of the medical device 10 to be received within the housing 302. Such a configuration may be particularly useful fitting and securing to a wide variety of y-site medical devices (*e.g.*, medical devices of differing sizes and configurations and medical devices made by differing manufacturers) such as the medical device 10 shown in FIG. 13 having a non-threaded portion and the medical device 20 shown in FIG. 12 having a threaded portion in order to disinfect a portion of the medical devices.

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FIGS. 14 and 15 illustrate a cross-sectional side view of an antimicrobial device 400 and an exploded view of the antimicrobial device 400, respectively, that may be the same or somewhat similar to and may include one or more features of the antimicrobial devices 100, 200, 300 discussed above with regard to FIGS. 1 through 8.

The antimicrobial device 400 may include a membrane 408 (*e.g.*, a flexible membrane) configured to at least partially yield (*e.g.*, elastically yield) about a portion of a medical device when inserted within the housing 102. For example, the membrane 408 of the antimicrobial device 400 may be positioned proximate to (*e.g.*, at) a proximal end 420 of the housing 102. The membrane 408 may be secured to the proximal end 420 of the housing 102. In some embodiments, the antimicrobial device 400 includes a retaining ring 110 extending around an outer surface of the housing 102 for securing (*e.g.*, via an interference or friction fit) at least a portion of the membrane 408 (*e.g.*, a longitudinal portion 409 of the membrane 408 extending along a longitudinal axis 124 of the housing 102) to the housing 102. For example, the retaining ring 110 may be sized to have a diameter substantially equal to or slightly smaller than the diameter of housing 102 or the combined diameter of the housing 102 and the longitudinal portion 409 of the membrane 408. The retaining ring 110 may be forced over the housing 102 and the longitudinal portion 409 of the membrane 408 to secure the membrane 408 to the housing 102. In other embodiments, one or more portions of the membrane 408 (*e.g.*, the longitudinal portion 409) is secured to the housing 102 by any other suitable process (*e.g.*, by adhesion, welding, overmolding, or combinations thereof).

The membrane 408 may extend across the proximal end 420 of the housing 102 at least partially enclosing the housing 102. For example, the membrane 408 may include a lateral portion 411 extending in a direction transverse to (*e.g.*, perpendicular to) the longitudinal axis 124 of the housing 102.

The membrane 408 may include a throat portion 416 forming an opening 412 in the antimicrobial device 400 for receiving the portion of the medical device. For example, the membrane 408 may include the throat portion 416 extending along the longitudinal axis 124 of the housing 102. In some embodiments, the throat portion 416 is formed to have a substantially cylindrical shape (*e.g.*, a cylinder being coaxial

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with the housing 102) and extends from a portion of the membrane 408 (*e.g.*, the lateral portion 411) into the housing 102 (*e.g.*, toward the volume of antimicrobial substance 106 within the housing 102). The throat portion 416 may extend around a portion of the medical device received within the housing 102 and act to enhance the coupling (and retaining) of the portion of the medical device in the housing 102 by the membrane 408.

In some embodiments, the throat portion 416 of the membrane 408 includes threads 418 (*e.g.*, threads of Luer connector) extending from an inner surface of the throat portion 416. The threads 418 may be configured to receive and engage with a complementary threaded portion of a medical device as discussed below (*see* FIG. 18). The threads 418 may also be formed from a flexible material (*e.g.*, from the same material as the membrane and/or integral with the membrane 408). The flexible threads 418 may yield (*e.g.*, elastically yield) with other portions of the membrane 408 (*e.g.*, the throat portion 416, the lateral portion 411, or combinations thereof) to receive a non-threaded portion of a medical device (*see* FIG. 17). In other words, portions of the flexible membrane 408 (*e.g.*, the flexible threads 418 and the throat portion 416) may enable both a threaded and non-threaded portion of a medical device to be received and secured by the membrane 408.

Referring still to FIGS. 14 and 15, the depicted housing 102 of the antimicrobial device 400 is configured as a cap for receiving at least a portion of one or more medical devices. For example, the housing 102 of the antimicrobial device 400 may have a substantially smooth inner surface 126 (*e.g.*, a substantially flat surface, a substantially even surface, a substantially continuous surface). In other words, the housing 102 of the antimicrobial device 400 may lack threads such that the inner surface 126 extending along the longitudinal axis 124 (*e.g.*, centerline) of the housing 102 is substantially smooth and unencumbered for receiving one or more portions of a medical device (*e.g.*, portions of varying sizes, portion lacking threading, or combinations thereof). That is, the lack of protrusions such as threads within the housing 102 enable the inner volume or diameter of the housing 102 to be maximized for receiving one or more portions of a medical device therein. In some embodiments, and as discussed above, the threads 418 may be provided on the membrane 408 rather than on the housing 102 formed as a cap.

The sealing member 104 may be secured to (*e.g.*, adhered to) a portion of the antimicrobial device 400 (*e.g.*, the housing 102, the membrane 408, the retaining ring 110, or combinations thereof) to seal the volume of antimicrobial substance 106 within the housing 102.

5 FIG. 16 illustrates a perspective view of the antimicrobial device 400 with the sealing member 404 removed. Referring to FIG. 16, the membrane 408 includes the opening 412 formed by the lateral portion 411 and the throat portion 416 of the membrane 408 for receiving a portion of a medical device. In some embodiments, the opening 412 is a circular opening positioned at the center of the membrane 408.

10 In other embodiments, the opening 412 is formed as any suitable shape or as one or more slits in the membrane 408 suitable for enabling a portion of a medical device to pass therethrough. In some embodiments, the membrane 408 is formed to initially seal the housing 102 (*e.g.*, initially, the membrane 408 is without opening 412) and at least a portion of the membrane 408 is formed to fail (*e.g.*, tear) under a force

15 applied to the membrane 408 (*e.g.*, by a portion of the medical device) in order to form the opening 412. In other words, at least a portion of the membrane 408 (*e.g.*, one or more slits) may be formed as a relatively weaker portion of the membrane 408 configured to fail under a force applied thereto in order to form the opening 412.

FIG. 17 illustrates a cross-sectional side view of an antimicrobial device such

20 as, for example, the antimicrobial device 400 shown in FIGS. 14 through 16 received on a portion of a medical device 10. As shown in FIG. 17, the portion of the medical device 10 (*e.g.*, a non-threaded portion of a needle access site) may be inserted through the opening 412 in the membrane 408 and at least partially into the throat portion 416 of the membrane 408. For example, the portion of the medical

25 device 10 may be forced through the opening to elastically deform at least a portion of the membrane 408. For example, the portion of the medical device 10 having a substantially smooth surface (*e.g.*, lacking threads) may be forced through the opening to elastically deform one or more of the lateral portion 411, the throat portion 416, and the threads 418 of the membrane 408. The throat portion 416 (and,

30 in some embodiments, the threads 418) of the membrane 408 may provide a greater contact surface area between the portion of the medical device 10 and the membrane 408 to retain the portion of the medical device 10 in the housing 102.

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The portion of the medical device 10 may be inserted into the housing 102 in order to at least partially disinfect the portion of the medical device 10 with the volume of antimicrobial substance 106. In some embodiments, the portion of the medical device 10 at least partially deforms the volume of antimicrobial substance 106 (*e.g.*, the pad holding the volume of antimicrobial substance 106).

In some embodiments, an inner portion of the membrane 408 (*e.g.*, the throat portion 416 and/or threads 418) will act to secure the portion of the medical device 10 within the housing 102. For example, the opening 412 and throat portion 416 may be sized such that the membrane 408 must be elastically deformed in order to insert or remove the portion of the medical device 10. Accordingly, the portion of the medical device 10 may be retained in the housing 102 until enough force is applied to remove the portion of the medical device 10 from the housing 102 by pulling the portion of the medical device 10 back through the opening 412 in the membrane 408. In some embodiments, the membrane 408 is sized such that the inner portion of the membrane 408 (*e.g.*, the throat portion 416 and/or threads 418) surrounding and forming the opening 412 contact a portion of the medical device 10 such that friction between the portion of the medical device 10 and the inner portion of the membrane 408 acts to retain the portion of the medical device 10 within the housing 102. In some embodiments, the throat portion 416 (and, in some embodiments, the threads 418) of the membrane 408 provides a greater contact surface area between the portion of the medical device 10 and the membrane 408 to retain the portion of the medical device 10 in the housing 102.

FIG. 18 illustrates a cross-sectional side view of an antimicrobial device such as, for example, the antimicrobial device 400 shown in FIGS. 14 through 16 received on a threaded portion 22 of a medical device 20. As shown in FIG. 18, the threaded portion 22 of the medical device 20 (*e.g.*, a threaded Luer connection of a needleless access site) may be inserted through the opening 412 in the membrane 408 and at least partially into the throat portion 416 of the membrane 408. In some embodiments, the threads 418 in the throat portion 416 of the membrane 408 engages with complementary threads 24 on the threaded portion 22 of the medical device 20 to secure the threaded portion 22 of the medical device 20 within the housing 102.

In other embodiments, and similar to that discussed above with reference to FIG. 17, the threaded portion 22 of the medical device 20 may be forced through the opening 412 to elastically deform at least a portion of the membrane 408 (*e.g.*, the throat portion 416 and/or the threads 418). For example, the inner portion of the membrane 408 surrounding and forming the opening 412 (*e.g.*, the throat portion 416 and/or threads 418) may contact a portion of the medical device 20 (*e.g.*, the threads 24 of the threaded portion 22) such that friction between the threaded portion 22 of the medical device 20 and the inner portion of the membrane 408 acts to retain the threaded portion 22 of the medical device 20 within the housing 102.

10 The portion of the medical device 20 may be inserted into the housing in order to at least partially disinfect the portion of the medical device 20 with the volume of antimicrobial substance 106. In some embodiments, the portion of the medical device 20 at least partially deforms the volume of antimicrobial substance 106 (*e.g.*, the pad holding the volume of antimicrobial substance 106).

15 Accordingly, as discussed herein, the membrane 108, 208, 308, 408 may enable the antimicrobial device 100, 200, 300, 400 to be retained on a non-threaded portion of a medical device such as, for example, a needle access site, a threaded portion of a medical device such as, for example, a needleless access site, or combinations thereof.

20 In some embodiments, the antimicrobial device is formed with one or more suitable materials such as, for example, metals, alloys, polymers, ceramics, combinations thereof, *etc.* For example, the membrane of the antimicrobial device may be formed from a flexible material such a silicon or a polymer. The housing of the antimicrobial device may be formed from a polymer such as, for example, a polyethylene, or other high-density polymers. The retaining ring of the antimicrobial device may be formed from polymer such as, for example, a polyethylene, polyvinylchloride, or other high-density polymers.

25 Once being apprised of the instant antimicrobial devices, one of ordinary skill in the art will be readily able to make (*e.g.*, by injection molding) and assemble
30 the device.

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CLAIMS

What is claimed is:

- 5 1. An antimicrobial device for use with at least a portion of a medical device, the antimicrobial device comprising:
a housing having a cavity formed therein and an amount of antimicrobial substance disposed within the cavity; and
a flexible membrane comprising a lateral portion extending at least partially across
10 the cavity of the housing to form an opening into the cavity of the housing, wherein only the flexible membrane is configured to secure the housing to a portion of the medical device.
- 15 2. The antimicrobial device of claim 1, wherein the flexible member comprises a throat portion extending from the lateral portion of the flexible member along a longitudinal axis of the housing into the cavity of the housing.
- 20 3. The antimicrobial device of claim 2, wherein the throat portion of the flexible member comprises threads formed on an inner surface of the throat portion.
- 25 4. The antimicrobial device of claim 3, wherein the threads of the throat portion of the flexible member are configured to engage with and extend along complementary threads of a threaded portion of the medical device when the threaded portion of the medical device is received within the housing.
5. The antimicrobial device of claim 3, wherein the threads of the throat portion of the flexible member comprise a Luer connection.
- 30 6. The antimicrobial device of any one of claims 2 through 5, wherein the throat portion of the flexible member is configured to engage with and extend along a non-threaded portion of the medical device when the portion of the medical device is received within the housing.

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7. The antimicrobial device of any one of claims 2 through 5, wherein the throat portion of the flexible member is configured to engage with and extend along a threaded portion of the medical device when the portion of the medical device is received within the housing.

8. The antimicrobial device of any one of claims 1 through 5, wherein the flexible member is configured to engage with both a needle access site and a needleless access site.

9. The antimicrobial device of any one of claims 1 through 5, wherein the housing does not have threads formed on an inner surface of the housing.

10. The antimicrobial device of any one of claims 1 through 5, wherein the housing comprises a smooth inner surface extending in a direction along at least a portion of the longitudinal axis of the housing.

11. The antimicrobial device of claim 1, wherein a proximal end of the housing is oriented to angularly correspond with an end of a y-site medical device proximate a needle access valve.

12. The antimicrobial device of claim 1, wherein an end surface at a proximal end of the housing and the flexible member lies in a plane that forms an oblique angle with a longitudinal axis of the housing.

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13. An antimicrobial device for use with at least a portion of a medical device, the antimicrobial device comprising:
- a housing comprising an amount of antimicrobial substance, wherein the inner surface of the housing is free of threads formed thereon; and
- 5 a flexible member configured to secure the housing to the at least a portion of the medical device.
14. An antimicrobial device for use with at least a portion of a medical device, the antimicrobial device comprising:
- 10 a housing having a cavity formed therein and an amount of antimicrobial substance disposed within the cavity; and
- a flexible member configured to secure the housing to the at least a portion of the medical device, the flexible member comprising a lateral portion extending at least partially across the cavity of the housing to form an opening into the
- 15 cavity of the housing and a throat portion extending from the lateral portion of the flexible member along the longitudinal axis of the housing into the cavity of the housing.
15. The antimicrobial device of claim 14, wherein the throat portion of
- 20 the flexible member comprises threads formed on an inner surface of the throat portion.
16. An antimicrobial device for use with at least a portion of a medical device, comprising:
- 25 a housing comprising an amount of antimicrobial substance; and
- a flexible membrane configured to secure the housing to a non-threaded portion of the medical device.

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17. A medical device assembly comprising:
an access port configured to at least one of sample fluid from a subject and deliver
fluid to a subject; and
the antimicrobial device of any one of claims 1 through 16 adapted to disinfect at
5 least a portion of the access port.

18. The medical device assembly of claim 17, wherein the access port
comprises a needle injection site.

10 19. The medical device assembly of claim 17, wherein the access port
comprises a Luer connection having threads and wherein the flexible element of the
antimicrobial device is configured to engage the threads of the access port when the
access port is received within the housing.

15 20. A method of disinfecting a portion of a device, the method
comprising:
coupling the antimicrobial device of any one of claims 1 through 16 to the portion of
the device;
retaining the antimicrobial device on the portion of the device with only the flexible
20 member for a selected period of time; and
removing the antimicrobial device from the portion of the device.

21. A method of disinfecting a portion of a device, the method
comprising:
25 coupling an antimicrobial device comprising a flexible member having an elongated
throat portion extending along a longitudinal axis of a housing of the
antimicrobial device to the portion of the device; and
engaging the portion of the device with the elongated throat portion of the flexible
member of the antimicrobial device.

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22. A method of disinfecting a portion of a device, the method comprising:

coupling an antimicrobial device comprising a flexible member to the portion of the device;

- 5 retaining the antimicrobial device on the portion of the device with only the flexible member for a selected period of time; and
removing the antimicrobial device from the portion of the device.

23. The method according to claim 22, further comprising engaging a
10 threaded portion of the device with the flexible member of the antimicrobial device.

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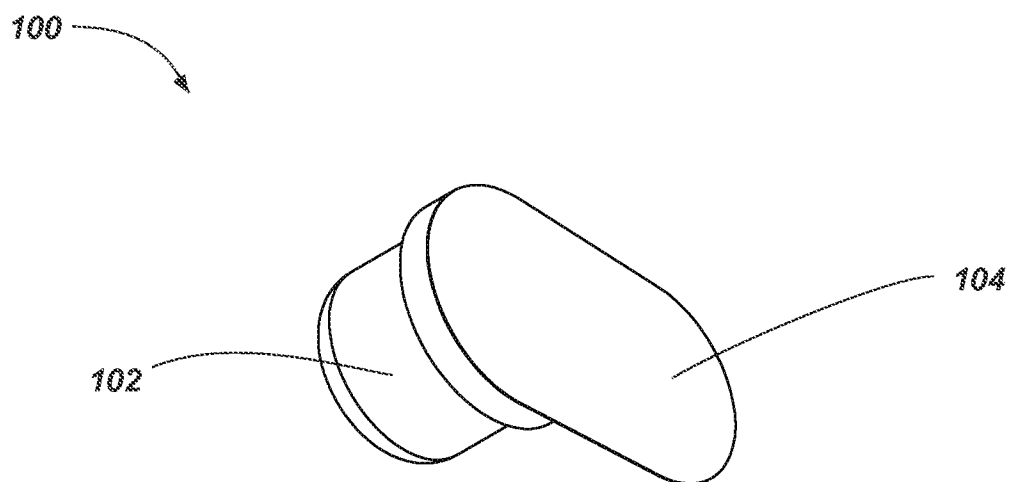


FIG. 1

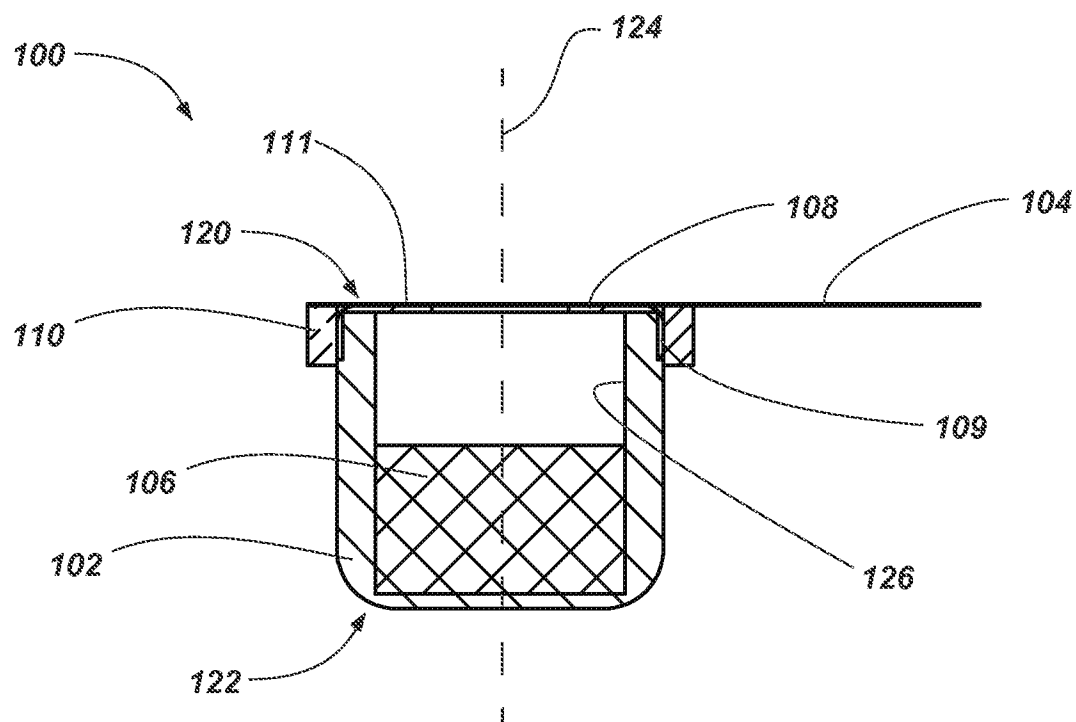


FIG. 2

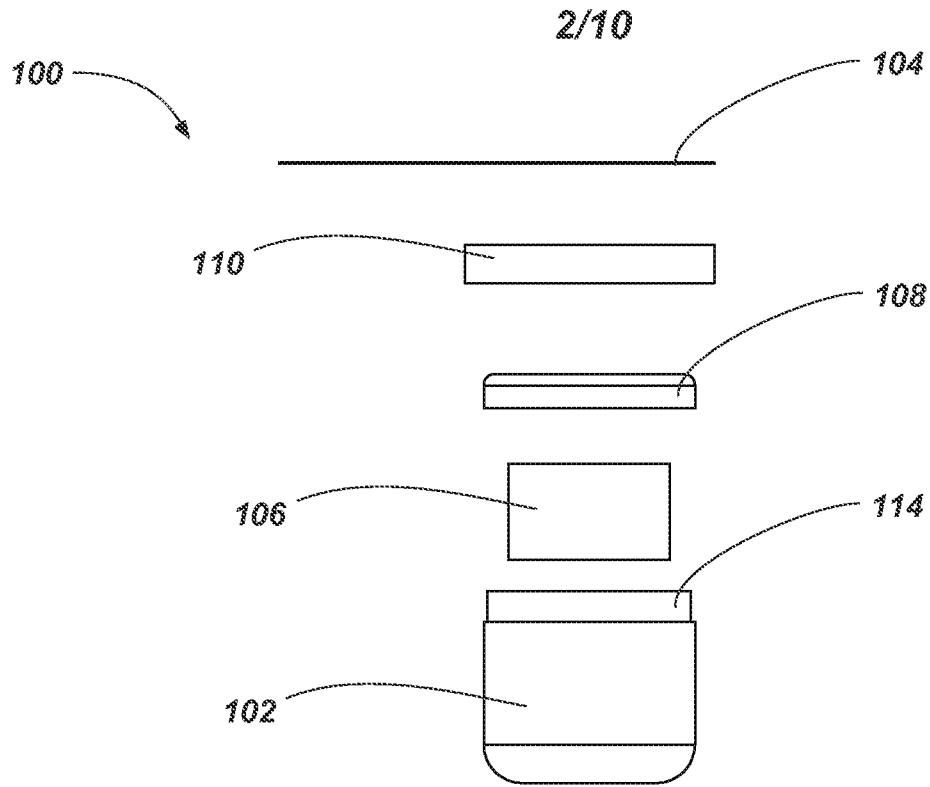


FIG. 3

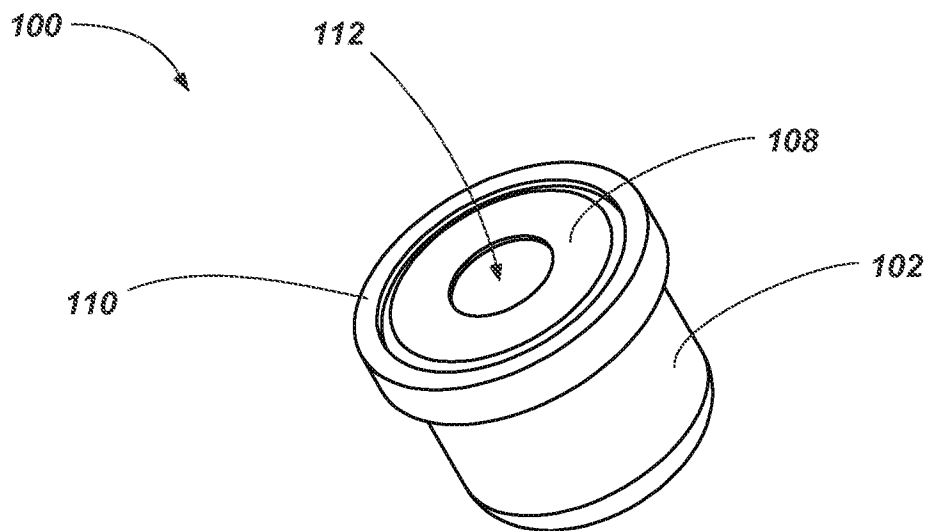


FIG. 4

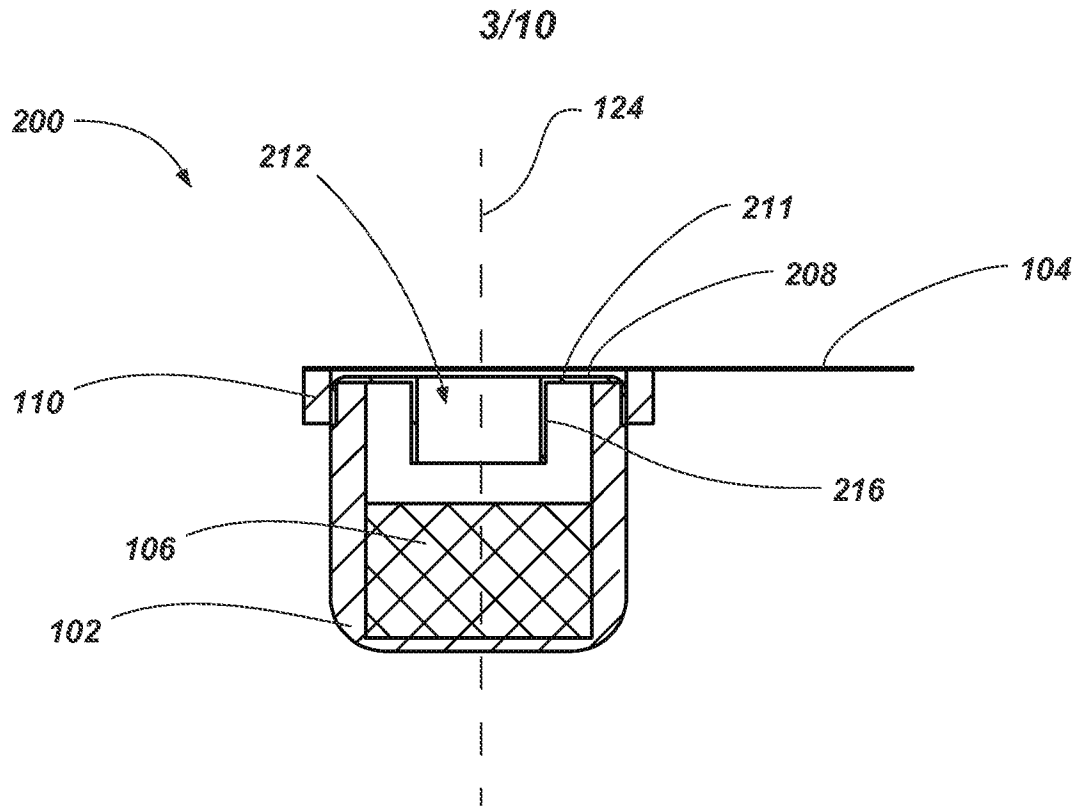


FIG. 5

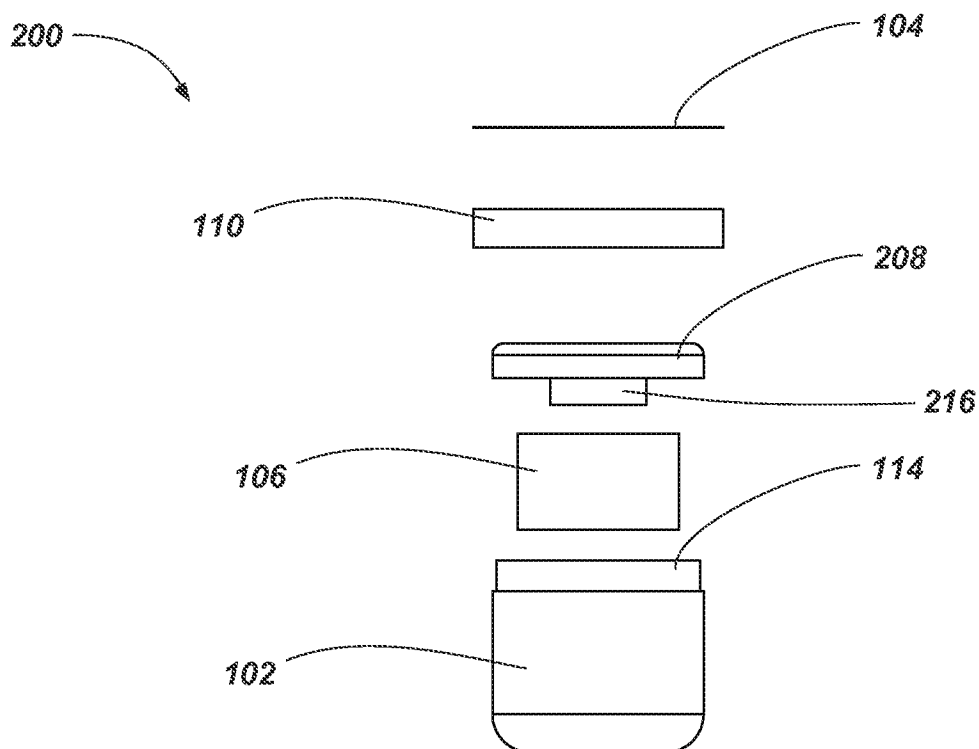


FIG. 6

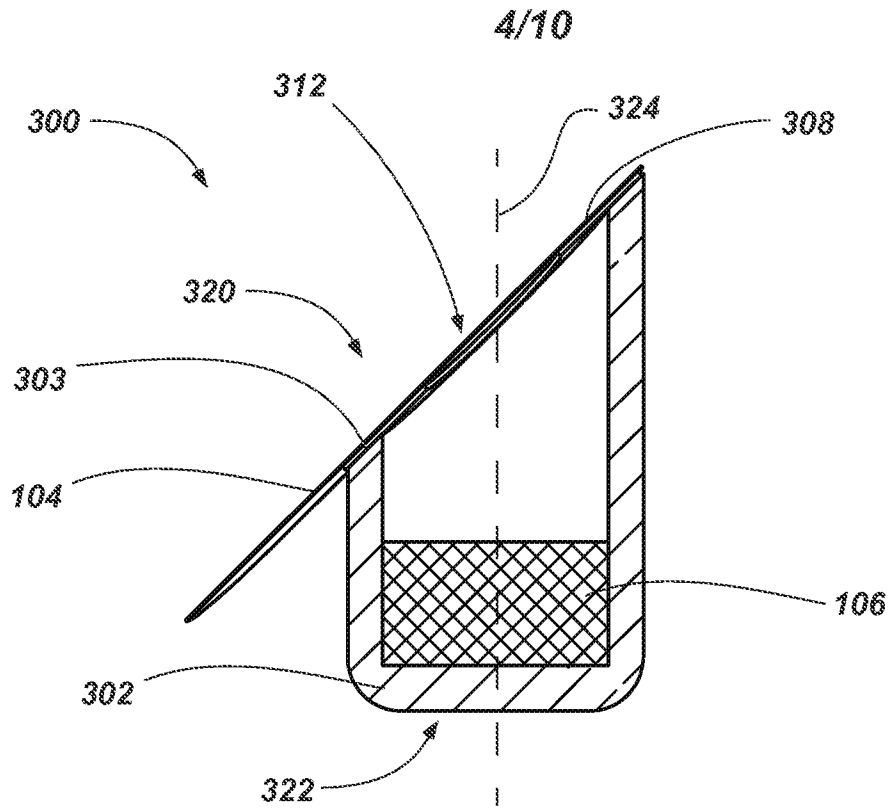


FIG. 7

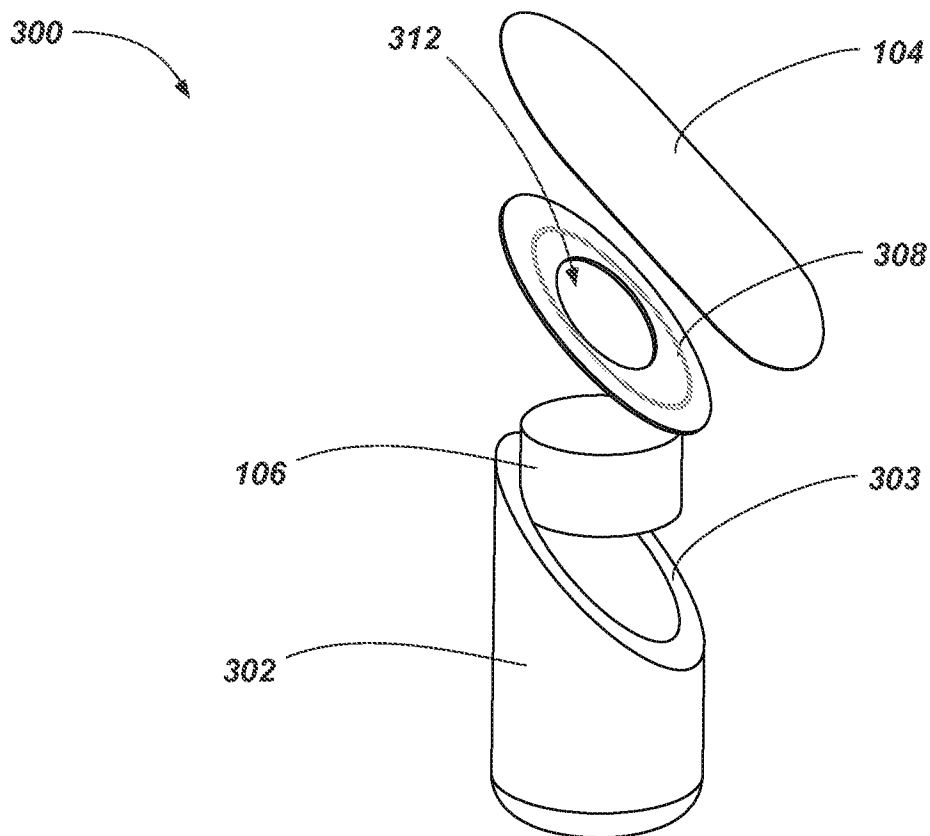
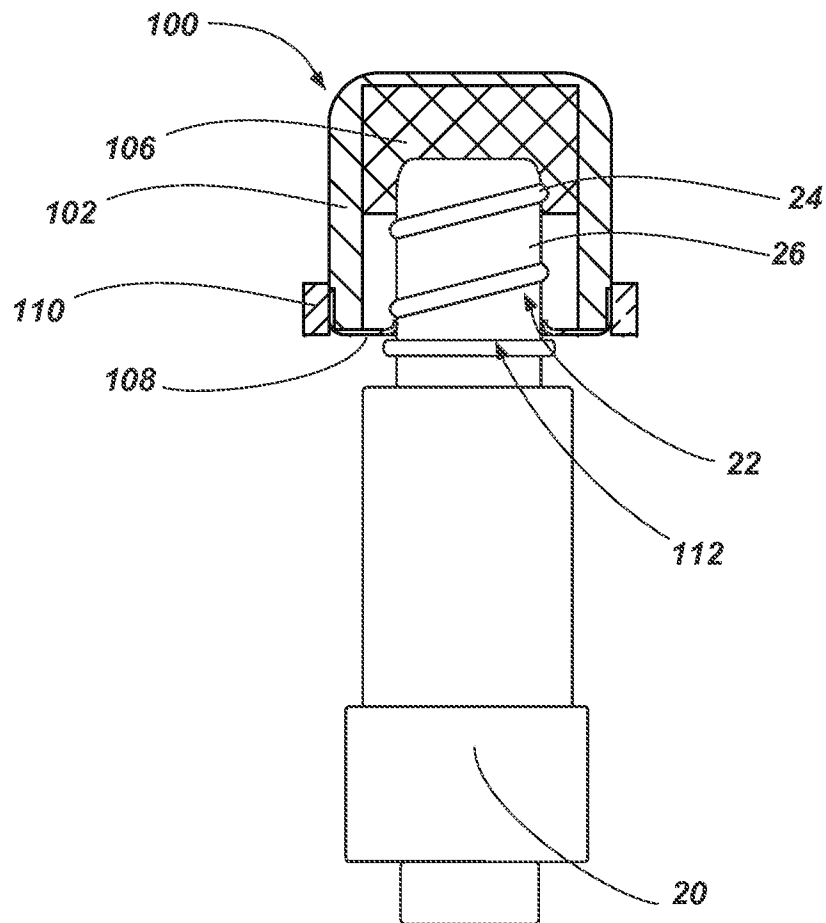
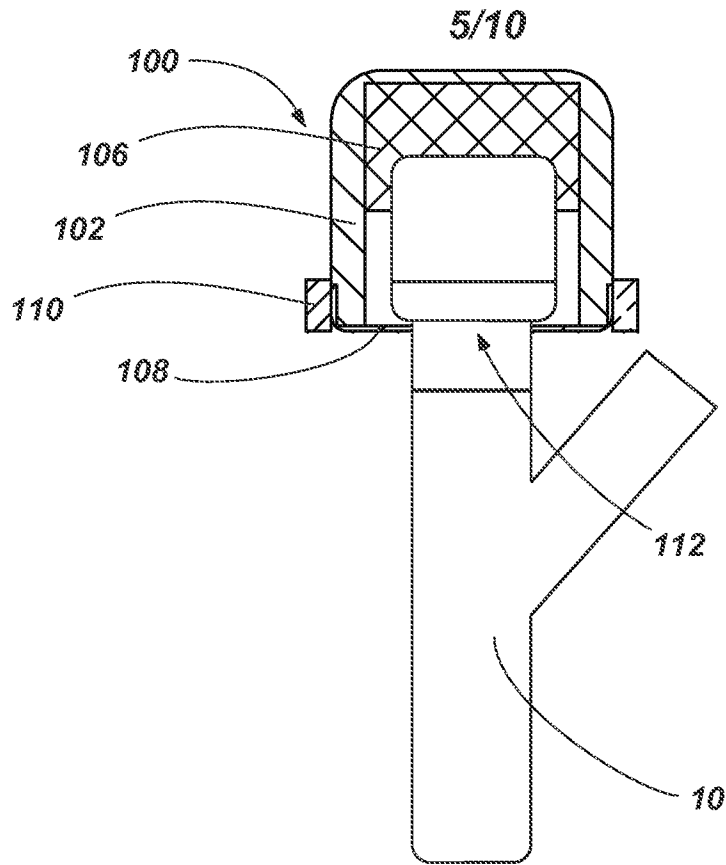


FIG. 8



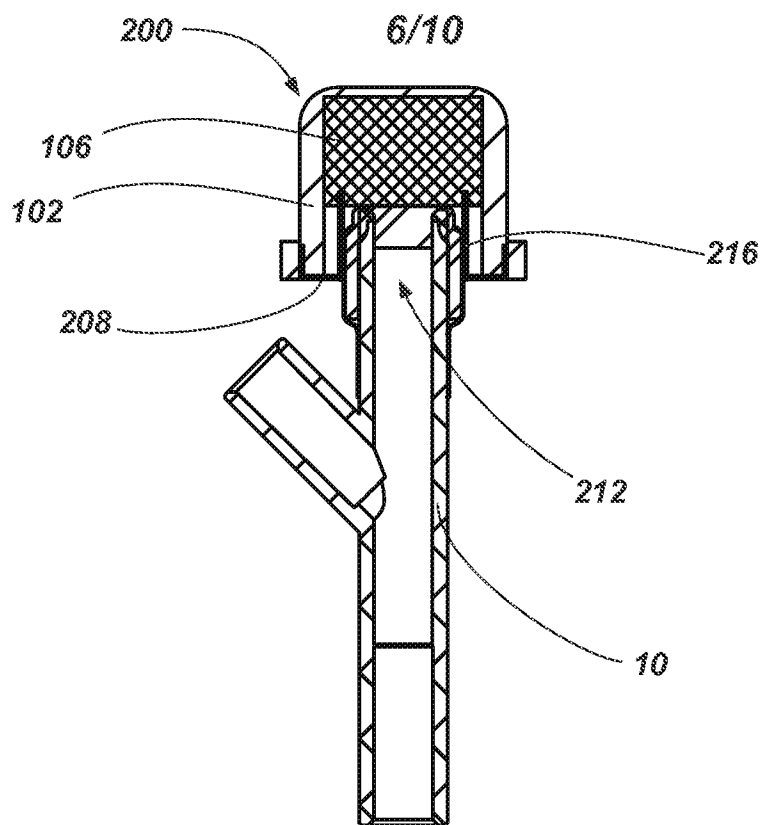


FIG. 11

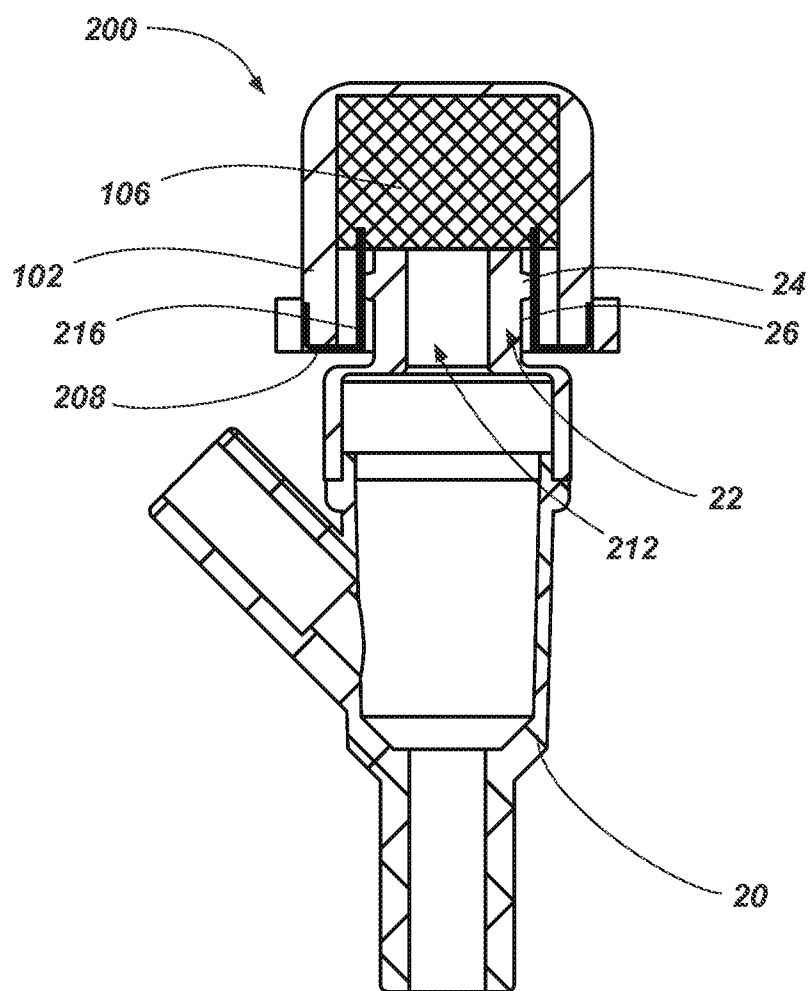


FIG. 12

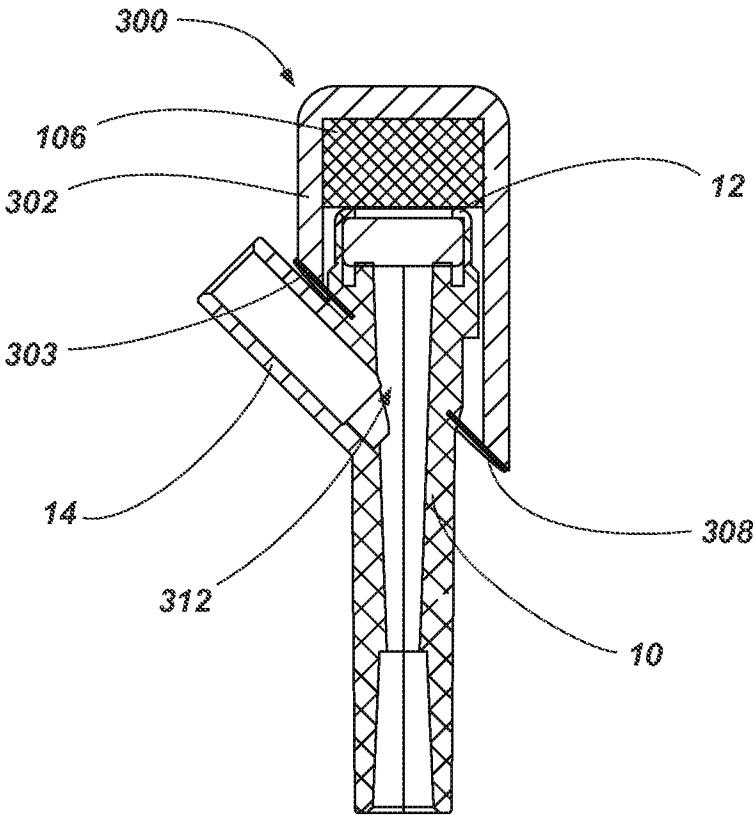


FIG. 13

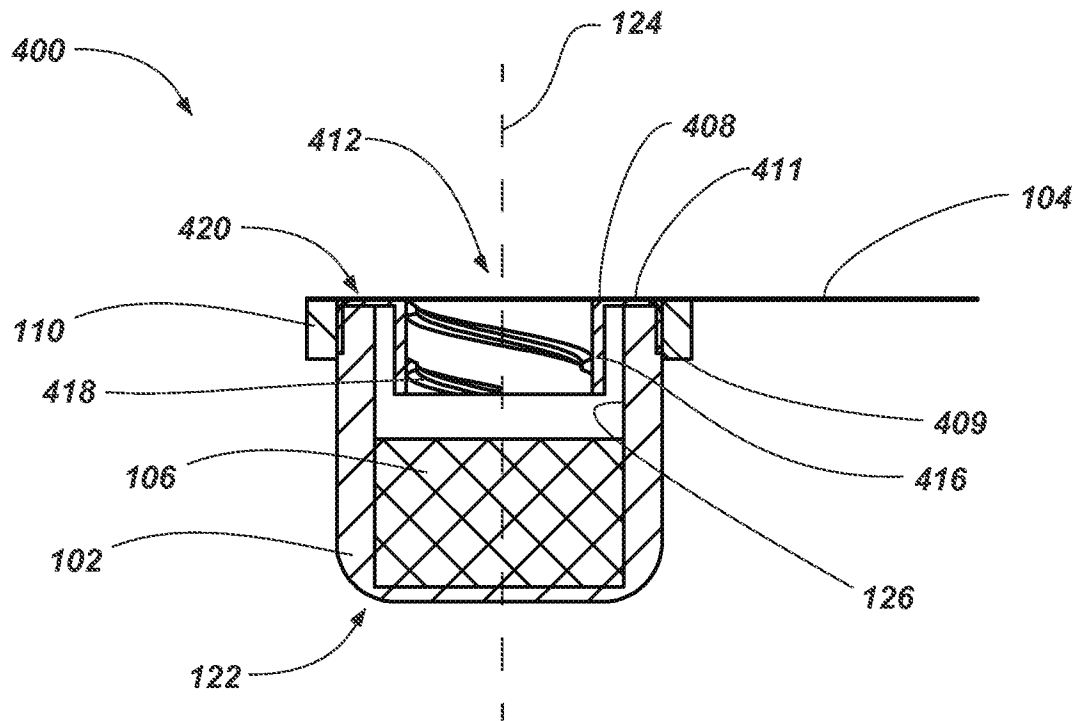


FIG. 14

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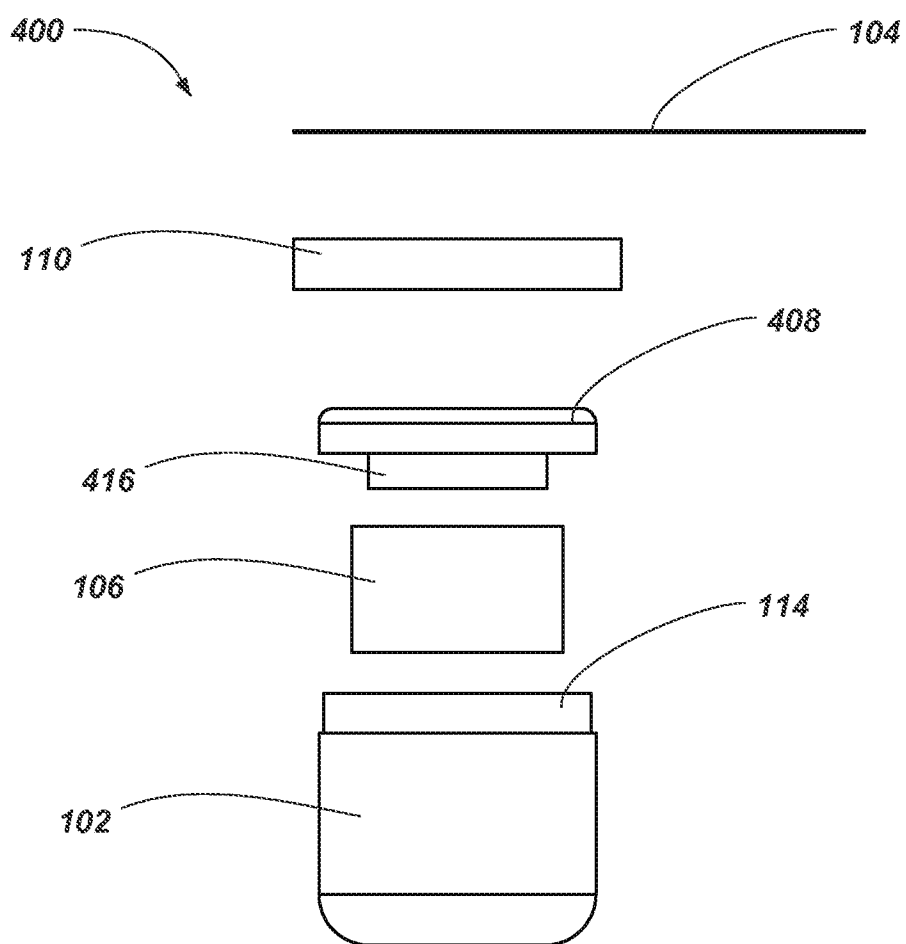


FIG. 15

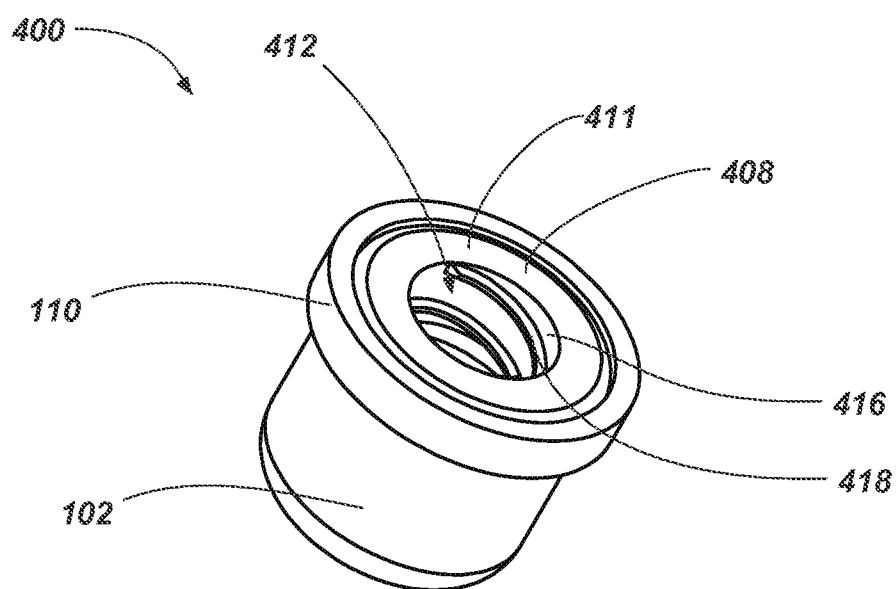


FIG. 16

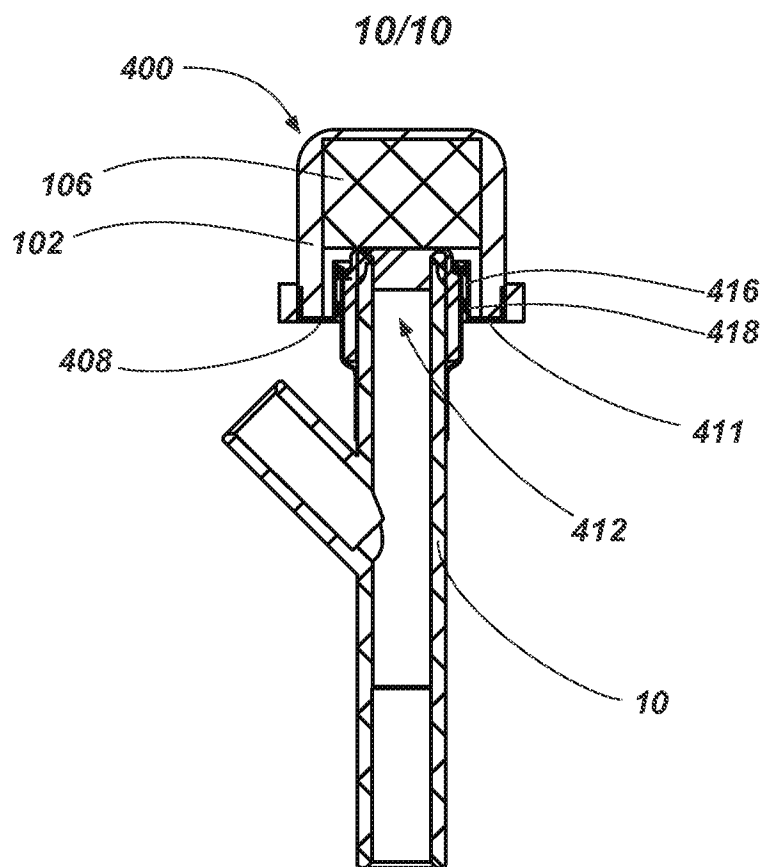


FIG. 17

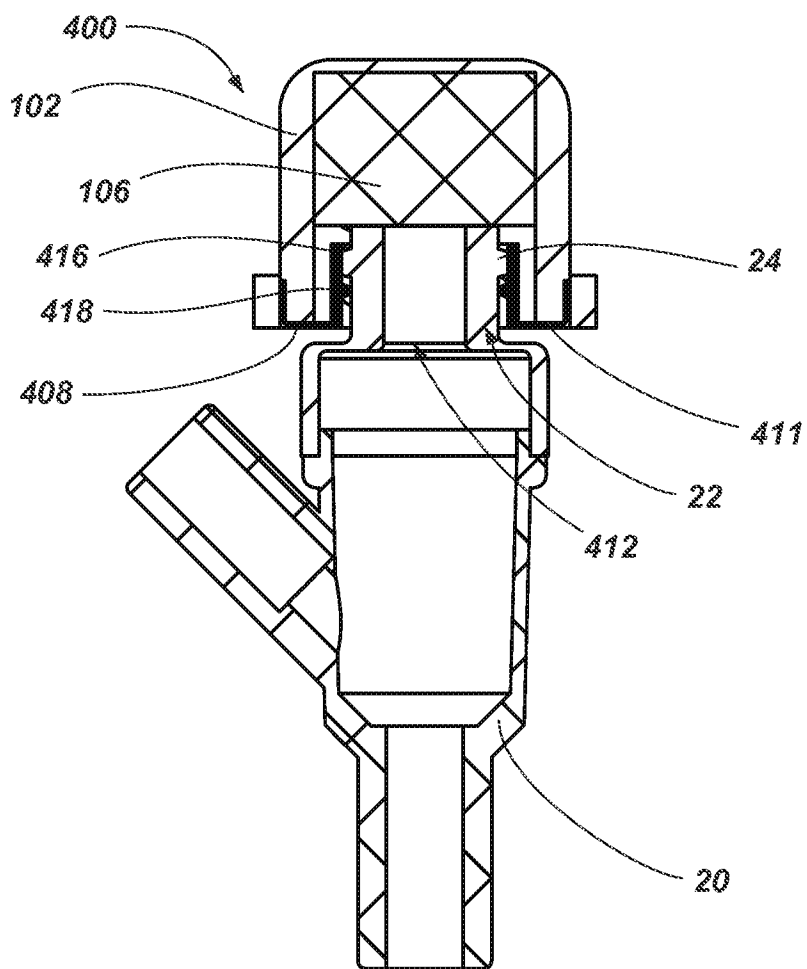


FIG. 18

A. CLASSIFICATION OF SUBJECT MATTER**A61L 2/16(2006.01)i, A61M 5/178(2006.01)i, A61M 5/00(2006.01)i, A61M 39/22(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61L 2/16; B08B 1/00; A61M 25/00; A61M 5/31; A61M 39/16; A61B 19/02; A61M 5/178; A61M 5/00; A61M 39/22

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: antimicrobial device, medical device, syringe, flexible membrane, throat portion, threads, Luer connection**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009-0137969 A1 (COLANTONIO et al.) 28 May 2009 see claims 1, 11 and 12; figures 1-7.	1-16, 21-23
A	US 2009-0062766 A1 (HOWLETT et al.) 05 March 2009 see the whole document.	1-16, 21-23
A	US 2010-0306938 A1 (ROGERS et al.) 09 December 2010 see the whole document.	1-16, 21-23
A	US 2010-0050351 A1 (COLANTONIO et al.) 04 March 2010 see the whole document.	1-16, 21-23
A	US 2011-0054440 A1 (LEWIS) 03 March 2011 see the whole document.	1-16, 21-23



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

16 September 2013 (16.09.2013)

Date of mailing of the international search report

17 September 2013 (17.09.2013)

Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/047154

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

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

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

2. ☒ Claims Nos.: 18,19
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 18,19 are unclear since they refer to claims which are not searchable due to not being drafted in accordance with Rule 6.4(a).

3. ☒ Claims Nos.: 17,20
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

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

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

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/047154

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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