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(54) **Title**: ANTISEPTIC LINE CAP

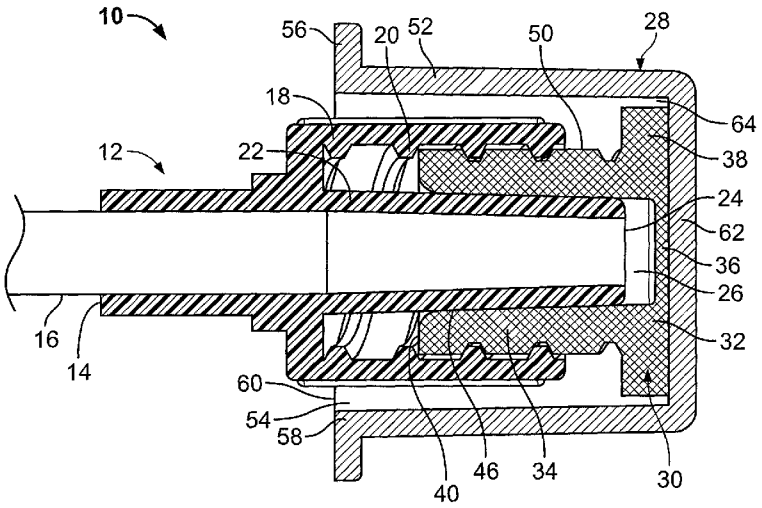

FIG. 1

(57) **Abstract**: An antiseptic cap assembly for use with a connector includes a cap with a base and an annular portion extending from the base. The annular portion defines a first chamber having an open end. The cap is made of an absorbent material. The antiseptic cap assembly also includes a cap holder having a generally cylindrical sidewall defining a second chamber sized to receive the cap.

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ANTISEPTIC LINE CAP

FIELD OF THE INVENTION

The present invention relates to an antiseptic cap, and more particularly, to an antiseptic line cap for a medical connector.

BACKGROUND OF THE INVENTION

Catheters are widely used to treat patients requiring a variety of medical procedures. Catheters can either be acute, or temporary, for short-term use or chronic for long-term treatment. Catheters are commonly caped into central veins (such as the vena cava) from peripheral vein sites to provide access to a patient's vascular system.

In a IV dispensing system, one end of a luer connector includes a fluid line which is connected to a fluid source, such as a IV bag filled with fluid. The other end of the male luer connector may be removably attached to one end of a female needleless luer connector. The other end of the female needleless luer connector may be attached to a catheter that has been caped into a patient.

When the male luer connector and the female needleless luer connector are attached to each other, fluid from the IV bag can flow into the patient. These connectors are often separated from each other at various times, for example, when a patient needs to use the bathroom. When the connectors are disengaged from each other, the connectors are exposed and are prone to contamination. Current procedures to reduce contamination of the connectors involve swabbing the connectors with a disinfection. These procedures are prone to human error and are often not implemented. Furthermore, when a male luer connector is disengaged from a female needleless connector, there is no standard manner in which to store the male luer connector, and protect it, until it is reattached to the female connector.

SUMMARY OF THE INVENTION

The present invention relates to an antiseptic cap for use with a connector. The antiseptic cap includes a cap having a base and an annular portion extending from the base. The annular portion defines a chamber having an open end. The cap could be made of an absorbent material.

An antiseptic cap assembly for use with a connector includes a cap having a base and an annular portion extending from the base. The annular portion defines a first chamber having an open end. The cap is made of a porous plastic material, and at least a portion of the cap includes an antiseptic fluid. The antiseptic cap assembly also includes a cap holder having a generally cylindrical sidewall defining a second chamber sized to receive the cap.

In another aspect, an antiseptic cap assembly for use with a connector includes a cap having a base and an annular portion extending from the base. The annular portion defines a first chamber having an open end. At least a portion of the cap is coated with an antiseptic material, and configured to release the antiseptic material when compressed.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention, reference is made to the following Detailed Description of the Invention, considered in conjunction with the accompanying drawings, in which:

FIG. 1 is a cross-sectional view of an antiseptic cap assembly engaged to a luer connector according to the present invention;

FIG. 2 is a perspective view of a sealed antiseptic cap assembly;

FIG. 3 is an exploded perspective view showing the antiseptic cap assembly of FIG. 1 and a luer connector;

FIG. 4 is a perspective view of the antiseptic cap assembly of FIG. 1 engaged to a luer connector;

FIG. 5 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein a cap has an outer wall;

FIG. 6 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein the cap includes a center insert;

FIG. 7 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein the cap includes a center plug;

FIG. 8 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein a cap holder includes an inner-facing flange;

FIG. 9 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein a center plug is provided and the cap holder includes an inner-facing flange;

FIG. 10 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein a cap includes an annular portion without threads;

FIG. 11 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein an antiseptic cap assembly includes an antiseptic chamber;

FIG. 12 is a perspective view of the antiseptic cap assembly shown in FIG. 11;

FIG. 13 is a perspective view showing another embodiment of the antiseptic cap assembly, wherein a cap holder includes retainers;

FIG. 14 is a cross-sectional view, taken along section lines 14-14 and looking in the direction of the arrows, of the antiseptic cap assembly shown in FIG. 13;

FIG. 15 is a cross-sectional view, taken along section lines 15-15, of the antiseptic cap assembly shown in FIG. 13;

FIG. 16 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein an antiseptic cap assembly includes a ratchet assembly;

FIG. 17 is an exploded view of the antiseptic cap assembly shown in FIG. 16 and a luer connector;

FIG. 18 is a partially cut away perspective view of an antiseptic cap assembly shown in FIG. 16 showing the ratchet assembly;

FIG. 19 is a perspective view showing an antiseptic cap assembly without a cap holder;

FIG. 20 is a cross-sectional view showing another embodiment of the antiseptic cap assembly of FIG. 19 having hydrophobic and hydrophilic sections;

FIG. 21 is a perspective view showing another embodiment of the antiseptic cap assembly, wherein a cap holder has a flange with a recess for receiving a line;

FIG. 22 is a cross-sectional view showing another embodiment of the antiseptic cap assembly, wherein a plug is supported by an arm; and

FIGS. 23-27 are perspective views showing an antiseptic cap assembly with various fastening mechanisms.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to an antiseptic cap assembly that engages a male end of a luer connector. It should be understood, however, that the teachings herein can be used with other types of medical connectors.

FIG. 1 is a cross-sectional view of an antiseptic cap assembly **10** engaged to a luer connector **12**. A proximal end **14** of the luer connector **12** is attached to a fluid line **16** which is connected to a fluid source (not shown), such as a IV bag filled with fluid. The luer connector **12** includes an annular threaded portion **18** with internal threads **20** and a frustoconical male luer **22** positioned for insertion into a female luer connector (not shown). The male luer **22** includes a tip **26** having an opening **24** in fluid communication with the fluid line **16**. The male luer **22** is arranged substantially concentrically within the threaded portion **18**. As a result of their generally coaxial arrangement, the male luer **22** and the threaded portion **18** cooperate to form an annular space therebetween.

The antiseptic cap assembly **10** includes a cap holder **28** and a cap **30** sized to be positioned within the cap holder **28**. The cap **30** includes a base **32** and an annular threaded portion **34** extending from the base **32**. The base **32** could include a substantially flat surface **36** and an outer flange **38**.

The threaded portion **34** of the cap **30** includes a rim **40** that defines an open end **42** (see **FIG. 3**). The base **32** closes the opposite end of the threaded portion **34**. The threaded portion **34** could be formed with a tapered inner surface **46** that compliments the male luer **22** of the luer connector **12**. In particular, the tapered inner surface **46** narrows from the rim **40** toward the base **32**. The threaded portion **34** defines a chamber **48** (see **FIG. 3**) sized to receive the male luer **22**. The threaded portion **34** includes external threads **50** for engaging the threads **20** of the luer connector **12**. The external threads **50** and the threads **20** of the luer connector **12** cooperate with each other so as to allow the cap **30** to be securely threadedly connected to the luer connector **12** and also to allow relative movement between the cap **30** and the luer connector **12**, as the cap **30** is rotated relative to the luer connector **12**. The external threads **50** extend between the base **32** and the rim **40**.

The configuration of the cap **30** is shown in perspective in **FIG. 3**. It should be noted that this configuration is exemplary. For example, the cap **30** could be configured without threads and sized to engage the luer connector **12** with a push-on friction fit, as will be described hereinafter.

The cap **30** could be made from an absorbent material. The cap **30** could be made from porous plastic, for example, a medical grade sintered porous plastic material which is available from Porex Corporation, based in Fairburn, GA. Other suitable manufacturers of the porous plastic material include Filtrona, Genpore, and Thermopore. It is desirable that the material can absorb and retain a fluid such as an antiseptic fluid. It is also desirable that the material is sufficiently rigid to maintain its structure. It is also desirable that the material is compressible and that the absorbed fluid is released on compression. The porous plastic material could be made of any suitable polymer, such as polyethylene, polypropylene, nylon, etc.

The use of the porous plastic material is only exemplary. It will be understood that the cap **30** could be made from any other suitable material, such as bonded fiber, cotton, silicone, urethane, polyester, cellulose, etc. The material could be natural or synthetic.

The threaded portion **34** of the cap **30** could be coated or impregnated with an antiseptic fluid, an anticoagulant fluid, and/or an antimicrobial fluid. An example of a suitable antiseptic fluid is isopropyl alcohol. The concentration of the isopropyl alcohol could vary, and is preferably 70% v/v. The concentration of alcohol could be in a range from 20% to 100%. It will be understand that other materials could be used, such as other alcohols, including ethanol, propanol, and/or butanol, or iodine, hydrogen peroxide, chlorhexidine gluconate, chlorhexidine acetate, etc. The antiseptic, anticoagulant, and/or antimicrobial agent could be in liquid or solid form.

The cap holder **28** includes a cylindrically shaped sidewall **52** that defines a chamber **54** sized to receive the cap **30** and accommodate the male luer **22**. The cap holder **28** could include an outer flange **56** that protrudes radially outwardly from a distal end **58** of the sidewall **52**. The outer flange **56** defines an open end **60**. The cap holder **28** could include a substantially flat surface **62** that defines the opposite, closed end. The cap holder **28** could be made from a

thermoplastic elastomer, such as the thermoplastic elastomer sold by ExxonMobil under the trademark SANTOPRENE, or any other suitable material. The cap holder **28** could be made from a more rigid material, such as a high-density polyethylene. The cap holder **28** and the cap **30** could be bonded to each other, or attached to each other by any suitable method, such as by adhesive or by molding.

When the cap **30** is attached to the cap holder **28**, a gap **64** exists between the flange **38** of the cap **30** and the cap holder **28**, and between the threaded portion **34** of the cap **30** and the cap holder **28**. Also, the cap **30** is attached to the cap holder **28** such that the cap **30** rotates conjointly with the cap holder **28**.

As shown in **FIG. 2**, the cap holder **28** could be sealed with a material, such as a film **66**, a foil material or lid stock material, which can be attached to the flange **56** by any suitable method such as by adhesive or by conductive or inductive heat sealing techniques. A pull tab **68** could be provided to facilitate removal of the film **66** to provide access to the antiseptic cap **10**.

Generally, the cap **30** may be hydrophobic. However, because the hydrophobic material could serve to inhibit or minimize an antiseptic fluid, such as isopropyl alcohol, from passing through the cap **30**, it may be desirable to make at least a portion of the cap **30** hydrophilic. For example, it may be desirable to treat at least a portion of the cap **30** with a hydrophilic surfactant. In this manner, the hydrophilic portion could allow the alcohol to pass therethrough, whereas the hydrophobic portion could serve to inhibit or minimize an antiseptic fluid, such as isopropyl alcohol, from passing therethrough. In one embodiment, the threaded portion **34** could be treated with a hydrophilic surfactant whereas the base **32** could remain hydrophobic, so as to be resistant to an antiseptic fluid, such as alcohol. The hydrophobic section could also act as a plug to prevent IV fluid from leaking through the tubing to go past the cap **30**.

Referring to **FIG. 1**, the antiseptic cap assembly **10** is shown attached to the luer connector **12** such that the threaded portion **34** of the cap **30** mates with the threads **20** of the luer connector **12** and the base **32** is positioned adjacent the opening **24** of the male luer **22**. Also, in this position, the inner surface **46** of the threaded portion **34** is adjacent the male luer **22** and the male

luer **22** compresses the cap **30** to release at least a portion of the antiseptic fluid to disinfect the luer connector **12**. The antiseptic cap assembly **10** can be allowed to remain attached to the luer connector **12** for any suitable period of time. When the antiseptic cap assembly **10** is attached to the luer connector **12**, as shown in the perspective view of **FIG. 4**, the luer connector **12** is exposed to the antiseptic fluid.

The cap holder **28** could be configured to remain on the cap **30** after the antiseptic cap assembly **10** engages the luer connector **12**. Alternatively, the cap holder **28** could be configured to be removably attached to the cap **30**. For example, the cap holder **28** could be removed from the cap **30** after the antiseptic cap assembly **10** engages the luer connector **12**.

FIG. 5 shows another embodiment of an antiseptic cap assembly, indicated generally as **110**, that is sized to engage and disinfect the male luer **22**. The antiseptic cap assembly **110** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **110** includes a cap holder **128** and a cap **130** sized to be positioned within the cap holder **128**.

In this embodiment, the cap **130** includes an annular sidewall **111** extending from an outer flange **138** and substantially concentric with the threaded portion **134**. When the cap holder **128** is used, the annular sidewall **111** is positioned proximate an inner surface of the cap holder **12**. When the antiseptic cap assembly **110** is attached to the luer connector **12**, the annular sidewall **111** bears against the outer surface of the threaded portion **18** of the luer connector **12**. The annular sidewall **111** can be made from porous plastic like the remainder of the cap **130** or any other suitable material. The annular sidewall **111** covers and protects the outer surface of the threaded portion **18** of the luer connector **12**. The annular sidewall **111** may contain antiseptic fluid and release at least a portion of an antiseptic fluid.

FIG. 6 shows another embodiment of an antiseptic cap assembly, indicated generally as **210**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **210** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **210**

includes a cap holder **228** and a cap **230** sized to be positioned within the cap holder **228**.

In this embodiment, the cap **230** includes a center insert **211** that is integrally connected therewith. Alternatively, the cap **230** and the center insert **211** could be separate components. The center insert **211** may be made from porous plastic like the remainder of the cap **230** or any other suitable material, and may contain antiseptic fluid and release at least a portion of an antiseptic fluid. The center insert **211** could be treated with a hydrophilic surfactant, or otherwise made hydrophilic.

The center insert **211** protrudes from a base **232** of the cap **230** and is positioned within a threaded portion **234** of the cap **230**. The center insert **211** has a distal end **213** that may have angled edges **215**, thereby giving the center insert **211** a generally trapezoidal shape. The center insert **211** could define other shapes such as conical, square, rectangle, etc.

When the cap **230** is attached to a luer connector **12**, the center insert **211** is positioned within the opening **24** formed in the male luer **22** and allows the antiseptic fluid to enter the male luer **22** to apply the antiseptic fluid to the inner tip **26** of the male luer **22**.

FIG. 7 shows another embodiment of an antiseptic cap assembly, indicated generally as **310**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **310** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-3**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **310** includes a cap holder **328** and a cap **330** sized to be positioned within the cap holder **328**.

In this embodiment, a sealing mechanism, such as a center plug **311**, is sized to extend from a base **332** of the cap **330** and is sized to be positioned within the threaded portion **334** of the cap **330**. The cap **330** and the center plug **311** could be separate components as shown or, alternatively, the cap **330** and the center plug **311** could be integrally formed. Alternatively, the center plug **311** could be an extension of the cap holder **328** molded in.

The center plug **311** has a distal end **313** that may have angled edges **315**, thereby giving the center plug **311** a generally trapezoidal shape. The center plug **311** could define other shapes such as conical, square, rectangle, etc.

The center plug **311** bears against the opening **24** formed in the male luer **22** to prevent the antiseptic fluid from entering the male luer **22**. The center plug **311** extends a distance from the base **332** sufficient to engage the opening **24** in the male luer **22** before the threaded portion **334** of the cap **330** is compressed by the male luer **22**, to seal the opening **24** in the male luer **22**.

The center plug **311** could be made of a non-porous material, such as rubber, or any other suitable material. The center plug **311** could be made of porous plastic and left in a hydrophobic state, i.e., not treated with a surfactant like the threaded portion **334** of the cap **330**, thereby inhibiting or minimizing antiseptic fluid from passing therethrough and into the opening **24** formed in the male luer **22**. In this manner, the center plug **311** serves to limit or prevent alcohol from entering the fluid line **316** of the luer connector **312**. Also the center plug **311** could act as a plug to prevent IV fluid from dripping out of the line.

The configuration of the sealing mechanism is only exemplary. It will be understood that the present invention could employ other sealing mechanisms. For example, the sealing mechanism could be a center pin (not shown) sized to extend further into the opening **24** formed in the male luer **22** than the center plug **311**. The center plug **311** may extend past the threads on the threaded portion **324** and inserted prior to thread engagement.

FIG. 8 shows another embodiment of an antiseptic cap assembly, indicated generally as **410**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **410** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **410** includes a cap holder **428** and a cap **430** sized to be positioned within the cap holder **428**.

In this embodiment, the cap holder **428** includes an inner-facing flange **411** that may form a protective seal that closes off the interior of the cap holder **428** when the antiseptic cap assembly **410** is engaged to the luer connector **12**. The inner flange **411** extends radially inward from a distal end **458** of the

sidewall **452** of the cap holder **428**. When the antiseptic cap assembly **410** is engaged to the luer connector **12**, the inner-facing flange **411** of the cap holder **428** may contact the threaded portion **18** of the luer connector **12** to seal the interior of the cap holder **428**.

The inner-facing flange **411** of the cap holder **428** may provide a physical barrier to the ingress of pathogens, dust or other contaminants into the cap holder **428**. The inner-facing flange **411** may serve to retain at least a portion of the antiseptic fluid from the antiseptic cap assembly **410** from leaking out. The inner-facing flange **411** may prevent evaporation of at least a portion of the antiseptic fluid that is retained.

The configuration of the cap holder **428** could vary. For example, the cap holder **428** could include an outer flange (not shown), such as the outer flange **56** (**FIG. 1**) that protrudes radially outwardly from the distal end **458** of the sidewall **452**, as well as the inner-facing flange **411** that protrudes radially inward from the distal end **458** of the sidewall **452**.

FIG. 9 shows another embodiment of an antiseptic cap assembly, indicated generally as **510**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **510** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **510** includes a cap holder **528** and a cap **530** sized to be positioned within the cap holder **528**.

In this embodiment, the antiseptic cap assembly **510** includes a center plug **511**, such as the center plug **311** shown in **FIG. 7**. In addition, the cap holder includes an inner-facing flange **513**, such as the flange **411** shown in **FIG. 8**.

It should be understood that various features of various embodiments disclosed herein could be used together without departing from the spirit or scope of the present invention.

FIG. 10 shows another embodiment of an antiseptic cap assembly, indicated generally as **610**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **610** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated

otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **610** includes a cap holder **628** and a cap **630** sized to be positioned within the cap holder **628**.

In this embodiment, the cap **630** includes an annular portion **611** extending from a base **632**. The annular portion **611** is configured without threads but is sized to engage the luer connector **12** with a push-on friction fit. The antiseptic cap assembly **610** could be removed by pulling out of the luer connector **12**.

The annular portion **611** of the cap **630** could be configured such that the inner surface contacts the male luer **22** and is compressed by the male luer **22** to release antiseptic fluid when the cap **630** is pushed on to the male luer **22**. The outer surface of the annular portion **611** could also contact against the inner threads **18** of the threaded portion **18** of the male luer **22** and could also release antiseptic fluid on this side. Alternatively, the annular portion **611** could be configured to avoid contact with the threads **20** of the luer connector **12**. The annular portion **611** does not need to be tapered as shown.

FIGS. 11 and **12** show another embodiment of an antiseptic cap assembly, indicated generally as **710**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **710** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-3**, unless stated otherwise. The antiseptic cap assembly **710** includes an antiseptic chamber **715** and a cap **730**.

In this embodiment, the cap **730** includes an annular portion **711** extending from a base **732**. The annular portion **711** is configured and sized to engage the luer connector **12** with a push-on friction fit.

The antiseptic chamber **715** is attached to the base **732** of the cap **730** and is formed by a continuous sidewall **713** and an end wall **723**. The sidewall **713** includes an inner flange **717** that extends radially inward from the sidewall **713**. The flange **717** defines an open end **721**.

The base **732** of the cap **730** is keyed to the antiseptic chamber **715**. The base **732** of the cap **730** is positioned within the antiseptic chamber **715** such that the outer flange **738** of the base **732** is captured in the antiseptic chamber **715** by the inner flange **717** of the antiseptic chamber **715** which extends over the base

732. The base **732** closes off the disinfectant chamber **715** and the annular portion **711** of the cap **730** is in contact with the inner flange **717** of the antiseptic chamber **715**. The cap **730** could be attached to the antiseptic chamber **715** such that the cap **730** rotates conjointly with the antiseptic chamber **715**. In one embodiment, the base **732** of the cap **730** does not need to be keyed to the antiseptic chamber **715** in a push-on design.

The antiseptic chamber **715** can include an absorbent material **725**, such as a pad, sponge, or elastomeric foam, configured to retain an antiseptic fluid. The absorbent material **725** could be wetted or soaked with the antiseptic fluid. The absorbent material **725** could be deformable. The cap **730** could be made from a porous plastic material that serves as a carrier for the transfer of antiseptic fluid from the disinfectant chamber **715**. When the cap holder **728** is compressed, the absorbent material **725** releases at least a portion of the antiseptic fluid. The fluid can then flow through the base **732** and along the annular portion **711** to be delivered to the male luer **22.** **FIG. 12** shows a perspective view of the antiseptic cap assembly **710**.

It will be understood that the present invention could employ other mechanisms that involve pushing on a component of an antiseptic cap assembly to activate or release the antiseptic fluid.

FIGS. 13-15 show another embodiment of an antiseptic cap assembly, indicated generally as **810**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **810** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-3**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **810** includes a cap holder **828** and a cap **830** sized to be positioned within the cap holder **828**.

In this embodiment, the cap **830** includes an annular portion **811** extending from a base **832**. The annular portion **811** is configured without threads and sized to engage the luer connector **12** with a push-on friction fit. The antiseptic cap assembly **810** could be removed by pulling out of the luer connector **12**.

The cap holder **828** includes retainers **813** that serve to retain or secure the cap **830** on the luer connector **12**. The retainers **813** include a pair of

shoulders **815**, **817** that extend perpendicularly from opposite sides of the outer flange **856** of the cap holder **828** and a pair of arms **823, 825** that extend radially inward from the shoulders **815**, **817**.

When the antiseptic cap assembly **810** is engaged to the luer connector **12**, the arms **823, 825** of the retainers **813** extend over the male luer **22** to retain the cap **830**. The retainers **813** could be made from a thermoplastic elastomer, such as SANTOPRENE, or any other suitable material. The retainers **813** could be made from a flexible material.

The cap holder **828** may include gripping areas defined by a recessed portion **827** (**FIGS. 13** and **15**) and a recessed portion **829** (**FIGS. 13** and **15**) on opposite sides of the outer sidewall **852**. The recessed portions **827**, **829** are configured for gripping the cap **830** to attach the cap **830** to the male luer **22**.

FIGS. 16-18 show another embodiment of an antiseptic cap assembly, indicated generally as **910**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **910** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **910** includes a cap holder **928** and a cap **930** inserted within the cap holder **928**. This embodiment includes a mechanism to prevent overtightening of the cap **930** on the male luer **22** which could damage the male luer **22**. This is addressed with a ratchet assembly.

The cap **930** includes a base **932** and an annular threaded portion **934** extending from the base **932**. The base **932** includes an outer flange **938** with a plurality of teeth **911** (see **FIGS. 17** and **18**), along the outer perimeter that allows for rotation in only one direction. Alternatively, it could be configured to allow for rotation in both directions by angling both surfaces of the teeth. The teeth **911** have angled faces **912** and generally perpendicular faces **914**.

The cap holder **928** includes a retaining mechanism for retaining the cap **930** in the cap holder **928**. The retaining mechanism could include a first protrusion **913** that extends from one section of the sidewall **952** of the cap holder **928**, and a second protrusion **915** that extends from an opposite section of the sidewall **952** of the cap holder **928**. The first and second protrusions **913**, **915** are

configured to extend over the base **932** of the cap **930**. Alternatively, the retaining mechanism could include a single ring around the interior of the cap holder **928**.

The cap holder **928** includes a plurality of teeth **917** that mate with the teeth **911** to form a ratchet mechanism. The teeth **917** interact with the teeth **911** to allow the cap **930** to rotate in the cap holder **928** in only one direction, and have angled faces **916** and generally perpendicular faces **918**, like the teeth **911** of the base **932**. Alternatively, it could be configured to allow for rotation in both directions.

The ratchet mechanism provides an audible or a tactile feedback to indicate that the antiseptic cap assembly **910** is properly secured. Also, the ratchet mechanism could limit torque to prevent damage to the luer connector **12** or to the cap **930**. The cap **930** is threaded on the male luer **22** in accordance with other embodiments of the cap **930**. If the cap **930** is turned beyond the limit of the threads, instead of damaging the male luer **22**, the cap **930** will slide with respect to the cap holder **928**, the angled teeth **911, 917** of the base **932** of the cap **930** and the cap holder **930** respectively sliding past one another to prevent further tightening of the cap **930** onto the male luer **22**. When removing the cap **930** from the male luer **22**, the generally perpendicular faces **914, 918** engage and do not permit sliding.

FIG. 19 shows another embodiment of an antiseptic cap assembly, indicated generally as **1010**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **1010** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated otherwise.

In this embodiment, the cap **1030** is used without a cap holder. The cap **1030** includes a base **1032** and an annular threaded portion **1034** extending from the base **1032**. Antiseptic fluid can be associated with the interior surface of the annular threaded portion **1034**.

The configuration of the cap **1030** is only exemplary. For example, the cap **1030** could be configured without threads and sized to engage the luer connector **12** with a push-on friction fit. Likewise, the cap **1030** could also include a sidewall, like that shown in **FIG. 5**.

FIG. 20 shows another embodiment of an antiseptic cap assembly, indicated generally as **1110**, that is sized to engage and disinfect a male luer. The antiseptic cap assembly **1110** operates and is constructed in manners consistent with the antiseptic cap assembly **1010** shown in **FIG. 18**, unless stated otherwise.

In this embodiment, at least a portion of the cap **1130** could be treated with a hydrophilic surfactant, or otherwise made hydrophilic. In one embodiment, the threaded portion **1134** could be treated with a hydrophilic surfactant whereas the base **1132** could remain hydrophobic, so as to be resistant to and non-absorbent of an antiseptic fluid.

A center plug **1111** could bear against the opening **24** formed in the male luer **22** to prevent the antiseptic fluid from entering the male luer **22**. The center plug **1111** could be made of porous plastic and left in a hydrophobic state, thereby inhibiting or minimizing antiseptic fluid from passing therethrough and into the opening **24** formed in the male luer **22**. The hydrophobic section could also act as a plug in the IV line to prevent ingress of antiseptic fluid or to stop leakage of IV fluid.

FIG. 21 shows another embodiment of an antiseptic cap assembly, indicated generally as **1210**, that is sized to engage and disinfect a male luer **22**. The antiseptic cap assembly **1210** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-4**, unless stated otherwise.

The cap holder **1228** has a notch **1211** in an outer flange **1256** that is configured to attached to a supporting surface, such as a fluid line **1213**. As shown, the cap holder **1228** has a plurality of ribs **1215** extending along a sidewall **1252** from one end **1217** of the cap holder **1228** to the opposite end **1219** of the cap holder **1228**. The ribs **1215** facilitate gripping of the cap holder **1228**.

FIG. 22 shows another embodiment of an antiseptic cap assembly, indicated generally as **1310**, that is sized to engage and disinfect a male luer. The antiseptic cap assembly **1310** operates and is constructed in manners consistent with the antiseptic cap assembly **10** shown in **FIGS. 1-3**, unless stated otherwise. Like the antiseptic cap assembly **10**, the antiseptic cap assembly **1310** includes a cap holder **1328** and a cap **1330** sized to be positioned within the cap holder **1328**.

In this embodiment, a sealing mechanism, such as a center plug **1311**, is sized to extend from the cap holder **1328** through the base **1332** and is sized to be positioned within the threaded portion **1334** of the cap **1330**. As such, the center plug **1311** is made of a non-porous material such as SANTOPRENE, or any other suitable material. In particular, the center plug **1311** includes an arm **1313** with one end **1315** extending from the base **1332**, and a sphere **1317** attached to an opposite end **1319** of the arm **1313**. The sphere **1317** is configured to bear against the opening **24** formed in the male luer **22** to limit the distance that the antiseptic fluid can travel into the male luer **22**. Alternatively, the center plug **1311** could extend from the base **1332** and be made of another material such as rubber. The sphere **1317** could be replaced with a non-spherical device.

Any of the antiseptic cap assemblies **10**, **110**, **210**, **310**, **410**, **510**, **610**, **710**, **810**, **910**, **1010**, **1110**, **1210**, and **1310** disclosed herein could be configured to be removably attached to a suitable surface (not shown), such as a IV bag, IV pump, or IV pole, etc., for use. For example, in **FIG. 23**, the substantially flat surface **62** of the cap holder **28** includes a clip **80** sized to removeably secure the antiseptic cap assembly **10** to a supporting surface (not shown), such as a IV bag. In **FIG. 24**, a hook **82** could be provided extending from the substantially flat surface **62** of the cap holder **28** and sized to removeably secure the antiseptic cap assembly 10 to a supporting surface (not shown).

In **FIG. 25**, a horseshoe-shaped clip **84** could be provided extending from the substantially flat surface **62** of the cap holder **28** and sized to releasably fasten an antiseptic cap assembly **10** to a supporting surface (not shown). The location of a fastening member could vary. For example, in **FIG. 26**, the sidewall **52** of the cap holder **28** includes a clip **86**.

In **FIG. 27**, the end surface **62** of the cap holder **28** includes an adhesive **88** that could be covered by a release sheet **89**. The adhesive **88** could be used to attach the antiseptic cap assembly **10** to a supporting surface, such as a IV pole. A pull tab **90** could be provided to remove the release sheet **89** to expose the adhesive **88**.

Alternative fastening mechanisms could be provided. For example, the antiseptic cap assembly could include a ring (not shown).

The antiseptic cap assembly could be incorporated in kits with flush syringes, caps for treating a catheter or needleless connector, and line access devices, etc. The antiseptic fluid used could include an anticoagulant material, and/or an antimicrobial material. Examples of antiseptic fluid that could be used are disclosed in U.S. patent application Nos. 11/821,190, filed on June 22, 2007, and 12/214,526, filed on June 19, 2008. The entire disclosures of U.S. patent application Nos. 11/821,190 and 12/214,526 are incorporated herein by reference in their entirety.

Antiseptic coatings

It is contemplated that the devices described herein can be coated with an antiseptic coating by any suitable technique such as immersion of the part into an antiseptic solution, by spray coating the part with the antiseptic solution, by blending the antiseptic solution or material into the polymeric material used to fabricate the device.

A quantity of physiological, antimicrobial metal compound is added to the resin for direct molding of an article. Physiological, antimicrobial metals are meant to include the precious metals, such as silver, gold and platinum, and copper and zinc. Physiological, antimicrobial metal compounds used herein include oxides and salts of preferably silver and also gold, for example: silver acetate, silver benzoate, silver carbonate, silver citrate, silver chloride, silver iodide, silver nitrate, silver oxide, silver sulfa diazine, silver sulfate, gold chloride and gold oxide. Platinum compounds such as chloroplatinic acid or its salts (e.g., sodium and calcium chloroplatinate) may also be used. Also, compounds of copper and zinc may be used, for example: oxides and salts of copper and zinc such as those indicated above for silver. Single physiological, antimicrobial metal compounds or combinations of physiological, antimicrobial metal compounds may be used.

Preferred physiological, antimicrobial metal compounds used in this invention are silver acetate, silver oxide, silver sulfate, gold chloride and a combination of silver oxide and gold chloride. The particles of the silver compounds are sufficiently able to be extracted to form a zone of inhibition to prevent and kill bacteria growth.

In another preferred form of the invention the devices herein are impregnated with triclosan and silver compounds or triclosan and chlorhexidine, or chlorhexidine gluconate, or chlorhexidine acetate.

It will be understood that the embodiments described herein are merely exemplary and that a person skilled in the art may make many variations and modifications without departing from the spirit and scope of the invention. All such variations and modifications are intended to be included within the scope of the invention as defined by the appended claims.

CLAIMS

What is claimed is:

1. An antiseptic cap for use with a connector, comprising:

a cap having a base and an annular portion extending from the base, the annular portion defining a chamber having an open end, the cap being made of an absorbent material.

2. The antiseptic cap of Claim 1, wherein the cap is made of porous plastic material.

3. The antiseptic cap of Claim 2, wherein at least a portion of the cap includes an antiseptic fluid.

4. The antiseptic cap of Claim 3, wherein the annular portion includes a plurality of threads.

5. The antiseptic cap of Claim 4, wherein the annular portion includes a rim defining the open end, the annular portion being tapered such that the annular portion narrows from the rim toward the base.

6. The antiseptic cap of Claim 1, wherein the annular portion is hydrophilic, and the base is hydrophobic.

7. The antiseptic cap of Claim 1, wherein the cap includes a center plug extending from the base and positioned within the annular portion of the cap.

8. The antiseptic cap of Claim 1, wherein the cap includes a center insert integrally connected therewith, the center insert protruding from the base of the cap, and positioned within the annular portion of the cap.

9. The antiseptic cap of Claim 8, wherein the center insert is made from a porous plastic material.

10. The antiseptic cap of Claim 1, further comprising an antiseptic chamber attached to the base of the cap, the antiseptic chamber including a continuous sidewall and an end wall.

11. The antiseptic cap of Claim 10, wherein the antiseptic chamber includes an absorbent material configured to retain an antiseptic fluid.

12. The antiseptic cap of Claim 1, wherein the annular portion is coated with an antiseptic material, the annular portion configured to release the antiseptic material when compressed.

13. The antiseptic cap of Claim 1, wherein the cap includes a second annular portion made of an absorbent material, the second annular portion being substantially concentric with the annular portion.

14. An antiseptic cap assembly for use with a connector comprising:

a cap having a base and an annular portion extending from the base, the annular portion defining a first chamber having an open end, the cap being made of an absorbent material; and

a cap holder having a generally cylindrical sidewall defining a second chamber sized to receive the cap.

15. The antiseptic cap assembly of Claim 14, wherein the cap is made of porous plastic material.

16. The antiseptic cap assembly of Claim 15, wherein at least a portion of the cap includes an antiseptic fluid.

17. The antiseptic cap assembly of Claim 15, wherein the base of the cap includes a substantially flat surface and an outer flange.

18. The antiseptic cap assembly of Claim 15, wherein the annular portion includes a plurality of threads.

19. The antiseptic cap assembly of Claim 17, wherein the cap includes an annular sidewall extending from the outer flange of the cap and being substantially concentric with the annular portion.

20. The antiseptic cap assembly of Claim 19, wherein the cap holder includes an outer flange protruding radially outwardly from the sidewall, the outer flange defining an open end.

21. The antiseptic cap assembly of Claim 20, wherein the cap holder includes a retainer sized to retain the cap, the retainer including a shoulder extending from the outer flange of the cap holder and an arm extending radially inward from the shoulder.

22. The antiseptic cap assembly of Claim 21, wherein the cap holder includes a pair of recessed areas configured to grip the cap.

23. The antiseptic cap assembly of Claim 20, wherein the cap holder includes a notch in the outer flange, the notch configured to be attached to a supporting surface.

24. The antiseptic cap assembly of Claim 14, wherein the cap includes a center insert integrally connected therewith, the center insert protruding from the base of the cap, and positioned within the annular portion of the cap.

25. The antiseptic cap assembly of Claim 24, wherein the center insert is made from a porous plastic material.

26. The antiseptic cap assembly of Claim 14, wherein the cap includes a center plug extending from the base and positioned within the annular portion of the cap.

27. The antiseptic cap assembly of Claim 26, wherein the center plug is made of non-porous plastic material.

28. The antiseptic cap assembly of Claim 27, wherein the center plug is hydrophobic.

29. The antiseptic cap assembly of Claim 14, wherein the cap holder includes an inner-facing flange extending radially outwardly from the sidewall.

30. The antiseptic cap assembly of Claim 14, wherein the cap includes a plurality of teeth with angled faces and generally perpendicular faces, and the cap holder includes a plurality of teeth configured to interact with the teeth of the cap.

31. The antiseptic cap assembly of Claim 30, wherein the cap holder includes a retaining mechanism sized to retain the cap in the cap holder.

32. The antiseptic cap assembly of Claim 14, wherein the cap holder includes a center plug positioned within the annular portion of the cap.

33. The antiseptic cap assembly of Claim 14, wherein the annular portion is coated with an antiseptic material, the annular portion configured to release the antiseptic material when compressed.

34. The antiseptic cap assembly of Claim 14, further comprising a clip sized to removably secure the cap holder to a supporting surface.

35. The antiseptic cap assembly of Claim 14, further comprising a hook sized to removably secure the cap holder to a supporting surface.

36. The antiseptic cap assembly of Claim 14, further comprising a horseshoe-shaped clip sized to removably secure the cap holder to a supporting surface.

37. The antiseptic cap assembly of Claim 14, wherein the cap holder includes an adhesive and a release sheet sized to cover the adhesive.

38. An antiseptic cap assembly for use with a connector comprising:

a cap having a base and an annular portion extending from the base, the annular portion defining a first chamber having an open end, at least a portion of the cap including an antiseptic material, the at least portion of the cap configured to release the antiseptic material when compressed.

39. The antiseptic cap assembly of Claim 38, further comprising a cap holder having a generally cylindrical sidewall defining a second chamber sized to receive the cap.

40. The antiseptic cap assembly of Claim 39, wherein the cap is made of porous plastic material.

41. An antiseptic cap for use with a connector, comprising:

a cap having a base and an annular portion extending from the base, the annular portion defining a chamber having an open end and having an inner surface; and

an antiseptic material coated onto the inner surface of the annular portion.

42. The antiseptic cap of Claim 41, further comprising an antiseptic coating on an external surface of the annular portion.

43. The antiseptic cap of Claim 41, wherein the antiseptic material comprises a metal.

44. The antiseptic cap of Claim 43, wherein the metal is silver.

45. The antiseptic cap of Claim 41, wherein the antiseptic material comprises an alcohol.

46. The antiseptic cap of Claim 45, wherein the alcohol is isopropyl alcohol.

47. The antiseptic cap of Claim 41, wherein the antiseptic material comprises chlorhexidine.

48. The antiseptic cap of Claim 41, wherein the cap is made of an absorbent material.

49. The antiseptic cap of Claim 41, wherein the cap comprises porous plastic material, bonded fiber, cotton, silicone, urethane, polyester, or cellulose.

50. The antiseptic cap of Claim 49, wherein the porous plastic material comprises a polymer.

51. The antiseptic cap of Claim 50, wherein the polymer comprises polyethylene, polypropylene, or nylon.

52. The antiseptic cap of Claim 41, wherein the annular portion includes a plurality of threads.

53. The antiseptic cap of Claim 41, wherein the annular portion includes a rim defining the open end, the annular portion being tapered such that the annular portion narrows from the rim toward the base.

54. The antiseptic cap of Claim 41, wherein the antiseptic material is coated onto the cap by immersion of the cap into an antiseptic solution.

55. The antiseptic cap of Claim 41, wherein the antiseptic material is coated onto the cap by spray coating the inner surface of the cap with an antiseptic solution.

56. The antiseptic cap of Claim 41, wherein the antiseptic material is coated onto the cap by blending an antiseptic solution or material into a polymeric material and forming the cap therefrom.

57. An antiseptic cap for use with a connector, comprising:

a cap having a base and an annular portion extending from the base, the annular portion defining a chamber having an open end and having an inner surface; and

an antiseptic material impregnated into the cap.

58. The antiseptic cap of Claim 57, wherein the impregnated antiseptic material is present on an external surface of the annular portion.

59. The antiseptic cap of Claim 57, wherein the impregnated antiseptic material is present on the inner surface of the annular portion.

60. The antiseptic cap of Claim 57, wherein the cap is made of an absorbent material.

61. The antiseptic cap of Claim 57, wherein the annular portion includes a plurality of threads.

62. The antiseptic cap of Claim 57, wherein the annular portion includes a rim defining the open end, the annular portion being tapered such that the annular portion narrows from the rim toward the base.

63. The antiseptic cap of Claim 57, wherein the antiseptic material is impregnated into the cap by blending an antiseptic solution or material into a polymeric material and forming the cap therefrom.

64. The antiseptic cap of Claim 57, wherein the antiseptic cap is molded from a resin and the antiseptic material is added to the resin for molding into the antiseptic cap.

65. A method of making an antiseptic cap for use with a connector, comprising:

molding a base and an annular portion extending from the base, the annular portion defining a chamber having an open end and having an inner surface; and

coating an antiseptic material onto the inner surface of the annular portion.

66. The method of Claim 65, further comprising coating an antiseptic material onto an external surface of the annular portion.

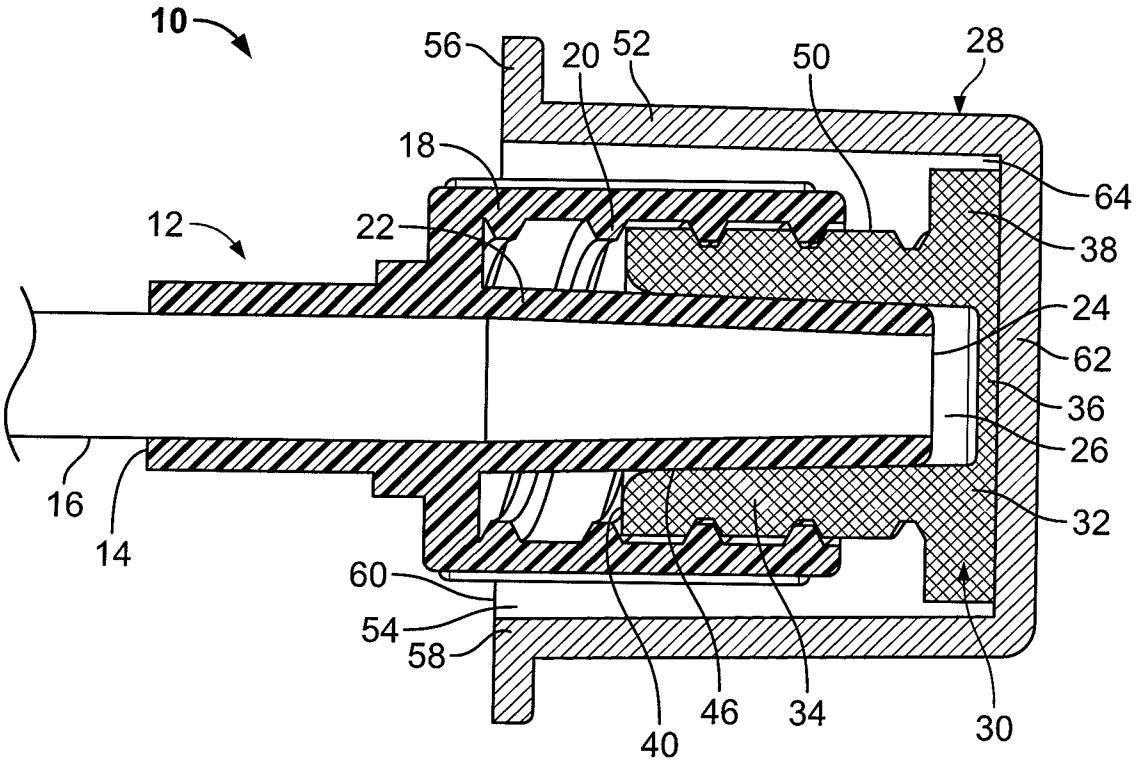
67. The method of Claim 65, wherein the step of coating the antiseptic material comprises immersing the cap into an antiseptic solution.

68. The method of Claim 65, wherein the step of coating the antiseptic material comprises spraying an antiseptic solution onto the inner surface of the cap.

69. A method of making an antiseptic cap for use with a connector, comprising:

mixing an antiseptic material into a resin to form a mixture; and

molding the mixture into a cap having a base and an annular portion extending from the base, the annular portion defining a chamber having an open end and having an inner surface, the antiseptic material impregnated into the cap.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52
50
28
18
64
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62
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26
16
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32
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58
40
46
34
30

FIG. 1

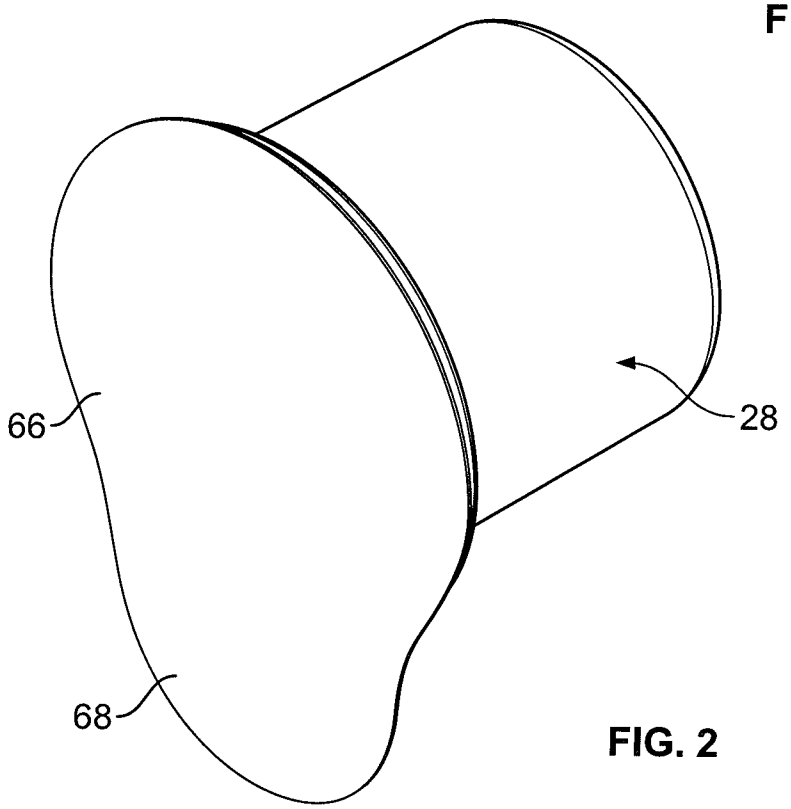

66
28
68

FIG. 2

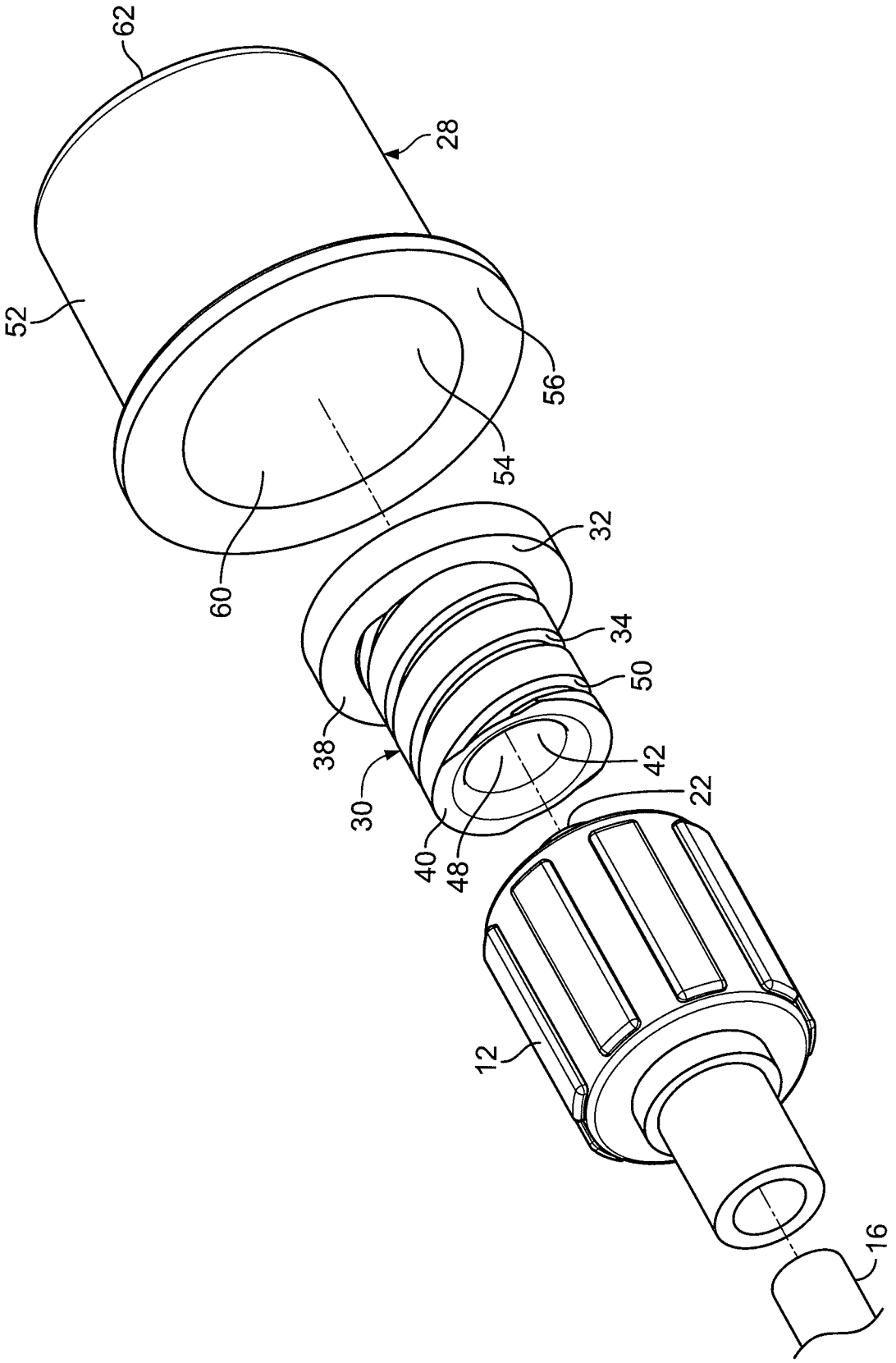


FIG. 3

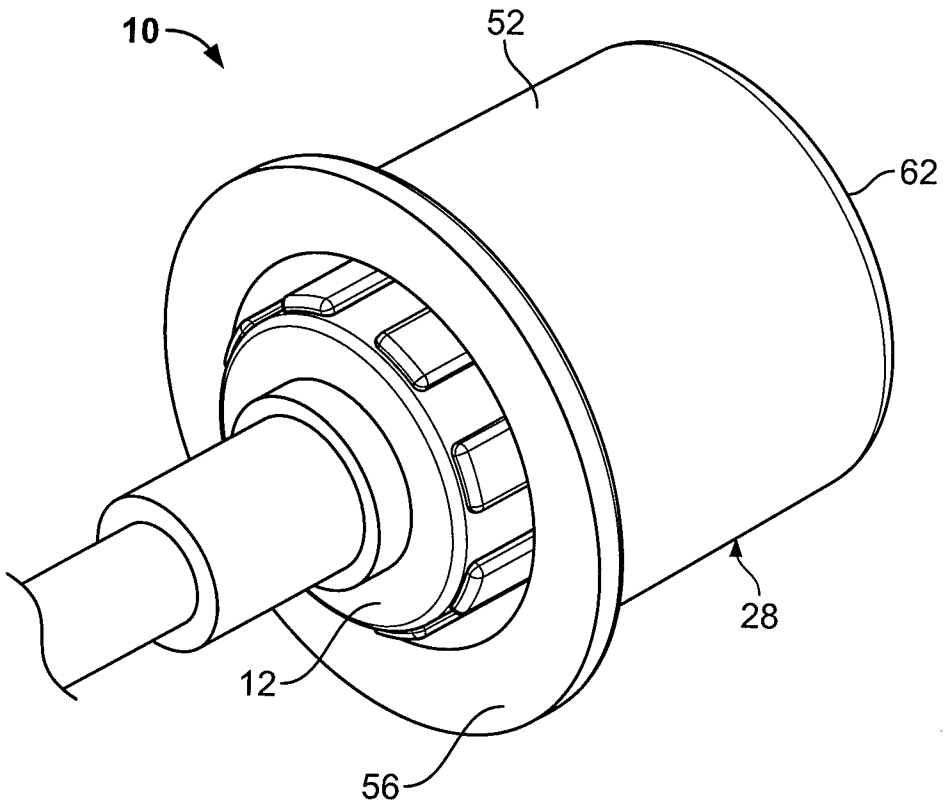
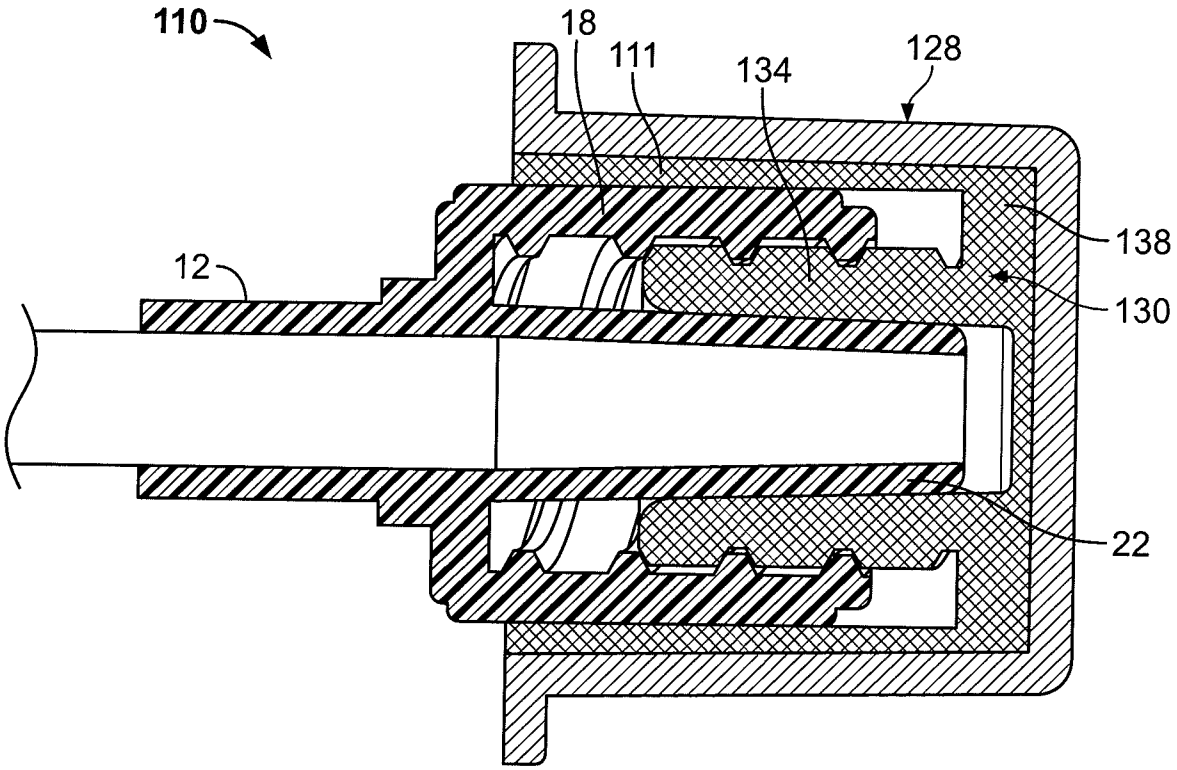


FIG. 4


110
18
111
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128
138
12
130
22

FIG. 5

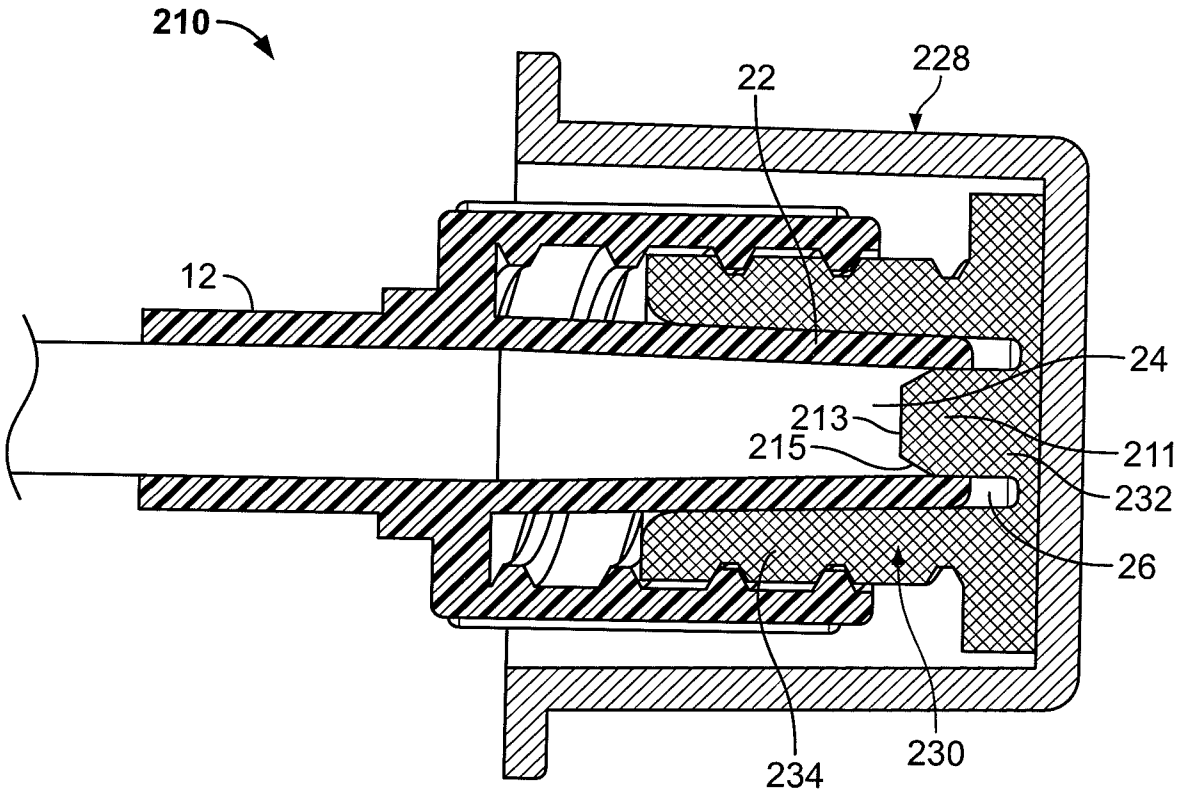

210
228
22
12
24
213
211
215
232
26
234
230

FIG. 6

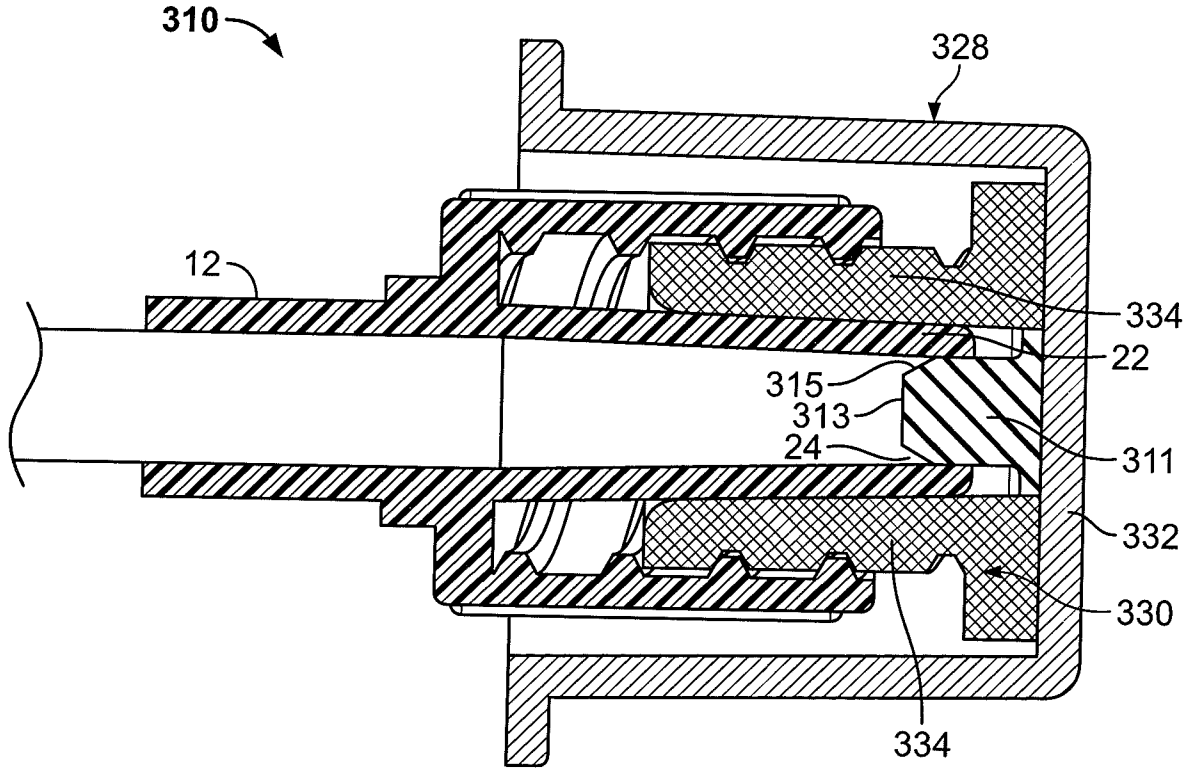

310
328
12
334
22
315
313
24
311
332
330
334

FIG. 7

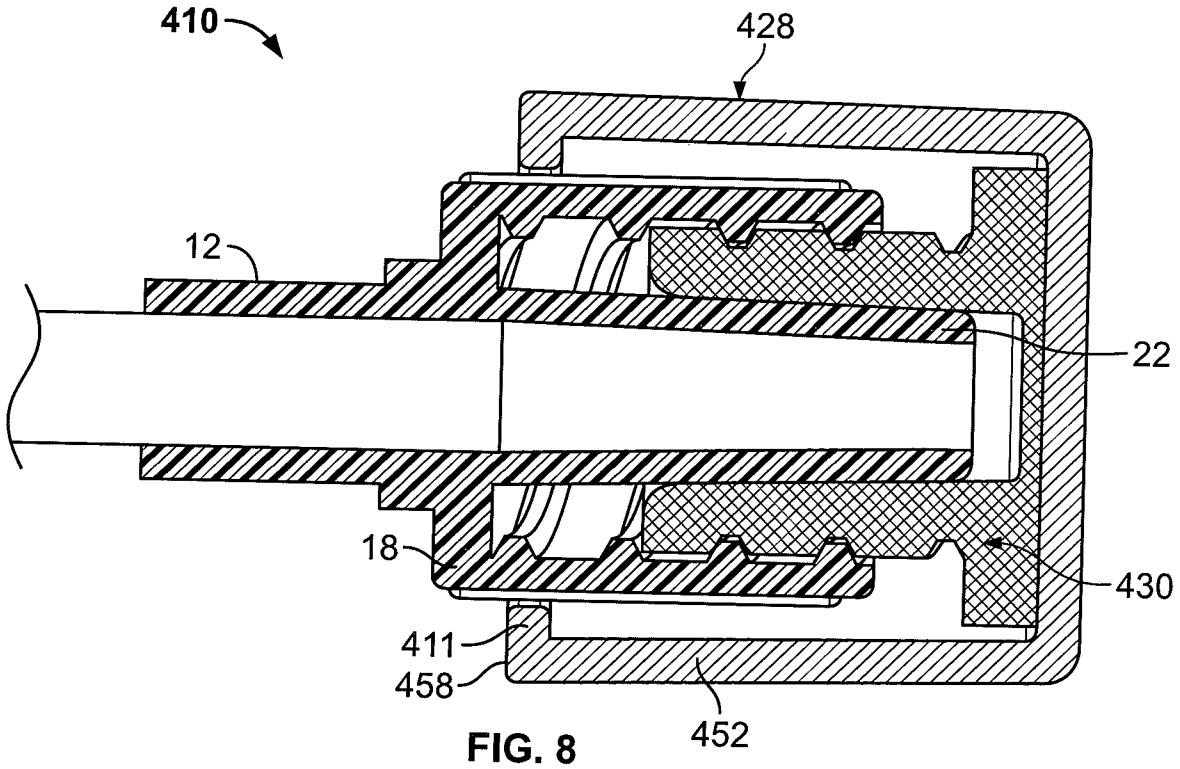

410
428
12
22
18
430
411
458
452

FIG. 8

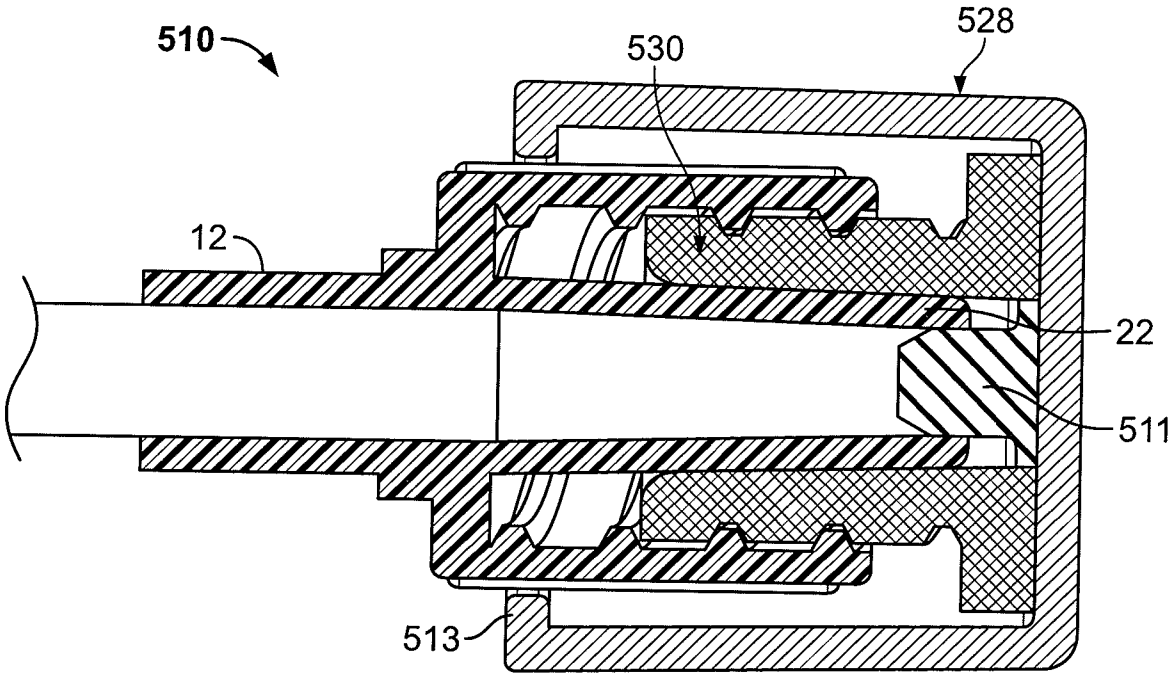


FIG. 9

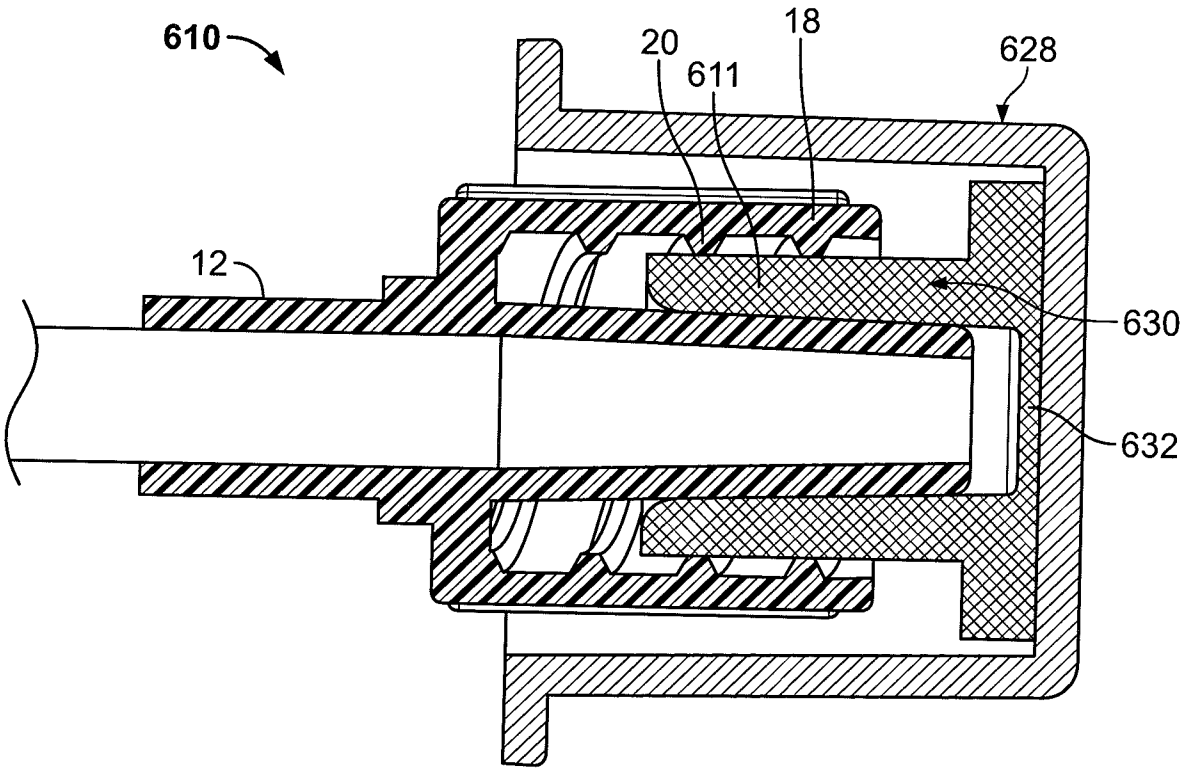


FIG. 10

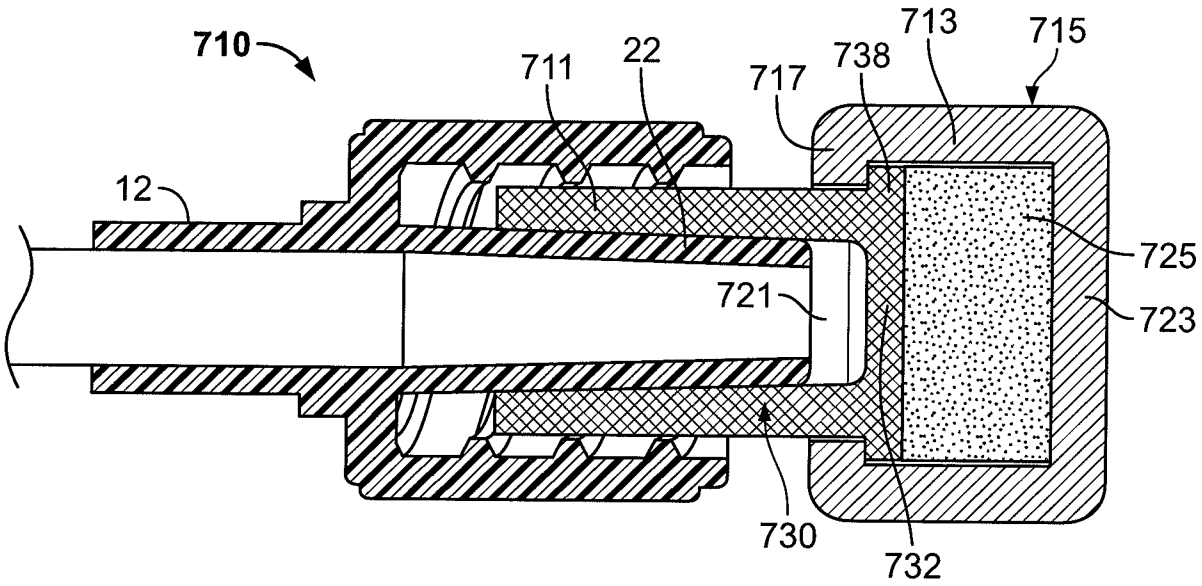


FIG. 11

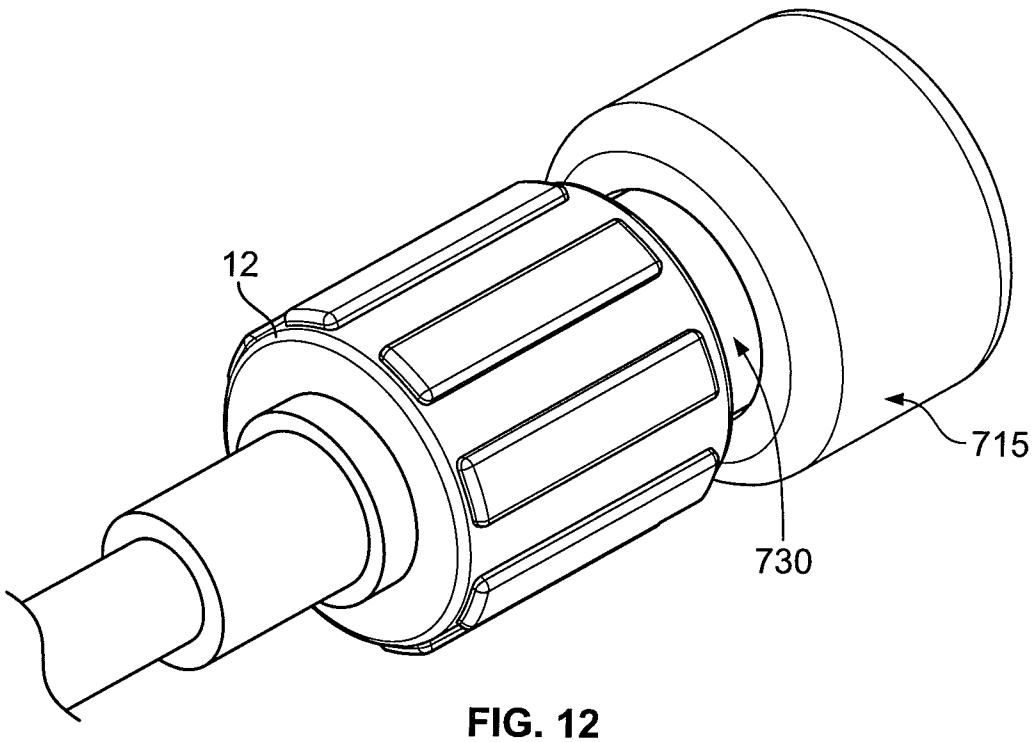


FIG. 12

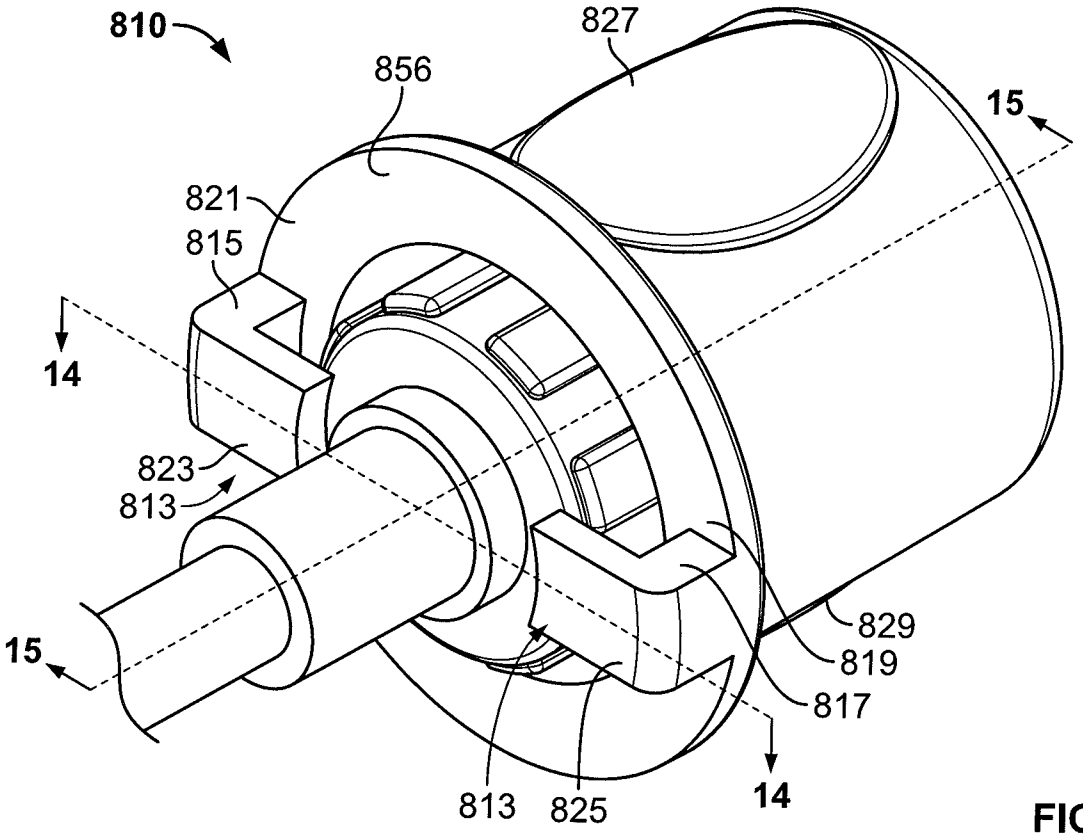
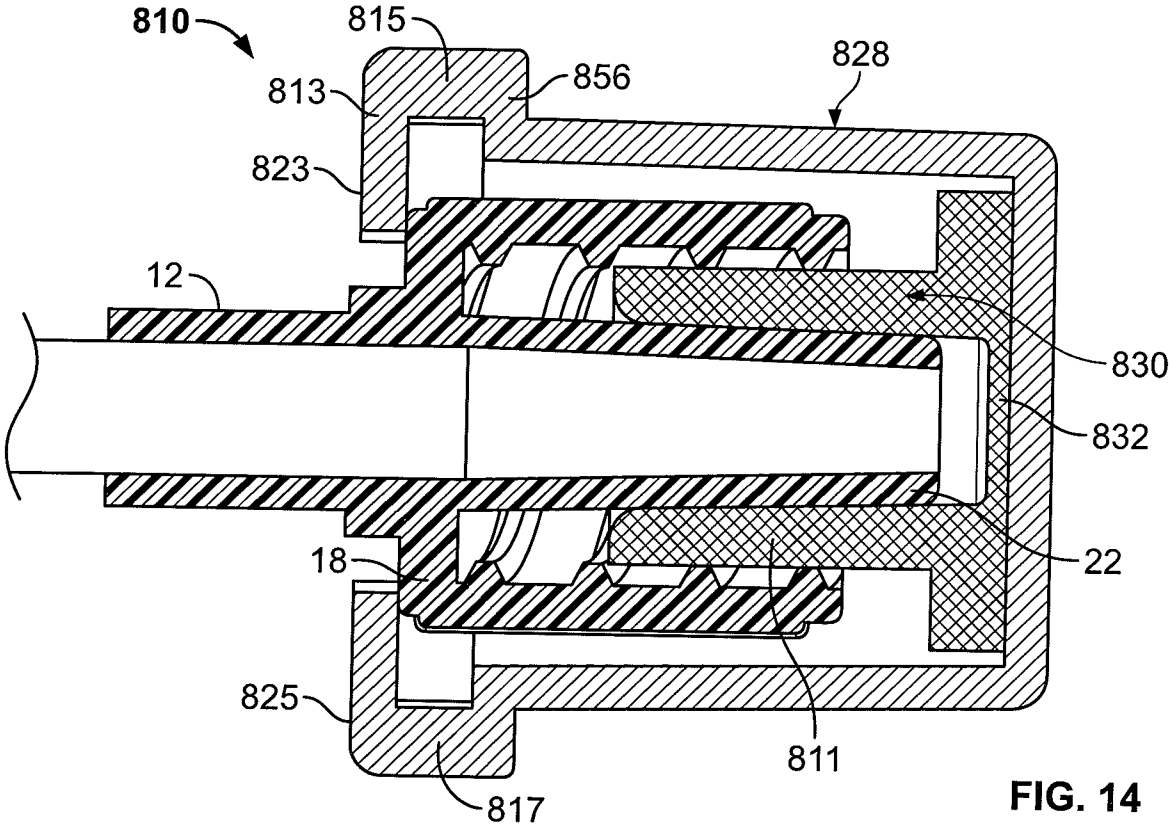

810
827
856
15
821
815
14
823
813
15
829
819
817
813
825
14

FIG. 13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815
828
813
856
823
12
830
832
18
22
825
811
817

FIG. 14

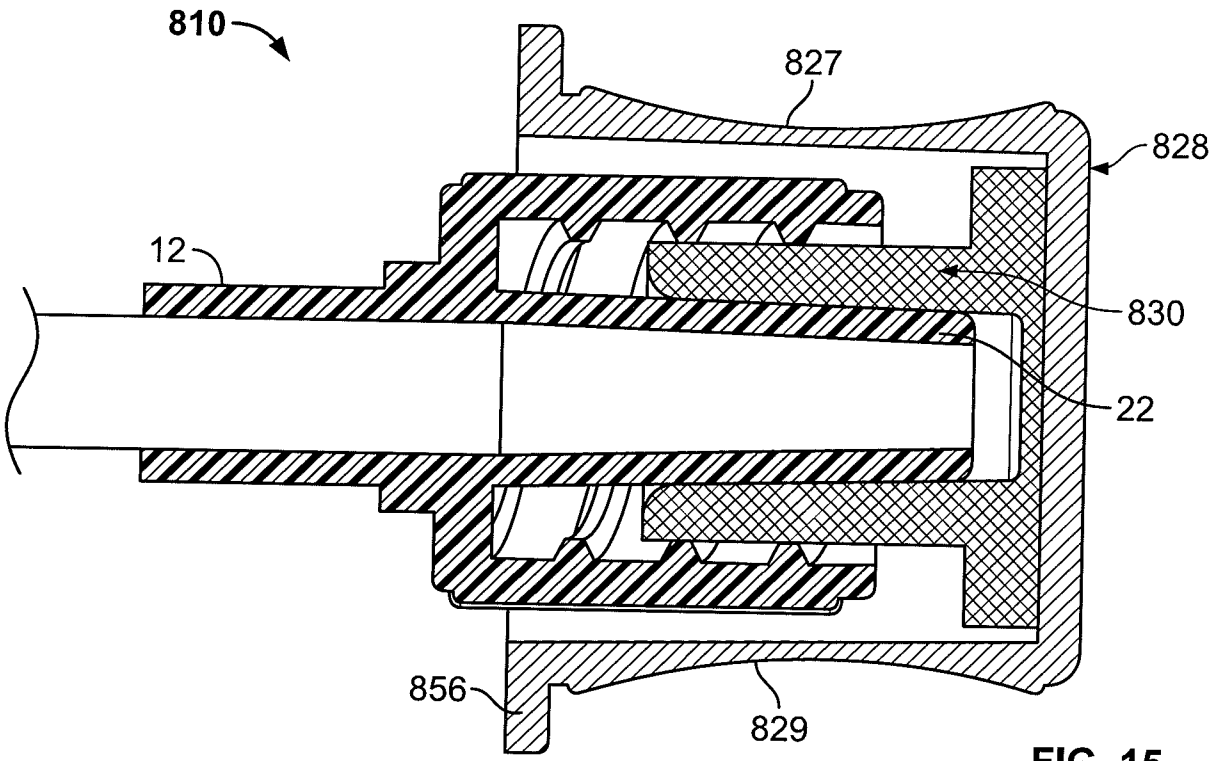
810
827
828
12
830
22
856
829

FIG. 15

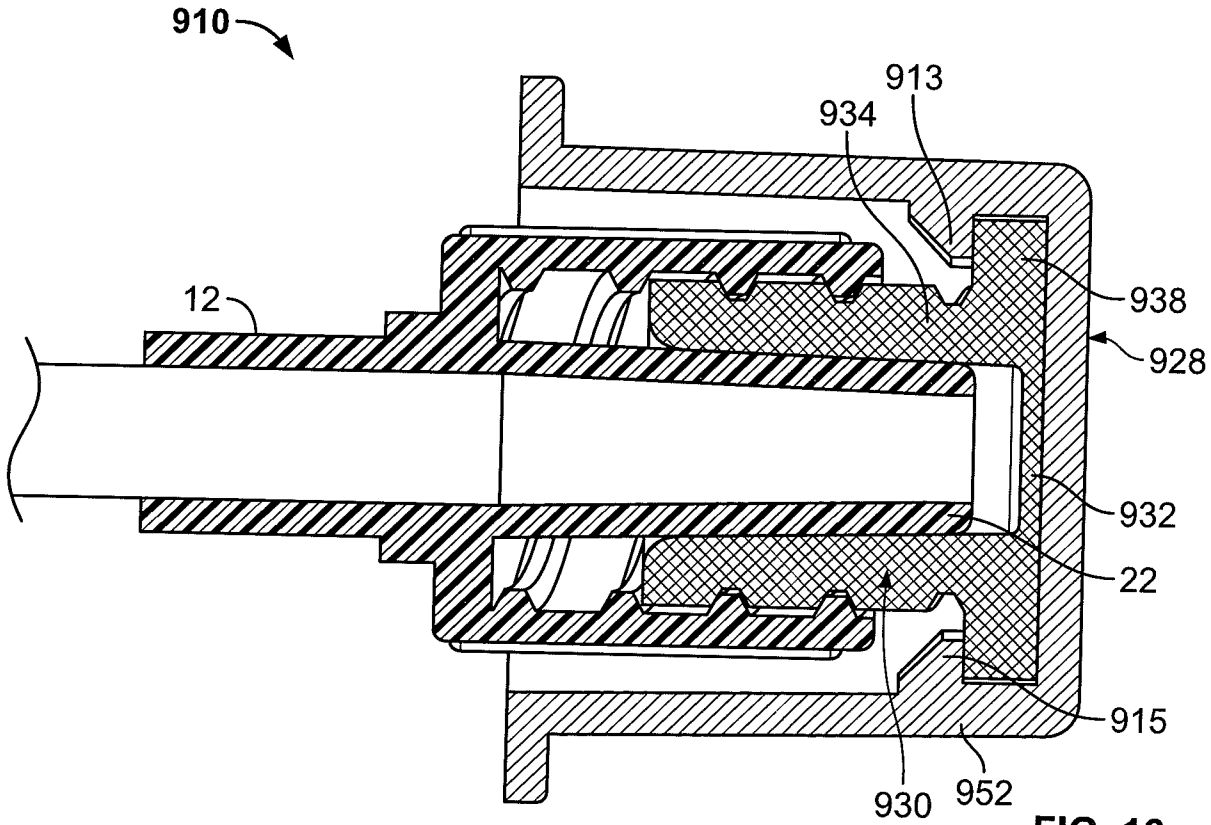
910
913
934
12
938
928
932
22
915
930
952

FIG. 16

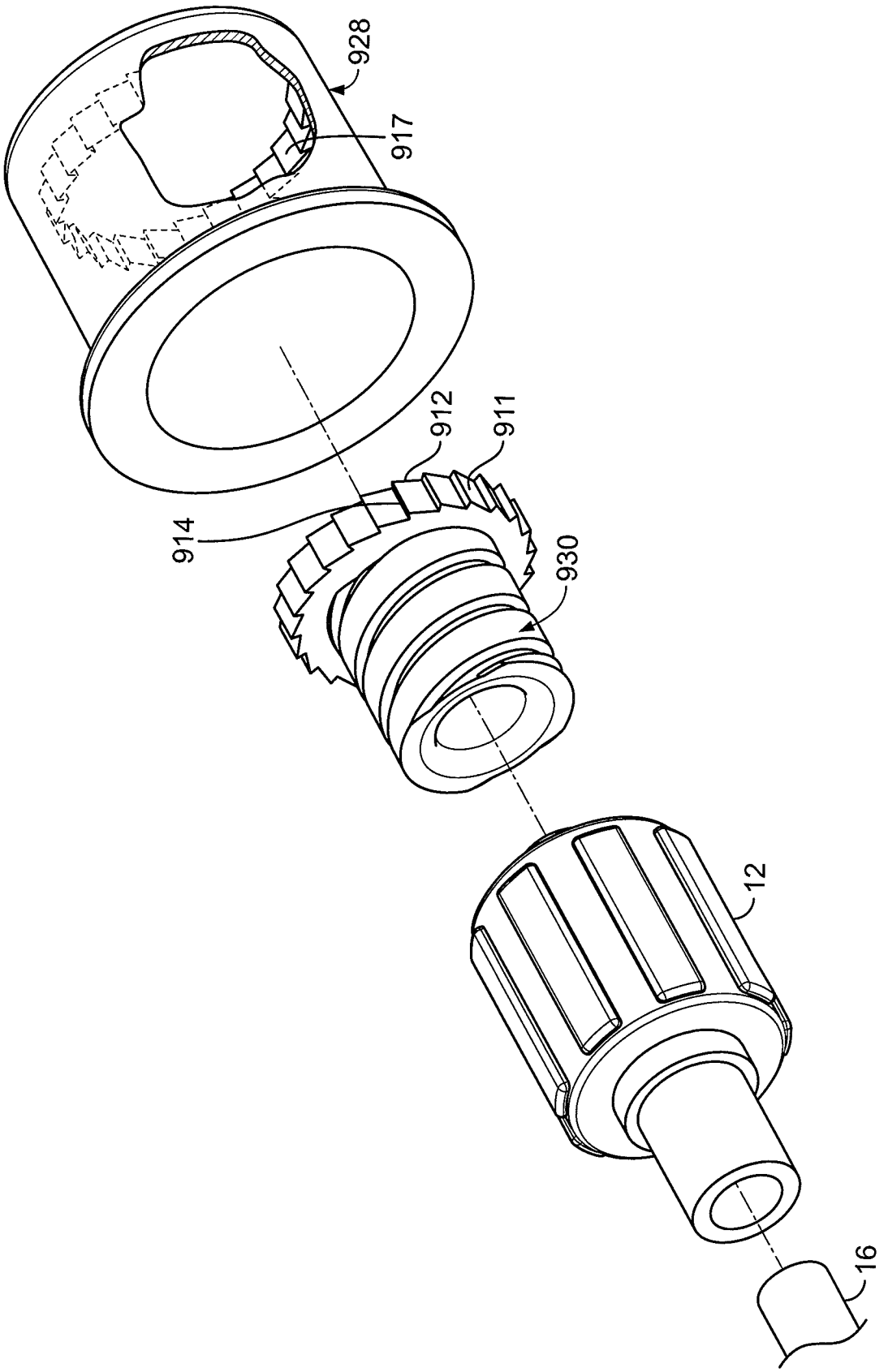

FIG. 17

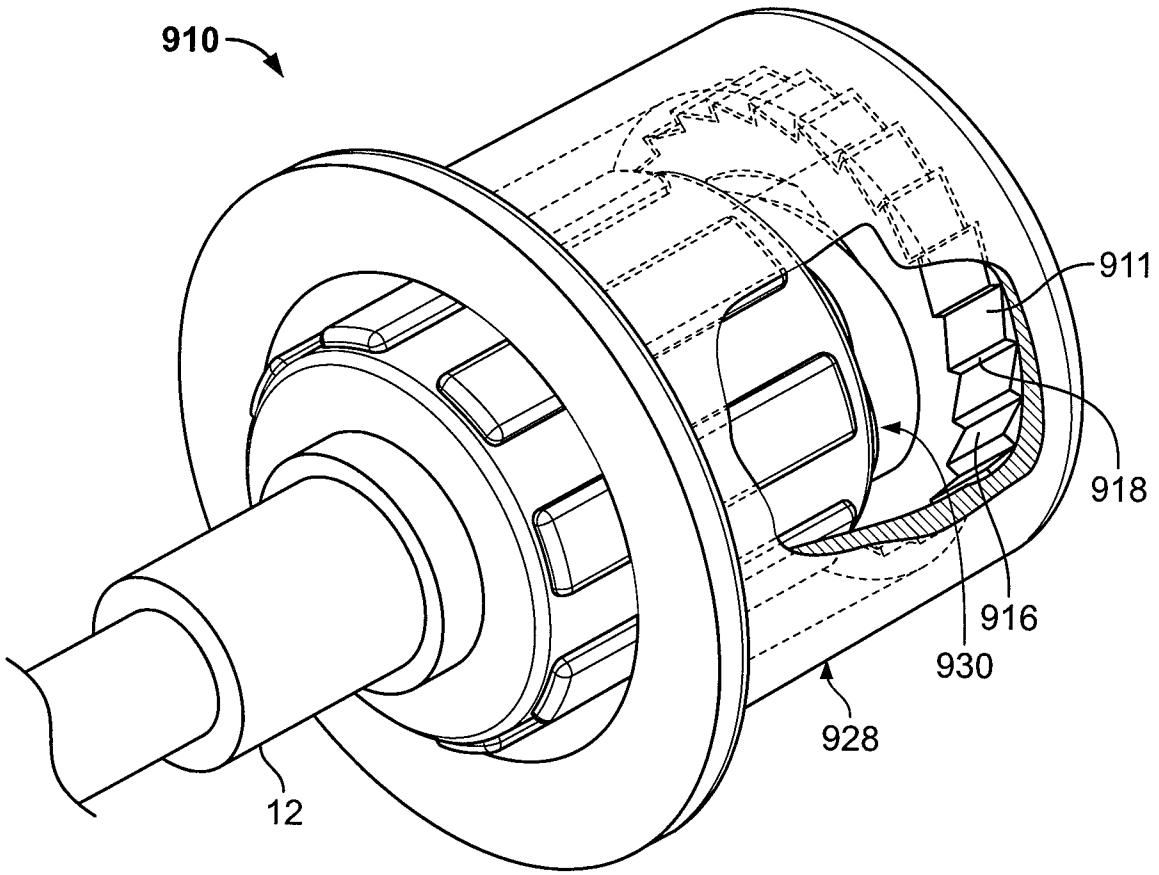

FIG. 18

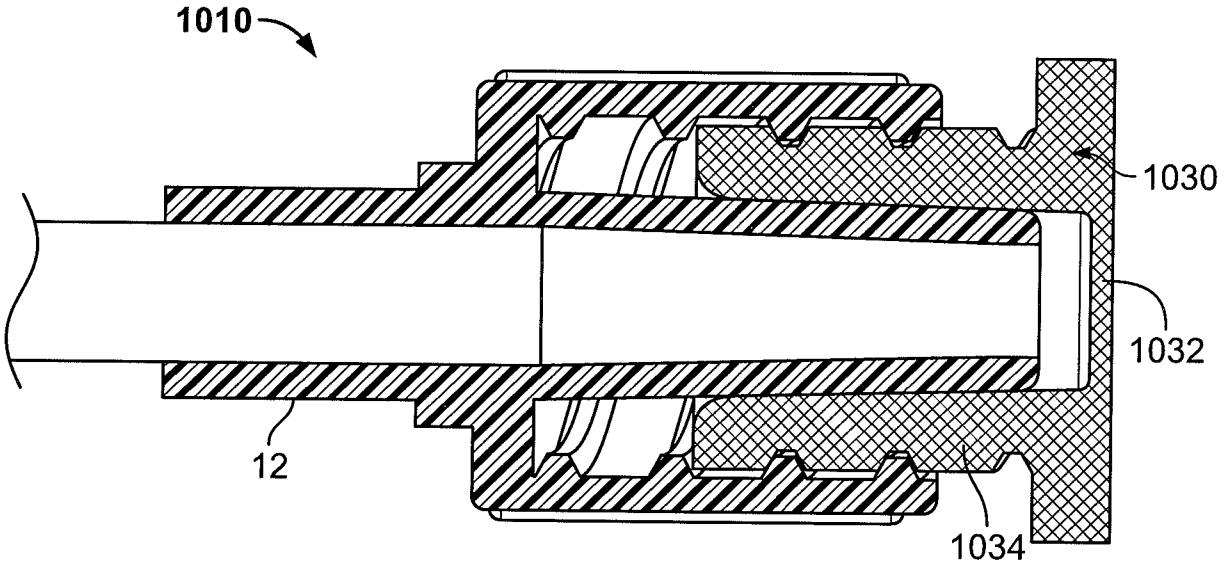

FIG. 19

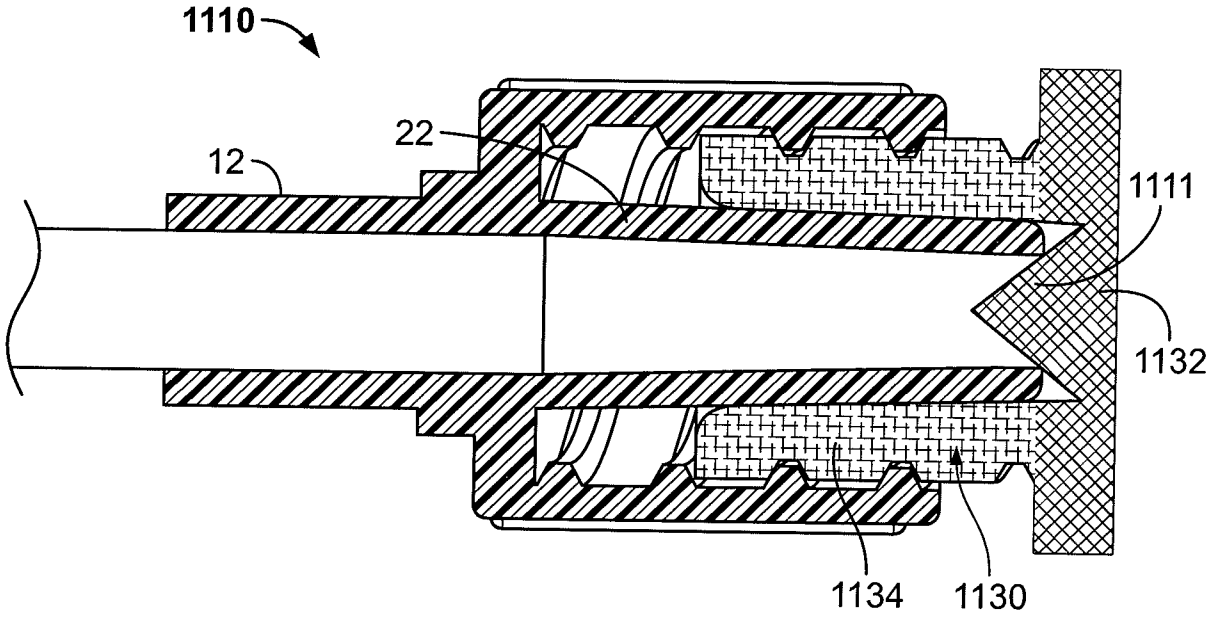

FIG. 20

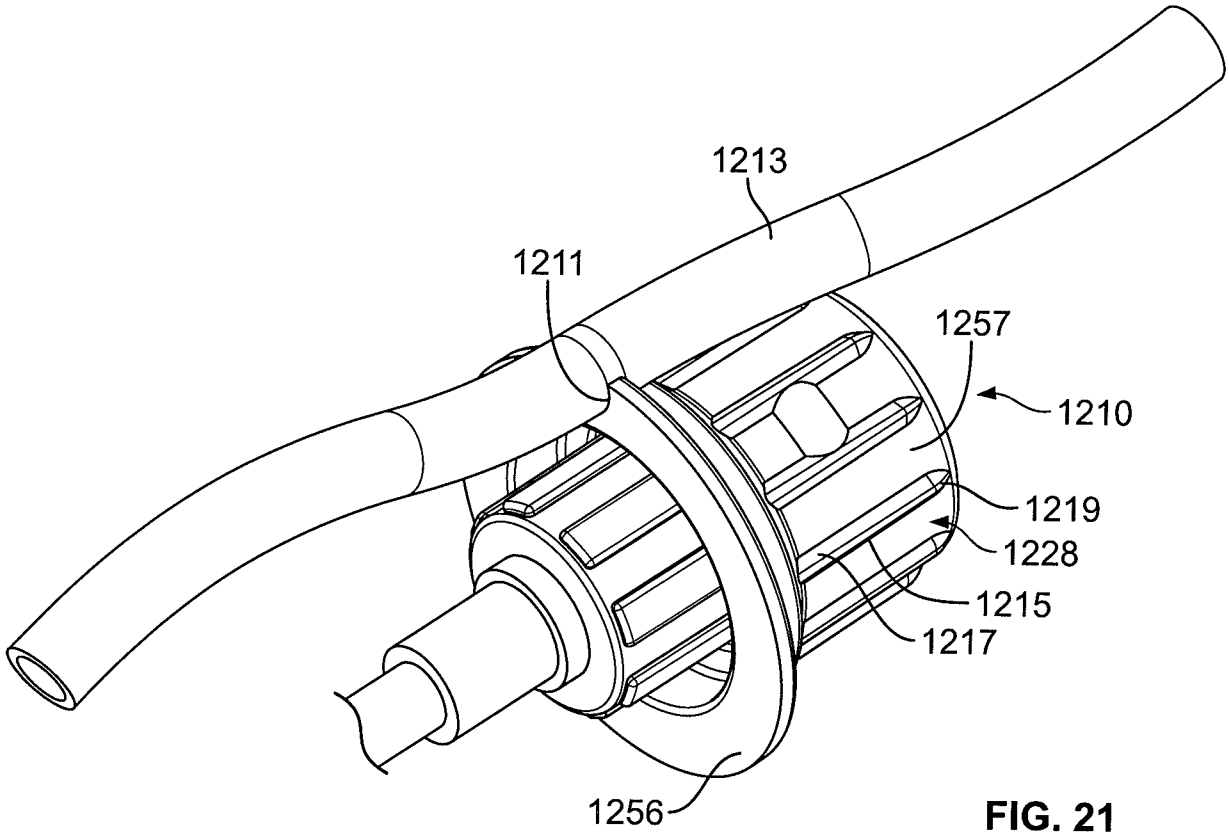
1213
1211
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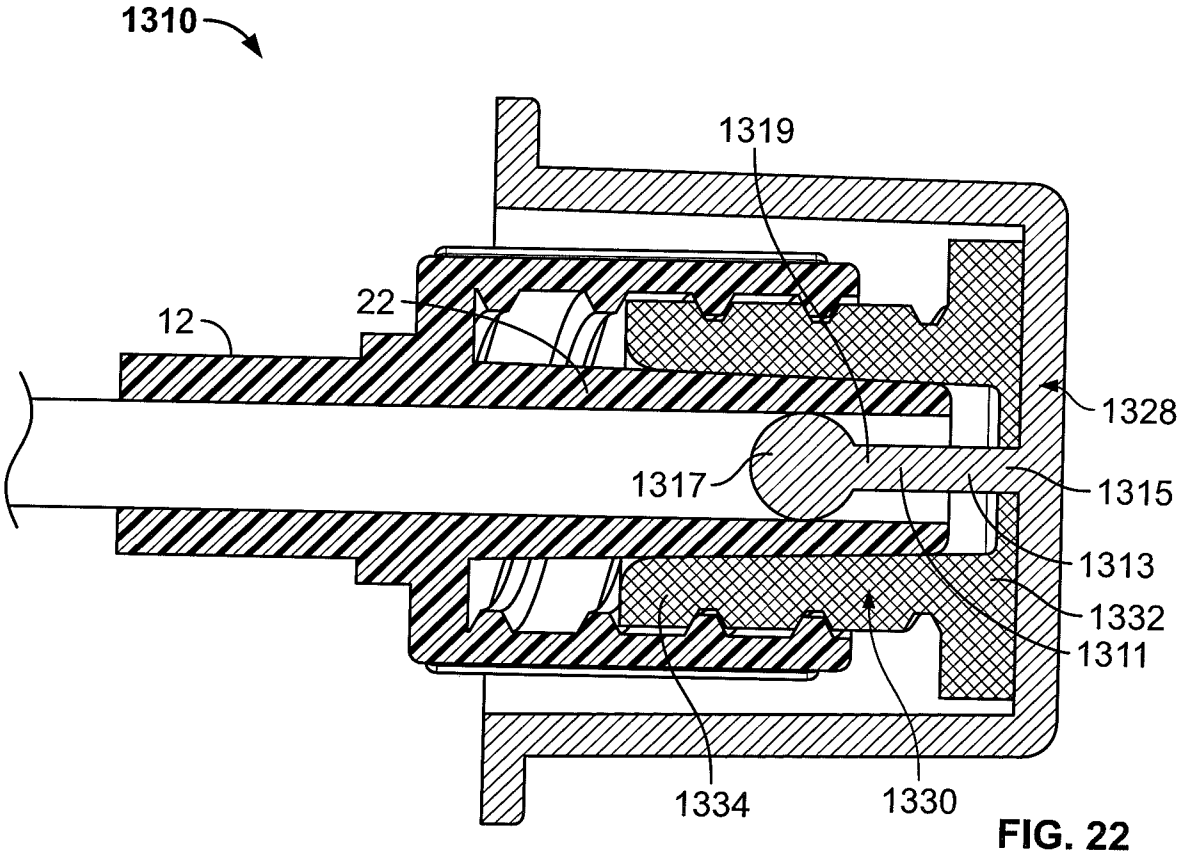
FIG. 21


1310
1319
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1328
1317
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1313
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1330

FIG. 22

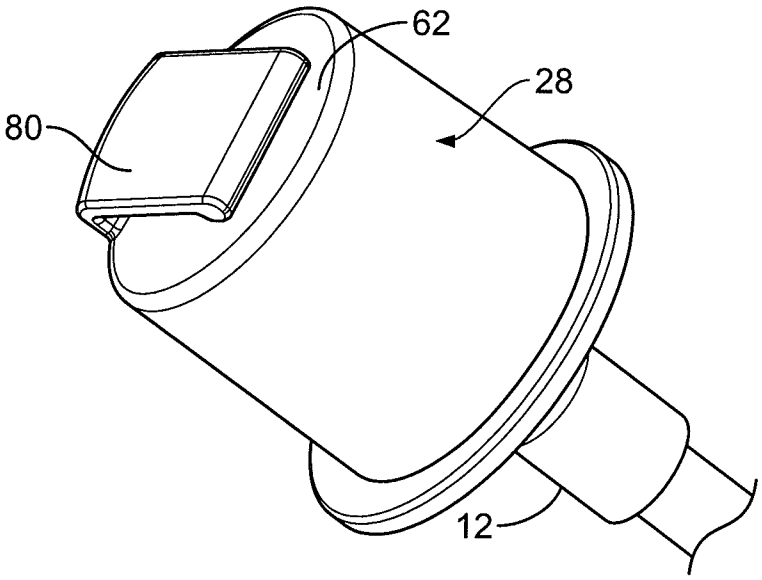

FIG. 23

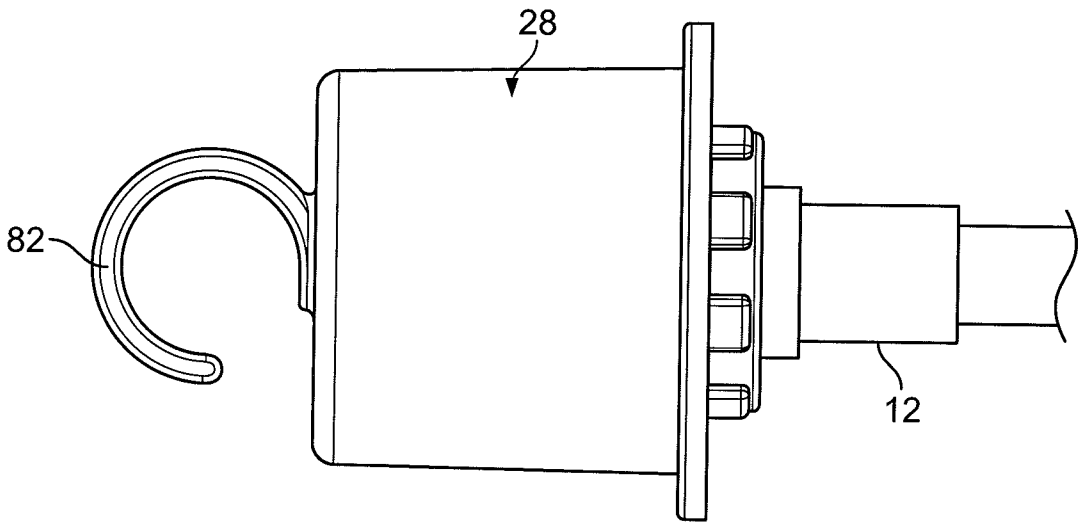

FIG. 24

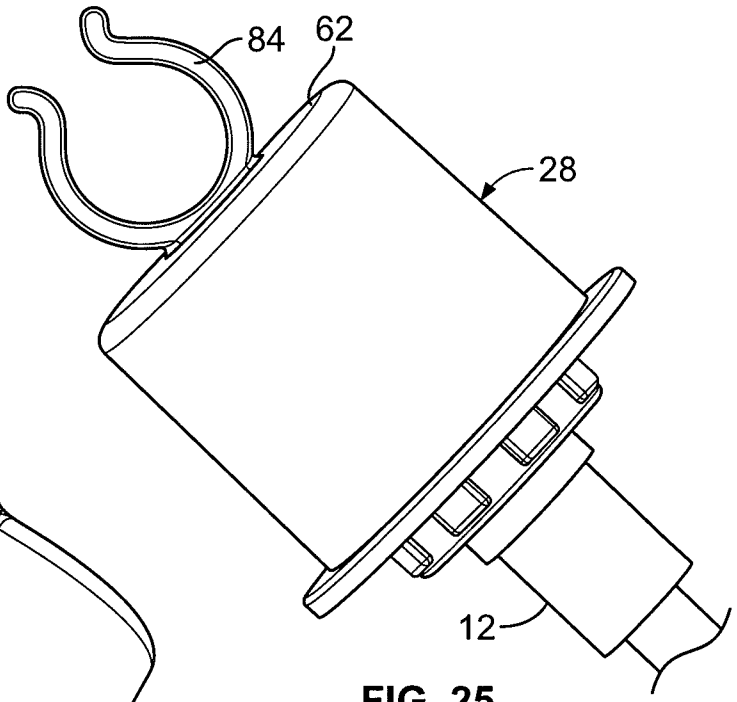

FIG. 25

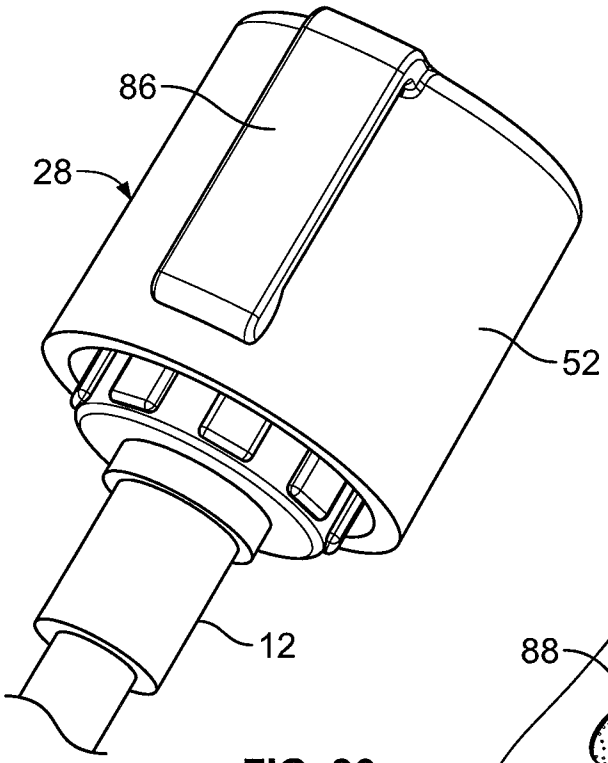

FIG. 26

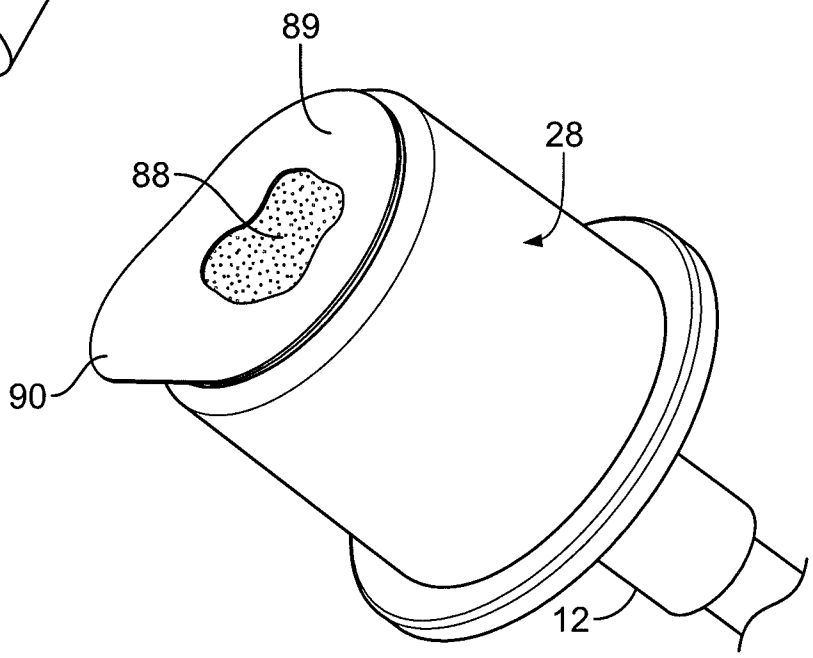

FIG. 27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/37772

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 39/20 (2012.01)
USPC - 604/267, 905
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)
IPC(8) - A61M 39/20 (2012.01)
USPC - 604/267, 905

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) - A61M 39/20 (2012.01)
USPC - 604/027.29, 265, 267, 280, 283, 093, 256, 905,

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB, USPT, EPAB, JPAB); Google (Patents, Scholar, Web)
Search Terms: Cap, cover, lid, luer, connector, male, absorb, plastic, porous, pore, base, annular, chamber, cavity, antiseptic, antibacterial, antibiotic, fluid, liquid, chamber, reservoir, sponge, coat, layer, release, compress, polymer, mix, blend, resin, thread, rim,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0064456 A (FERLIC) 18 March 2010 (18.03.2010) Fig. 1-2C; Para [0049], [0051], [0056]-[0057]	1
X ====== Y	US 2011/0030726 A1 (VAILLANCOURT et al.) 10 February 2001 (10.02.2001) Fig. 4, 7-8; Para [0065]-[0068], [0070]-[0071], [0076]	1-3, 7-9, 57-58, 60, 62 ========== 4-5, 12, 13, 59, 63, 64, 69
X ====== Y	US 4,666,427 A (LARSSON et al.) 19 May 1987 (19.05.1987) Fig. 1; col 1, ln 32 to col 2, ln 22,col 2, ln 34-51	1-2, 6-9, 57, 60 ========== 10-11, 13
X ====== Y	US 2010/0049170 A1 (SOLOMON et al.) 25 February 2010 (25.02.2010) Fig. 10-13; Para [0111]-[0112], [0115]-[0116]	57, 61-62 ========== 4-5, 10-11
X	US 20080019889 A1 (ROGERS et al.) 24 January 2008 (24.01.2008) Fig. 1-5, para[0034]-para[0036]	1
Y	US 2009/0099529 A1 (ANDERSON et al.) 16 April 2009 (16.04.2009) Fig. 5; Para [0071], [0173]-[0174]	12, 59
Y	US 5,190,534 A (KENDELL) 02 March 1993 (02.03.1993) Fig. 2-3; col 10, ln 29 to col 11, ln 2	13
Y	US 2008/0058733 A1 (VOGT et al.) 06 March 2008 (06.03.2008) Abstract	63
Y	US 3,882,858 A (KLEMM et al.) 13 May 1975 (13.05.1975) Abstract; col 4, ln 49 to col 5, ln 41	64, 69

☒ Further documents are listed in the continuation of Box C. ☐

* 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 another 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	Date of mailing of the international search report
01 October 2012 (01.10.2012)	26 OCT 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/37772

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.:
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:

3. ☐ Claims Nos.:
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:

--- please see continuation sheet ---

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 additional fees, this Authority did not invite payment of additional fees.

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.:
1-13, 57-64, 69

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

International application No.
PCT/US 12/37772

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,440,207 A (GENATEMPO et al.) 03 April 1984 (03.04.1984) entire document.	1-13, 57-64, 69
A	US 2005/0203460 A1 (KIM) 15 September 2005 (15.06.2005) Fig. 2-3; Para [0023]-[0026]	10-11, 13
A	US 5,554,135 A (MENYHAY) 10 September 1996 (10.09.1996) entire document.	1-13, 57-64, 69

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/37772

--- continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet) -----

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-13, 57-64, 69 drawn to systems and methods of manufacture of an absorbent antiseptic cap
Group II: Claims 14-40, drawn to systems of an absorbent antiseptic cap, with the additional feature of a cap holder
Group III: Claims 41-56, 65-68, drawn to systems and methods of manufacture of an coated antiseptic cap

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The shared common technical feature is systems of an antiseptic cap, namely as taught by US 2008/0235888 A1 to Kerr et al. (hereinafter: Kerr) who describes An antiseptic cap for use with a connector (Abstract), comprising:
a cap (22, FIG. 8) having a base (unlabeled bottom portion of 22, FIG. 8), and an annular portion (sidewall of 22, FIG. 7, 8) extending from the base, the
annular portion defining a chamber having an open end (FIG. 4), the cap being made of an absorbent material (Abstract: foam).
Kerr further discloses a cap holder (21) having a generally cylindrical sidewall defining a second chamber sized to receive the cap (FIGS. 2, 4).

Accordingly the remaining technical features of group II, which details the cap holder is not present in group I or group III, while the remaining technical feature of systems and methods to manufacture a coated antiseptic cap is not presend in group I or group II. Accordingly, unity of invention is lacking under PCT Rule 13.1.