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(54) **DISINFECTING CAP WITH RE-USE PREVENTION**

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A61M 39/10 (2006.01)

A61M 39/02 (2006.01)

(52) **U.S. Cl.**

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(2013.01); **A61M 2039/0258** (2013.01); **A61M**
2205/273 (2013.01)

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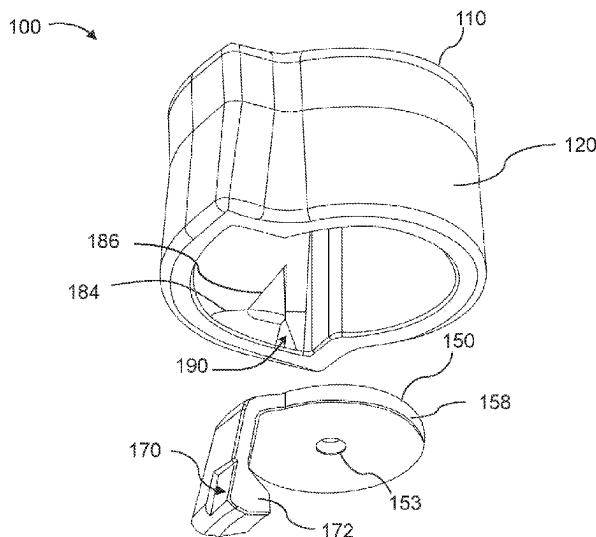
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ABSTRACT

A medical connector for connection to a corresponding medical connector is described. The medical connector includes a housing having a radial protrusion and a cavity, the cavity defined by a closed end, an open end, a partially cylindrical sidewall and a radial sidewall. The medical connector further includes an insert disposed within the housing, the insert including a locking tab having at least one thread on the inner wall of the locking tab and a recessed notch on the outer wall of the locking tab. The at least one thread of the locking tab engages at least one thread of a corresponding medical connector. Disposed within the cavity, the recessed notch rotates from a first position to a second position, wherein the second position contains a locking structure for non-removably securing the insert to the housing, while allowing for removal of the corresponding medical connector.

13 Claims, 20 Drawing Sheets



(58) **Field of Classification Search**

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2039/1033; A61M 2039/1044; A61M
39/10; A61M 2005/3104; A61M
2005/312; A61M 2039/0288; A61M
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A61M 2205/0205; A61M 39/165; A61M
39/18; A61M 2039/0036; A61M
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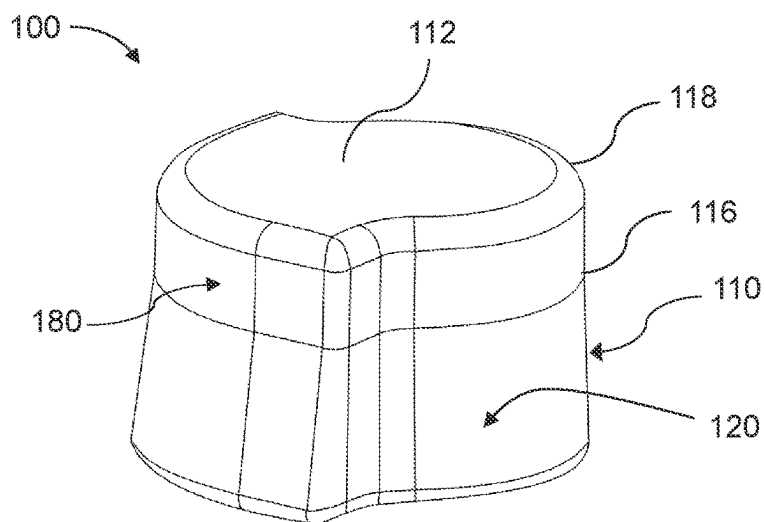


FIG. 1A

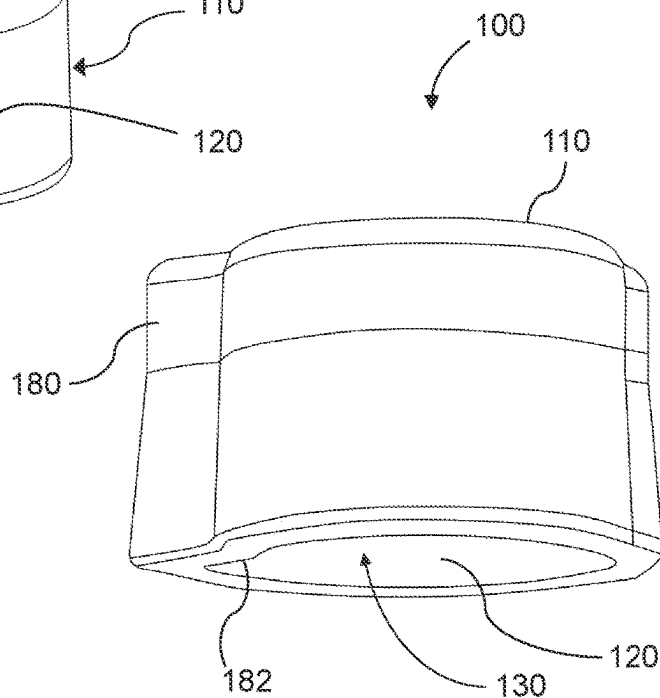


FIG. 1B

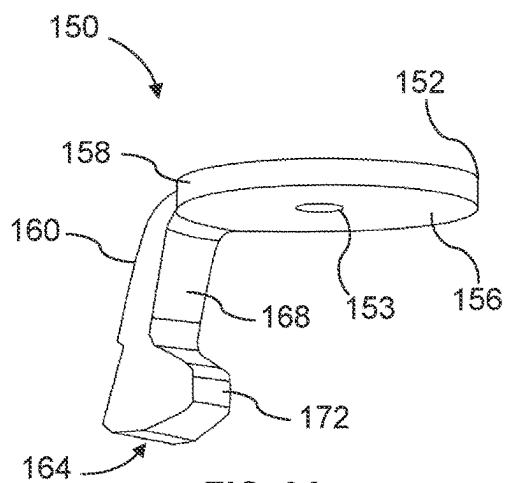


FIG. 2A

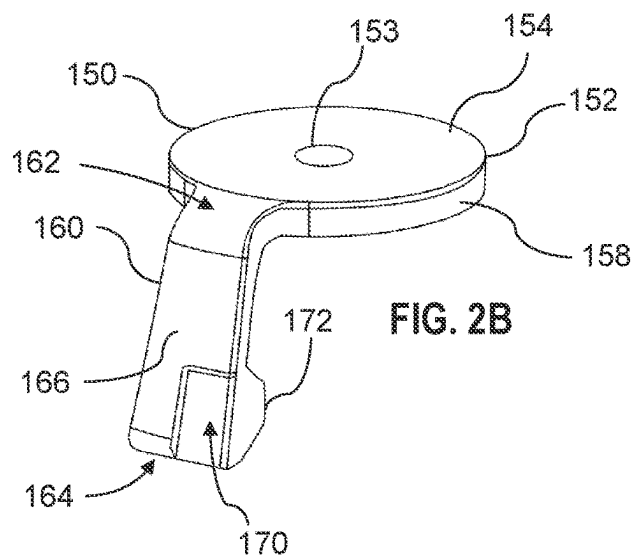


FIG. 2B

FIG. 3

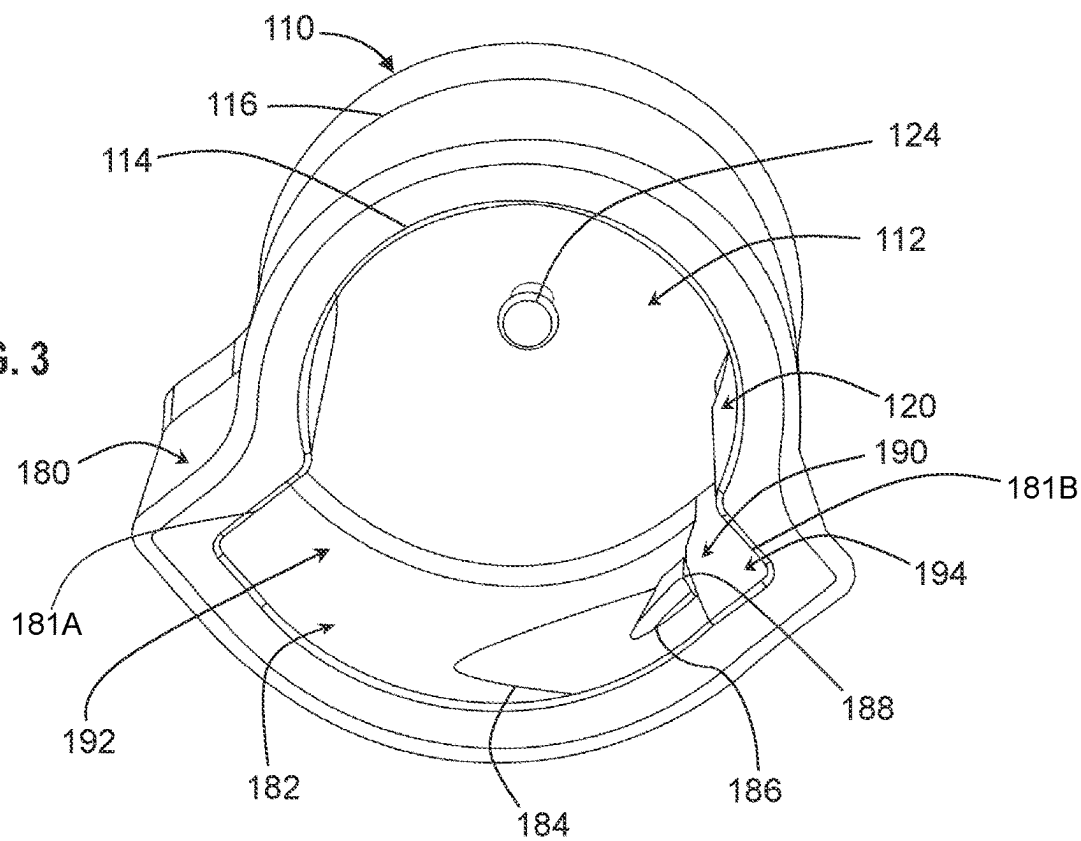


FIG. 4

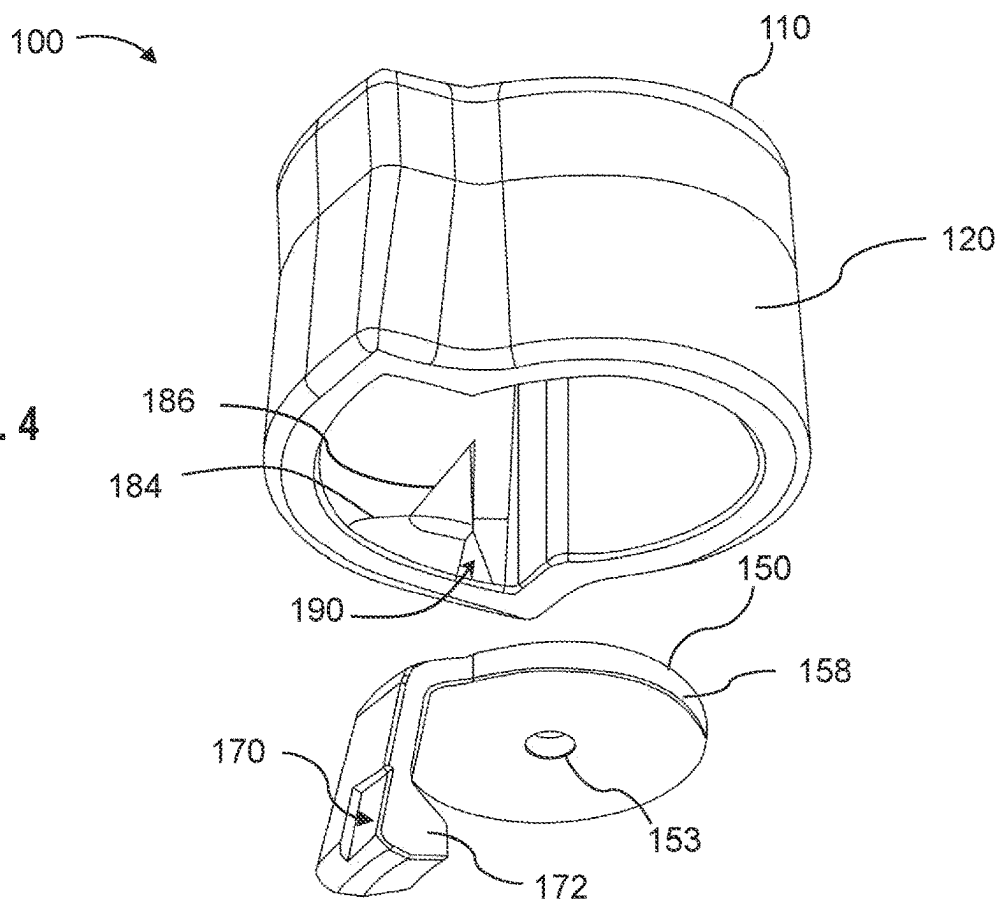


FIG. 5

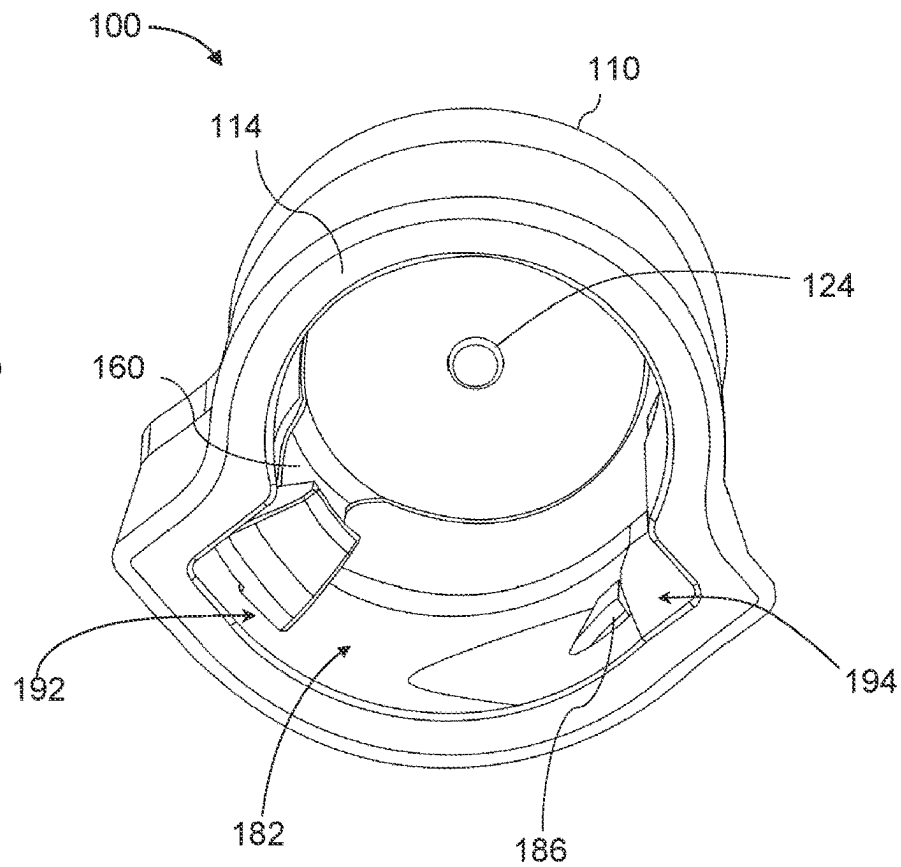
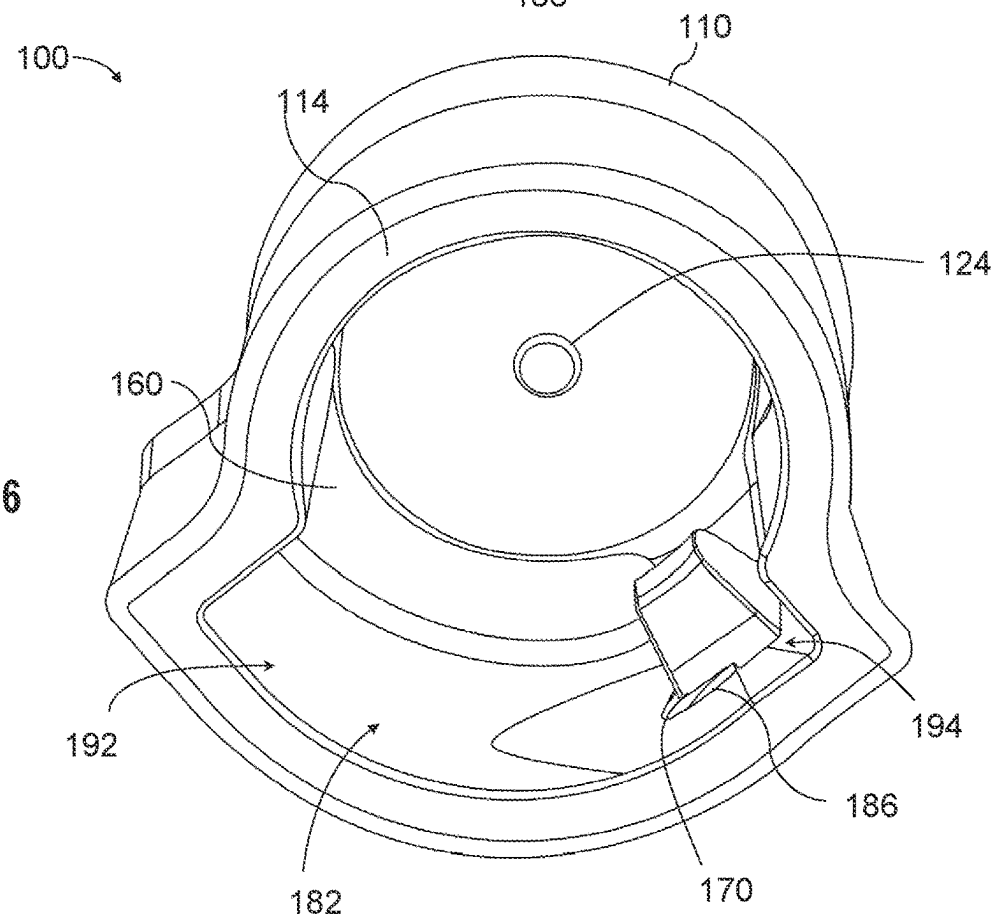
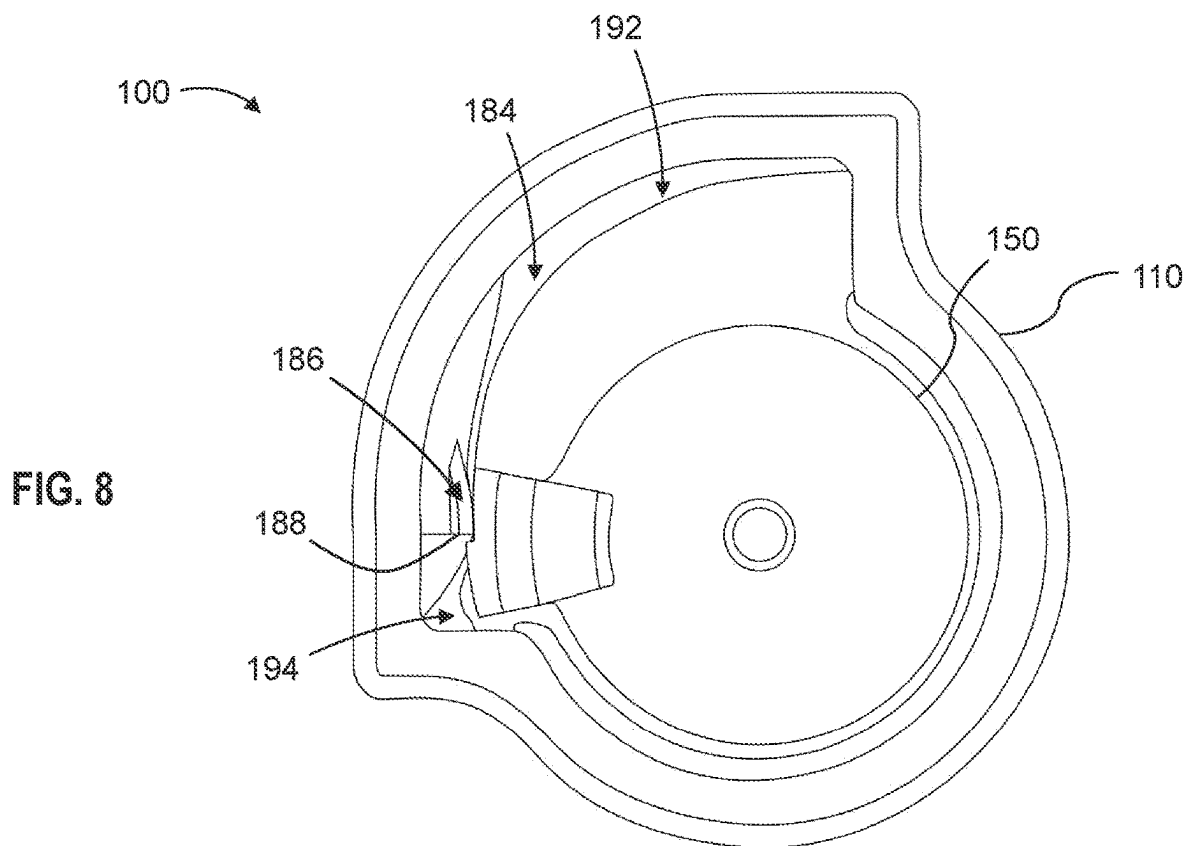
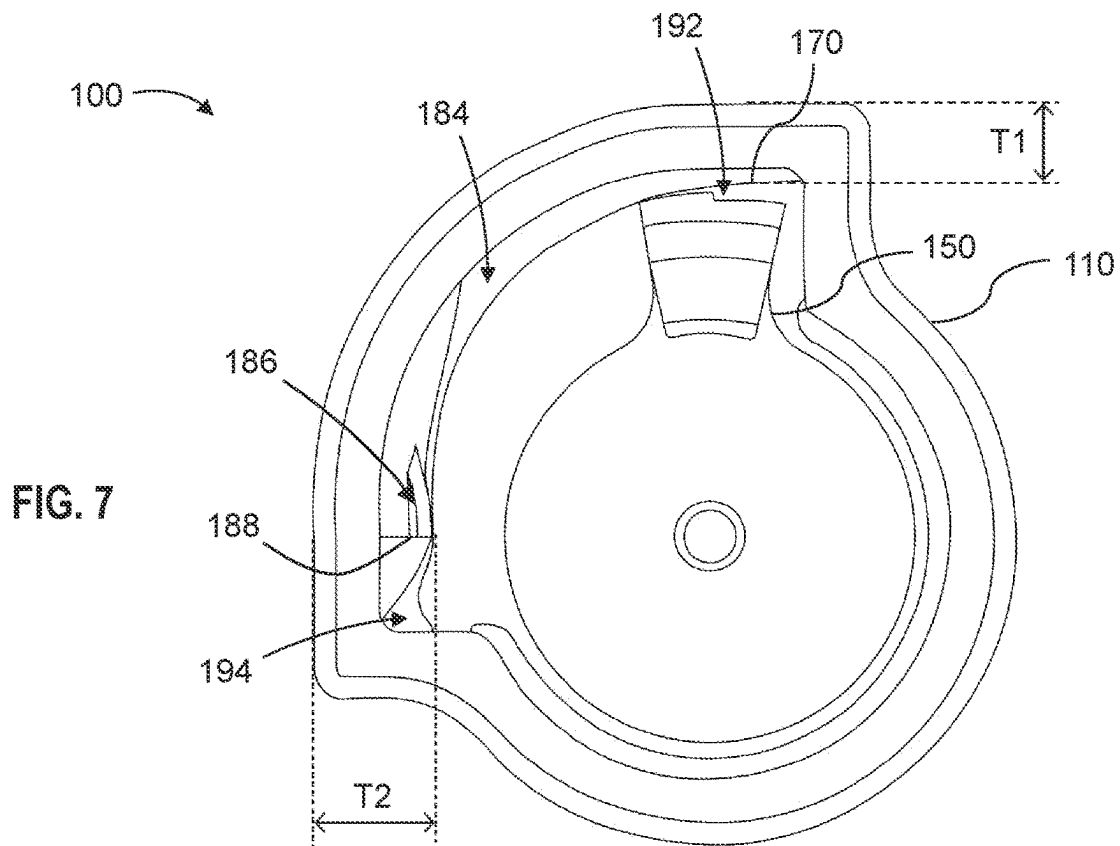
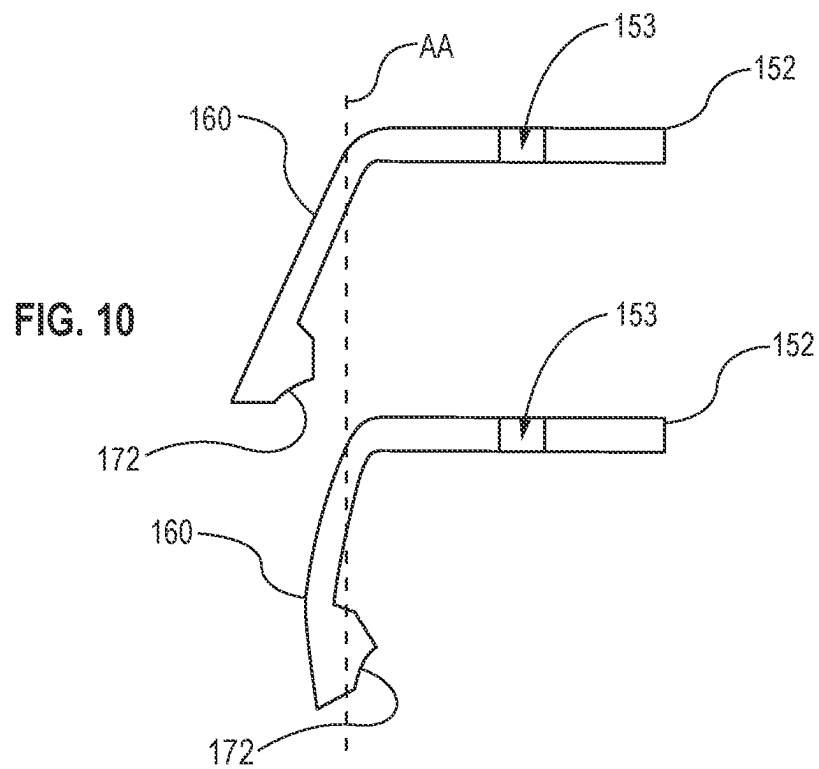
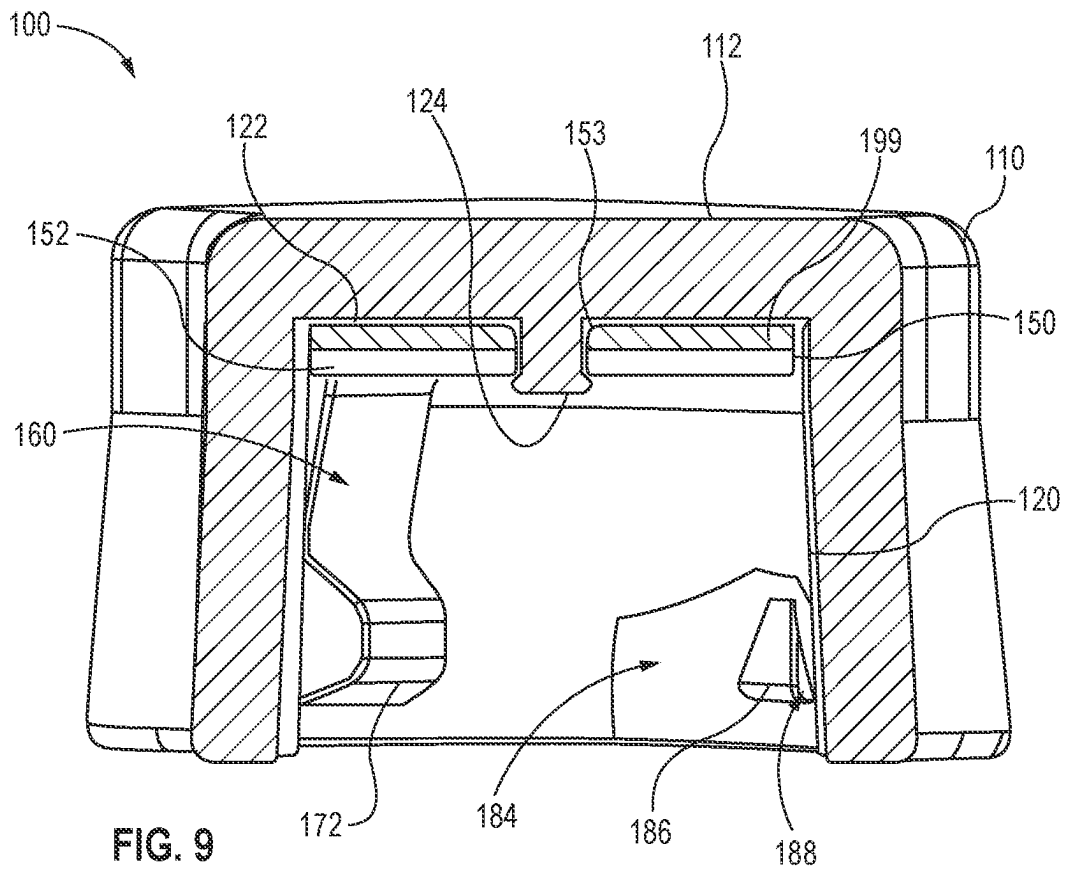
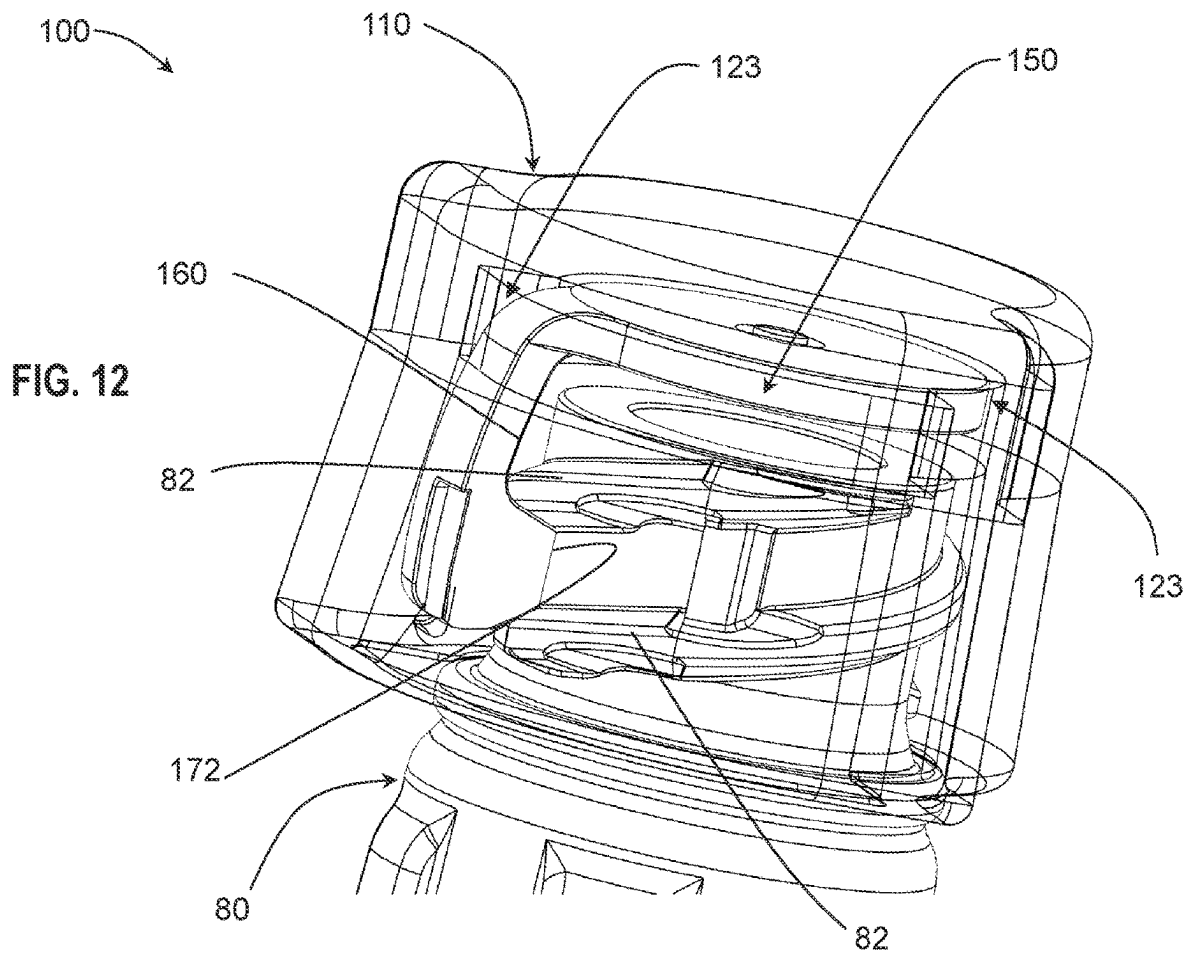
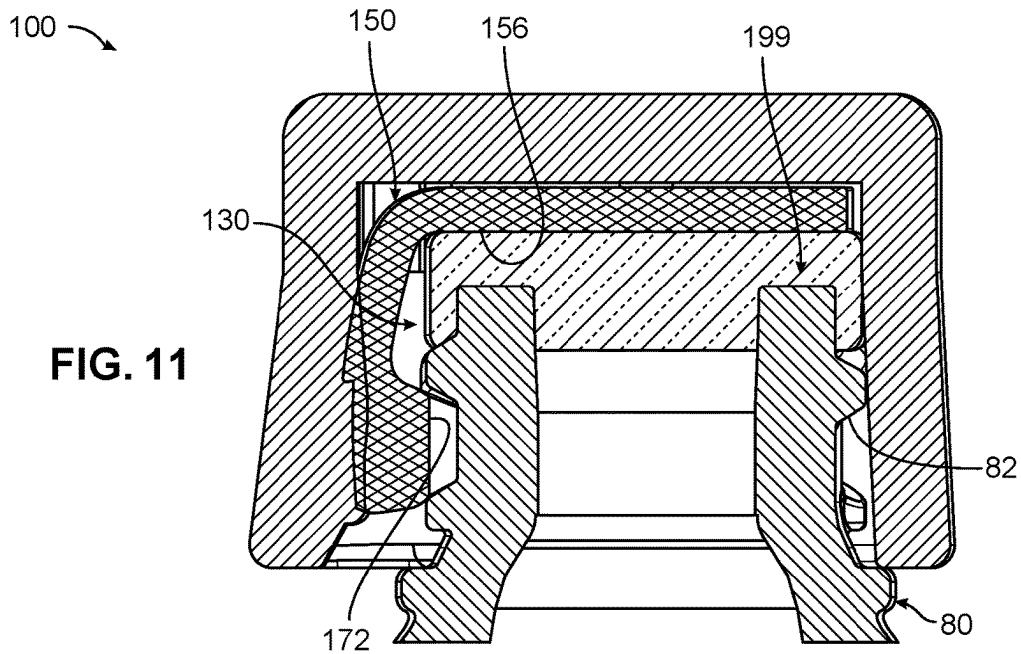


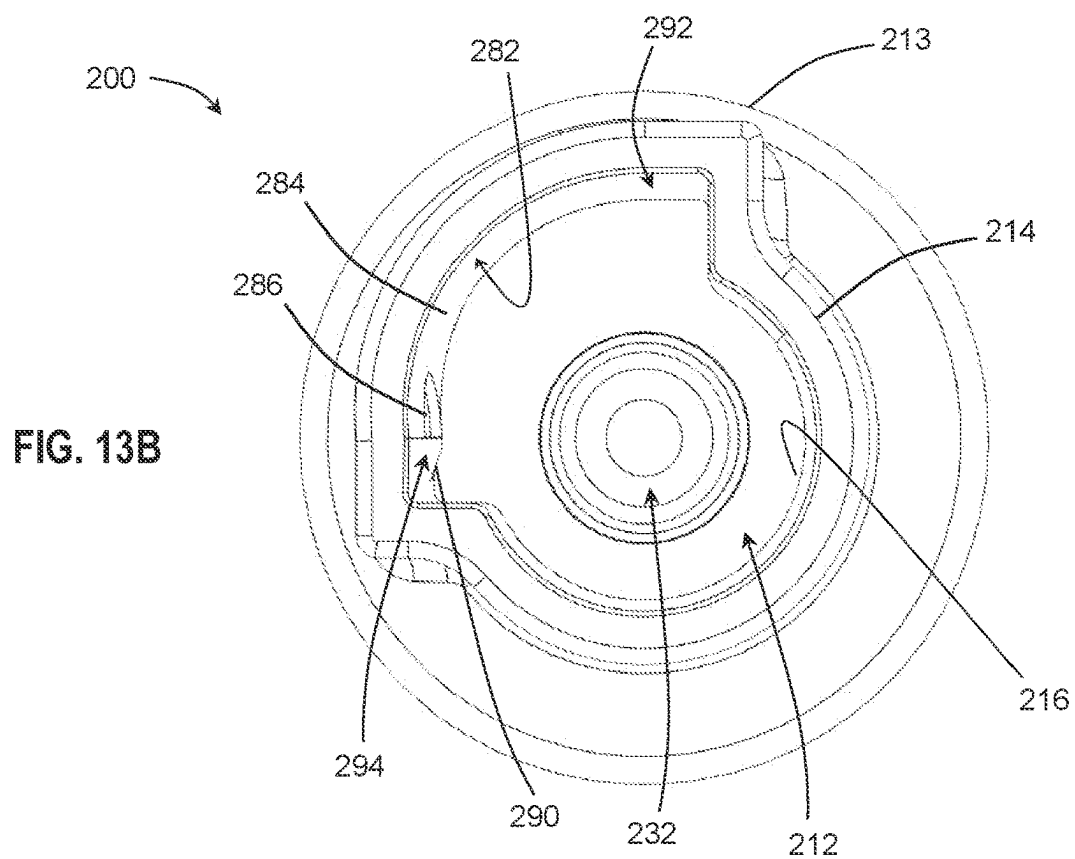
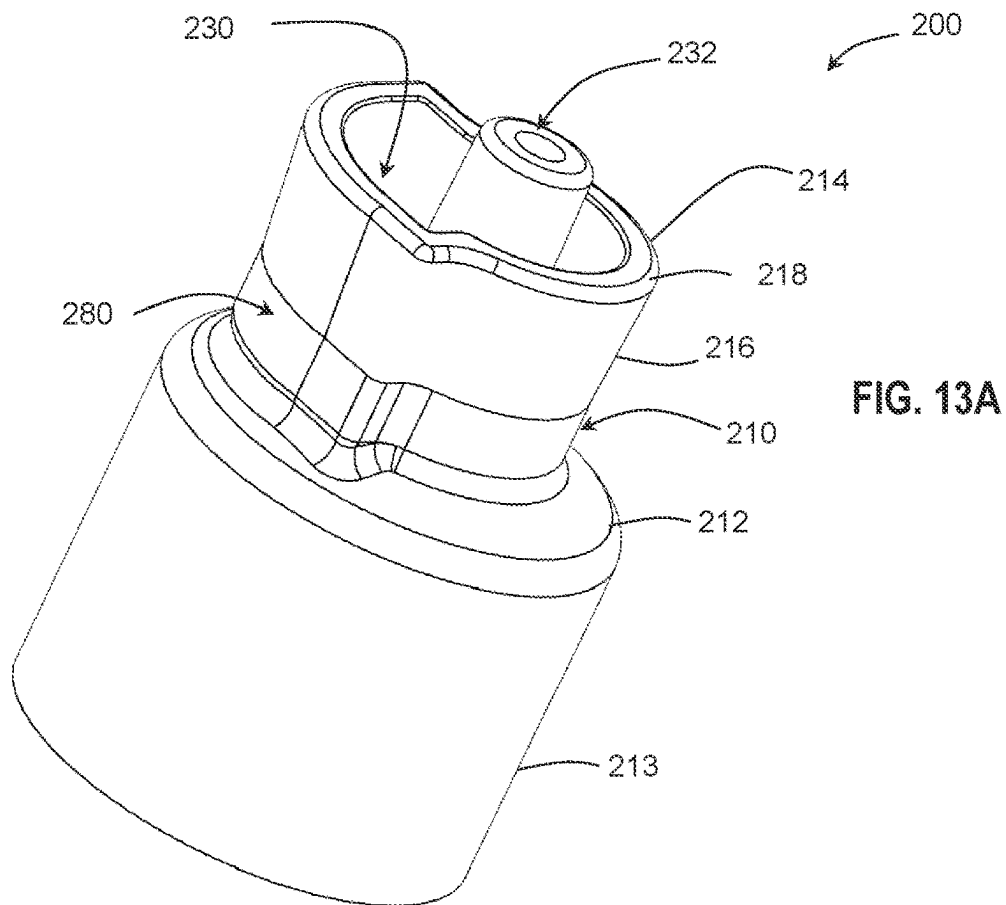
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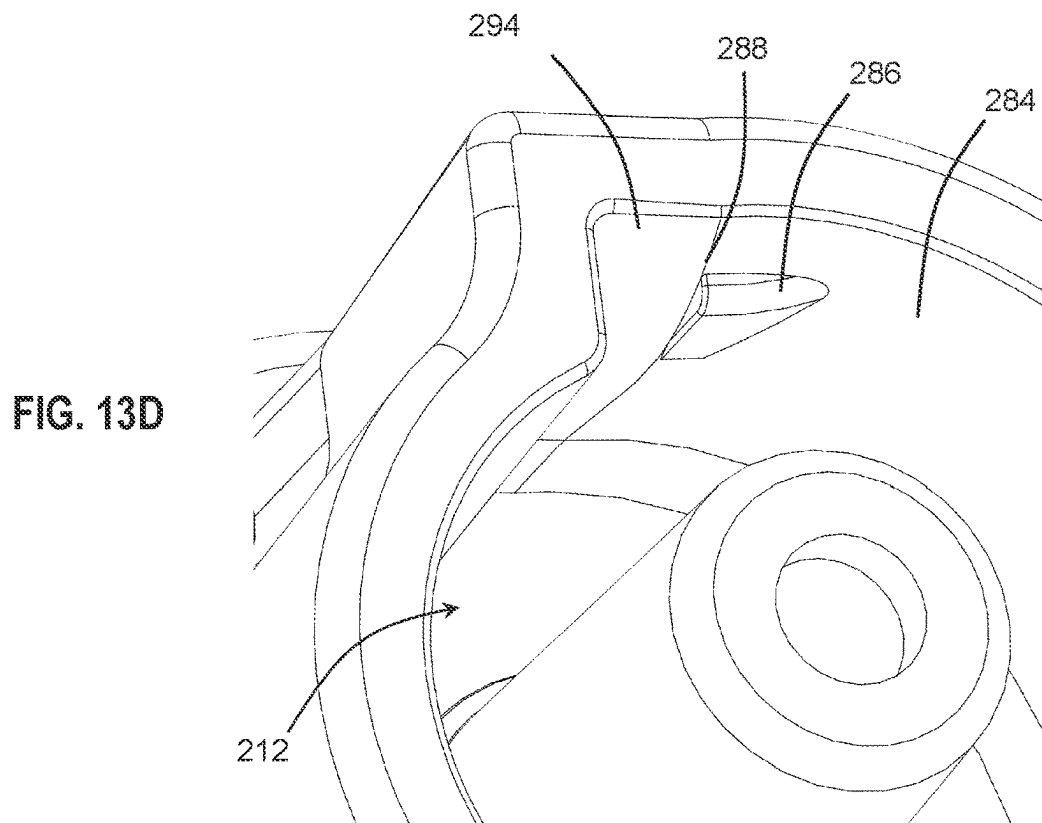
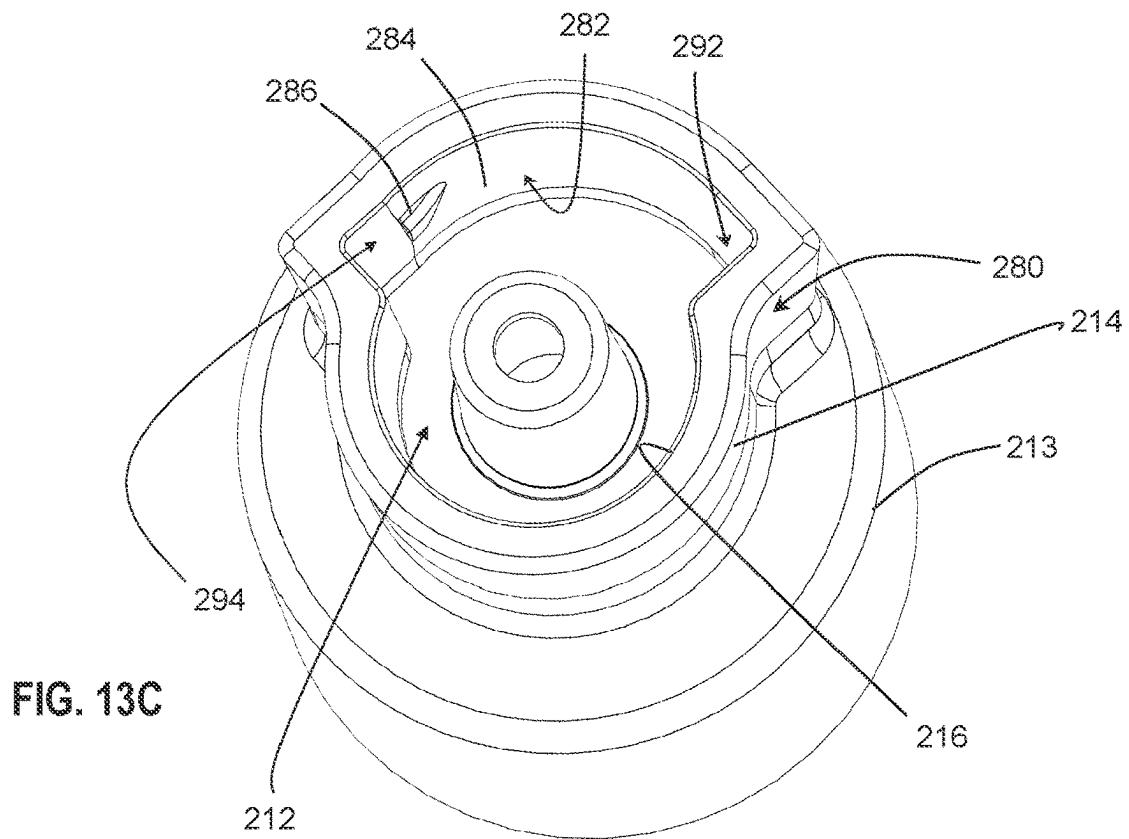












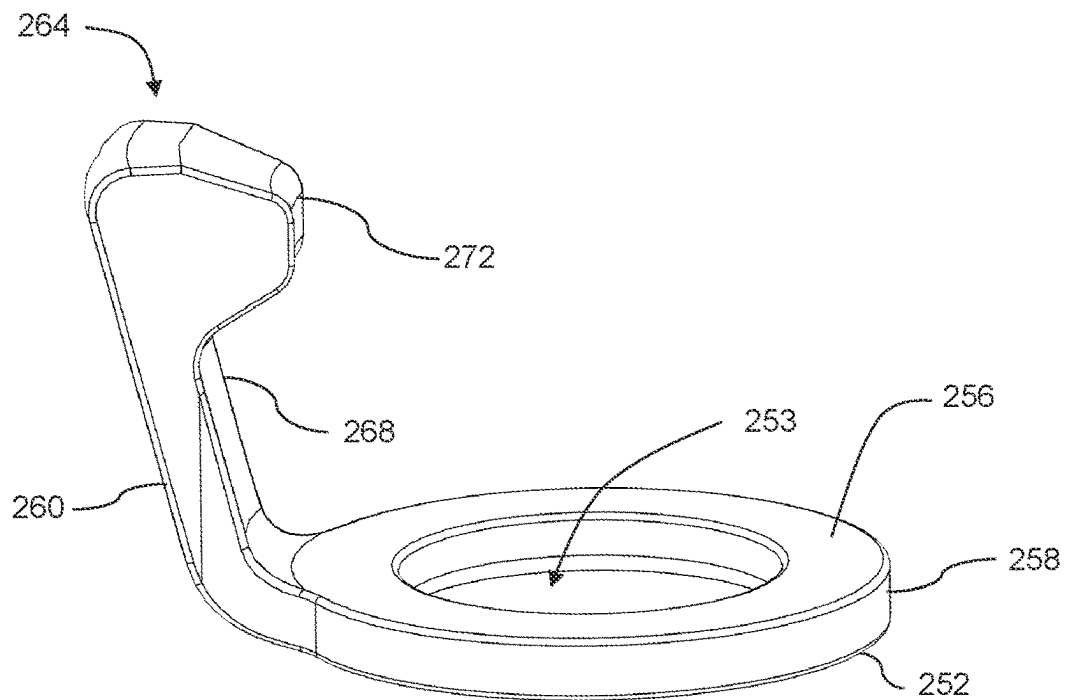


FIG. 14A

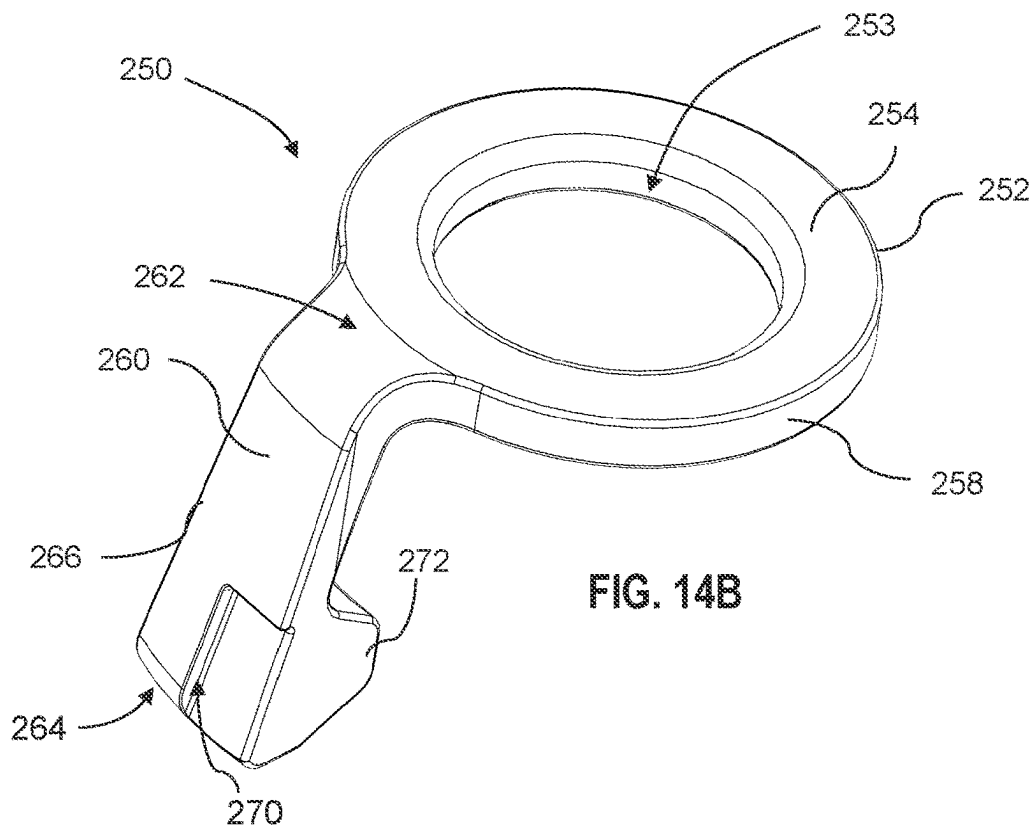


FIG. 14B

FIG. 15

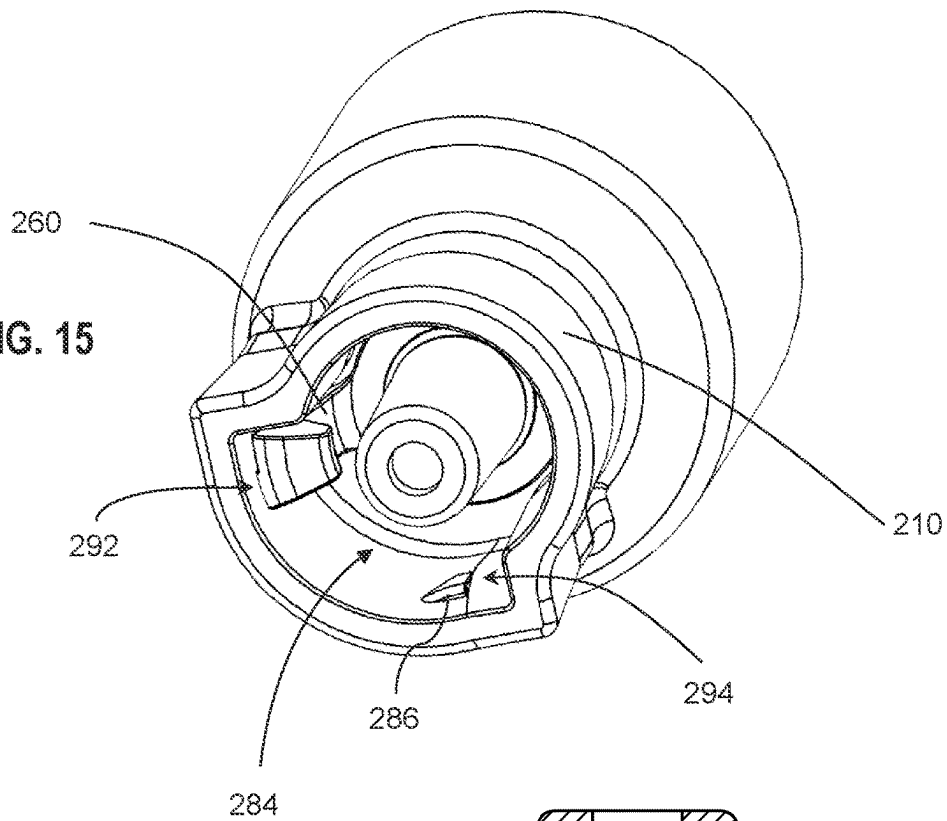
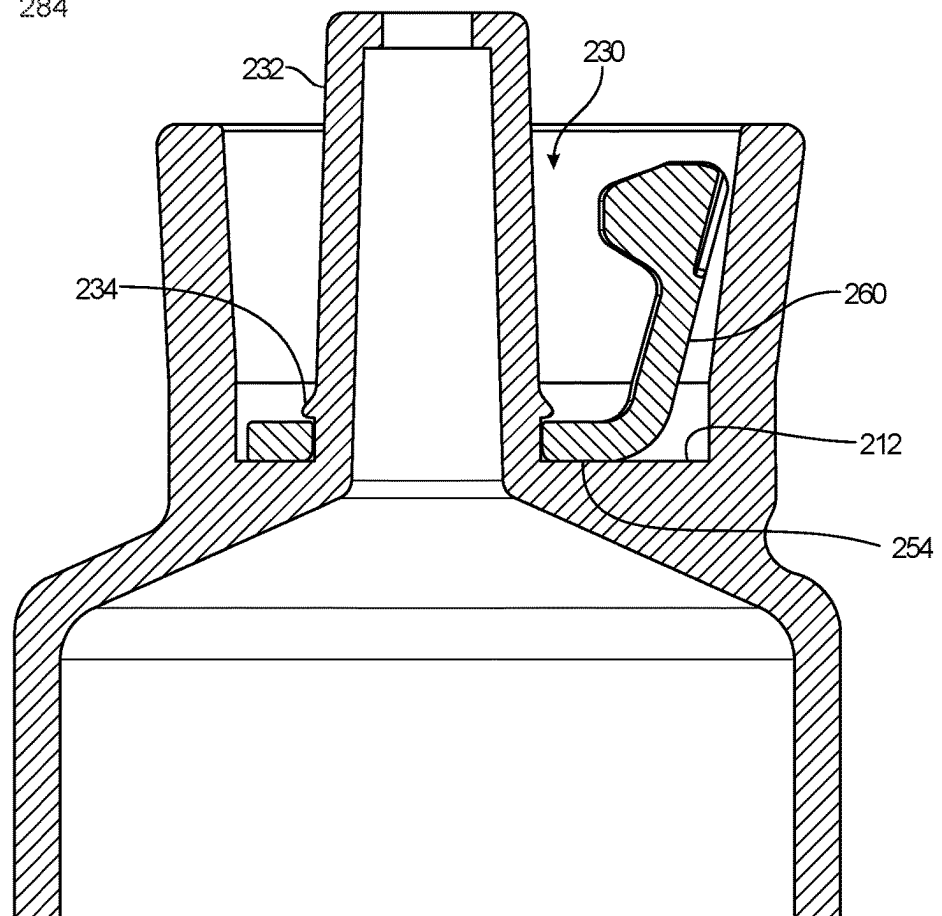
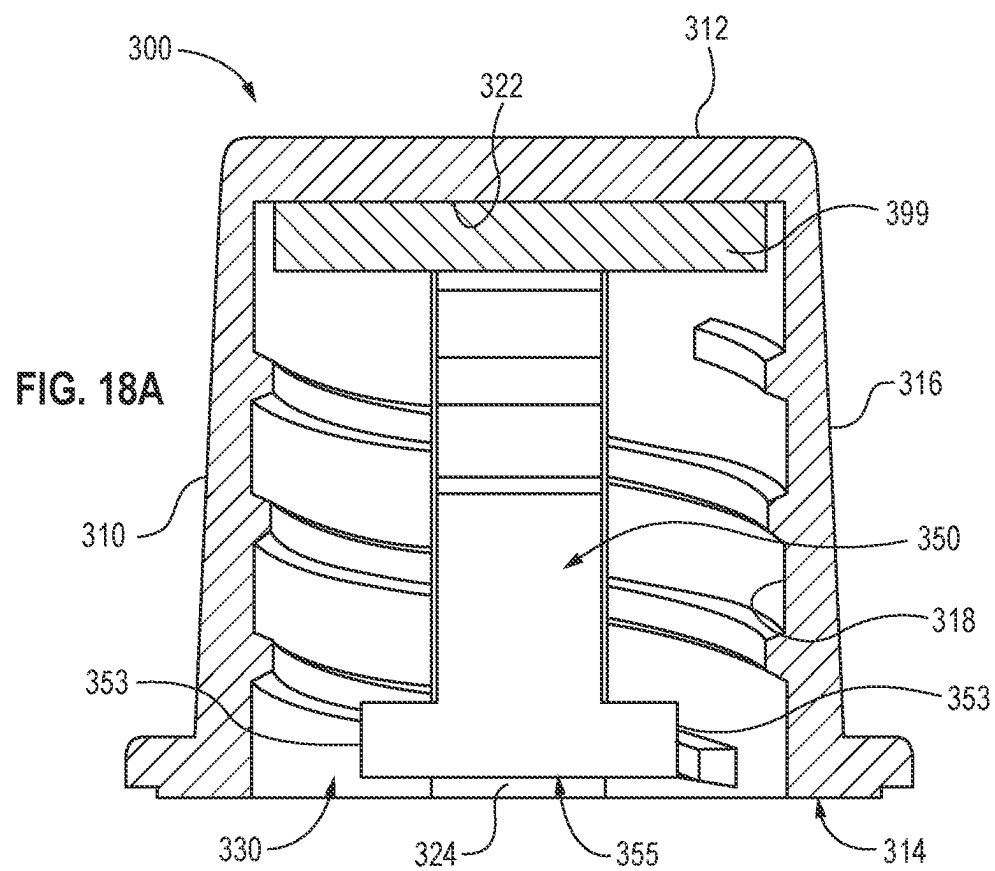
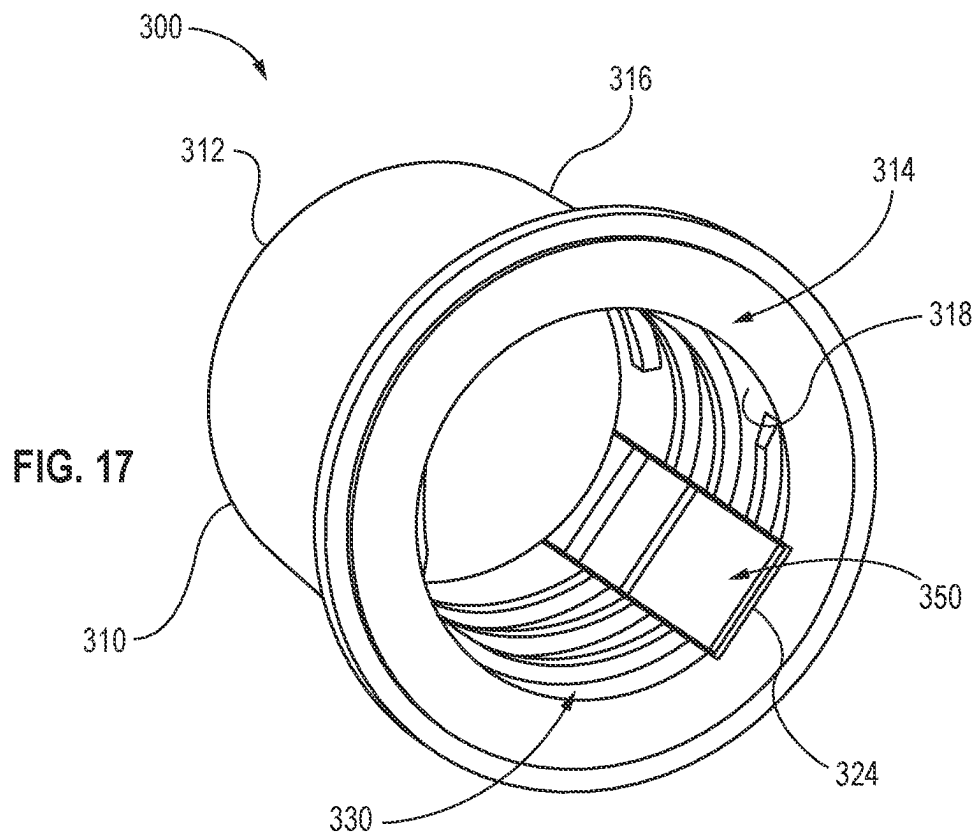
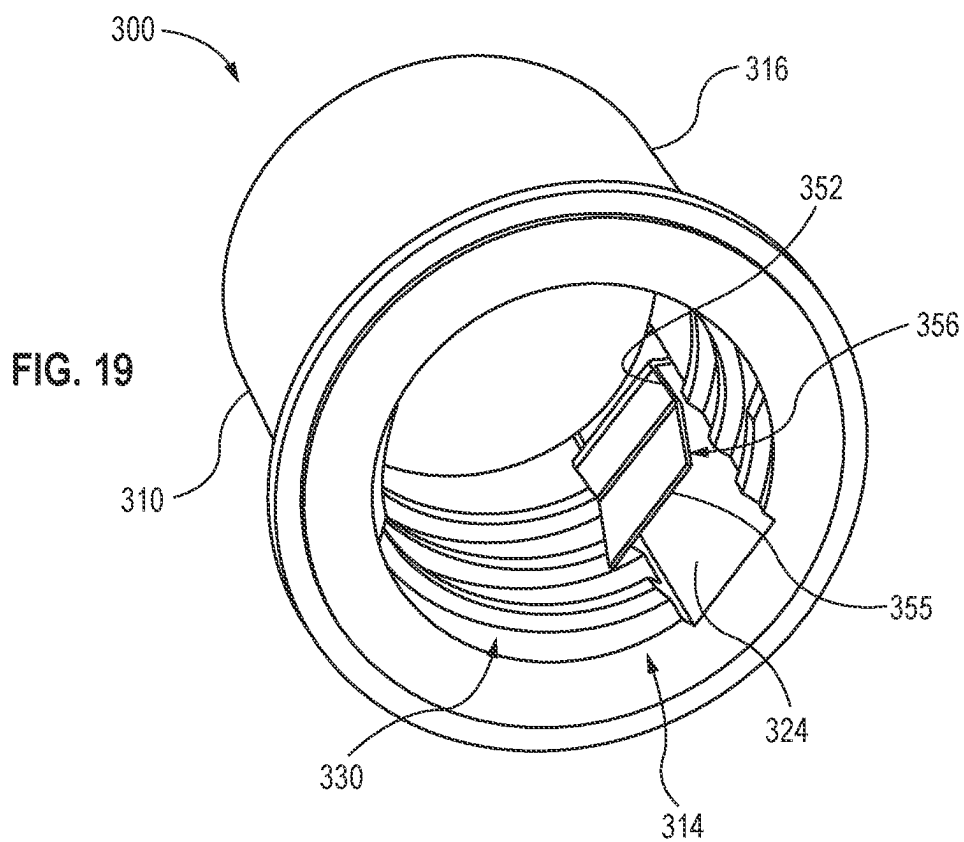
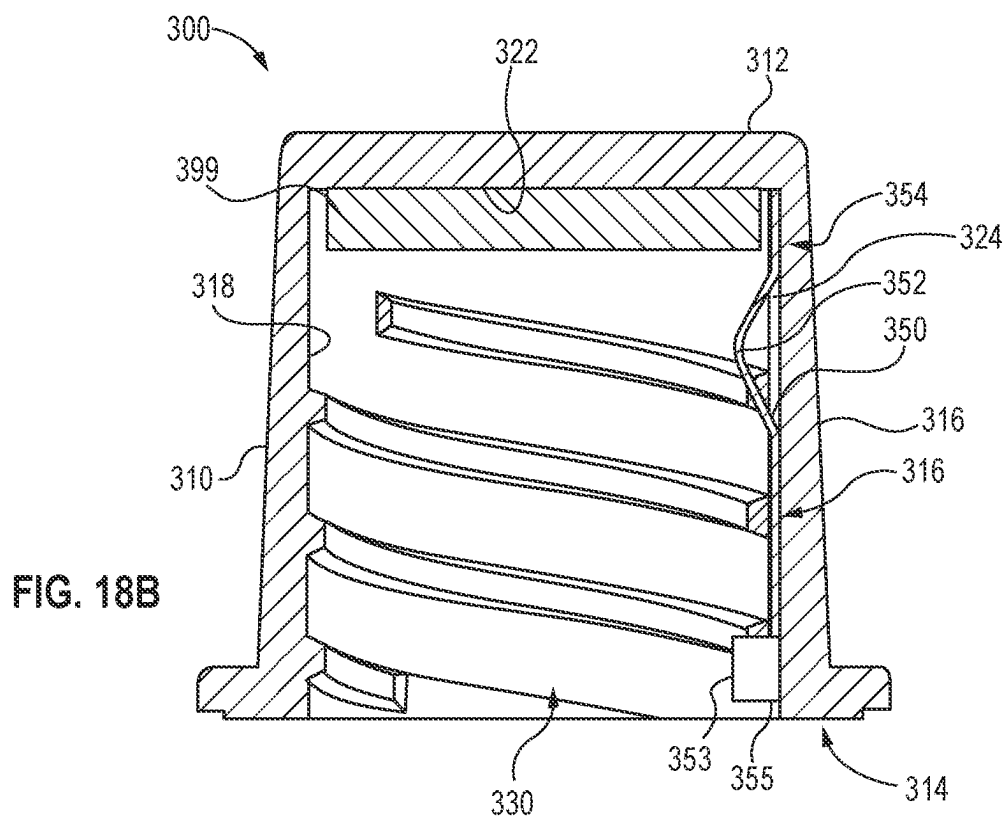
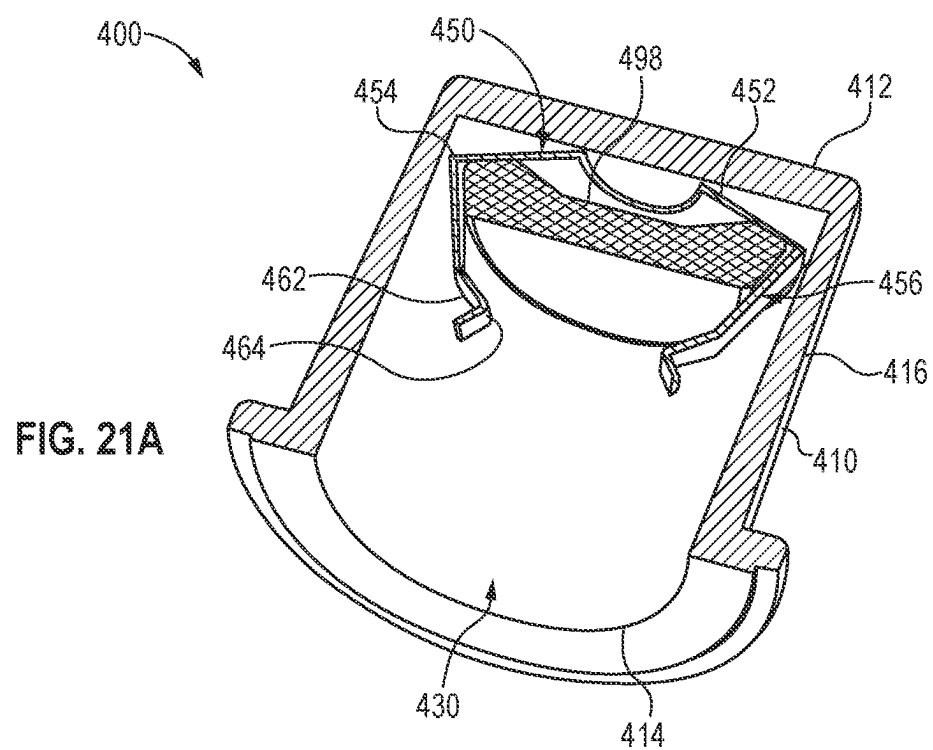
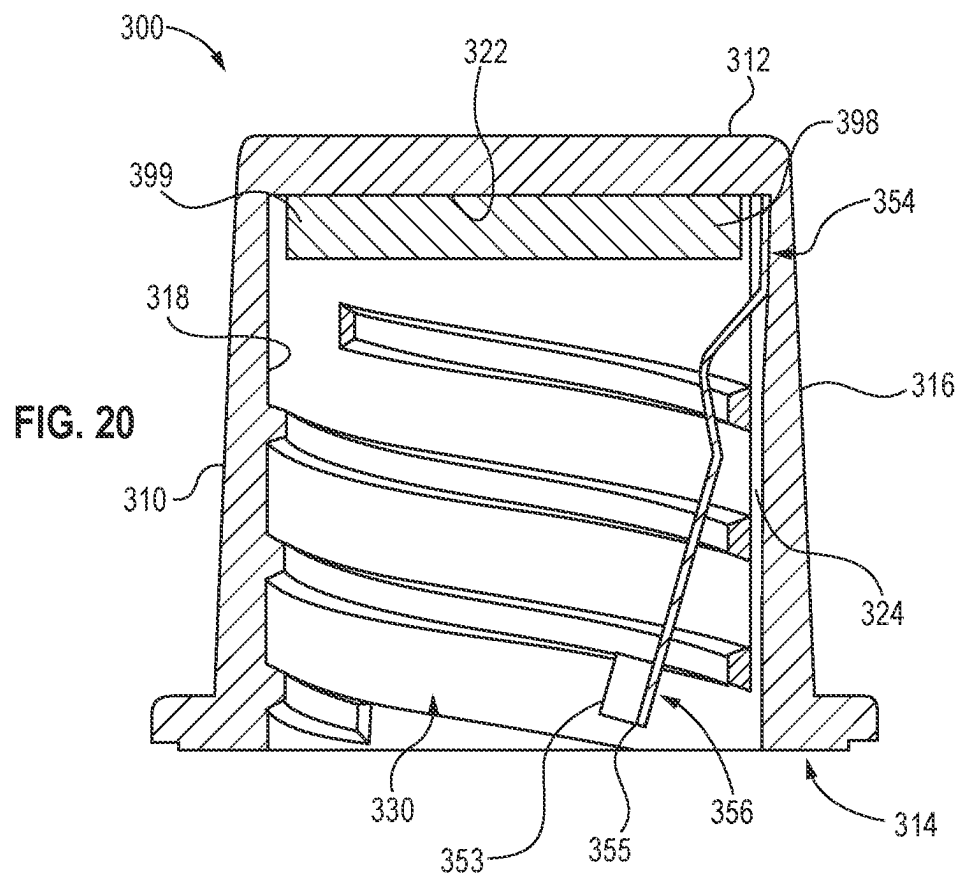


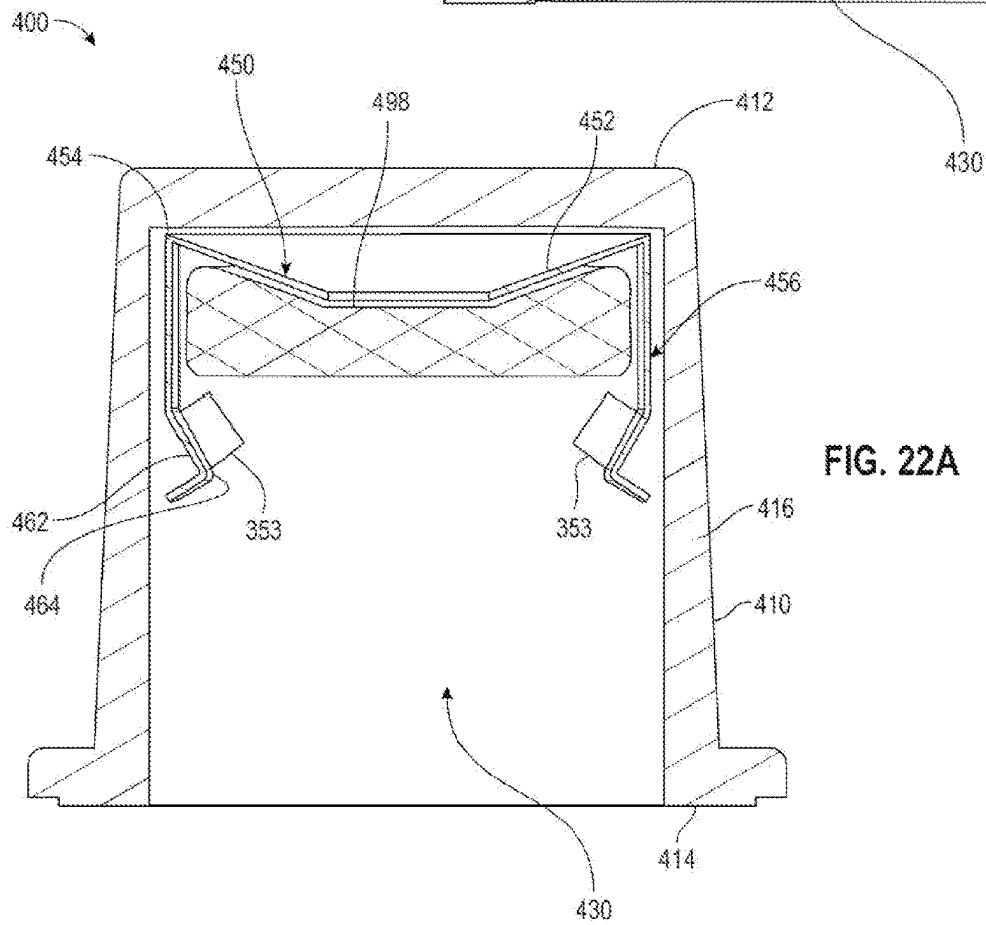
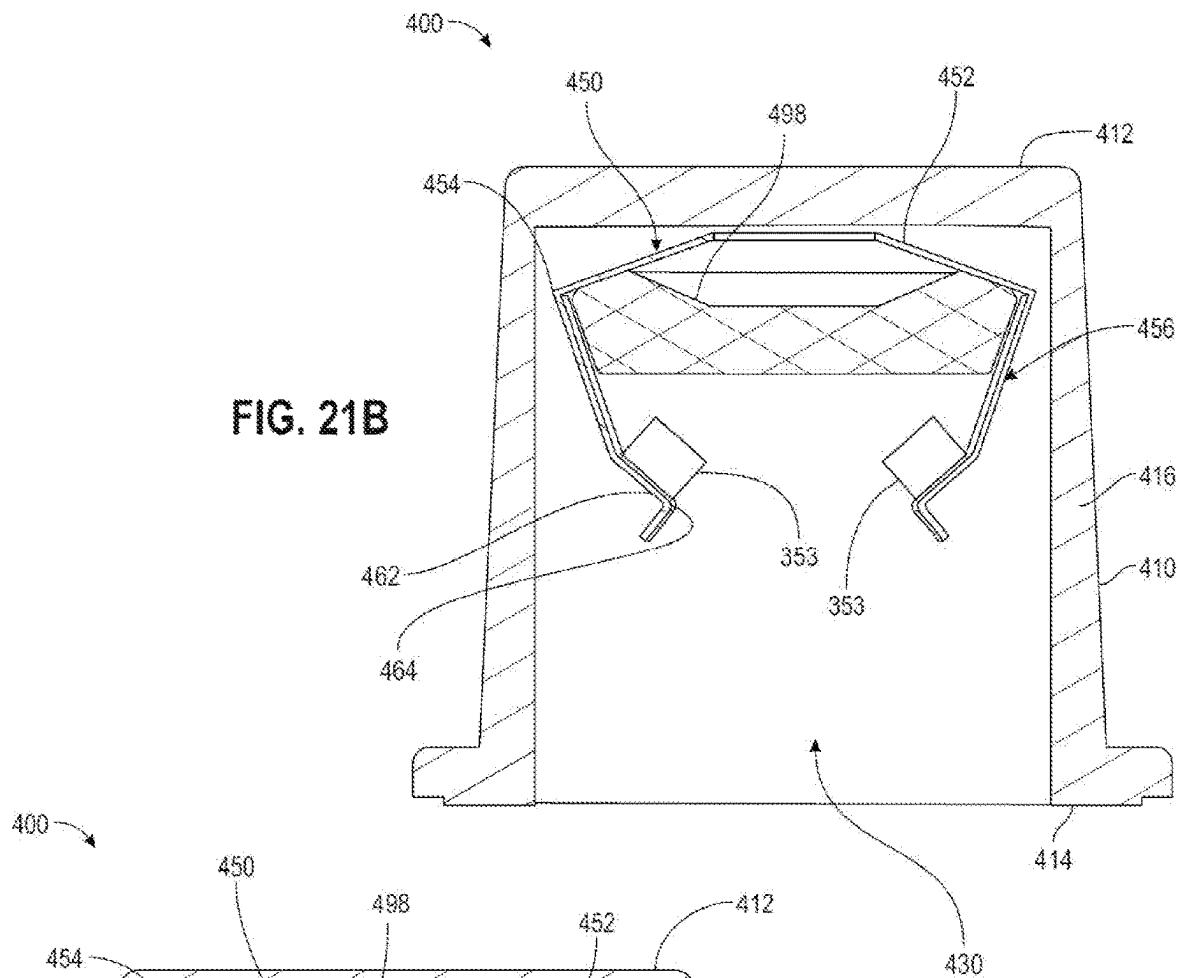
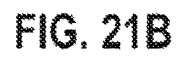
FIG. 16

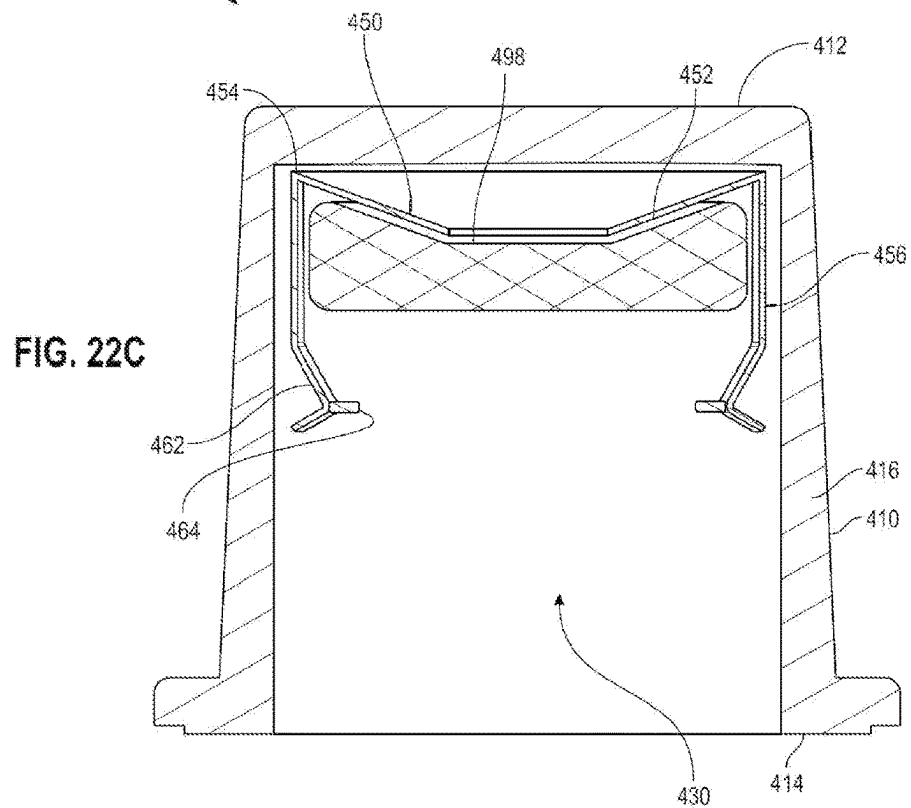
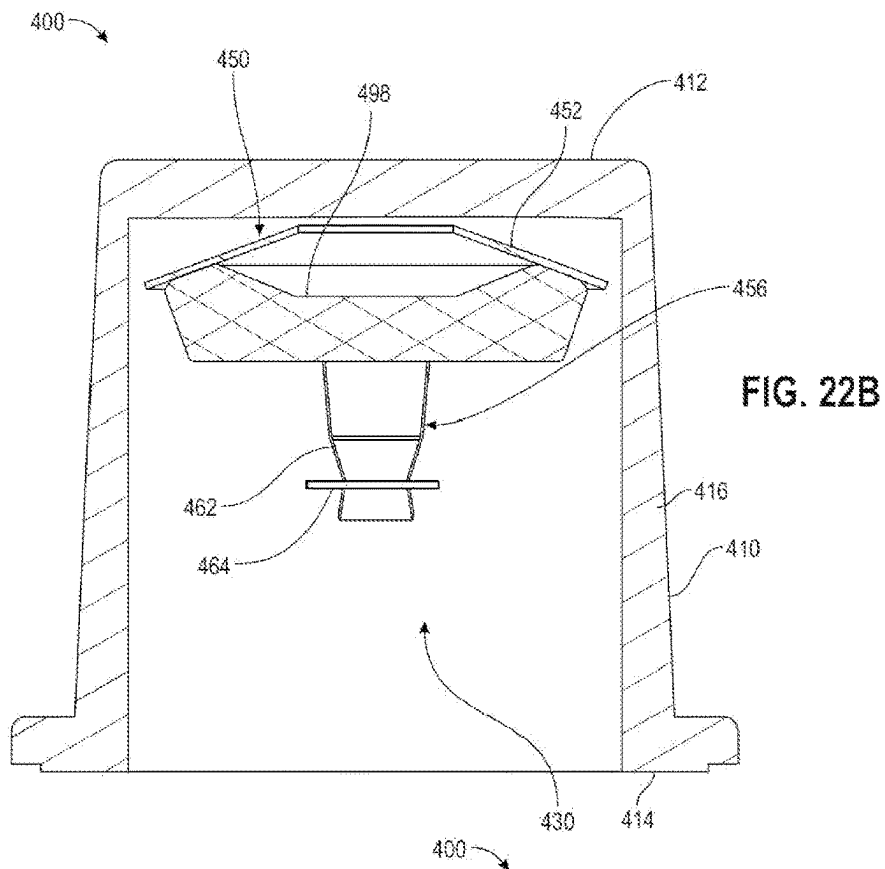


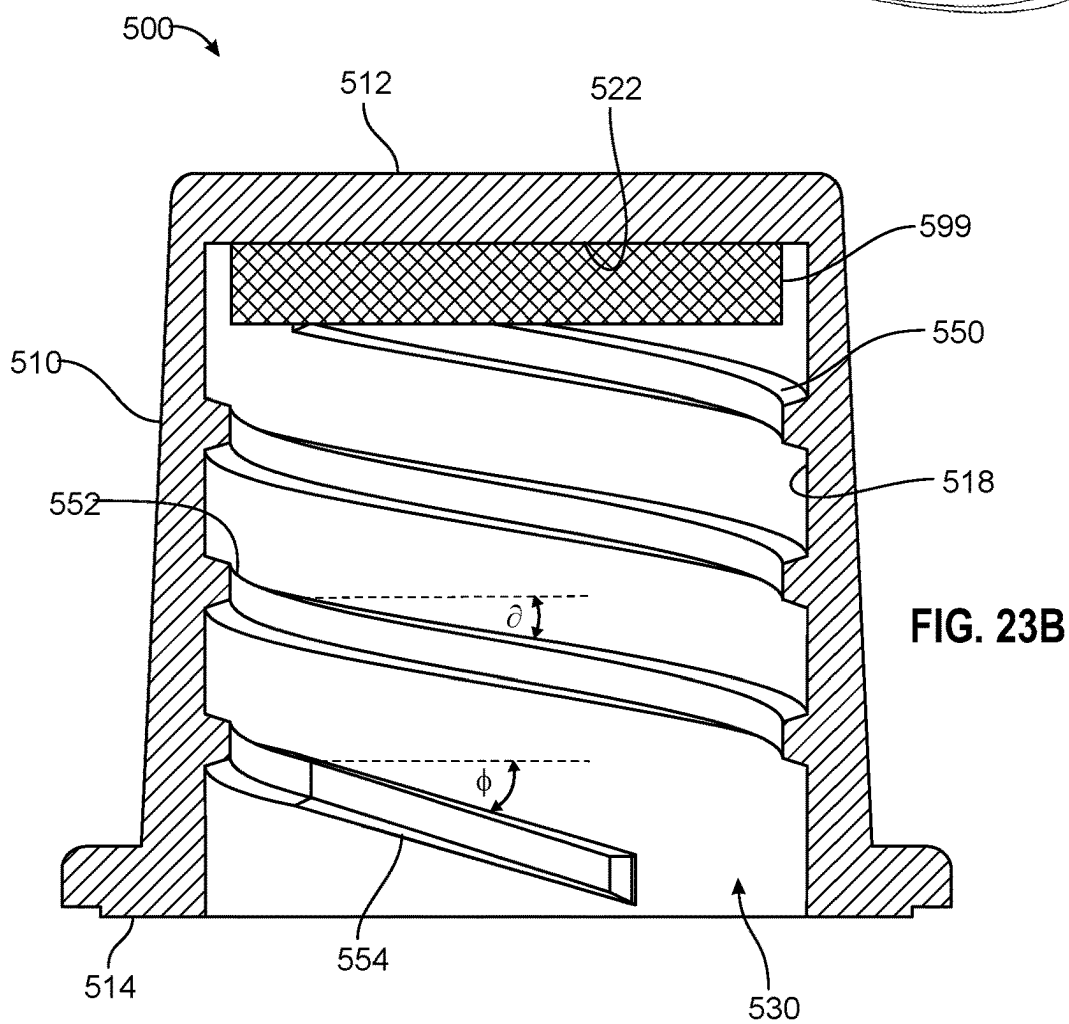
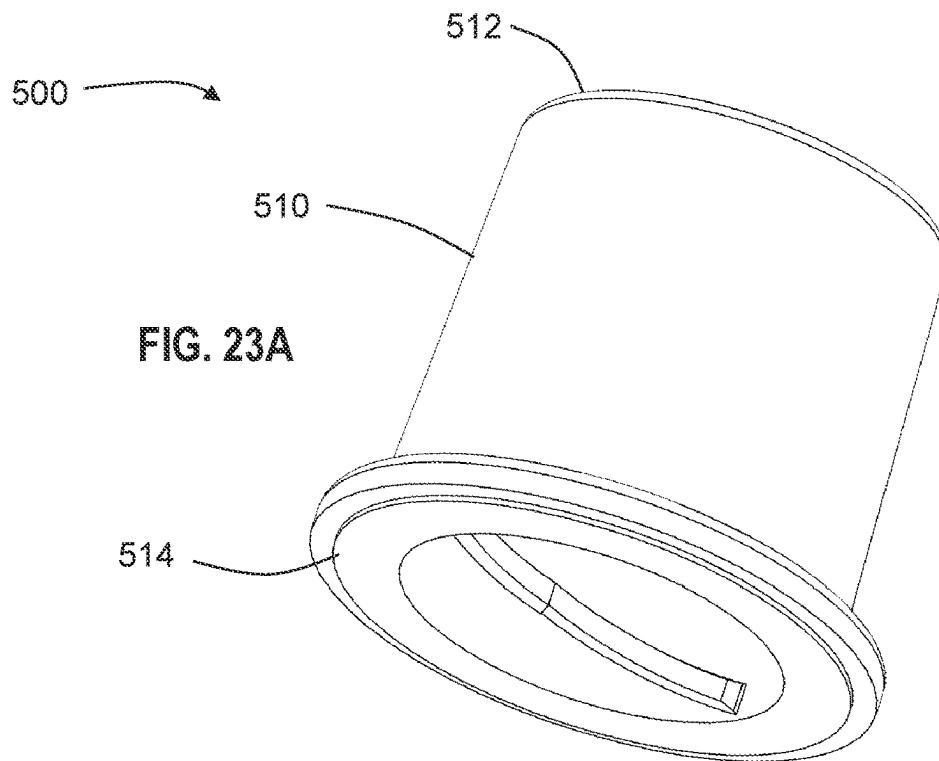


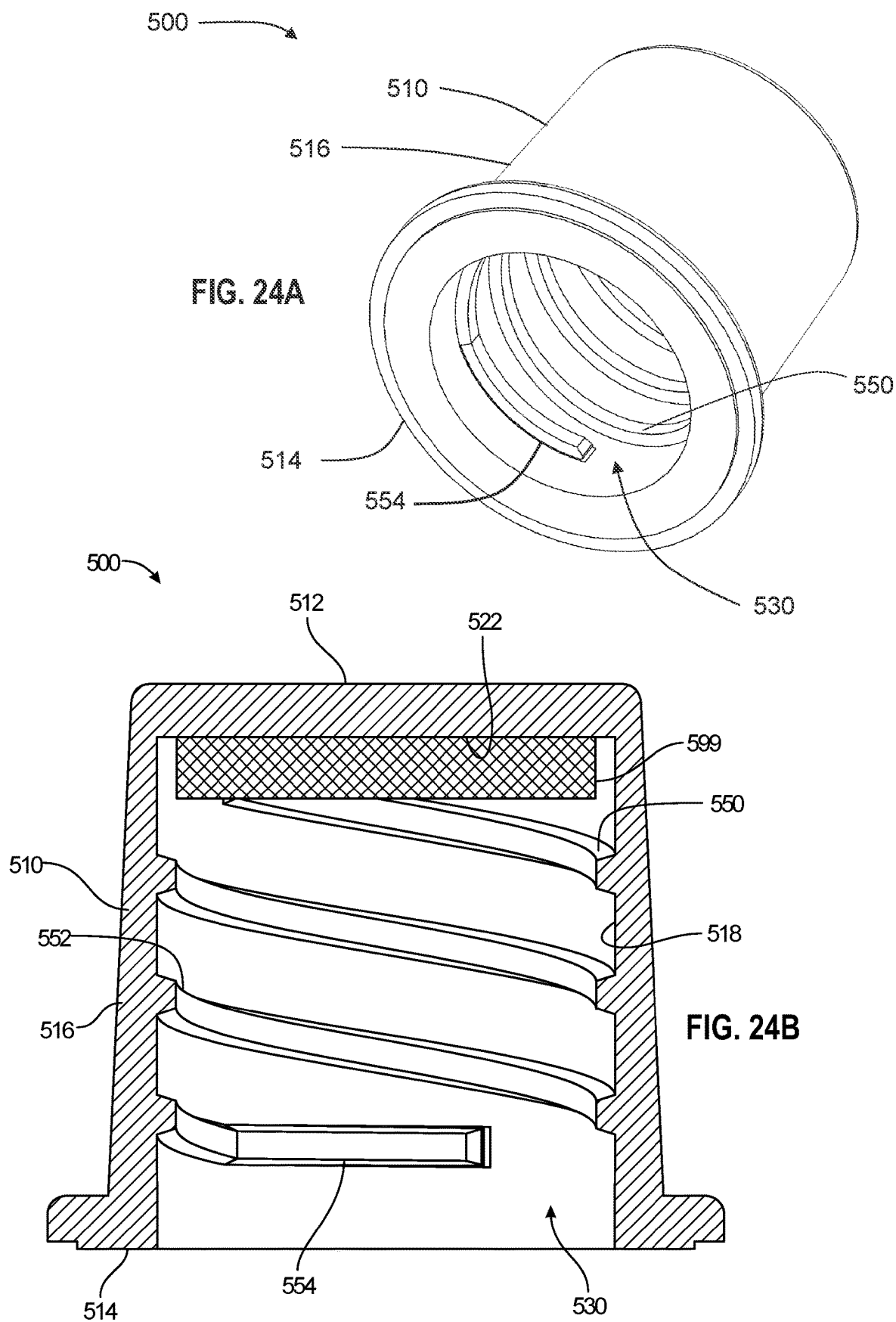












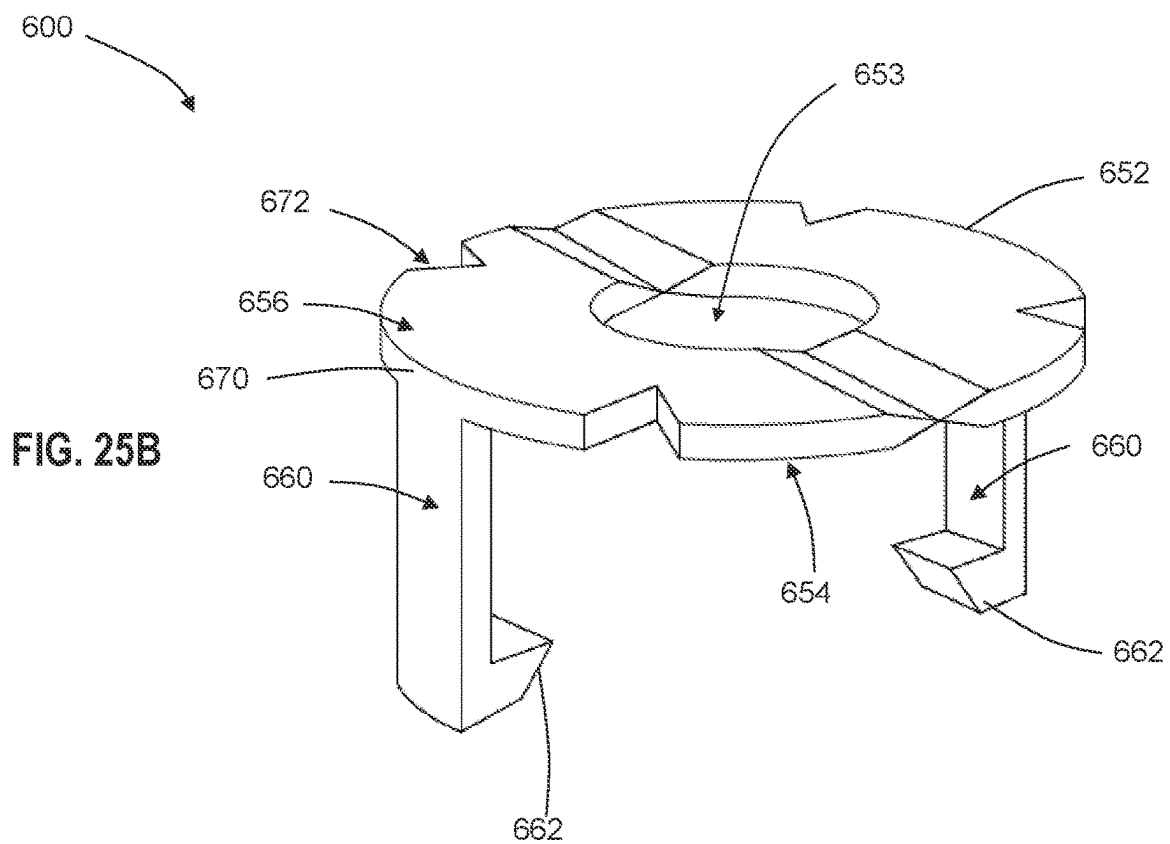
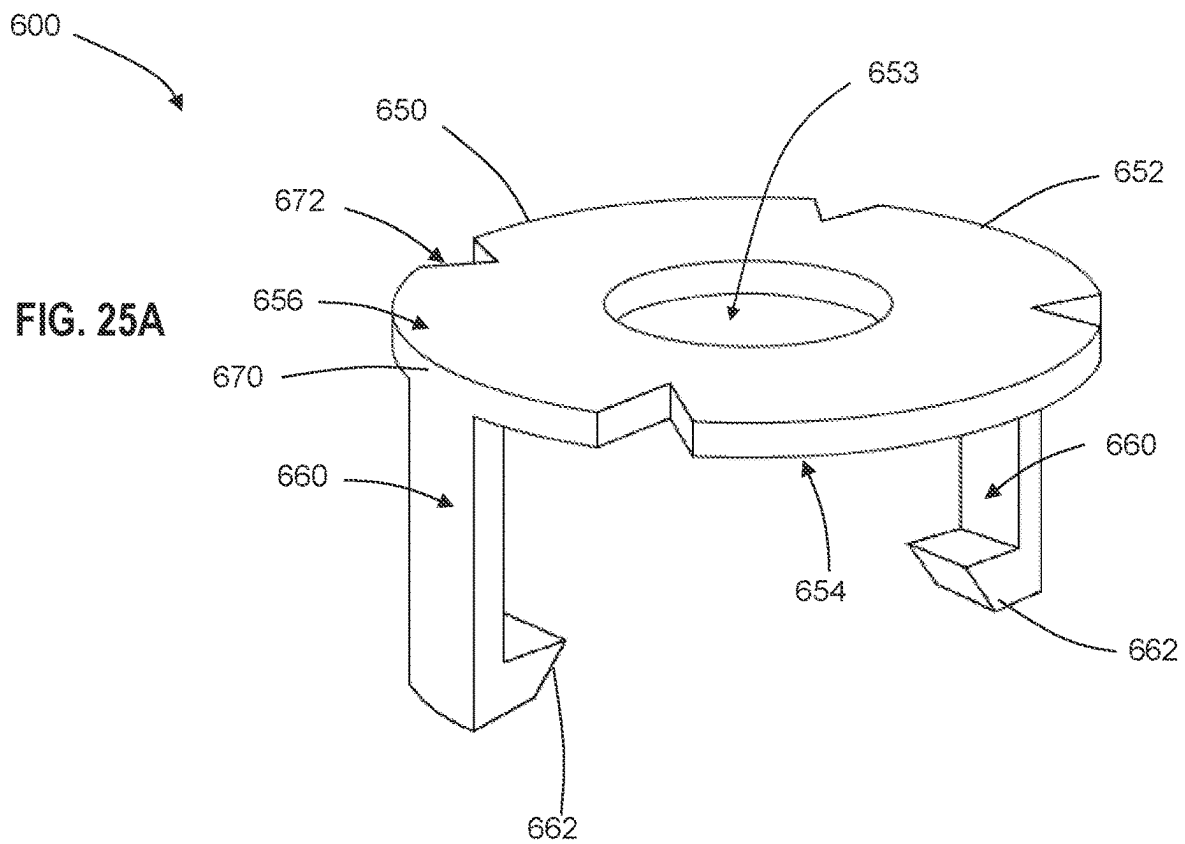


FIG. 26

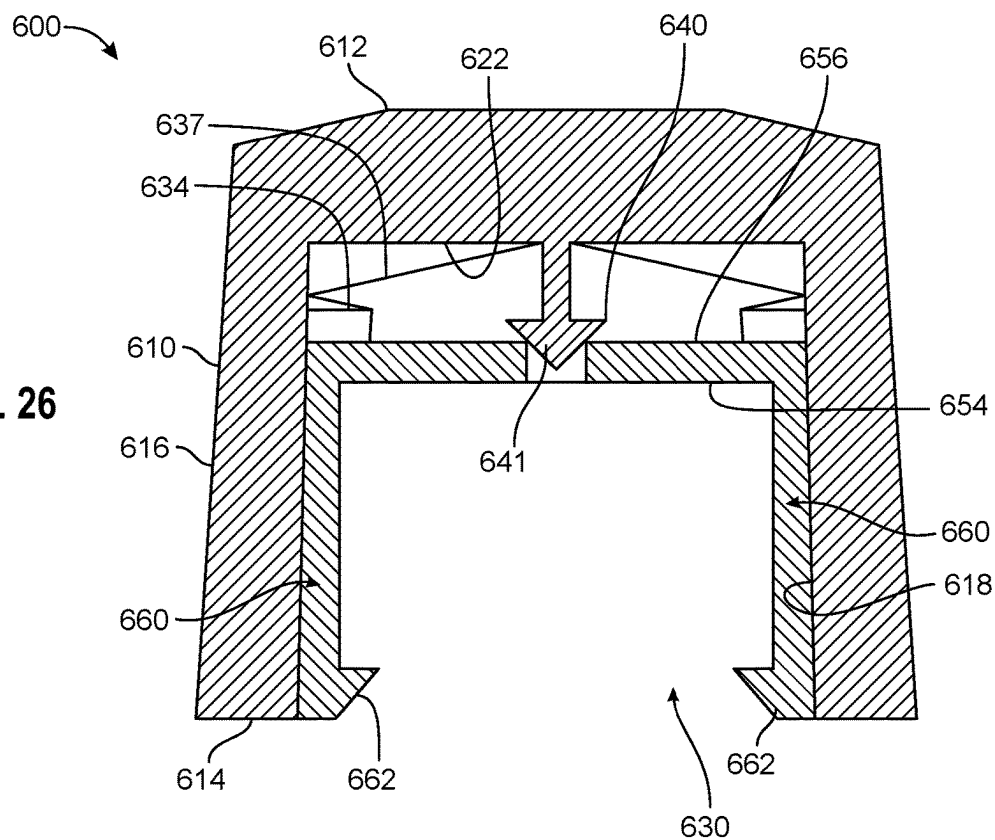
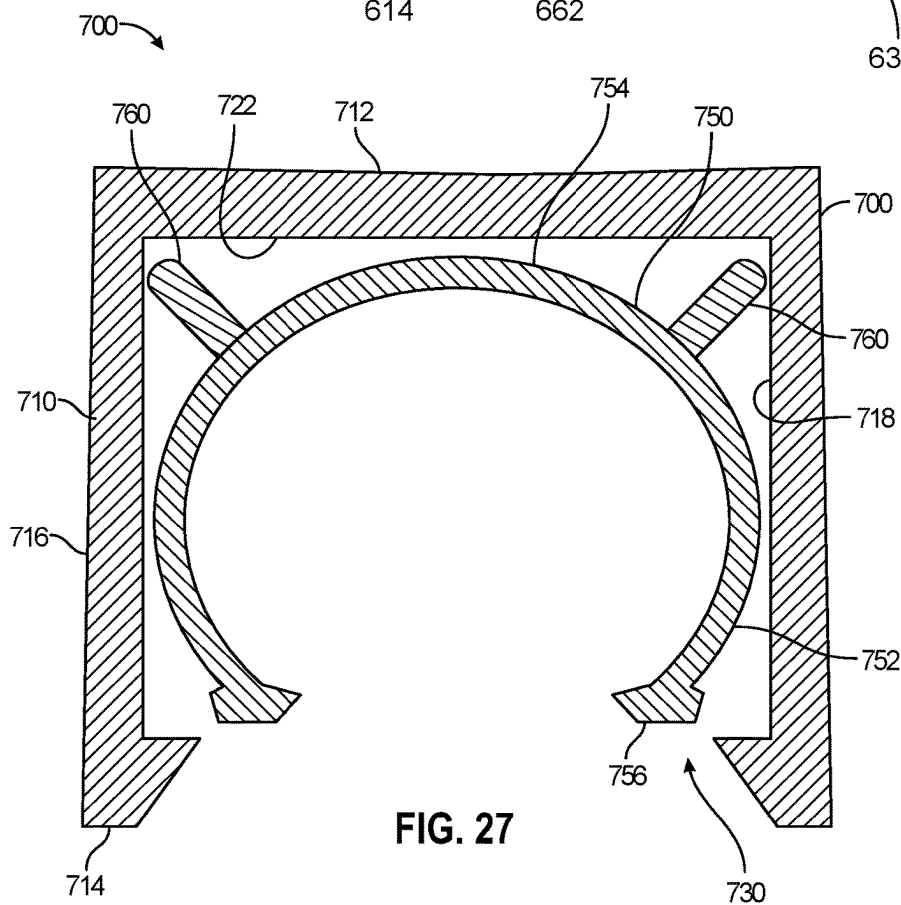


FIG. 27



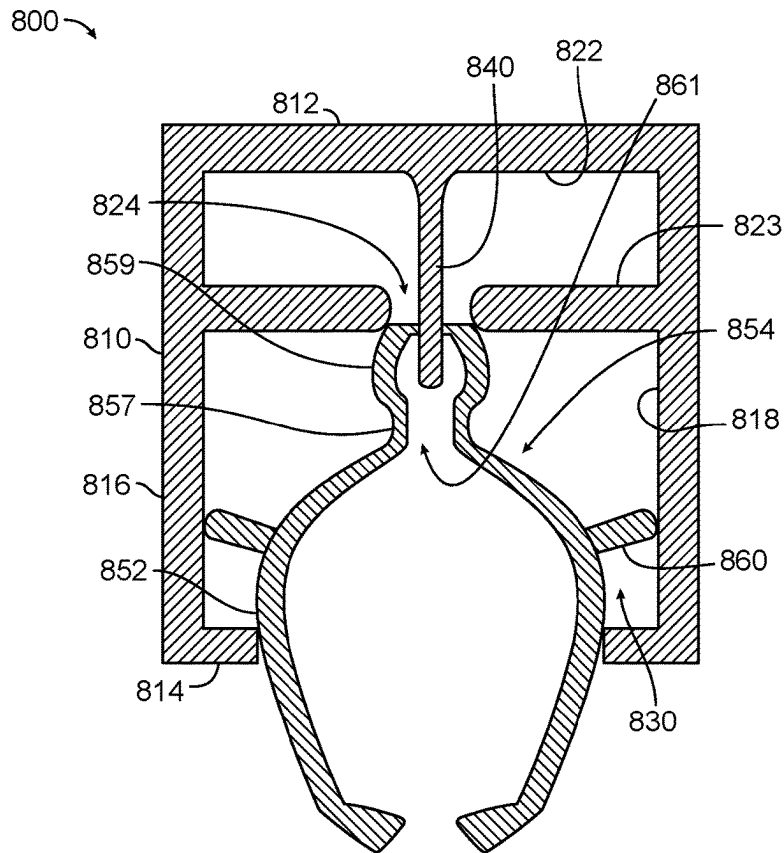
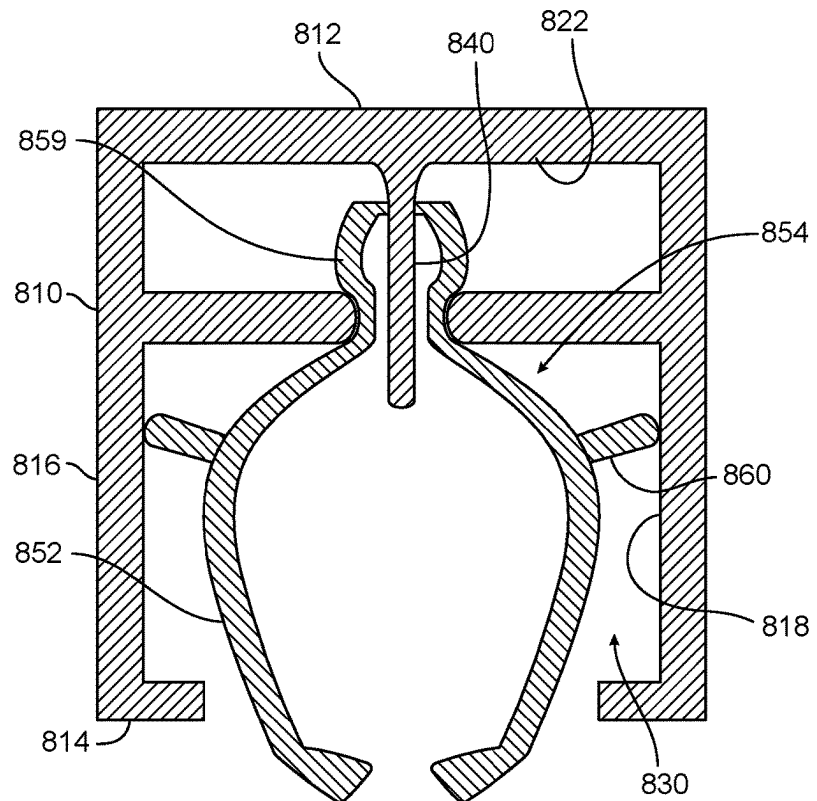


FIG. 28B



1

DISINFECTING CAP WITH RE-USE PREVENTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application No. 63/011,359, filed Apr. 17, 2020, and U.S. Provisional Application No. 63/131,007, filed Dec. 28, 2020, the entire disclosures of which are hereby incorporated by reference herein.

TECHNICAL FIELD

The present disclosure generally relates to medical connectors. In particular, the present disclosure relates to mating elements of medical connectors having re-use prevention features and disinfection features.

BACKGROUND

Vascular access devices (VAD's) are commonly used therapeutic devices and include intravenous (IV) catheters. There are two general classifications of VAD's: peripheral catheters and central venous catheters. Bacteria and other microorganisms may gain entry into a patient's vascular system from access hubs and ports/valves upon connection to the VAD when delivering fluids or pharmaceuticals to a patient. Each access hub, connection, port or valve is associated with some risk of transmitting a catheter related bloodstream infection (CRBSI), which can be costly and potentially lethal.

In order to decrease CRBSI cases and to ensure VAD's are used and maintained correctly, standards of practice have been developed, which include disinfecting and cleaning procedures.

Disinfection caps have been added to the Society for Healthcare Epidemiology of America (SHEA) guidelines and have also been incorporated into the Infusion Nurses Standards (INS) guidelines.

In developed markets, when utilizing an IV catheter, a needleless connector will typically be used to close off the system and then subsequently accessed to administer medication or other necessary fluids via the catheter to the patient. INS Standards of Practice recommend the use of a needleless connector and state that it should be "consistently and thoroughly disinfected using alcohol, tincture of iodine or chlorhexidine gluconate/alcohol combination prior to each access." The disinfection of the needleless connector is ultimately intended to aid in the reduction of bacteria that could be living on the surface and possibly lead to a variety of catheter related complications including CRBSI. Nurses will typically utilize a 70% isopropyl alcohol (IPA) pad to complete this disinfection task by doing what is known as "scrubbing the hub." However, compliance and the level of disinfection attributed to this practice typically relies on the ability and competency of the user. In addition to a lack of compliance to "scrubbing the hub", it has also been noted through clinician interviews that there is often a variation in scrub time, dry time and the number of times the needleless connector is scrubbed.

Threaded needleless connectors are used to decrease CRBSI cases and to ensure VAD's are used and maintained properly as threaded connectors are more secure than slip connectors. However, while threaded needleless connectors, such a threaded luer connectors, are more secure, they

2

require more manipulation by the clinician and the connection is not as quick as luer slip connectors

Thus, there is a need for medical connectors capable of disinfecting luer connectors and reuse prevention thereby reducing risk of the disinfectant entering the blood stream. Further, there is a need for devices which mate with medical connectors which provide for the security of threaded connectors but the ease of use of slip-connectors.

SUMMARY

One aspect of the present disclosure pertains to medical connectors and mating elements of a medical connector (i.e., a needleless connector) having a housing, a locking structure and an insert disposed within the medical connector. The housing has a substantially cylindrical housing body having a radial protrusion extending from the cylindrical housing body and a cavity defined by a closed end, an open end, a partially cylindrical inner sidewall of the housing body and a radial sidewall of the radial protrusion. In some embodiments, the closed end further includes a lumen for the transfer of fluid beyond the closed end. The locking structure is disposed on a lateral portion of the radial sidewall of the cavity, the locking structure including a sloped tab. The insert is advanced into the cavity of the housing, the insert comprising a discoid body having a distal surface, a proximal surface, a sidewall and a locking tab extending proximally from the sidewall, the insert includes at least one thread on an inner wall of the locking tab and a recessed notch disposed on a distal portion of an outer wall of the locking tab.

In one or more embodiments, the insert rotates from a first position to a locking position, the first position being defined by a medial portion of the radial sidewall and the locking position being defined by the lateral portion, the lateral portion including the locking structure. In one or more embodiments, the recessed notch engages a ledge of the sloped tab when the recessed notch is advanced past the sloped tab. In one or more embodiments, the locking tab elastically deforms.

In one or more embodiments, the locking structure further includes an outwardly sloped surface which slopes outwardly from a medial or leftward position to a lateral or rightward position.

In one or more embodiments, the outwardly sloped surface extends at least partially a length of the arc of the radial sidewall. In one or more embodiments, the outwardly sloped surface extends an entire length of the arc of the radial sidewall.

In one or more embodiments, the sloped tab extends from a lateral portion of the outwardly sloped surface. In one or more embodiments, the outwardly sloped surface causes deformation of the locking tab.

In one or more embodiments, the locking structure further includes a proximally sloped surface, the proximally sloped surface located adjacent to a ledge of the sloped surface.

In one or more embodiments, the proximally sloped surface slopes inwardly with respect to the radial sidewall from a distal position to a proximal position.

In one or more embodiments, the distal surface of the insert abuts an inner top surface of the cavity of the housing when the insert is fully advanced into the cavity.

In one or more embodiments, the medical connector further comprises an absorbent material disposed between the distal surface of the insert and an inner top surface of the cavity of the housing when the insert is fully advanced into

3

the cavity. In one or more embodiments, the absorbent material contains a disinfectant.

In one or more embodiments, fully advancing the insert into the cavity in a distal direction causes the distal surface of the insert and the inner top surface of the cavity of the housing to compress the absorbent material, the absorbent material releasing the disinfectant. Disinfectant evacuates into the cavity by a gap defined by the partially cylindrical inner sidewall of the housing and the sidewall of the insert.

In one or more embodiments, the diameter of the partially cylindrical inner sidewall of the housing has a larger diameter than the sidewall of the insert.

In one or more embodiments, a retention tab is disposed on an inner top surface of the housing, the inner top surface non-removably securing an aperture disposed on the distal surface of the insert, the aperture extending therethrough.

A second aspect of the present disclosure pertains to a medical connector having a housing, a locking structure and an insert disposed within medical connector. The housing has a substantially cylindrical housing body having a radial protrusion extending from the cylindrical housing body and a cavity defined by a closed end, an open end, a partially cylindrical inner sidewall of the housing body and a radial sidewall of the radial protrusion. The locking structure is disposed on a lateral portion of the radial sidewall of the cavity, the locking structure including a sloped tab. The insert is advanceable into the cavity of the housing, the insert comprising a discoid body having a distal surface, a proximal surface, a sidewall and a locking tab extending proximally from the sidewall, the insert including at least one thread on an inner wall of the locking tab and a recessed notch disposed on a distal portion of an outer wall of the locking tab. Threading a corresponding medical connector into the cavity causes the insert to be advanced into the cavity, the corresponding medical connector having at least one thread to engage the at least one thread of the insert.

In one or more embodiments, the corresponding medical connector is removably threaded into the cavity.

A third aspect of the present disclosure pertains to a medical connector of a syringe having a housing protruding in a distal direction from a distal wall of a syringe barrel of the syringe, the housing including a cavity defined by the distal wall of the syringe barrel, an open end opposite the distal wall and a partially cylindrical sidewall extending from the distal wall to the open end, the housing further including a radial sidewall defined by a radial protrusion extending laterally from the housing, the radial protrusion and the radial sidewall being in the shape of a laterally protruding arc.

The syringe further comprises a tapered hub disposed within the cavity of the housing, the tapered hub extending in a distal direction from the distal wall of the syringe barrel, the tapered hub configured to interdigitate with a corresponding cavity of a housing of a vascular access device.

The syringe further comprises a locking structure disposed on the radial sidewall including an outwardly sloped surface, and a sloped tab, the sloped surface slopes outwardly from a medial or leftward position to a lateral or rightward position, the outwardly sloped surface extending at least partially the length of the arc of the radial sidewall, the sloped tab slopes outwardly from a lateral or rightward position to a medial or leftward position, the sloped tab including a ledge formed by a wall at a substantially right angle with respect to the radial sidewall.

The syringe further comprises an insert having a generally discoid body, the discoid body having a proximal surface, a distal surface a sidewall, a locking tab and an aperture, the

4

locking tab extending from the distal surface, the aperture is disposed on the proximal surface of the discoid body and extends therethrough, the insert further includes at least one thread is disposed on the inner wall of the locking tab.

A first position is defined by the medial or leftward portion of the radial sidewall and a locking position is defined by the sloped tab and the ledge. The housing is configured as a medical connector able to receive a male luer fitting of a vascular access device. When the insert is advanced proximally into the cavity of the housing, the locking tab is disposed in the first position causing the locking tab insert to elastically deform outwardly with respect to the radial sidewall. When the insert rotationally approaches the locking position, the outwardly sloped surface further elastically deforms the locking tab inward until the recessed notch passes the ledge of the radial sidewall, when the notch has passed the ledge and the notch non-releasably engages the ledge, thereby preventing medial or leftward movement of the locking tab.

A third embodiment of the present disclosure pertains to a medical connector comprising a substantially cylindrical housing having a distal wall, a proximal open end, an inner sidewall extending between the distal wall to the open end and a cavity. At least one helical thread disposed on an inner sidewall of the cavity. A channel is disposed on the inner sidewall having a substantially rectangular profile extending from the distal wall to the open end. An absorbent material abutting an inner distal surface of the housing

The medical connector further comprises a leaf spring disposed within the channel, the leaf spring having a rectangular cross-section and an arc, the arc is between a distal portion and a proximal portion, the distal portion is non-removably attached to the channel, the proximal portion abutting the channel in an initial state.

Upon advancement of a corresponding medical connector into the cavity, at least one thread of the corresponding medical connector depresses the arc of the spring into the channel causing the proximal portion of the spring to defect away from the channel defining a final state; A proximal end of the proximal portion of the spring engages a lower segment of the least one thread of the corresponding medical connector, thereby locking the corresponding medical connector within the cavity in a threaded fit and an interference fit

A fourth embodiment of the present disclosure relates to a medical connector comprising a substantially cylindrical housing having a distal wall, a proximal open end, an inner distal surface and a cavity defined by the proximal open end and the closed distal end. The medical connector further comprises a cupped spring comprising a frusto-conical shaped disk body having at least two prongs extending from a proximal edge of the disk body, the at least two prongs extending from a proximal edge of the disk body in a proximal direction, each of the at least two prongs comprise a proximal portion and a distal portion adjacent to the proximal portion, the distal portion forming a medial hook extending toward a center of the disk body, the medial hook comprising a medial edge configured to engage with a corresponding thread of a corresponding medical connector. The medical connector further comprises an absorbent material abutting an inner distal surface of the housing.

Advancement of the corresponding medical connector into the cavity causes the disk body to deform inward, pushing the proximal edge of the disk body against a lower segment of the least one thread of the corresponding medical connector, thereby locking the corresponding medical connector within the cavity.

5

A fifth embodiment of the present disclosure relates to a medical connector comprising a substantially cylindrical housing having a distal wall, a proximal open end, an inner sidewall extending between the distal wall to the open end and a cavity. At least one helical thread disposed on an inner sidewall of the cavity, the helical thread having a distal portion unitarily formed onto the inner sidewall and a frangible portion proximal to the distal portion configured to detach and cross-thread upon threading and advancing a corresponding thread of a corresponding medical connector into the cavity. An absorbent material abutting an inner distal surface of the housing

A sixth embodiment of the present disclosure relates to a medical connector comprising a substantially cylindrical housing having a distal wall, a proximal open end, a sidewall extending between the distal wall to the open end, a cavity extending from the open end to the distal wall, an inner distal surface, and at least one tooth extending medially into the cavity from an inner sidewall of the housing, the at least one tooth positioned a distance from the inner distal surface of the housing.

The medical connector further comprises an insert in the shape of a discoid body, the discoid body having a proximal surface and a distal surface, at least two locking tabs extending from the distal surface in a distal direction away from the distal surface, each of the at least two locking tabs having a hooked proximal end configured to interlock with corresponding thread of a corresponding medical connector, and a plurality of ridges disposed on a sidewall of the discoid body, the plurality of ridges configured to interdigitate with the least one tooth of the housing. An absorbent material abuts the inner distal surface of the distal wall of the housing.

A seventh aspect of the present disclosure relates to a medical connector comprising a substantially cylindrical housing having a distal wall, a proximal open end, a sidewall extending between the distal wall to the open end and a cavity. The medical connector further comprises an insert in the shape of a C-shaped body having a distal end in the form of an arc and an open proximal end, and two living hinges extending from the distal end. An absorbent material abuts the inner distal surface of the distal wall of the housing.

Advancement of a corresponding medical connector into the cavity causes deflection of the c-shaped body, thereby locking the open proximal end against threads of a corresponding medical connector.

An eighth aspect of the present disclosure relates to a medical connector comprising a substantially cylindrical housing having a distal wall, a proximal open end, a sidewall extending between the distal wall to the open end and a cavity, an inner distal surface, a medial wall positioned a distance from the inner distal surface of the housing.

The medical connector further comprises an insert in the shape of a C-shaped body having a distal portion in the form of an arc, an open proximal portion and at least two living hinges extending tangential to the distal portion. An absorbent material abuts the inner distal surface of the distal wall of the housing. Advancement of a corresponding medical connector into the cavity causes deflection of the insert, thereby locking the open proximal end against threads of the medical connector. The medial wall further includes an aperture configured to receive the distal portion of the insert.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a perspective view of a housing of a medical connector assembly according to a first exemplary embodiment of the disclosure;

6

FIG. 1B illustrates a perspective side view of a housing body of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 2A illustrates a perspective view of an insert bottom view of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 2B illustrates a perspective view of an insert bottom view of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 3 illustrates a perspective bottom view of the housing body of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 4 illustrates a perspective side view of the housing body and the insert of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 5 illustrates a perspective bottom view of the housing body of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 6 illustrates a perspective bottom view of the housing body and the insert of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 7 illustrates a bottom view of the housing body and the insert of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 8 illustrates a bottom view of the housing body and the insert of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 9 illustrates a cross-sectional side view of the housing body and the insert of the medical connector in accordance with the embodiment as shown in FIG. 1;

FIG. 10 illustrates the elastic deformation of the locking tab in the first position and the locking position;

FIG. 11 illustrates a cross-sectional view of a medical connector inserted in the housing body and the insert of the medical connector;

FIG. 12 illustrates a side perspective view of the medical connector inserted in the housing body and the insert of the medical connector;

FIG. 13A illustrates a perspective view of a housing of a syringe in accordance with a second embodiment of the present disclosure.

FIG. 13B illustrates a top view of the housing of the syringe in accordance with the second embodiment as shown in FIG. 13A;

FIG. 13C illustrates a perspective side view of the housing of the syringe in accordance with the second embodiment as shown in FIG. 13A;

FIG. 13D illustrates a perspective side view of the housing of the syringe in accordance with the second embodiment as shown in FIG. 13A;

FIG. 14A illustrates a perspective side view of an insert in accordance with the second embodiment as shown in FIG. 13A;

FIG. 14B illustrates a perspective side view of the insert in accordance with the second embodiment as shown in FIG. 13A;

FIG. 15 illustrates a perspective side view of the insert inserted into the housing of the syringe in accordance with the second embodiment as shown in FIG. 13A;

FIG. 16 illustrates a cross-sectional view of the insert inserted into the housing of the syringe in accordance with the second embodiment as shown in FIG. 13A;

FIG. 17 illustrates a perspective view of a housing of a medical connector in accordance with a third embodiment of the present disclosure.

7

FIG. 18A illustrates a cross-sectional view of the housing in an initial state in accordance with the third embodiment as shown in FIG. 17;

FIG. 18B illustrates a cross-sectional view of the housing in the initial state in accordance with the third embodiment as shown in FIG. 17;

FIG. 19 illustrates a perspective view of the housing in a final state in accordance with the third embodiment as shown in FIG. 17;

FIG. 20 illustrates a cross-sectional view of the housing in the final state in accordance with the third embodiment as shown in FIG. 17;

FIG. 21A illustrates a cross-sectional view of a housing in an initial state in accordance with a fourth embodiment of the present disclosure;

FIG. 21B illustrates a cross-sectional view of the housing in the initial state in accordance with a fourth embodiment as shown in FIG. 21A;

FIG. 22A illustrates a cross-sectional view of the housing in a final state in accordance with a fourth embodiment as shown in FIG. 21A;

FIG. 22B illustrates a cross-sectional view of the housing in a final state in accordance with a fourth embodiment as shown in FIG. 21A;

FIG. 22C illustrates a cross-sectional view of the housing in a final state in accordance with a fourth embodiment as shown in FIG. 21A;

FIG. 23A illustrates a perspective side view of a housing in an initial state in accordance with a fifth embodiment of the present disclosure;

FIG. 23B illustrates a cross-sectional view of the housing in the initial state in accordance with a fifth embodiment as shown in FIG. 23A;

FIG. 24A illustrates a perspective view of the housing in a final state in accordance with a fifth embodiment as shown in FIG. 23A;

FIG. 24B illustrates a cross-sectional view of the housing in the final state in accordance with a fifth embodiment as shown in FIG. 23A;

FIGS. 25A and 25B illustrate perspective views of an insert in accordance with a sixth embodiment of the present disclosure;

FIG. 26 illustrates a cross-sectional view of the insert of FIGS. 25A and 25B disposed within a housing of an exemplary medical connector in accordance with the sixth embodiment of the present disclosure;

FIG. 27 illustrates a cross-sectional view of an insert disposed within a housing of an exemplary medical connector in accordance with a seventh embodiment of the present disclosure; and

FIGS. 28A and 28B illustrate a cross-sectional view of an insert disposed within a housing of an exemplary medical connector in accordance with an eighth embodiment of the present disclosure.

DETAILED DESCRIPTION

Embodiments of the disclosure pertain to a sterile, medical connector for connection to and disinfection of a corresponding medical connector having an open lumen, including male, female needleless connectors, luer connectors, and stopcocks. In some embodiments, the medical connectors can be male or female luer connectors. In some embodiments, the medical connector can be a cap or a connector of a syringe. In some embodiments, the medical connectors of the present disclosure are incorporated in medical devices. In some embodiments, the medical connectors of the present

8

disclosure are mating elements incorporated in medical devices. Embodiments of the medical connector comprise a housing, an insert and an absorbent material, the insert and absorbent material disposed within the housing. Upon inserting a corresponding medical connector into the housing, the corresponding medical connector is advanced against the housing and insert which compresses the absorbent material thereby releasing antimicrobial disinfectant fluid or gel (hereinafter “disinfectant”), and in some embodiments, prevents reuse of the medical connector and the corresponding medical connector. The disinfectant disinfects the corresponding medical connector. In one or more embodiments, the medical connector and corresponding medical connector as described in detail below has the means to be of a single use, wherein the insert of the medical connector non-releasably locks onto the housing of the medical connector.

The housing comprises a substantially cylindrical body having a radial protrusion and a cavity defined by a closed end, an open end, a partially cylindrical inner sidewall of the housing and a radial sidewall of the radial protrusion. The inner sidewall of the housing having a length L_c extending from the closed end to a distal wall. In one or more embodiments, the open end includes an engagement surface wherein a peelable seal is attached to.

In one or more embodiments, the insert includes an inner wall. In one or more embodiments, the inner wall of the insert has at least one thread adapted to engage a female luer connector. The medical connector provides a mechanical barrier for connectors and contains an antimicrobial agent for disinfection. The medical connector of the present disclosure also allows the practitioner to streamline the disinfecting process while blocking the lumen of open luers to facilitate the mitigation of the ingress of contaminants and disinfectant into the open lumens of the connectors, thereby reducing risk of the contaminants and disinfectant entering the blood stream.

With respect to terms used in this disclosure, the following definitions are provided.

As used herein, the use of “a,” “an,” and “the” includes the singular and plural.

As used herein, the term “catheter related bloodstream infection” or “CRBSI” refers to any infection resulting from the presence of a catheter or IV line.

As used herein, the terms “medical connector” and “corresponding medical connector” refer to needleless and needle-free medical connectors such as BD MAXPLUS, BD MAXZERO™, STARTSITE™, NEUTRACLEAR™, BD Q-SYTE™ by BECTON DICKENSON AND COMPANY®. Furthermore, the terms “medical connector” and “corresponding medical connector” refer to sterile connectors having a male or female open lumen, luer connectors, and stopcocks. The terms “medical connector” and “corresponding medical connector” also refer to mating elements of needleless and needle-free connectors and can be incorporated into medical devices which connect to medical connectors, such as a cap or a connector of a syringe. The medical connector can include elements which connect or mate to the corresponding medical connector, such as a male medical connector having elements which mate to a corresponding female medical connector.

As used herein, the term “needleless connector” and “corresponding needleless connector” refer to a male and female connector combination. Where the needleless connector is a male needleless connector, the corresponding needleless connector is a female needleless connector. Likewise, where the needleless connector is a female needleless

connector, the corresponding needleless connector is a male needleless connector. The needleless connector can be a cap, a connector of a syringe, a connector of a vascular access device, a connector of a stopcock, a luer connector with a corresponding open luer connector, a connector having a valve, a connector lacking a valve, a manifold port, stopcock, any conventional medical device having needleless connectors, or a regular open luer connector.

As used herein, the term “Luer connector” refers to a connection collar that is the standard way of attaching syringes, catheters, hubbed needles, IV tubes, etc. to each other. The Luer connector consists of male and female interlocking tubes, slightly tapered to hold together better with even just a simple pressure/twist fit. Luer connectors can optionally include an additional outer rim of threading, allowing them to be more secure. The Luer connector male end is generally associated with a flush syringe and can interlock and connect to the female end located on the vascular access device (VAD). Luer connector also has a distal end that releasably attaches the Luer connector to the hub of a VAD, and a proximal end that releasably attaches the Luer connector to the barrel of a syringe.

As used herein, ISO 80369-7:2016 defines a specification for standard Luer connectors including a 6% taper between the distal end and the proximal end. A male standard luer connector increases from the open distal end to the proximal end. A female standard luer connector decreases from the open proximal end to the distal end. According to ISO 80369-7:2016, a male standard luer connector has an outer cross-sectional diameter measured 0.75 mm from the distal end of the tip of between 3.970 mm and 4.072 mm. The length of the male standard luer taper is between 7.500 mm to 10.500 mm. The outer cross-sectional diameter measured 7.500 mm from the distal end of the tip is between 4.376 mm and 4.476 mm. As used herein, the phrases “male standard luer connector” and “female standard luer connector” shall refer to connectors having the dimensions described in ISO 80369-7, which is hereby incorporated by reference in its entirety.

As would be readily appreciated by skilled artisans in the relevant art, while descriptive terms such as “lock”, “tip”, “hub”, “thread”, “sponge”, “prong”, “protrusion/insert”, “tab”, “slope”, “wall”, “top”, “side”, “bottom” and others are used throughout this specification to facilitate understanding, it is not intended to limit any components that can be used in combinations or individually to implement various aspects of the embodiments of the present disclosure.

The matters exemplified in this description are provided to assist in a comprehensive understanding of exemplary embodiments of the disclosure. Accordingly, those of ordinary skill in the art will recognize that various changes and modifications of the embodiments described herein can be made without departing from the scope and spirit of the disclosure. Also, descriptions of well-known functions and constructions are omitted for clarity and conciseness.

In one or more exemplary implementation of the embodiments of present disclosure, the medical connector is in the form of a cap having mating elements which connect to a corresponding medical connector, such as threads, a tab or a flange. The cap comprising a housing and an insert. The insert of the cap, connector cap or disinfecting cap includes at least one thread and other features in any and all combinations allowing it to interface with a corresponding thread or plurality of threads of female threaded fittings.

According to further exemplary implementations of the embodiments of the present disclosure, configuration of structural elements making up the insert include a tab

protruding from the insert, the tab comprising at least one thread to connect to the corresponding thread or plurality of threads of corresponding medical connectors.

According to still further exemplary implementations of the embodiments of the present disclosure, female threads are sized and have a thread pattern that will engage with a standard ISO594-2 type of male fitting and/or a male threads that are sized and have a thread pattern that will engage with a standard ISO594-2 type of female fitting. An example of an ISO594-2 type of fitting is a Q-style fitting.

According to still further exemplary implementations of the embodiments of the present disclosure, the tab of the insert may bend or elastically deform in order to allow better interference fit compliance with the fittings.

In one or more embodiments, the female medical connector may be selected from the group consisting essentially of needle-free connectors, catheter luer connectors, stopcocks, and hemodialysis connectors. In one or more embodiments, the medical connector is selected from a Q-Syte connector, MaxPlus, MaxPlus Clear, MaxZero, UltraSite, Caresite, InVision-Plus, Safeline, OneLink, V-Link, Clear-Link, NeutraClear, Clave, MicroClave, MicroClave Clear, Neutron, NanoClave, Kendall, Nexus, InVision, Vadsite, Bionector, etc.

In one or more embodiments, the male medical connector may be an intravenous tubing end or a stopcock. In some embodiments, the medical connectors described are configured to receive slip connectors such as luer slip connectors. In some embodiments, the medical connectors described include one or more engagement elements such as teeth or c-clips which are configured to engage onto threaded connectors and slip connectors by advancing the threaded connector or slip connector into the medical connector. In some embodiments, the medical connectors described can engage with threaded connectors, such as threaded luer connectors, only by advancement of the threaded connector into the medical connector without requiring the clinician to thread, rotate, or torque the threaded connector or its mating element.

In some embodiments, the teeth or c-clips further comprise a set of tabs protruding from a distal end of the teeth or c-clips. In a fully advanced position, the set of tabs interlock with a thread of a corresponding medical connector. The set of tabs engage the thread of the needleless connector to non-removably lock the corresponding medical connector. In some embodiments, the set of tabs is wider than the spring. In some embodiments, the set of tabs is configured to de-thread from the corresponding thread and jump off the thread path to prevent re-use.

In some embodiments, upon full advancement of a corresponding threaded medical connector the medical connector of embodiments described herein are configured to create an audible click or sound detectable by either the clinician or ancillary detection systems.

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

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

A first aspect of the present disclosure relates to a housing 110 of a medical connector 100. As shown in FIGS. 1A and 1B, the medical connector is in the form of a cap. In some

11

embodiments, the housing 110 pertains to elements which connect or mate to a corresponding medical connector. The housing 110 of the medical connector 100 is of a partially cylindrical shape which is integral with a radial protrusion 180, the radial protrusion 180 being in the form of a protruding arc. The angle of the protruding arc ranges from 10 degrees to 350 degrees. The housing 110 includes a cavity defined by a closed end 112, an open end 114 and a partially cylindrical inner sidewall 120. The partially cylindrical inner sidewall 120 is integral with a radial sidewall 182. The radial protrusion 180 includes a first sidewall 181A and a second sidewall 181B. The radial sidewall 182 of the housing 110 includes a locking structure described in further detail below.

The closed end 112 is in a distal location and the open end 114 is in a proximal location relative to the closed end 112. In one or more embodiments, the partially cylindrical inner sidewall 120 has a substantially constant diameter DB. In one or more embodiments, the partially cylindrical inner sidewall 120 can further be outwardly tapered, wherein the taper increases proximally towards the open end 114. A corresponding medical connector is received through the open end 114 into the cavity 130.

The housing 110 further includes an outer sidewall 116. The outer sidewall 116 in the depicted embodiment has partially cylindrical shape with a smooth surface and a chamfer 118. In one or more embodiments, the chamfer 118 may be rounded. In one or more embodiments the chamfer 118 may extend partially around the outer sidewall 116. In one more embodiments, the outer sidewall 116 may have a plurality of axial ribs. In one or more embodiments, the outer sidewall 116 may have a plurality of radial ribs. In one or more embodiments, the outer sidewall 116 may have a grip surface for ease of manipulation by a practitioner. The grip surface may be textured or have a coating.

A second aspect of the present disclosure relates to an insert 150 disposed within the housing 110. As shown in FIGS. 2A and 2B, insert 150 has a generally discoid body 152 having a distal surface 154, a proximal surface 156 and a sidewall 158. From the sidewall 158 extends a locking tab 160, the locking tab 160 extending from the proximal surface 156 in a proximal direction away from the proximal surface 156 of the discoid body 152. In one or more embodiments, the discoid body 152 includes an aperture 153 disposed on the distal surface 154 of the discoid body 152, the aperture 153 extending therethrough. The center of the aperture 153 is concentric with the center of the discoid body 152. The discoid body 152 has a diameter D_{DB} , the diameter D_{DB} being smaller than the diameter Dis of the partially cylindrical inner sidewall 120, defining a gap between the gap between the sidewall 158 and the partially cylindrical inner sidewall 120 of the housing 110.

In one or more embodiments, the locking tab 160 is a cantilevered prong having a distal portion 162 and a proximal portion 164. In one or more embodiments, the distal portion 162 is integral with the sidewall 158 of the discoid body 152. In one or more, the distal portion 162 and the sidewall 158 of the discoid body 152 can be bonded together through ultrasonic welding or solvent resistant biocompatible adhesive. In the preferred embodiment, the distal portion 162 is at an obtuse angle with respect to the proximal surface 156 of the discoid body 152. In one or more embodiments, the distal portion is at a right angle or at an acute angle with respect to the proximal surface 156 of the discoid body 152. In one or more embodiments, the locking tab 160, the distal portion 162 and the proximal portion bend deflect or elastically deform, either in combination or indi-

12

vidually. In an exemplary implementation, at least a portion of the locking tab 160 elastically deforms inwardly to cause an interference fit between the locking tab 160 and the corresponding medical connector.

The proximal portion 164 of the locking tab 160 further comprises an outer wall 166 and an inner wall 168. The outer wall 166 of the locking tab 160 includes a recessed notch 170. The recessed notch 170 is adjacent to the proximal edge of proximal portion 164 and extends in a distal direction at least partially the length of the proximal portion 164. In one or more embodiments, the recessed notch 170 is adjacent to the lateral or right edge of the outer wall 166 with respect to the outer wall 166. In one or more embodiments, the recessed notch 170 is adjacent to the medial edge or left edge of the outer wall 166 with respect to the outer wall 166.

In one or more embodiments, where the corresponding medical connector is advanced distally into the housing 110 by threading the corresponding medical connector in a rightward or lateral angular direction as per ISO 80369-7:2016 standards, the recessed notch 170 is disposed on the lateral or right edge of the outer wall 166 with respect to the outer wall 166. In one or more embodiments, where the corresponding medical connector is advanced distally into the housing 110 by threading the corresponding medical connector in a leftward angular direction, the recessed notch 170 is disposed on the medial or left edge of the outer wall 166 with respect to the outer wall 166. The depicted embodiment of FIGS. 2A and 2B show the recessed notch 170 disposed on the lateral or right edge of the outer wall 166 with respect to the outer wall 166. In one or more embodiment of the current disclosure, the recessed notch 170 is rectangular. In one or more alternate embodiments of the current disclosure, the recessed notch may also be semi-circular, semi-ovular, triangular, or any other geometric shape.

At least one thread 172 is disposed on the inner wall 168 of the locking tab 160. In the preferred embodiment, the at least one thread 172 has a helical shape. The helical shape is essentially tapered from one direction to another. In one or more embodiments, the taper decreases from a rightward or lateral direction to a medial or left direction with respect to the outer wall 166.

In one or more embodiments, where the corresponding medical connector is advanced distally into the housing 110 by threading the corresponding medical connector in a clockwise, rightward or lateral angular direction as per ISO 80369-7:2016 standards, the taper decreases from a clockwise direction with respect to the outer wall 166. In one or more embodiments, where the corresponding medical connector is advanced distally into the housing 110 by threading the corresponding medical connector in a counter-clockwise or leftward angular direction, the taper decreases from a counter-clockwise direction with respect to the outer wall 166. The depicted embodiment of FIGS. 2A and 2B show the taper decreasing from a clockwise direction with respect to the outer wall 166.

In one or more embodiments, the corresponding medical connector is first partially advanced distally into the housing 110 until a luer tip of the corresponding medical connector abuts the proximal surface 154 of the discoid body 152. In one or more embodiments, the corresponding medical connector is first partially advanced distally into the housing 110 until threads of the corresponding medical connector abut the at least one thread 172. In one or more embodiments, advancement of the corresponding medical connector into the housing 110 causes advancement of the discoid body 152 into the housing 110. The corresponding medical

13

connector can then be rotated which causes locking and final advancement of the discoid body **152** into the housing **110**.

A third aspect of the present disclosure, as shown in FIG. 3, relates to the locking structure disposed within the cavity **130** of housing **110**, the locking structure having features which are disposed or integral with the radial sidewall **182** of the housing **110**. The locking structure includes an outwardly sloped surface **184** which slopes outwardly counter-clockwise from a first sidewall **181A** to a second sidewall **181B**. In the depicted embodiment, the outwardly sloped surface **184** extends at least partially the length of the arc of the radial sidewall **182**. In one or more embodiments, the outwardly sloped surface **184** extends the entire length of the arc of the radial sidewall **182**. From a lateral portion of the outwardly sloped surface **184** extends a sloped tab **186**. The sloped tab **186** slopes outwardly clockwise. The sloped tab **186** includes a ledge **188** formed by a wall at a substantially right angle with respect to the radial sidewall **182**. In one or more embodiments, adjacent to the ledge **188** is a proximally sloped surface **190**, the proximally sloped surface **190** slopes inwardly with respect to the radial sidewall **182** from a distal position to a proximal position.

As shown in FIG. 3, a portion of the radial sidewall **182** adjacent to the first sidewall **181A** is substantially smooth with no protrusions or indentations, and portion of the radial sidewall **182** adjacent to the second sidewall **181B** includes the outwardly sloped surface **184**, sloped tab **186**, the ledge **188** and the proximally sloped surface **190**. As used herein, a first position **192** is defined by the portion of the radial sidewall **182** adjacent to the first sidewall **181A** and a locking position **194** is defined by the sloped tab **186** and the ledge **188**. As shown in FIG. 4, when insert **150** is advanced distally into the cavity **130** of the housing **110**, the locking tab **160** is disposed in the first position **192**. In one or more embodiments, advancement of the insert **150** into the cavity **130** causes the locking tab to elastically deform outwardly with respect to the radial sidewall **182**. With the insert **150** fully advanced into the cavity **130**, the insert **150** can rotate freely along the arc of the radial sidewall **182**. As the insert **150** approaches the locking position **194**, the outwardly sloped surface **184** further elastically deforms the locking tab **160** until the recessed notch **170** passes the ledge **188** of the radial sidewall **182**. When the notch **170** has passed the ledge **188**, the notch nonreleasably engages the ledge **188**, thereby preventing clockwise movement of the locking tab **160**.

In some embodiments, when the notch **170** has passed the ledge **188**, an audible click or sound is created and is detectable by the clinician or ancillary detection systems to indicate that the insert **150** and thus the needleless connector has reached a fully locked position.

FIGS. 5 and 6 illustrate perspective views of the insert **150** in the first position **192** and the locking position **194**, respectively. Likewise, FIGS. 7 and 8 illustrate a top view of the insert **150** in the first position **192** and the locking position **194**, respectively. As depicted in FIGS. 7 and 8, the thickness of the radial sidewall **182** gradually increases from a value of T_1 to T_2 due to the outwardly sloped surface **184**.

FIG. 9 depicts a partially cross-sectional view of the cavity **130** wherein the insert **150** is fully advanced into the cavity **130** and is in the first position **192**. For illustration purposes, the distal surface **154** of the discoid body **152** directly abuts the inner top surface **122** of the housing **110**, however, in one or more embodiments, an absorbent material **199** containing disinfectant is disposed between the distal surface **154** of the discoid body **152** and the inner top surface **122** of the housing **110**. Advancement of a corre-

14

sponding medical connector into cavity **130** compresses the absorbent material **199** thereby releasing disinfectant. In one or more embodiments, the closed end **112** includes a concentric retention tab **124** which mechanically locks onto the aperture **153** of the discoid body **152**, thereby preventing removal of the insert **150**. In one or more embodiments, the concentric retention tab comprises a distal cylindrical shape and a proximal cylindrical shape, the proximal cylindrical shape having a greater diameter than the distal cylindrical shape. In one or more embodiments, the diameter of the proximal cylindrical shape is greater than the diameter of the aperture **153** of the discoid body **152**, creating a snap-fit connection between the retention tab **124** and the aperture **153** of the discoid body **152**.

In one or more embodiments, the retention tab **124** is long enough to allow for placement of a cylindrical absorbent material disk between the discoid body **152** and the inner top surface **122** of the housing **110**, the cylindrical absorbent material disk having an aperture extending therethrough. The total length of the retention tab **124** is equal or slightly greater than the thickness of the discoid body **152** and the thickness of the cylindrical absorbent material disk, whereby the cylindrical absorbent material disk is in an uncompressed state. Insertion of a connector compresses the cylindrical absorbent material disk, thereby releasing disinfectant into the cavity **130**.

As shown in FIGS. 11 and 12, the corresponding medical connector is a female needleless connector **80**.

As shown in FIG. 11, in one or more embodiments, the absorbent material **199** is placed in the cavity **130**, the absorbent material **199** abutting the proximal surface **156** of the discoid body **152**. Insertion of a female needleless connector **80** compresses the absorbent material **199**, thereby releasing disinfectant into the cavity **130**. At least one thread **82** of the connector **80** engages at the at least one thread **172** of the insert **150**. The at least one thread **82** is disposed on a hub **84** of the female needleless connector **80**.

As shown in FIG. 12, in operation, a female connector **80** having at least one thread **82** engages the at least one thread **172** of the insert **150**, thereby causing advancement of the female connector **80** and the insert **150** into the housing **110**. As the locking tab **160** nonreleasably locks into the second position and the absorbent material **199** (not shown for purposes of clarity) is compressed, disinfectant is released into the cavity **130**. In embodiments where the absorbent material **199** is disposed against the closed distal end **112** of the housing **110**, the released disinfectant evacuates through the gap **123** created between the discoid body **152** and the partially cylindrical inner sidewall **120**. After disinfection is complete, the female connector **80** is un-threaded in the opposite direction, allowing for release of the female connector **80** while the ledge **188**, engaged to the recessed notch **170**, prevents the removal of the insert **150**. FIG. 10 depicts the elastic deformation of the locking tab **160** in the first position **192** and the locking position **194**, respectively. The deformation causes the at least one thread **172** to further securely engage the at least one thread of the female connector **80**. For purposes of illustration, the locking tab **160** in the first position **192** is depicted directly above the locking tab **160** in the locking position. Deformation of the locking tab **160** is illustrated relative to the line AA, with the locking tab **160** deforming inward.

A second embodiment of the present disclosure relates to a housing **210** of syringe **200**. As shown in FIGS. 13A through 13D, the housing **210** protrudes in a distal direction from a distal wall **212** of a syringe barrel **213** of the syringe **200**. As shown in 13A, the housing **210** of the second

15

embodiment is configured as a needleless connector able to receive a male luer fitting commonly associated with VADs. The housing 210 includes a cavity 230 defined by the distal wall 212 of the syringe barrel 213, an open end 214 opposite the distal wall 212 and a partially cylindrical sidewall 216 extending from the distal wall 212 to the open end 214. A tapered hub 232 is disposed within the cavity 230, the tapered hub 232 extending in a distal direction from the distal wall 212 of the syringe barrel 213. The tapered hub 232 is configured to interdigitate with a corresponding cavity of a housing of the VAD (not shown). In some embodiments, the tapered hub 232 is configured to create a fluid-tight seal with the housing of the VAD. In some embodiments, the tapered hub 232 is configured to create an interference fit with the housing of the VAD.

The housing 210 and the partially cylindrical sidewall 216 are of a partially cylindrical shape, the partially cylindrical sidewall 216 having an integral radial protrusion 280 extending laterally from the housing 210. The radial protrusion 280 defines a radial sidewall 282, the radial sidewall 282 including a locking structure described in further detail below. The radial protrusion 280 and the radial sidewall 282 are in the shape of a laterally protruding arc. The angle of the protruding arc ranges from 10 degrees to 350 degrees.

In one or more embodiments, the partially cylindrical inner sidewall 216 has a substantially constant diameter. In one or more embodiments, the partially cylindrical inner sidewall 216 can include an outward taper, wherein the taper increases distally towards the open end 214.

The housing 210 further includes an outer sidewall 216. The outer sidewall 216 in the depicted embodiment has partially cylindrical shape which includes a smooth surface and a chamfer 218. In one or more embodiments, the chamfer 218 may be rounded. In one or more embodiments the chamfer 218 may extend partially around the distal end of the outer sidewall 216.

The locking structure, as best shown in FIGS. 13B through 13D, is disposed within the cavity 230 of housing 210, the locking structure having features which are integral with the radial sidewall 282 of the housing 210. The locking structure includes an outwardly sloped surface 284 which slopes outwardly from a medial or leftward position to a lateral or rightward position. In the depicted embodiment, the outwardly sloped surface 284 extends at least partially the length of the arc of the radial sidewall 282. In one or more embodiments, the outwardly sloped surface 284 extends the entire length of the arc of the radial sidewall 282. From a lateral portion of the outwardly sloped surface 284 extends a sloped tab 286. The sloped tab 286 slopes outwardly from a lateral or rightward position to a medial or leftward position. The sloped tab 286 includes a ledge 288 formed by a wall at a substantially right angle with respect to the radial sidewall 282. In one or more embodiments, adjacent to the ledge 288 is a proximally sloped surface 290, the proximally sloped surface 290 slopes inwardly with respect to the radial sidewall 282 from a distal position to a proximal position.

As best shown in FIGS. 13C and 13D, a medial or leftward portion of the radial sidewall 282 is substantially smooth with no protrusions or indentations, and a lateral or rightward portion of the radial sidewall 282 includes the outwardly sloped surface 284, sloped tab 286, the ledge 288 and the proximally sloped surface 290. As used herein, a first position 292 is defined by the medial or leftward portion of the radial sidewall 282 and a locking position 294 is defined by the sloped tab 286 and the ledge 288.

As shown in FIGS. 14A and 14B, insert 250 has a generally discoid body 252 having a proximal surface 254,

16

a distal surface 256 and a sidewall 258. From the sidewall 258 extends a locking tab 260, the locking tab 260 extending from the distal surface 256 in a distal direction away from the distal surface 256 of the discoid body 252. In one or more embodiments, the discoid body 252 includes an aperture 253 disposed on the proximal surface 254 of the discoid body 252, the aperture 253 extending therethrough. The center of the aperture 253 is concentric with the center of the discoid body 252. The discoid body 252 has a diameter D_{DB} , the diameter D_{DB} being smaller than the diameter D_{is} of the partially cylindrical inner sidewall 220, defining a gap between the gap between the sidewall 258 and the partially cylindrical inner sidewall 220 of the housing 210.

In one or more embodiments, the locking tab 260 is configured as a cantilevered prong having a proximal portion 262 and a distal portion 264. In one or more embodiments, the proximal portion 262 is integral with the sidewall 258 of the discoid body 252. In one or more, the proximal portion 262 and the sidewall 258 of the discoid body 252 can be bonded together through ultrasonic welding or solvent resistant biocompatible adhesive. In the preferred embodiment, the proximal portion 262 is at an obtuse angle with respect to the distal surface 256 of the discoid body 252. In one or more embodiments, the proximal portion 262 is at a right angle or at an acute angle with respect to the distal surface 256 of the discoid body 252. In one or more embodiments, the locking tab 260, the proximal portion 262 and the distal portion bend deflect or elastically deform, either in combination or individually. In an exemplary implementation, at least a portion of the locking tab 260 elastically deforms inwardly to cause an interference fit between the locking tab 260 and the corresponding medical connector.

The proximal portion 264 of the locking tab 260 further comprises an outer wall 266 and an inner wall 268. The outer wall 266 of the locking tab 260 includes a recessed notch 270. The recessed notch 270 is adjacent to the distal edge of the distal portion 264 and extends in a proximal direction at least partially the length of the distal portion 264. In one or more embodiments, the recessed notch 270 is adjacent to the lateral or right edge of the outer wall 266 with respect to the outer wall 266. In one or more embodiments, the recessed notch 270 is adjacent to the medial edge or left edge of the outer wall 266 with respect to the outer wall 266.

As shown in FIGS. 15 and 16, in one or more embodiments, where the VAD is advanced proximally into the housing 210 by threading the VAD in a leftward angular direction as per ISO 80369-7:2016 standards, the recessed notch 270 is disposed on the medial or left edge of the outer wall 266 with respect to the outer wall 266. In one or more embodiments, where the VAD is advanced distally into the housing 210 by threading the VAD in a rightward angular direction, the recessed notch 270 is disposed on the medial or left edge of the outer wall 266 with respect to the outer wall 266. Referring back to the depicted embodiment of FIGS. 14A and 14B show the recessed notch 270 disposed on the lateral or right edge of the outer wall 266 with respect to the outer wall 266. In one or more embodiment of the current disclosure, the recessed notch 270 is rectangular. In one or more alternate embodiments of the current disclosure, the recessed notch 270 may also be semi-circular, semi-ovular, triangular, or any other geometric shape.

At least one thread 272 is disposed on the inner wall 268 of the locking tab 260. In the preferred embodiment, the at least one thread 272 has a helical shape. The helical shape is essentially tapered from one direction to another. In one

17

or more embodiments, the taper decreases from a rightward or lateral direction to a medial or left direction with respect to the outer wall 266.

In one or more embodiments, where the VAD is advanced distally into the housing 210 by threading the VAD clockwise, rightward or lateral angular direction as per ISO 80369-7:2016 standards, the taper decreases from a leftward or medial direction with respect to the outer wall 266. In one or more embodiments, where the VAD is advanced proximally into the housing 210 by threading the VAD connector in a counter-clockwise or leftward angular direction, the taper decreases from a rightward or lateral direction with respect to the outer wall 266. The depicted embodiment of FIGS. 14A and 14B show the taper decreasing from a leftward or medial direction with respect to the outer wall 266.

As previously described with respect to the first embodiment, and as shown in FIGS. 15 and 16, when insert 250 is advanced proximally into the cavity 230 of the housing 210, the locking tab 260 is disposed in the first position 292. In one or more embodiments, advancement of the insert 250 into the cavity 230 causes the locking tab to elastically deform outwardly with respect to the radial sidewall 282. With the insert 250 fully advanced into the cavity 230, the insert 250 can rotate freely along the arc of the radial sidewall 282. As the insert 250 rotationally approaches the locking position 294, the outwardly sloped surface 284 further elastically deforms the locking tab 260 inward until the recessed notch 270 passes the ledge 288 of the radial sidewall 282. When the notch 270 has passed the ledge 288, the notch non-releasably engages the ledge 288, thereby preventing medial or leftward movement of the locking tab 260.

In some embodiments, when the notch 270 has passed the ledge 288, an audible click or sound is created and is detectable by the clinician or ancillary detection systems to indicate that the insert 250 and thus the medical connector has reached a fully locked position.

As best shown in FIG. 16, the proximal surface 254 of the insert 250 abuts the distal wall 212 of a syringe barrel 213 of the syringe 200 in the fully advanced position. In one or more embodiments, a circular protrusion 234 is disposed on the tapered hub 232. The circular protrusion 234 is configured to non-removably lock the insert 250 in the fully advanced position. The circular protrusion 234 is located a distance from the distal wall 212 of a syringe barrel 213 and the distance is configured to be equal to or slightly larger than the thickness of the discoid body of the insert 250. In one or more embodiments, the circular protrusion 234 has a substantially triangular cross section, the triangular cross section having a proximal right angled surface with respect to the tapered hub 232 and a distal acute angled surface with the tapered hub 232. The distal acute angled surface of the circular protrusion 234 is configured to create slight deformation of the insert 250 as the insert 250 comes into contact with the distal acute angled surface of the circular protrusion 234 as the insert 250 is advanced proximally. The proximal right surface of the circular protrusion 234 is configured to non-removably secure the insert 250 when the insert 250 completely transverses over the triangular cross section of the circular protrusion 234.

A third embodiment of the present disclosure relates to a housing 310 of a medical connector 300. FIGS. 17, 18A and 18B illustrate the medical connector 300 in an initial, un-activated state and FIGS. 19 and 20 illustrate the medical connector 300 in a final, activated state where a correspond-

18

ing medical connector (not shown) has been fully advanced into a cavity 330 the housing 310.

As shown in FIG. 17 through 18B, the medical connector 300 comprises a substantially cylindrical housing 310 having a distal wall 312, a proximal open end 314, a sidewall 316 extending between the distal wall 312 to the open end 314 and a cavity 330. The cavity 330 extends from the open end 314 to the distal wall 312. In one or more embodiments, an absorbent material 399 in the form of a disk is disposed within the cavity 330, abutting an inner distal surface 322 of the distal wall 312. An inner sidewall surface 318 of the sidewall 316 includes a channel 324 extending from the distal wall 312 to the open end 314. On the inner sidewall surface 318, the channel 324 has a substantially rectangular profile, while the channel 324 extends a depth into the sidewall 316. The depth of the channel 324 is configured to at least partially interdigitate with a spring 350 as discussed in further detail below.

The housing further includes a plurality of threads 320 disposed on the inner sidewall surface 318, however the plurality of threads 320 are not disposed on the channel 324. The plurality of threads 320 are configured to thread with a corresponding thread 82 of a female needleless connector 80 of one of the previous embodiments (as seen in FIGS. 11 and 12).

As shown in FIGS. 17 through 18B, and as best shown in FIG. 18B, the spring 350 is configured as a leaf spring having a rectangular cross-section and an arc 352. In one or more embodiments, the arc 352 is pointed, forming a ramp. The arc 352 is between a distal portion 354 and a proximal portion 356. The distal portion 354 is non-removably attached to the channel 324, while the proximal portion 356 is not attached to the channel 324 and may freely deflect. In operation, the proximal portion 356 abuts the channel 324 in the initial state, as shown in FIGS. 17-18B. As the needleless connector 80 is advanced into the cavity 330, the least one thread 82 depresses the arc 352 of the spring 350 into the channel 324. Depression of the arc 352 cause the proximal portion 354 of the spring 350 to deflect outward, away from the channel 324. In the fully advanced position as shown in FIGS. 19 and 20, a proximal end 355 of the proximal portion 354 of the spring 350 engages a lower segment of the least one thread 82 of the needleless connector 80, thereby locking the needleless connector 80 within the cavity 330 in a threaded fit and an interference fit. In one or more embodiments, the needleless connector 80 is removably locked within the cavity 330. In one or more embodiments, the needleless connector 80 is non-removably locked within the cavity 330 by means of configurations of the spring 350 including, but not limited to, utilizing a stiffer spring.

In embodiments where the needleless connector 80 is removable from the cavity 330, the spring 350 does not return to the initial state, thereby preventing re-use of the housing 310.

In some embodiments, when the needleless connector 80 is fully advanced into the cavity 330 and the spring 350 engages corresponding thread 82, an audible click or sound is created and is detectable by the clinician or ancillary detection systems to indicate that the needleless connector 80 is fully advanced into the cavity 330.

In some embodiments, the proximal end 355 of the spring 350 further comprises a set of tabs 353 protruding from the proximal end 355. In some embodiments, the set of tabs 353 are in the form of a C-clip. In the fully advanced position, the set of tabs 353 interlock with a thread of the corresponding needleless connector 80. The set of tabs 353 engage the thread of the needleless connector 80 to non-removably lock

the corresponding needleless connector **80**. In some embodiments, the set of tabs **353** is wider than the spring **350**. In some embodiments, the set of tabs **353** is configured to de-thread from the corresponding thread **82** and jump off the thread path to prevent re-use.

A fourth embodiment of the present disclosure relates to a housing **410** of a medical connector **400**. FIGS. **21A** and **21B** illustrate the medical connector **400** in an initial, un-activated state and FIG. **22** illustrates the medical connector **400** in a final, activated state where a needleless connector (not shown) has been fully advanced into a cavity **430** the housing **410**.

As shown in FIGS. **21A** and **21B**, the medical connector **400** comprises a substantially cylindrical housing **410** having a distal wall **412**, a proximal open end **414**, a sidewall **416** extending between the distal wall **412** to the open end **414** and a cavity **430**. The cavity **430** extends from the open end **414** to the distal wall **412**. A cupped spring **350** (also known in the art as a Belleville spring) is disposed within the cavity **330**, wherein an open distal end **352** of the cupped spring **350** abuts an inner distal surface **422** of the distal wall **412** of the housing **410**.

The cupped spring **450** comprises a frusto-conical shaped disk body **452** having at least two prongs **456** extending from a proximal edge **454** of the disk body **452**. While the dimensions of the frusto-conical shape of the disk body **452** determine the spring constant and spring characteristics generally, the at least two prongs **456** may have different spring constant and spring characteristics in relation to the disk body **452**. In one or more embodiments, the at least two prongs **456** have a stiffer spring constant and spring characteristics in relation to the disk body **452**. In one or more embodiments, the at least two prongs **456** are rigid.

The at least two prongs **456** extend from a proximal edge **454** of the disk body **452** in a proximal direction. Each of the at least two prongs **456** comprise a proximal portion **458** and a distal portion **460** adjacent to the proximal portion **458**. The distal portion **460** forms a medial hook **462** extending toward a center of the disk body **452**. The medial hook **562** comprises a medial edge **464** configured to engage with a corresponding thread **82** of a corresponding needleless luer connector **80** of one of the previous embodiments (as seen in FIGS. **11** and **12**). In one or more embodiments, an absorbent material **498** in the form of a disk is disposed within the cavity **430**. The absorbent material **498** abuts a proximal surface of the disk body **452**.

FIGS. **21A** and **21B** illustrate the medical connector **400** in an initial, un-activated state and FIGS. **22A** through **22C** illustrate the medical connector **400** in a final, activated state where a needleless connector (not shown) has been fully advanced into a cavity **430** the housing **410**. In operation, the hub **84** of the corresponding needleless connector **80** of one of the previous embodiments (as seen in FIGS. **11** and **12**) is advanced into the cavity **430** of the housing **410**. As the hub **84** comes into contact and advances against the disk body **452**, the disk body **452** deforms from the initial state of FIGS. **21A** and **21B** to the final state of FIG. **22A** through **22C**. The disk body **452** deforms inward, pushing the proximal edge **454** of the disk body **452** in a proximal direction, thereby causing the least two prongs **456** to advance in a proximal direction, whereby the medial hook **462** is further advanced in a lateral direction. In the final state, the medial hook **462** latches onto the at least one thread **82**, thereby locking the needle connector **80** into the housing **410** due to the spring force. In the fully advanced position as shown in FIGS. **19** and **20**, a proximal end **355** of the proximal portion **354** of the spring **350** engages a lower

segment of the least one thread **82** of the needleless connector **80**, thereby locking the needleless connector **80** within the cavity **330** in a threaded fit and an interference fit. In one or more embodiments, the needleless connector **80** is removably locked within the cavity **330**. In one or more embodiments, the needleless connector **80** is non-removably locked within the cavity **330** by means of configurations of the spring **350** including, but not limited to, utilizing a stiffer spring. The medial hook **456** in the fully advanced position creates a threaded fit and an interference fit with the at least one thread **82** of the needleless connector **80**. In one or more embodiments, the needleless connector **80** is removably locked within the cavity **430**. In one or more embodiments, the needleless connector **430** is non-removably locked within the cavity **430** by means of configurations of the spring **450** including, but not limited to, utilizing a stiffer spring.

In embodiments where the needleless connector **80** is removed from the cavity **330**, the spring **450** does not return to the initial state, thereby preventing re-use of the housing **310**.

As shown in FIG. **22A** through **22C**, in some embodiments, when the needleless connector **80** is fully advanced into the cavity **430** and the spring **450** engages corresponding thread **82**, an audible click or sound is created and is detectable by the clinician or ancillary detection systems to indicate that the needleless connector **80** is fully advanced into the cavity **430**.

As shown in **22A**, in some embodiments, the medial hook **462** further comprises a set of tabs **453** protruding from the medial hook **462**. In some embodiments, the set of tabs **453** are in the form of a C-clip. In the fully advanced position, the set of tabs **453** interlock with a thread of the corresponding needleless connector **80**. The set of tabs **653** engage the thread of the needleless connector **80** to non-removably lock the corresponding needleless connector **80**. In some embodiments, the set of tabs **353** is wider than the spring **350**. In some embodiments, the set of tabs **353** is configured to de-thread from the corresponding thread **82** and jump off the thread path to prevent re-use.

As shown in **22B** and **22C**, in some embodiments, the medial edge **464** is elongated in a lateral and medial direction. In some embodiments, the medial edge **464** is configured as a c-clip. In the fully advanced position, the medial edge **464** interlocks with a thread of the corresponding needleless connector **80**. The elongated medial edge **464** engages the thread of the needleless connector **80** to non-removably lock the corresponding needleless connector **80**. In some embodiments, the medial edge **464** is wider than the spring **350**. In some embodiments, the medial edge **464** is configured to de-thread from the corresponding thread **82** and jump off the thread path to prevent re-use.

A fifth embodiment of the present disclosure relates to a housing **510** of a medical connector **500**. FIGS. **23A** and **23B** illustrate the medical connector **500** in an initial, un-activated state and FIGS. **24A** and **24B** illustrate the medical connector **500** in a final, activated state where a needleless connector (not shown) has been fully advanced into a cavity **530** the housing **510**. In the final state, the needleless connector is removable however the medical connector **500** has integrated features preventing re-use of the medical connector **500**, as explained in further detail below.

The medical connector **500** comprises a substantially cylindrical housing **510** having a distal wall **512**, a proximal open end **514**, a sidewall **516** extending between the distal wall **512** to the open end **514** and a cavity **530**. The cavity **530** extends from the open end **514** to the distal wall **512**. On

an inner sidewall **518** of the cavity **530** at least one helical thread **550** is disposed, the helical thread **550** extending at least partially the length of the inner sidewall **518**.

The at least one helical thread **550** comprises a distal portion **552** which is unitarily formed onto the inner sidewall **518** and a frangible portion **554** proximal to the distal portion configured to detach and cross-thread upon threading and advancing a corresponding thread **82** of a corresponding needleless luer connector **80** of one of the previous embodiments (as seen in FIGS. **11** and **12**) into the cavity. Upon removal of the luer connector **80**, the frangible portion **554** does not return to the initial state, thereby preventing re-use of the housing **510**.

In one or more embodiments, the frangible portion **554** in the initial state as shown in FIG. **23B** does not follow the thread pattern of the at least one helical thread **550**. In one or more embodiments, as shown in FIG. **23B**, the frangible portion **554** has a greater approach angle \emptyset than the approach angle \emptyset of the distal portion **552** of the at least one helical thread **550**. The greater approach angle \emptyset is configured to cause deformation of the frangible portion **554**. Deformation of the frangible portion **554** prevents re-use of the needleless connector **500** due to thread miss-alignment. Removal of the corresponding needleless luer connector **80** does not return the frangible portion **554** to the original angle \emptyset of the frangible portion **554**, and thus the medical connector **500** cannot be reused. Specifically, as shown in FIG. **24B**, insertion and subsequent removal of the corresponding needleless luer connector **80** causes frangible portion **554** to have a near-zero approach angle, whereby the frangible portion **554** is substantially parallel to the inner distal surface **522** of the housing **510**.

In one or more embodiments, and as specifically shown in FIG. **23B**, the frangible portion **554** extends a quarter turn. In one or more embodiments the frangible portion **554** extends a half turn. In one or more embodiments the frangible portion **554** extends a three quarter turn.

In one or more embodiments, absorbent material **599** is placed in the cavity **530**, the absorbent material **599** abutting an inner distal surface **522** of the housing **510**. Insertion of a corresponding needleless connector **80** compresses the absorbent material **599**, thereby releasing disinfectant into the cavity **530**.

A sixth embodiment of the present disclosure relates to an insert **650** disposed within a housing **610** of a medical connector **600**. FIGS. **25A** and **25B** illustrate embodiments of the insert **650** and FIG. **26** illustrates the medical connector **600** in an initial, un-activated state. In a final, activated state, as described in further detail below, a needleless connector (not shown) is fully advanced into a cavity **630** of the housing **610**.

As shown in FIGS. **25A** and **25B**, insert **650** has a generally discoid body **652** having a proximal surface **654** and a distal surface **656**. From the proximal surface **654** extend at least two locking tabs **660**, the at least two locking tabs **660** extending from the distal surface **656** in a distal direction away from the distal surface **656** of the discoid body **652**. Each of the at least two locking tabs **660** comprise a hooked proximal end **662**. The hooked proximal end **662** is configured to interlock with corresponding thread **82** of a corresponding needleless luer connector **80** of one of the previous embodiments (as seen in FIGS. **11** and **12**) upon threading and advancing the corresponding thread of a corresponding needleless luer connector into the cavity.

In one or more embodiments, the discoid body **652** further includes an aperture **653** disposed on the proximal surface **654** of the discoid body **652**, the aperture **653** extending

therethrough. The center of the aperture **653** is concentric with the center of the discoid body **652**. As shown in FIG. **26** and as explained in further detail below, the aperture **653** is configured to non-removably interlock with a hooked protrusion **640** of the housing **610**.

In one or more embodiments, the discoid body **652** further includes a plurality of ridges **672** disposed on a sidewall **670** of the discoid body **652**. The plurality of ridges **672** extend into the discoid body **652** in a medial direction from the sidewall **670** of the discoid body **652**. As shown in FIG. **26** and as explained in further detail below, the plurality of ridges **672** are configured to interdigitate with at least one tooth **634** of the housing **610**.

In one or more embodiments, as shown in FIG. **25B**, the discoid body **652** further includes a living hinge **676** disposed across the discoid body **652**. As shown in FIG. **26** the living hinge **676** is configured to bend the discoid body **652**. Bending of the discoid body **652** causes the least two locking tabs **660** to threads of a medical connector.

As shown in FIG. **26**, the medical connector **600** comprises a substantially cylindrical housing **610** having a distal wall **612**, a proximal open end **614**, a sidewall **616** extending between the distal wall **612** to the open end **614** and a cavity **630**. The cavity **630** extends from the open end **614** to the distal wall **612**. In one or more embodiments, an absorbent material (not shown) in the form of a disk is disposed within the cavity **630**, abutting an inner distal surface **622** of the distal wall **612**.

In one or more embodiments, a hooked protrusion **640** extends concentrically from the inner distal surface **622** of the housing **610**. The hooked protrusion **640** is configured to non-removably interlock with the aperture **653** of the discoid body **652** upon full advancement of the discoid body **652** into the cavity **630** of the housing **610**, thereby preventing re-use of the medical connector **600**.

In one or more embodiments, at least one tooth **634** extends medially into the cavity **630** from an inner sidewall **618**. The at least one tooth **634** is positioned a distance from the inner distal surface **622** of the housing **610**. In one or more embodiments, the at least one tooth **634** is positioned substantially parallel to a proximal end **641** of the hooked protrusion **640**. The at least one tooth **634** and the plurality of ridges **672** of the discoid body **652** are configured to interdigitate with one another, wherein the at least one tooth **634** and the plurality of ridges **672** have substantially corresponding shapes. In one or more embodiments, the at least one tooth **634** has a substantially triangular shape and the plurality of ridges **672** have a corresponding triangular profile. In one or more embodiments, at least one ledge **637** is disposed on the inner distal surface **622** of the housing **610**.

As shown in FIG. **26**, the medical connector **600** is in an initial position. Upon full advancement of the corresponding needleless luer connector **80**, the hooked protrusion **640** is received within the aperture **653** of the discoid body **652**. However, full advancement is inhibited by misalignment of the plurality of ridges **672** and the at least one tooth **634**. Thus, full advancement can occur when the plurality of ridges **672** align with the at least one tooth **634**. In the final state, the insert **650** is non-removably locked due to the hooked protrusion **640** being received within the aperture **653** of the discoid body **652**.

In one or more embodiments, absorbent material (not shown) is placed in the cavity **630**, the absorbent material abutting the inner distal surface **622** of the housing **610**.

Insertion of a corresponding needleless connector **80** compresses the absorbent material, thereby releasing disinfectant into the cavity **630**.

As shown in FIG. 27, a seventh embodiment of the present disclosure relates to a medical connector **700** comprising of a housing **710** and an insert **750** disposed within the housing **710**. As explained in further detail below, the insert **750** is of a resilient and flexible material and comprises at least two living hinges **760** to grip onto a thread **82** of a corresponding needleless luer connector **80** of one of the previous embodiments (as seen in FIGS. 11 and 12).

The housing **710** has a substantially cylindrical shape and comprises a distal wall **712**, a proximal open end **714**, a sidewall **716** extending between the distal wall **712** to the open end **714** and a cavity **730**. The cavity **730** extends from the open end **714** to the distal end **712**. In one or more embodiments, an absorbent material (not shown) in the form of a disk is disposed within the cavity **730**, abutting an inner distal surface **722** of the housing **710**. In one or more embodiments, the distal end **712** of the housing **710** is in the shape of a medially facing hook.

The insert **750** comprises a C-shaped body **752** having a distal end **754** in the form of an arc and an open proximal end **756**. From the distal end **754** extend the two living hinges **760**. The two living hinges **760** are in the form of cantilevered prongs. As the corresponding needleless luer connector **80** is advanced into the cavity **730**, the C-shaped body **752**, including the distal end **754** and the living hinges **760**, deflect. The resilient material of the insert **750** causes the corresponding needleless luer connector **80** to be retained by the open proximal end **756** of the insert **750**. The two living hinges **760** provide a countering force against the C-shaped body **752** of the insert.

In one or more embodiments, absorbent material (not shown) is placed in the cavity **730**, the absorbent material abutting an inner distal surface **722** of the housing **510**. Insertion of a corresponding needleless connector **80** compresses the absorbent material, thereby releasing disinfectant into the cavity **730**.

As shown in FIGS. 28A and 28B, an eighth embodiment of the present disclosure relates to a medical connector **800** comprising of a housing **810** and an insert **850** disposed within the housing **810**. As explained in further detail below, the insert **850** is of a resilient and flexible material and at least two living hinges **860** to grip onto a thread **82** of a corresponding needleless luer connector **80** of one of the previous embodiments (as seen in FIGS. 11 and 12).

The housing **810** has a substantially cylindrical shape and comprises a distal wall **812**, a proximal open end **814**, a sidewall **816** extending between the distal wall **812** to the open end **814** and a cavity **830**. The cavity **830** extends from the open end **814** to the distal wall **812**. In one or more embodiments, an absorbent material (not shown) in the form of a disk is disposed within the cavity **830**, abutting an inner distal surface **822** of the distal wall **812**. In one or more embodiments, the distal wall **812** further protrudes in a medial direction.

In one or more embodiments, a protrusion **840** extends concentrically from the inner distal surface **822** of the housing **810**. The protrusion **840** is configured to non-removably interlock with an aperture **853** of the C-shaped body **852** upon full advancement of the C-shaped body **852** into the cavity **830** of the housing **810**, thereby preventing re-use of the needleless connector **800**. The protrusion **840** is configured to aid in alignment and advancement of the insert **850** into the cavity **830** of the housing **810**.

In one or more embodiments, a medial wall **823** is positioned a distance from the inner distal surface **822** of the housing **810**. The medial wall **823** further includes an aperture **824** configured to receive a distal portion **854** of the insert **850** explained in further detail below.

The insert **850** comprises a C-shaped body **852** having a distal portion **854** in the form of an arc and an open proximal end **856**. Tangential to the distal portion **854** extend at least two living hinges **860**. The two living hinges **860** are in the form of cantilevered prongs. As the corresponding needleless luer connector **80** is advanced into the cavity **830**, the C-shaped body **852**, including the distal portion **854** and the at least two living hinges **860**, deflect. The resilient material of the insert **850** causes the corresponding needleless luer connector **80** to be retained by the open proximal end **856** of the insert **850**. The two living hinges **860** provide a countering force against the C-shaped body **852** of the insert.

In one or more embodiments, the C-shaped body **852** further includes a stem **857** having a cylindrical profile extending in a distal direction from the distal portion **854**. From the stem extends a bulbous protrusion **859**. The C-shaped body **852**, stem **857** and the bulbous protrusion **859** form a unitary body through which an aperture **861** extends. The aperture **861** is configured to receive the protrusion **840** of the housing **810** while the stem **857** and the bulbous protrusion **859** are configured to interlock with the aperture **824** of the housing **810**.

As the corresponding needleless luer connector **80** is advanced into the cavity **830**, the C-shaped body **852**, including the distal portion **854** and the living hinges **860**, deflect. The resilient material of the insert **850** causes the corresponding needleless luer connector **80** to be retained by the open proximal end **856** of the insert **850**. The two living hinges **860** provide a countering force against the C-shaped body **852** of the insert.

In one or more embodiments, absorbent material (not shown) is placed in the cavity **830**, the absorbent material abutting the medial wall **823** of the housing **510**. Insertion of a corresponding needleless connector **80** compresses the absorbent material, thereby releasing disinfectant into the cavity **830**.

In one or more embodiments, the corresponding medical connector may be selected from the group consisting essentially of needle-free connectors, catheter luer connectors, stopcocks, and hemodialysis connectors. In one or more embodiments, the needleless connector is selected from a Q-Syte connector, MaxPlus, MaxPlus Clear, MaxZero, UltraSite, Caresite, InVision-Plus, Safeline, OneLink, V-Link, ClearLink, NeutraClear, Clave, MicroClave, MicroClave Clear, Neutron, NanoClave, Kendall, Nexus, InVision, Vadsite, Bionector, etc.

In one or more embodiments, the male connector may be an intravenous tubing end, a stopcock or male lock luer.

In some embodiments, the connector comprises a needleless injection site, which may sometimes be referred to as a needleless injection port, hub, valve, or device, or as a needleless access site, port, hub, valve, or device, and which can include such brands as, for example, Clave® (available from ICU Medical, Inc.), SmartSite® (available from Cardinal Health, Inc.), and Q-Syte™ (available from Becton, Dickinson and Company). In some embodiments, the needleless connector can be connected with any of a variety of different needleless injection sites, such as those previously listed. In one or more embodiments, after the needleless connector has been coupled with connector, it is unnecessary to disinfect (e.g., treat with an alcohol swab) the connector prior to each reconnection of the connector with

another connector, as the connector will be kept in an uncontaminated state while coupled with the needleless connector. Use of the needleless connector replaces the standard swabbing protocol for cleaning connectors.

Such connectors are generally and commonly used as catheter and other fluid-tight protective connectors in medical applications. In one or more embodiments, medical connector (100, 200, 300, 400, 500, 600, 700, 800) provides a protective cover for a corresponding needleless luer connector when engaged with the connector when threads from the corresponding needleless luer connector engage and form a releasable connection with the medical connector (100, 200, 300, 400, 500, 600, 700, 800).

The medical connector (100, 200, 300, 400, 500, 600, 700, 800) is made from any of a number of types of plastic materials such as polycarbonate, polypropylene, polyethylene, polyethylene terephthalate, polylactide, acrylonitrile butadiene styrene or any other moldable plastic material used in medical devices. In one or more embodiments, the medical connector (100, 200, 300, 400, 500, 600, 700, 800) comprises a polypropylene or polyethylene material.

The medical connector (100, 200, 300, 400, 500, 600, 700, 800) can achieve disinfection when used on luer connectors by integrating disinfectant in the cavity (130, 230, 330, 430, 530, 630, 730, 830). The disinfectant or antimicrobial agent can be directly included in the absorbent material or disinfectant or antimicrobial agent can be absorbed into sponges or foam material that fills the cavity (130, 230, 330, 430, 530, 630, 730, 830). Medical connector (100, 200, 300, 400, 500, 600, 700, 800) is designed to be compatible in interacting with various disinfectants. In one or more embodiments, the disinfectant or antimicrobial agent may include variations of alcohol or chlorhexidine. In one or more embodiments, the disinfectant or antimicrobial agent is selected from the group consisting essentially of isopropyl alcohol, ethanol, 2-propanol, butanol, methylparaben, ethylparaben, propylparaben, propyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene, t-butyl-hydroquinone, chloroxylenol, chlorhexidine, chlorhexidine diacetate, chlorhexidine gluconate, povidone iodine, alcohol, dichlorobenzyl alcohol, dehydroacetic acid, hexetidine, triclosan, hydrogen peroxide, colloidal silver, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, and mixtures thereof. In a specific embodiment, the disinfectant or antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate. In one or more embodiments, the disinfectant or antimicrobial agent is a fluid or a gel.

In one or more embodiments the absorbent material is a nonwoven material, foam, or a sponge. In a specific embodiment, the absorbent material is polyethylene foam. The foam may be open celled, semi-opened or closed celled and may be molded or extruded or die cut from sheeting. In one or more embodiments, the absorbent reservoir material is molded or extruded or die cut from sheeting to form a cylindrical block shape.

A peelable seal minimizes entry of potential particulate hazard and also provides a substantially impermeable enclosure for the medical connector (100, 200, 300, 400, 500, 600, 700, 800), provides a leak prevention and protection enclosure, protects the contents of absorbent material contained within the cavity (130, 230, 330, 430, 530, 630, 730, 830), and/or maintains a sealed, sterilized environment. The peelable seal provides a sufficient seal at a range of temperatures, pressures, and humidity levels. In one or more embodiments, the peelable seal comprises an aluminum or multi-layer polymer film peel back top. In a specific embodiment,

the peelable seal is heat-sealed or induction sealed to the end face of the locking lid or to the needleless connector open end. In one or more embodiments, the peelable seal comprises a moisture barrier.

In some embodiments, the medical connector is configured as a cap containing disinfectant within a cavity of the housing and capable of blocking the lumens of corresponding medical connectors to minimize ingress of disinfectant and microbial agents into connectors, thereby reducing risk of the disinfectant and microbial agents entering the blood stream of a patient.

While the present disclosure has been shown and described with reference to certain exemplary embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the embodiments of the present disclosure. For example, a disinfection sponge can comprise any suitable disinfecting or other application-specific substance, and can be made of any suitable material. Also, the inner and/or the outer housing of the medical connector can be single shot molded, or made by other suitable process. Furthermore, any of the features or elements of any exemplary implementations of the embodiments of the present disclosure as described above and illustrated in the drawing figures can be implemented individually or in any combination(s) as would be readily appreciated by skilled artisans without departing from the spirit and scope of the embodiments of the present disclosure.

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

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

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

What is claimed is:

1. A medical connector comprising:

a housing having a single, substantially cylindrical housing body having a radial protrusion extending from the substantially cylindrical housing body and a cavity within the substantially cylindrical housing body that is defined by a distal closed end, a proximal open end, a

27

partially cylindrical inner sidewall of the substantially cylindrical housing body and a radial inner sidewall of the radial protrusion, the radial inner sidewall of the radial protrusion has a larger diameter than the partially cylindrical inner sidewall of the substantially cylindrical housing body;

a locking structure disposed on the radial inner sidewall of the radial protrusion, the locking structure including a sloped tab, wherein a locking position is being defined by the sloped tab and a first position disposed circumferentially adjacent to the sloped tab;

an insert advanceable into, and rotatable from the first position to the locking position within the cavity of the substantially cylindrical housing body, the insert comprising a discoid body having a distal surface, a proximal surface, a peripheral sidewall and a cantilever locking tab extending proximally from the peripheral sidewall, the cantilever locking tab defining an inner wall facing the cavity and an outer wall facing the radial inner sidewall of the radial protrusion, the insert including at least one thread disposed on the inner wall of the cantilever locking tab for direct mating, threaded engagement with a corresponding thread formed on a corresponding medical connector inserted within the cavity, and a recessed notch disposed on a proximal portion of the outer wall of the locking tab, the notch opposing the sloped tab when the locking tab is rotated to the locking position; and

an absorbent material disposed between the distal surface of the insert and an inner top surface of the cavity of the housing, such that the absorbent material does not make direct contact with a corresponding medical connector, the absorbent material containing a disinfectant, wherein insertion of the corresponding medical connector into the cavity compresses the absorbent material, thereby releasing disinfectant into the cavity.

2. The medical connector of claim 1, wherein the recessed notch of the insert engages a ledge of the sloped tab of the locking structure when the recessed notch is advanced past the sloped tab during insert rotation.

3. The medical connector of claim 2, wherein an audible click or sound is created when the recessed notch is advanced past the ledge of the sloped tab.

4. The medical connector of claim 1, wherein the locking structure further includes an outwardly sloped surface that adjoins the sloped tab, which slopes radially outwardly from the radial inner sidewall toward the cavity and extends circumferentially from the first position to the locking position.

5. The medical connector of claim 4, wherein the outwardly sloped surface contacts the outer wall of the locking tab and causes deformation of the locking tab toward the cavity.

6. The medical connector of claim 1, wherein the locking structure further includes a proximally sloped surface that incorporates the sloped tab, the proximally sloped surface located adjacent to a ledge of the sloped tab, the proximally sloped surface slopes inwardly with respect to the radial inner sidewall of the radial protrusion from a distal position to a proximal position thereupon, wherein the recessed notch of the insert engages the ledge when the recessed notch is advanced past the sloped tab during insert rotation.

7. The medical connector of claim 1, wherein the distal surface of the insert abuts an inner top surface of the cavity of the housing when the insert is fully advanced into the cavity.

28

8. The medical connector of claim 1, wherein fully advancing the insert into the cavity in a distal direction causes the distal surface of the insert and the inner top surface of the cavity of the housing to compress the absorbent material, the absorbent material releasing the disinfectant.

9. The medical connector of claim 8, wherein the disinfectant evacuates into the cavity by a gap defined by the partially cylindrical inner sidewall of the housing and the peripheral sidewall of the insert.

10. The medical connector of claim 1, wherein a diameter of the partially cylindrical inner sidewall of the housing is larger than a corresponding diameter of the peripheral sidewall of the insert.

11. The medical connector of claim 1, wherein a retention tab is disposed on an inner top surface of the housing, the retention tab non-removably securing thereabout a through aperture disposed on the distal surface of the insert.

12. A medical connector comprising:

a housing having a single, substantially cylindrical housing body having a radial protrusion extending from the substantially cylindrical housing body and a cavity within the substantially cylindrical housing body that is defined by a distal closed end, a proximal open end, a partially cylindrical inner sidewall of the substantially cylindrical housing body and a radial inner sidewall of the radial protrusion, the radial inner sidewall of the radial protrusion has a larger diameter than the partially cylindrical inner sidewall of the substantially cylindrical housing body;

a locking structure disposed on the radial inner sidewall of the radial protrusion, the locking structure including a sloped tab; and

an insert advanceable into the cavity of the housing body, the insert comprising a discoid body having a distal surface, a proximal surface, a peripheral sidewall and a cantilever locking tab extending proximally from the peripheral sidewall, the locking tab defining an inner wall facing the cavity and an outer wall facing the radial inner sidewall, the insert including at least one thread disposed on the inner wall of the cantilever locking tab for direct mating, threaded engagement with a corresponding thread formed on a corresponding female needleless connector inserted within the cavity, and a recessed notch disposed on a proximal portion of the outer wall of the cantilever locking tab, wherein threading the female needleless connector into the cavity causes the insert to be advanced into the cavity, and causes the recessed notch to oppose and engage the sloped tab;

an absorbent material disposed between the distal surface of the insert and an inner top surface of the cavity of the housing, such that the absorbent material does not make direct contact with the corresponding female needleless connector, the absorbent material containing a disinfectant, wherein insertion of the corresponding female needleless connector into the cavity compresses the absorbent material, thereby releasing disinfectant into the cavity.

13. The medical connector of claim 12, wherein the female needleless connector is removably threaded into the cavity.

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