



(12) **DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION**

(13) **A1**

(86) Date de dépôt PCT/PCT Filing Date: 2020/06/20
 (87) Date publication PCT/PCT Publication Date: 2020/12/24
 (85) Entrée phase nationale/National Entry: 2021/12/13
 (86) N° demande PCT/PCT Application No.: US 2020/038858
 (87) N° publication PCT/PCT Publication No.: 2020/257741
 (30) Priorités/Priorities: 2019/06/20 (US62/864,500);
 2020/06/19 (US16/906,830)

(51) Cl.Int./Int.Cl. *A61J 1/05* (2006.01),
B01L 3/00 (2006.01), *G01N 1/00* (2006.01),
G01N 1/10 (2006.01)
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(54) Titre : SYSTEME DE COLLECTE D'ECHANTILLON COMPRENANT DES ENSEMBLES DE VANNE ET BOUCHON
 (54) Title: SAMPLE COLLECTION SYSTEM INCLUDING VALVE AND PLUG ASSEMBLIES

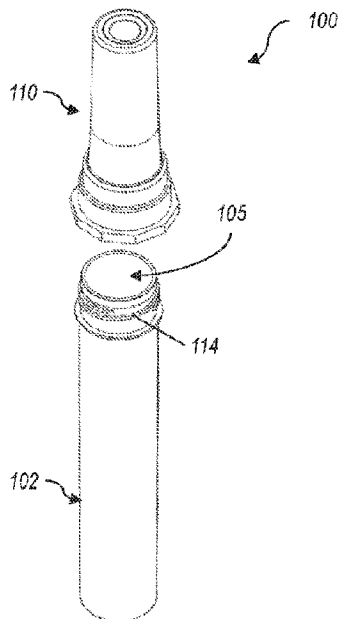


FIG. 1A

(57) **Abrégé/Abstract:**

A biological sample collection system can include (i) a sample collection vessel having an opening for receiving a biological sample, (ii) a selectively movable valve comprising a core and a collar disposed about the core, and (iii) a sealing cap coupled to the collar and comprising a reagent chamber for storing a measure of sample preservation reagent. The sealing cap is configured to associate—and form a fluid tight connection—with the sample collection vessel such that associating the sealing cap with the sample collection vessel causes a physical rearrangement of the core relative to the collar such that a fluid vent associated with the core is moved into fluid communication with the reagent chamber, thereby permitting sample preservation reagent to pass from the reagent chamber to the sample collection vessel.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(10) International Publication Number
WO 2020/257741 A1

(43) International Publication Date
24 December 2020 (24.12.2020)

(51) International Patent Classification:

A61J 1/05 (2006.01) *G01N 1/00* (2006.01)
B01L 3/00 (2006.01) *G01N 1/10* (2006.01)

(21) International Application Number:

PCT/US2020/038858

(22) International Filing Date:

20 June 2020 (20.06.2020)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/864,500 20 June 2019 (20.06.2019) US
16/906,830 19 June 2020 (19.06.2020) US

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(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,

CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: SAMPLE COLLECTION SYSTEM INCLUDING VALVE AND PLUG ASSEMBLIES

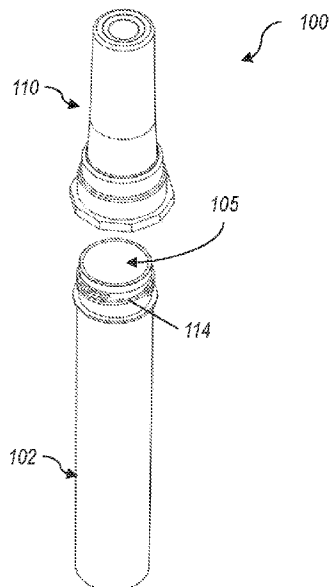


FIG. 1A

(57) Abstract: A biological sample collection system can include (i) a sample collection vessel having an opening for receiving a biological sample, (ii) a selectively movable valve comprising a core and a collar disposed about the core, and (iii) a sealing cap coupled to the collar and comprising a reagent chamber for storing a measure of sample preservation reagent. The sealing cap is configured to associate—and form a fluid tight connection—with the sample collection vessel such that associating the sealing cap with the sample collection vessel causes a physical rearrangement of the core relative to the collar such that a fluid vent associated with the core is moved into fluid communication with the reagent chamber, thereby permitting sample preservation reagent to pass from the reagent chamber to the sample collection vessel.



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SAMPLE COLLECTION SYSTEM INCLUDING VALVE AND PLUG ASSEMBLIES

BACKGROUND

Technical Field

[0001] This disclosure generally relates to vials and vessels for collecting and storing biological samples. More specifically, the present disclosure relates to systems and kits for the collection and preservation of biological samples for future testing in a laboratory or other biological sample analysis facility.

Background and Relevant Art

[0002] Field collection of biological samples can provide scientists, physicians, geneticist, epidemiologists, or similar personnel with invaluable information. For example, access to a fresh sample of a patient's blood, purulent discharge, or sputum can help a physician or epidemiologist to isolate or identify a causative agent of infection. Similarly, a saliva sample can permit a scientist or geneticist access to the requisite nucleic acid for genetic sequencing, phylotyping, or other genetic-based studies. In the foregoing examples, in addition to many other situations, it is desirable to work with a fresh biological sample to ensure procurement of accurate results. However, isolation of the probative composition (*e.g.*, nucleic acid, proteins, chemicals, etc.) often requires use of specialized equipment and often benefits from controlled laboratory conditions.

[0003] It can be inconvenient and sometimes improbable to require patients/individuals to travel to a biological sample collection center having the appropriate equipment and desirable controlled environment for sample preparation. Similarly, it may be difficult for personnel to directly access the patient/individual, particularly if the sample size is large and/or geographically diverse (*e.g.*, as can be found in large genetic studies of thousands of individuals across an entire country, ethnic population, or geographic region). Further complicating this issue, it is often beneficial to immediately process any procured biological sample, and field personnel may be limited by lack of access to appropriate specialized equipment or to a controlled environment for high-fidelity sample processing.

[0004] Some biological sample collection devices and kits have addressed some of the foregoing issues. For example, some commercial kits provide a user with a vial for receiving a biological sample and a preservation reagent that can be added to the collected biological sample, acting to preserve elements within the biological sample (to a certain extent and for a period of time). However, implementations of self-collection systems

often rely on inexperienced or untrained individuals to deposit the biological sample into the receiving vessel. This presents a number of problems, including, for example, technical training and precise measurements often required to properly preserve the biological sample for later processing. In the absence of such, it is important to provide a biological sample collection system that can be easily implemented by a novice user and which can preserve the received biological sample for later processing.

[0005] Accordingly, there are a number of disadvantages with biological sample collection and preservations systems that can be addressed.

BRIEF SUMMARY

[0006] Implementations of the present disclosure solve one or more of the foregoing or other problems in the art with kits, apparatuses, and methods for collecting and preserving a biological sample. In particular, one or more implementations can include a biological sample collection system—or a kit including the same—for collecting and preserving a biological sample.

[0007] In some embodiments, a biological sample collection system can include a sample collection vessel having an opening for receiving a biological sample, a selectively movable valve comprising a core and a collar disposed about the core that is configured to at least partially associate with the opening of the sample collection vessel, and a sealing cap configured to associate with the selectively movable valve and with the sample collection vessel. The sealing cap can include a reagent chamber for storing a measure of sample preservation reagent. Associating the sealing cap with the sample collection vessel causes a physical rearrangement of the core relative to the collar such that a fluid vent associated with the core is moved into fluid communication with the reagent chamber, thereby permitting sample preservation reagent to pass from the reagent chamber, to the sample collection vessel.

[0008] In other embodiments, a biological sample collection system can include a sample collection vessel having an opening for receiving a biological sample and a plug assembly. The plug assembly can include a post having a fluid vent that is configured to at least partially associate with the opening of the sample collection vessel and a plug associated with the post that obscures the fluid vent in a closed configuration of the plug assembly. The biological sample collection system can additionally include a sealing cap configured to associate with the plug assembly and with the sample collection vessel. The sealing cap can include a reagent chamber for storing a measure of sample preservation

reagent. Associating the sealing cap with the sample collection vessel can cause a physical rearrangement of the plug assembly such that the plug is removed from association with the post, thereby permitting sample preservation reagent to pass from the reagent chamber to the sample collection vessel.

5 [0009] The present disclosure also includes methods for collecting and preserving a biological sample. An exemplary method includes receiving a biological sample at a disclosed sample collection system and associating a sealing cap with the sample collection vessel, for example, to cause a selectively movable valve associated with the sealing cap to open and thereby release sample preservation reagent held within the sealing
10 cap into the sample collection chamber or to cause the plug of a plug assembly to dislodge, thereby releasing reagent held within the sealing cap into the sample collection chamber.

[0010] Accordingly, systems, methods, and kits for collecting a biological sample are disclosed herein. This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary
15 is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an indication of the scope of the claimed subject matter.

[0011] Additional features and advantages of the disclosure will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the disclosure. The features and advantages of the disclosure
20 may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. These and other features of the present disclosure will become more fully apparent from the following description and appended claims or may be learned by the practice of the disclosure as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

25 [0012] In order to describe the manner in which the above recited and other advantages and features of the disclosure can be obtained, a more particular description of the disclosure briefly described above will be rendered by reference to specific embodiments thereof, which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the disclosure and are not therefore to be
30 considered to be limiting of its scope. The disclosure will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0013] FIG. 1A illustrates a perspective view of an unassembled three-dimensional model of an exemplary sample collection system with the depicted sealing cap unsecured

from the sample collection vessel in accordance with one or more embodiments of the present disclosure.

[0014] FIG. 1B illustrates a cross-sectional view of an assembled three-dimensional model of the sample collection system of FIG. 1A with the depicted sealing cap secured to a sample collection vessel and the associated valve in a closed configuration in accordance with one or more embodiments of the present disclosure.

[0015] FIG. 2A illustrates a cross-sectional view of the selectively movable valve of FIG. 1B depicted in a closed configuration in accordance with one or more embodiments of the present disclosure.

[0016] FIG. 2B illustrates a cross-sectional view of the selectively movable valve of FIGS. 1B and 2A isolated away from other components of the sample collection system and depicted in a closed configuration in accordance with one or more embodiments of the present disclosure.

[0017] FIG. 2C illustrates a cross-sectional view of the selectively movable valve of FIGS. 1B and 2A isolated away from other components of the sample collection system and depicted in an open configuration in accordance with one or more embodiments of the present disclosure.

[0018] FIGS. 3A and 3B illustrate perspective views of a core component of a selectively movable valve in accordance with one or more embodiments of the present disclosure.

[0019] FIGS. 4A and 4B illustrate perspective views of a collar component of a selectively movable valve in accordance with one or more embodiments of the present disclosure.

[0020] FIG. 5A illustrates a cross-sectional view of an assembled three-dimensional model of another sample collection system with the depicted sealing cap secured to a sample collection vessel and the associated plug assembly in a closed configuration.

[0021] FIG. 5B is a zoomed view of a portion of the plug assembly and sealing cap as shown in FIG. 5A.

[0022] FIG. 6 illustrates a three-dimensional rendering of an exemplary plug.

[0023] FIGS. 7A and 7B illustrate perspective views of an exemplary post of a plug assembly.

DETAILED DESCRIPTION

[0024] Embodiments of the present disclosure address one or more problems in the art

of systems, kits, and/or methods for collecting and preserving a biological sample. A biological sample can be collected and its contents evaluated for various reasons, including, for example, identifying or characterizing a causative agent of disease (*e.g.*, for treatment of the affected individual, for epidemiological reasons, etc.) or for genetic analysis of a subject's nucleic acid (*e.g.*, genetic phylotyping, gene expression studies, genome sequencing, etc.). In most instances, including within the foregoing examples, it is desirable that the fidelity of the biological sample be maintained so that it retains its probative value. However, collecting and preparing biological samples for analysis has traditionally been a complex endeavor for the skilled technician or specialized professional. This is problematic for obvious reasons, including the time and cost associated with individually collecting and transporting biological samples, particularly when the subjects reside in disparate rural locations and require service from personnel with the proper skill set to properly collect and preserve the biological sample.

[0025] Embodiments of the present disclosure provide sample collection and preservation systems and kits, and methods for using the same, which address one or more of the foregoing problems. For example, utilizing systems, kits, and methods for collecting and preserving biological samples, as disclosed herein, removes the need of specialized personnel when collecting and initially preserving a biological sample. Furthermore, the disclosed embodiments simplify sample collection and preservation, which decreases the likelihood that even an unskilled user will err when collecting and preserving a biological sample.

[0026] As an illustrative example of the foregoing, biological sample collection kits disclosed herein include at least a two-piece sample collection and preservation system. A first portion includes a sample collection vessel or vessel, which can be detachably associated with a funnel. When used, the funnel acts to guide the receipt of a biological sample from a user into the sample collection chamber of the collection vessel or vessel. The funnel can also make it easier for a user to engage the collection vessel and deposit a biological sample into the sample collection chamber. After depositing the requisite amount of biological sample (which may be indicated by a mark on the sample collection vessel), a user can remove the funnel (if used) and associate the second portion of the two-piece sample preservation system—*e.g.*, a sealing cap associated with a selectively movable valve or plug assembly—with the collection vessel. The reagent chamber of the sealing cap is pre-filled with a predetermined amount of sample preservation reagent, and as the sealing cap is drawn down to seal the received biological sample within the sample

collection chamber of the collection vessel, the selectively movable valve or plug assembly enters an open configuration and the preservation reagent is released from the reagent chamber, through fluid vents in the valve core or plug assembly post, and into the sample collection chamber where it mixes with and preserves the received biological sample.

5 [0027] As described in more detail below, the selectively movable valves and valve assemblies can independently be opened (depending on the embodiment incorporating the same) to release reagents from the reagent chamber into the sample collection chamber.

[0028] With respect to embodiments having a selectively movable valve, the collar of the selectively movable valve is mechanically interlocked (*e.g.*, via a friction fit) with the
10 sealing cap such that the collar moves in unison with the sealing cap. The collar can be annular and surround the valve core forming a fluid tight connection therebetween. A flange associated with the core is sized and shaped to fit over the opening of the sample collection vessel (or structure associated therewith), preventing its ingress into the sample collection chamber. Upon association of the sealing cap with the sample collection vessel,
15 the core flange abuts the opening of the sample collection chamber. As the sealing cap is further secured to the sample collection vessel (*e.g.*, by threaded engagement), the collar moves in conjunction with the sealing cap, and the core remains stationary in relation to the sample collection vessel. In this way, the core moves (*e.g.*, translates longitudinally) relative to the collar and sealing cap, causing the selectively movable valve to open (*e.g.*,
20 by undergoing a physical rearrangement). The independent movement of core relative to the sealing cap can be enabled by, for example, the force (*e.g.*, frictional force or force required to overcome a mechanical interlock) between the core and the collar (which forms a fluid tight connection) being less than the force between the attachment mechanisms of the sealing cap and sample collection device. When moved to an open configuration, the
25 previously obstructed fluid vents provided by the core are at least partially unobstructed, thereby creating a conduit for communicating the sample preservation solution from the reagent chamber of the sealing cap into to the sample collection chamber.

[0029] It should be appreciated that in some embodiments, opening of the selectively movable valve is reversible. That is, the selectively movable valve can be moved from an
30 open configuration to a closed configuration. For example, embodiments of the disclosed apparatus can be configured so that the core can be manually repositioned within the collar (*e.g.*, by applying a longitudinal force against the head member of the core and toward the collar), thereby returning the selectively movable valve to the closed configuration.

[0030] With respect to embodiments having a plug assembly, a collar of the plug

assembly is mechanically interlocked (*e.g.*, via a friction fit) with the sealing cap such that the collar moves in unison with the sealing cap. The collar can be annular and surround the post of the plug assembly and may form a fluid tight connection therebetween. Additionally, or alternatively, a plug can be positioned within the aperture formed by the collar, forming a fluid tight connection therebetween. The plug can have a head sized and shaped to overlay a portion of the top surface of the collar (forming a fluid tight connection therebetween) and/or can have a plug body sized and shaped to fit within the aperture formed by the collar such that a fluid tight connection is formed between the plug body and a sidewall of the collar (*e.g.*, a sidewall defining the aperture). A flange associated with the post is sized and shaped to fit over the opening of the sample collection vessel (or structure associated therewith), preventing its ingress into the sample collection chamber. Upon association of the sealing cap with the sample collection vessel, the post flange abuts the opening of the sample collection chamber. As the sealing cap is further secured to the sample collection vessel (*e.g.*, by threaded engagement), the collar moves in conjunction with the sealing cap, and the post remains stationary. In this way, the post moves (*e.g.*, translates longitudinally) relative to the collar and sealing cap, causing the post to abut against and apply pressure to the plug, eventually causing the plug to dislodge from the collar and enter into the reagent chamber. The independent movement of post relative to the sealing cap can be enabled by, for example, the force (*e.g.*, frictional force or force required to overcome a mechanical interlock) between the post and the collar and/or plug (which forms a fluid tight connection) being less than the force between the attachment mechanisms of the sealing cap and sample collection device. When moved to an open configuration, the previously obstructed fluid vent formed by the post is at least partially unobstructed, thereby creating a conduit for communicating the sample preservation solution from the reagent chamber of the sealing cap into to the sample collection chamber.

[0031] As can be appreciated from the foregoing, in addition to alternative and/or additional embodiments provided herein, the systems, kits, and methods of the present disclosure can be used by skilled or unskilled individuals with reduced likelihood of error associated with collecting and at least initially preserving a biological sample. Accordingly, implementations of the present disclosure can reduce the cost associated with procuring biological samples for diagnostic, scientific, or other purposes and can increase the geographic reach of potential sample collection areas without the need of establishing the necessary infrastructure (*e.g.*, controlled environments conducive to sample collection and preservation, skilled personnel to physically collect, transport, and/or preserve the

biological samples, etc.).

[0032] As used herein, the term “biological sample” can include any cell, tissue, or secretory fluid (whether host or pathogen related) that can be used for diagnostic, prognostic, genetic, or other scientific analysis. This can include, for example, a human cell sample such as skin. It can also include a non-human cell sample that includes any of a bacterium, virus, protozoa, fungus, parasite, and/or other prokaryotic or eukaryotic symbiont, pathogen, or environmental organism. The term “biological sample” is also understood to include fluid samples such as blood, urine, saliva, and cerebrospinal fluid and extends to other biological samples including, for example, mucus from the nasopharyngeal region and the lower respiratory tract (*i.e.*, sputum).

[0033] As used herein, the “probative component” of the biological sample refers generally to any protein, nucleic acid, surface moiety, or other compound that can be isolated from the biological sample. Preferably, the probative component is or includes nucleic acid, more preferably DNA. In a preferred embodiment, the biological sample is or includes saliva, which presumptively contains a preferable probative component in the form of the user’s genetic material (*e.g.*, DNA and RNA).

Sample Collection Systems and Kits Having a Selectively Movable Valve

[0034] In one embodiment, a biological sample is collected, preserved, and stored in a collection vessel as part of a multi-piece sample collection system or kit. An example of a sample collection device similar to the embodiment illustrated in FIGS. 1-4 is set forth in U.S. Design App. No. 29/698,615, filed July 18, 2019, which is incorporated by reference. An example of a sample collection device similar to the embodiment illustrated in FIGS. 5-7 is set forth in U.S. Design App. No. 29/698,614, filed July 18, 2019, which is incorporated by reference.

[0035] As shown in FIG. 1A, a first piece of the system 100 or kit can include a sample collection vessel 102, a second piece includes a sample collection funnel (not shown), which may be packaged separately from or removably connected to the collection vessel, and a third piece includes a sealing cap 110 having a reagent chamber disposed within or integrated with the sealing cap selectively and a selectively movable valve comprised of a core and a collar. The sealing cap 110 is configured to associate with the sample collection vessel 102, to dispense sample preservation reagents into the sample collection vessel 102 through the selectively movable valve, and to seal the contents of the sample collection chamber therein.

[0036] For example, FIG. 1B illustrates a cross-sectional view of an assembled three-dimensional model of the sample collection system 100 of FIG. 1A. The system 100 includes a sample collection vessel 102 and optionally, a funnel (not shown), which can be associated with a top portion or opening 105 of the sample collection vessel 102 and thereby allow fluid communication with the sample collection chamber 103 of the sample collection vessel 102. The biological sample collection system 100 can also include a selectively movable valve 104 comprised of a core 106 and a collar 108 associated with the sealing cap 110 that has a reagent chamber 111 disposed within or integrated with the sealing cap 110. The sealing cap 110—together with the selectively movable valve 104—can be sized and shaped to associate with a top portion of the collection vessel 102 such that the cap 110 fits over and seals an opening 105 of the sample collection chamber 103 and at least a portion of the valve 104 (*e.g.*, a flange 107 of the core 106) extends over the opening 105 of the sample collection chamber 103.

[0037] In some embodiments, the reagent within the reagent chamber 111 includes a preservation or buffering solution that protects the integrity of the probative component of the biological sample prior to purification or testing. Examples of preservation reagents that can be used in conjunction with the sample collection systems described herein are disclosed in US Pat. No. 10,174,362, US Pat. Pub. No. 2019/0062806, and WO 2020/102570, which are incorporated by reference. Preservation reagents are typically chemical solutions and may contain one or more salts (*e.g.*, NaCl, KCl, Na₂HPO₄, KH₂PO₄, or similar, and which may, in some implementations, be combined as a phosphate buffered saline solution, as known in the art), lysing agents (*e.g.*, detergents such as Triton X-100 or similar), chelating agents (*e.g.*, ethylenediaminetetraacetic acid (EDTA), ethylene glycol-bis(β-aminoethyl ether)-N,N,N',N'-tetraacetic acid (EGTA), or similar), distilled water, or other reagents known in the art.

[0038] In one or more embodiments, the reagent or buffering solution stabilizes at least one probative component within the sample (*e.g.*, nucleic acids, such as DNA and RNA, protein, etc., and combinations thereof) during transfer, transportation, and/or storage at a laboratory, clinic, or other destination. After the preservation solution is added, the sample can be stored at or below room temperature for weeks or months without significant loss of the probative component. That is, the sample can still be utilized for diagnostic, genetic, epidemiologic, or other purposes for which it was collected after storage for weeks or months in the preservation solution.

[0039] With continued reference to FIG. 1, the sealing cap 110 and a saliva funnel (not

shown) can each independently attach to the sample collection vessel 102 using a connection mechanism. The connection mechanism can include, for example, threads, snap or press fit connections, tongue and groove members, bayonet connection, or other interlocking or mechanically coupling mechanisms. For example, a funnel can be first
5 attached to the sample collection vessel 102 via complementary connection mechanisms (*e.g.*, complementary threads; not shown). After facilitating receipt of a biological sample from a user, the funnel can be removed by reversing the complementary connection mechanism (*e.g.*, unscrewing the funnel; not shown), and a sealing cap 110 can be secured to the collection vessel 102 using a same or similar complementary connection
10 mechanism. For example, as shown in FIGS. 1A and 1B, the sealing cap 110 can include connection members 112 (*e.g.*, threads) located on an inner circumferential wall of the sealing cap 110 that are complementary to and work in conjunction with the connection members 114 (*e.g.*, complementary threads) disposed on an exterior surface of the sample collection vessel 102.

15 **[0040]** In some embodiments, the connection mechanism between the funnel and collection vessel is different than the connection mechanism between the solution cap and the collection vessel. For example, the funnel may be press fit or snap fit onto the collection vessel, whereas the solution cap is rotationally secured through engagement of complementary threads located on an exterior portion of the collection vessel and an
20 interior portion of the solution cap or vice versa. Regardless of the attachment mechanism used, a sample preservation fluid can be introduced into the sample collection chamber 103 and mixed with the deposited biological sample as a result of the sealing cap 110 being attached to the sample collection vessel 102. As provided earlier, this can be due to the selectively movable valve 104 opening and allowing reagent to be released through fluid
25 vent 116 defined by the open valve 104 and into the sample collection chamber 103.

[0041] The sealing cap 110 is configured to receive a measure of reagents into the reagent chamber 111, and as shown by the cross-sectional views of the assembled sample collection system 100 in FIG. 1B, a selectively movable valve 104 is associated with the
30 sealing cap 110. The collar 108 can be snap-fittingly received into the sealing cap 110, creating a fluid tight connection therebetween. As illustrated, the collar 108 includes a retaining ring or flange that engages the sealing cap 110 to stabilize the collar 108.

[0042] As further illustrated by FIGS. 2A–2C, the core 106 defines a fluid vent 116, and when the valve 104 is in a closed configuration (as shown in FIGS. 2A and 2B), any reagent disposed within the reagent chamber 111 is retained and sealed within the reagent

chamber 111. The valve 104 is shown in FIGS. 1B, 2A, and 2B as being aligned in a closed configuration. However, as shown in FIG. 2C, the selectively movable valve 104 can be arranged in an open configuration. When associated with the sealing cap 110 in an open configuration, reagent may be transferred from the reagent chamber 111 to the sample collection chamber 103 through the vent(s) 116.

[0043] That is, the fluid vent(s) 116 can be obstructed by the collar 108 of the selectively movable valve 104 when the valve 104 is in a closed configuration, as illustrated in FIGS. 2A and 2B. In this state, the interaction between the interior sidewall of the collar 108 and the head member 109 of the core 106 creates a fluid tight connection—at least at and/or around the fluid vent 116. The fluid tight connection between the collar 108 and the core 106 prevents the premature or unintentional expulsion of reagent from the reagent chamber 111.

[0044] It should be appreciated that in some embodiments, the fluid vent(s) and/or structure of the core can beneficially act as an agitator of fluids entering and/or traversing between the sample collection chamber and the sealing cap.

[0045] As the complementary threads 114, 112 between the sealing cap 110 and the sample collection vessel 102 are inter-engaged and the sealing cap 110 is advanced towards the sample collection vessel 102, the proximal flange 107 of the core 106 engages the upper lip of the sample collection tube defining the opening 105 thereof. As the sealing cap 110 is further secured to and moved toward the sample collection vessel 102 (e.g., by threaded engagement), the collar 108 moves in conjunction with the sealing cap 110, and the core 106 remains stationary relative to the sample collection vessel 102. In this way, the collar 108 is displaced longitudinally relative to the core 106, causing the selectively movable valve assembly 104 to enter an open configuration (e.g., by undergoing a physical rearrangement as shown in FIG. 2C). When moved to the open configuration, the previously obstructed fluid channels or vents 116 formed within the core 106 allow fluid communication between the reagent chamber 111 and the sample collection chamber 103.

[0046] The fluid channels/vents 116 formed within the core 106, and the various other components of the core 106 discussed above are illustrated in the perspective views of an exemplary core 106 in FIGS. 3A and 3B. Similarly, the collar 108 of FIGS. 1 and 2 is illustrated in multiple perspective views comprising FIGS. 4A and 4B.

[0047] As the core 106 transitions from the closed configuration to the open configuration, an annular retention element 113 disposed on the body of the core 106 forms a fluid tight seal with the inner sidewall of the collar 108. Upon fully entering the open

configuration, the annular retention element 113 is flush with the top surface of the collar 108 and maintains a fluid-tight connection therebetween. Accordingly, there is no pooling of sample preservation reagent (from the fluid chamber) between the interior sidewall of the collar 108 and the exterior sidewall of the core 106. Instead, the sample preservation reagent is directed from the reagent chamber 111, through the fluid vents 116 formed within the core 106, and into the sample collection chamber 103 it mixes with and preserves the received biological sample. In this way, the valve assembly 104 can move from a closed configuration to an open configuration when the sealing cap 110 is sealed onto the sample collection vessel 102.

10 [0048] In some embodiments, the resistive force derived from the engagement of the collar 108 with the chamber sidewall is the result of an interference fit formed between the collar 108 and the chamber sidewall. The interference fit can, in some embodiments, be a fluid-tight fit.

15 [0049] In some embodiments, the rotational distance required to open the selectively movable valve 104 is proportional to the distance required to at least partially unobstruct the fluid vent 116. This distance may be the same or less than the distance traversed by the sealing cap 110 from initial engagement of the connection members 114, 112 to a sealed position of the cap 110 and vessel 102. However, it should be appreciated that although a plurality of fluid vents 116 are illustrated in the Figures, in some embodiments there can be fewer (*e.g.*, a single fluid channel/vent or more than four fluid channels/vents).

Sample Collection Systems and Kits Having a Plug Assembly

25 [0050] Referring now to FIGS. 5-7, some sample collection systems can include a plug assembly. As shown, the hollow collar 202 of the plug assembly is mechanically interlocked (*e.g.*, via a friction fit) with the sealing cap 210 such that the hollow collar 202 moves in unison with the sealing cap 210 toward the sample collection vessel 201 when the sealing cap 210 is used to seal the sample collection vessel 201. As shown in FIGS. 5A, 5B, and 6, the plug 204 includes a cylindrical body and two flanges. An upper flange 205 is sized and shaped to span the aperture formed by the hollow collar 202 and can, as shown, extend beyond the diameter of the collar's aperture such that a bottom surface of the upper flange 205 can form a fluid tight seal with the upper surface of the hollow collar 202. A lower flange 207 of the plug 204 extends radially from the cylindrical body and is sized and shaped to engage the sidewall of the hollow collar 202 defining the aperture.

30 [0051] The post 206 defines a plurality of fluid vents 212 that pass uninterrupted

through the body of the post 206. A cylindrical upper portion of the post is sized and shaped to fit within the aperture defined by the hollow collar 202. A leading edge 208 of the upper portion of the post 206 is configured to associate with a bottom surface (e.g., the lower flange 207) of the plug 204. In the embodiment shown in FIGS. 5A and 5B, the leading edge 208 of the upper portion includes a crown that engages an indent formed within the bottom portion of the plug 204. In some embodiments, the outer rim of the crown is sized and shaped to engage the lower flange 207 of the plug 204. The post 206 additionally includes a base portion or flange 209 that is sized and shaped to engage the opening of the sample collection vessel (or structure associated therewith).

10 **[0052]** When provided to a user for collecting a biological sample (typically saliva), the plug-disc device (e.g., device 200) is included in two parts: (1) the sample collection vessel 201 and (2) the sealing cap 210, which includes the seal assembly (in a sealed configuration) forming a fluid-tight seal over the reagent chamber where it retains preloaded sample preservation solution. The user can deposit the biological sample within
15 the sample collection tube, and following use, the sealing cap is associated with the sample collection tube to seal the received biological sample.

[0053] Upon association of the sealing cap 210 with the sample collection vessel 201, the base portion or flange 209 of the post 206 engages the upper lip of the sample collection vessel defining the opening thereof. As the sealing cap 210 is further secured to and moved
20 toward the sample collection vessel 201 (e.g., by threaded engagement), the hollow collar 202 moves in conjunction with the sealing cap 210, and the post 206 remains stationary relative to the sample collection vessel 201. In this way, the hollow collar 202 is displaced longitudinally with respect to the post 206, and this causes the leading edge 208 (e.g., crown portion) of the post 206 to press against the bottom side (e.g., lower flange 207) of
25 the plug 204. At some point, the rotational force of tightening the sealing cap 210 is translated into a force sufficient to cause the plug 204 to disengage from the hollow collar 202. At first, the upper flange 205 is translated away from the hollow collar 202, thereby breaking the fluid-tight seal formed therebetween, while the second, lower flange 207 remains in contact with the sidewall of the hollow collar 202. Eventually, however, the
30 post 206 presses—and moves—the plug 204 such that the lower flange 207 becomes disengaged from the sidewall, causing the plug 204 to be ejected into the reagent chamber of the sealing cap 210.

[0054] Once the plug 204 is disengaged from the hollow collar 202, the upper end of the post 206 is brought into fluid communication with the reagent chamber—essentially

converting the seal assembly to an unsealed configuration. In this unsealed configuration, the fluid vents 212 are unobstructed and act as channels for transporting the sample preservation solution from the reagent chamber to the sample collection vessel 201. The body of the post 206 forms a fluid tight seal with the inner sidewall of the hollow collar 202, forcing egress of sample preservation solution through the fluid vents/channels 212. Accordingly, there is no pooling of sample preservation reagent (from the reagent chamber) between the interior sidewall of the hollow collar 202 and the exterior sidewall of the post 206. Instead, the sample preservation reagent is directed from the reagent chamber, through the fluid vents 212 formed within the post 206, and into the sample collection vessel 201 where it mixes with and preserves the received biological sample. In this way, the seal assembly can move from a sealed configuration to an unsealed configuration when the sealing cap 210 is sealed onto the sample collection vessel 201.

[0055] In some embodiments, the seal assembly can be reversibly sealed and unsealed. That is, the plug 204 from the seal assembly can be serially added and removed from the opening of the hollow collar 202 to iterate from the sealed configuration to the unsealed configuration. For example, associating the sealing cap 210 with the sample collection vessel 201 can cause the plug 204 to disengage, thereby causing the seal assembly to transition from the sealed configuration to the unsealed configuration. In the unsealed configuration, the post 206 can be retracted and the plug 204 again placed within the hollow collar 202 to transition the seal assembly from the unsealed configuration to the sealed configuration.

[0056] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present disclosure pertains.

[0057] It will also be appreciated that systems, devices, products, kits, methods, and/or processes, according to certain embodiments of the present disclosure may include, incorporate, or otherwise comprise properties, features (*e.g.*, components, members, elements, parts, and/or portions) described in other embodiments disclosed and/or described herein. Accordingly, the various features of certain embodiments can be compatible with, combined with, included in, and/or incorporated into other embodiments of the present disclosure. Thus, disclosure of certain features relative to a specific embodiment of the present disclosure should not be construed as limiting application or inclusion of said features to the specific embodiment. Rather, it will be appreciated that other embodiments can also include said features, members, elements, parts, and/or

portions without necessarily departing from the scope of the present disclosure.

[0058] Moreover, unless a feature is described as requiring another feature in combination therewith, any feature herein may be combined with any other feature of a same or different embodiment disclosed herein. Furthermore, various well-known aspects of illustrative systems, methods, apparatus, and the like are not described herein in particular detail in order to avoid obscuring aspects of the example embodiments. Such aspects are, however, also contemplated herein.

[0059] The present disclosure may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. While certain embodiments and details have been included herein and in the attached disclosure for purposes of illustrating embodiments of the present disclosure, it will be apparent to those skilled in the art that various changes in the methods, products, devices, and apparatus disclosed herein may be made without departing from the scope of the disclosure or of the invention, which is defined in the appended claims. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

1. A biological sample collection system, comprising:
 - a sample collection vessel having an opening for receiving a biological sample;
 - 5 a selectively movable valve comprising a core and a collar disposed about the core, the core being configured to at least partially associate with the opening of the sample collection vessel; and
 - a sealing cap coupled to the collar and comprising a reagent chamber for storing a measure of sample preservation reagent, the sealing cap being configured to associate—and form a fluid tight connection—with the sample collection vessel,
 - 10 wherein associating the sealing cap with the sample collection vessel causes a physical rearrangement of the core relative to the collar such that a fluid vent associated with the core is moved into fluid communication with the reagent chamber, thereby permitting sample preservation reagent to pass from the reagent chamber to the sample collection vessel.
 - 15
2. The biological sample collection system as in claim 1, wherein the physical rearrangement comprises a translational movement of the core along a longitudinal axis and in a direction opposite the direction of the sealing cap.
3. The biological sample collection system as in claim 1 or 2, wherein the
20 sample collection vessel further comprises a connection member.
4. The biological sample collection system as in any one of claims 1-3, wherein the sealing cap further comprises a complementary connection member configured to associate with the connection member of the sample collection vessel to couple the sample collection vessel and the sealing cap.
- 25 5. The biological sample collection system as in claim 4, wherein the connection member comprises a ridge projecting away from the sample collection vessel or a depression within the sample collection vessel and the complementary connection member comprises a hook or ridge sized and shaped to engage the connection member.
6. The biological sample collection system as in claim 4, wherein the
30 connection member and the complementary connection member comprise threads.
7. The biological sample collection system as in claim 6, wherein the threads of the complementary connection member comprise internal threads of the sealing cap.

8. The biological sample collection system as in any one of claims 1-7, wherein the sample collection system comprises a separable two-piece sample collection system, the sample collection vessel comprising a first piece of the separable two-piece sample collection system, and the selectively movable valve associated with the sealing cap comprising a second piece of the separable two-piece sample collection system.

9. The biological sample collection system as in any one of claims 1-8, wherein the fluid vent associated with the core is obstructed by the collar when the selectively movable valve is in a closed configuration, and wherein the fluid vent is at least partially unobstructed by the collar when the selectively movable valve is in an open configuration.

10. The biological sample collection system as in any one of claims 1-9, wherein the core comprises a head member configured to form a fluid-tight seal with the collar when the selectively movable valve is in a closed position.

11. The biological sample collection system as in claim 10, wherein one or more of the collar or the head member comprises an annular retention element configured to maintain a fluid-tight seal between the collar and head member when the selectively movable valve is in a closed position.

12. The biological sample collection system as in claim 10 or 11, wherein a retention force between the head member and the collar is less than a mechanical force of associating the sealing cap with the sample collection vessel.

13. The biological sample collection system as in any one of claims 1-12, wherein the core comprises a flange sized and shaped to prevent the core from traversing the opening of the sample collection vessel.

14. The biological sample collection system as in any one of claims 1-13, wherein the core comprises a plurality of fluid vents.

15. The biological sample collection system as in claim 14, wherein the plurality of fluid vents are disposed radially about the core.

16. The biological sample collection system as in claim 14 or 15, wherein the plurality of fluid vents span an interior portion of the core and are uninterrupted from an entrance aperture to an exit aperture of each fluid vent.

17. A kit for collecting and preserving a biological sample, comprising:
a sample collection vessel, comprising a sample collection chamber having an opening configured to receive the biological sample into the sample collection chamber;

a sealing cap, comprising:

a reagent chamber storing a measure of sample preservation reagent; and

a selectively movable valve oriented in a closed configuration and coupled to the sealing cap, the selectively movable valve configured to associate with the sample collection chamber and comprising:

a core defining a fluid vent; and

a collar valve head associated with a head member of the core, the collar forming a fluid-tight seal with the head member,

wherein when the selectively movable valve is in an open configuration, fluid communication from the reagent chamber to the sample collection vessel is enabled via the fluid vent.

18. The kit as in claim 17, further comprising a funnel configured to associate with the sample collection vessel and to guide receipt of a biological sample from a user into the sample collection chamber of the sample collection vessel.

19. A separable two-piece sample collection system, comprising:

a first piece, comprising a sample collection vessel having an opening for receiving a biological sample; and

a second piece, comprising a sealing cap coupled to a selectively movable valve, wherein the selectively movable valve comprises:

a collar coupled to an interior portion of the sealing cap; and

a core having a head member configured to form a fluid tight connection with the collar when the selectively movable valve is in a closed configuration and a flange opposite the head member that is sized and shaped to prevent the core from traversing the opening of the sample collection vessel,

wherein the core defines one or more fluid vents that are obstructed by the collar when the selectively movable valve is in a closed configuration and are at least partially unobstructed by the collar when the selectively movable valve is in an open configuration, the one or more fluid vents configured to permit sample preservation reagent stored within a reagent chamber of the sealing cap to pass from the reagent chamber and into the sample collection vessel when the selectively movable valve is in the open configuration.

20. The biological sample collection system of claim 19, wherein one or more of the collar or the head member comprises an annular retention element configured to

maintain a fluid-tight seal between the collar and head member when the selectively movable valve is in a closed position.

21. A biological sample collection system, comprising:
a sample collection vessel having an opening for receiving a biological
5 sample;
a plug assembly comprising:
a post having a fluid vent, the post configured to at least partially
associate with the opening of the sample collection vessel;
a plug associated with the post, the plug obscuring the fluid vent in
10 a closed configuration of the plug assembly; and
a sealing cap configured to associate with the plug assembly and with the
sample collection vessel, the sealing cap comprising a reagent chamber for storing
a measure of sample preservation reagent,
wherein associating the sealing cap with the sample collection vessel causes
15 a physical rearrangement of the plug assembly such that the plug is removed from
association with the post, thereby permitting sample preservation reagent to pass
from the reagent chamber to the sample collection vessel.
22. The biological sample collection system of claim 21, wherein the plug
assembly further comprises a collar disposed about the post.
- 20 23. The biological sample collection system of claim 22, wherein the collar is
secured to the sealing cap and creates a fluid tight seal with a sidewall of the post.
24. The biological sample collection system of claim 22 or 23, wherein the plug
forms a fluid tight seal with the collar in a closed configuration.
25. The biological sample collection system of any one of claims 21-24,
25 wherein the plug is dislodged into the reagent chamber in an open configuration.
26. The biological sample collection system of claim 25, wherein the
dislodged plug comprises an agitator within the reagent chamber.
27. A kit comprising the biological sample collection system of any one of
claims 20-26.

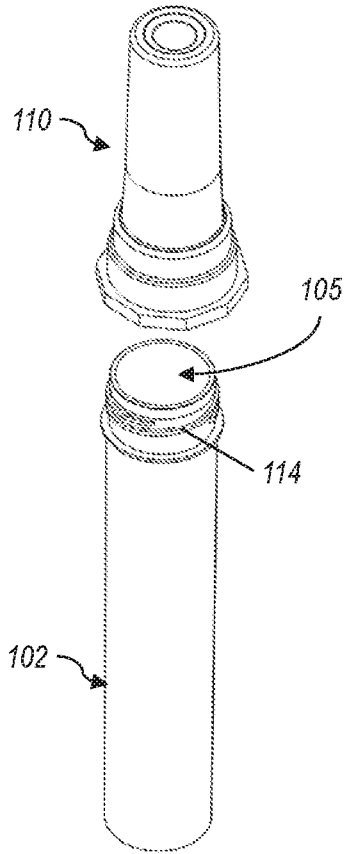


FIG. 1A

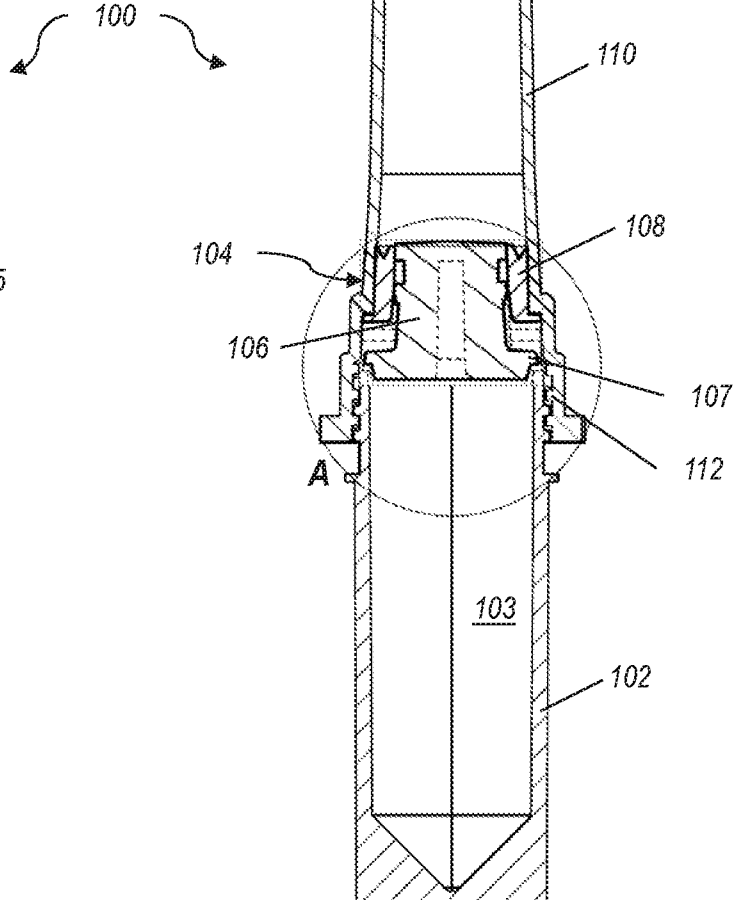


FIG. 1B

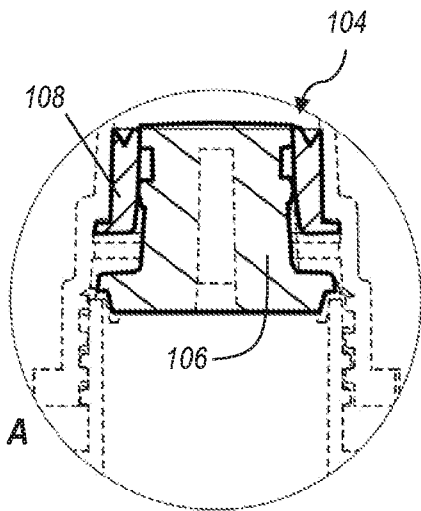


FIG. 2A

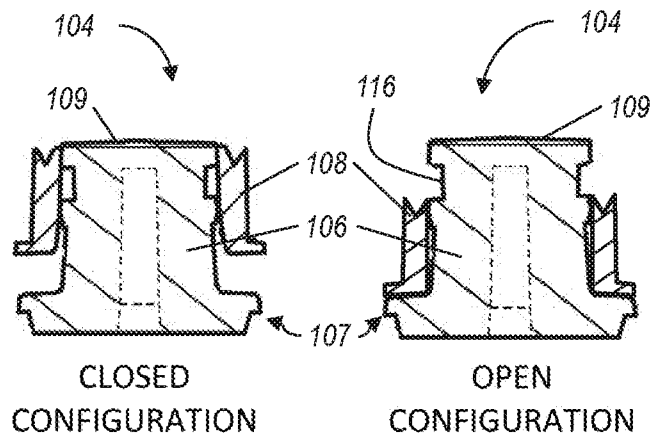


FIG. 2B

FIG. 2C

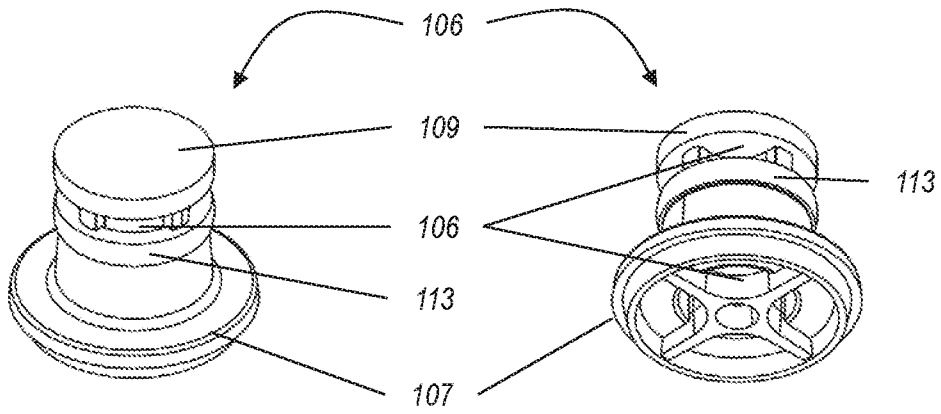


FIG. 3A

FIG. 3B

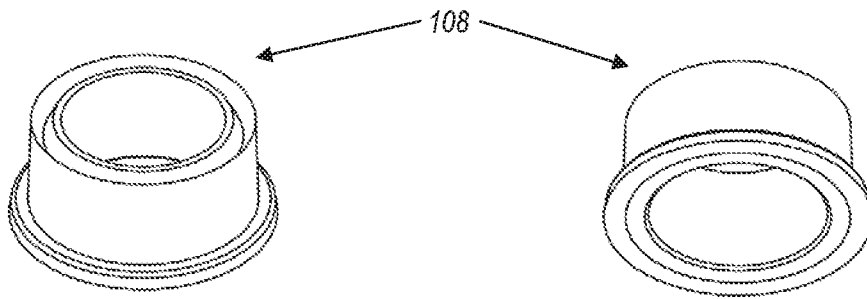
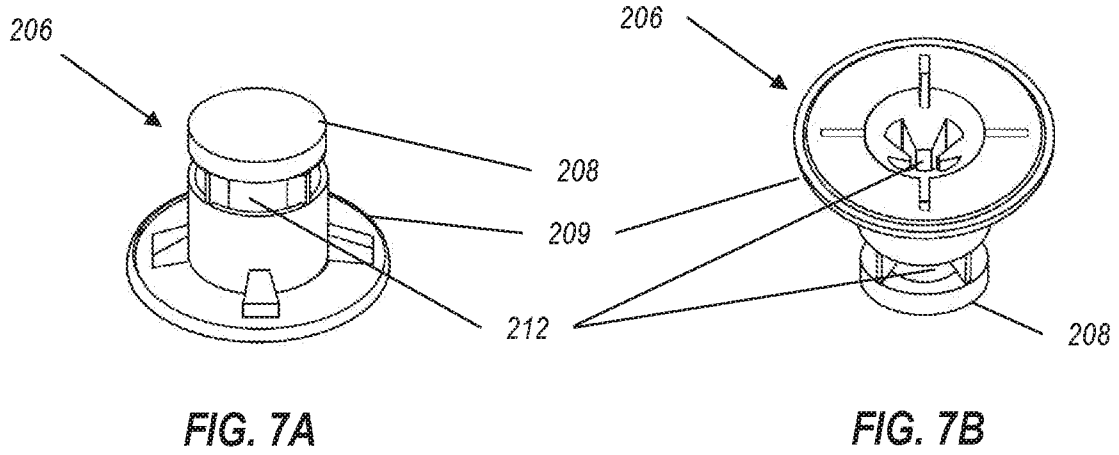
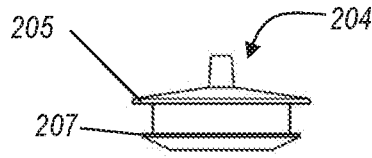
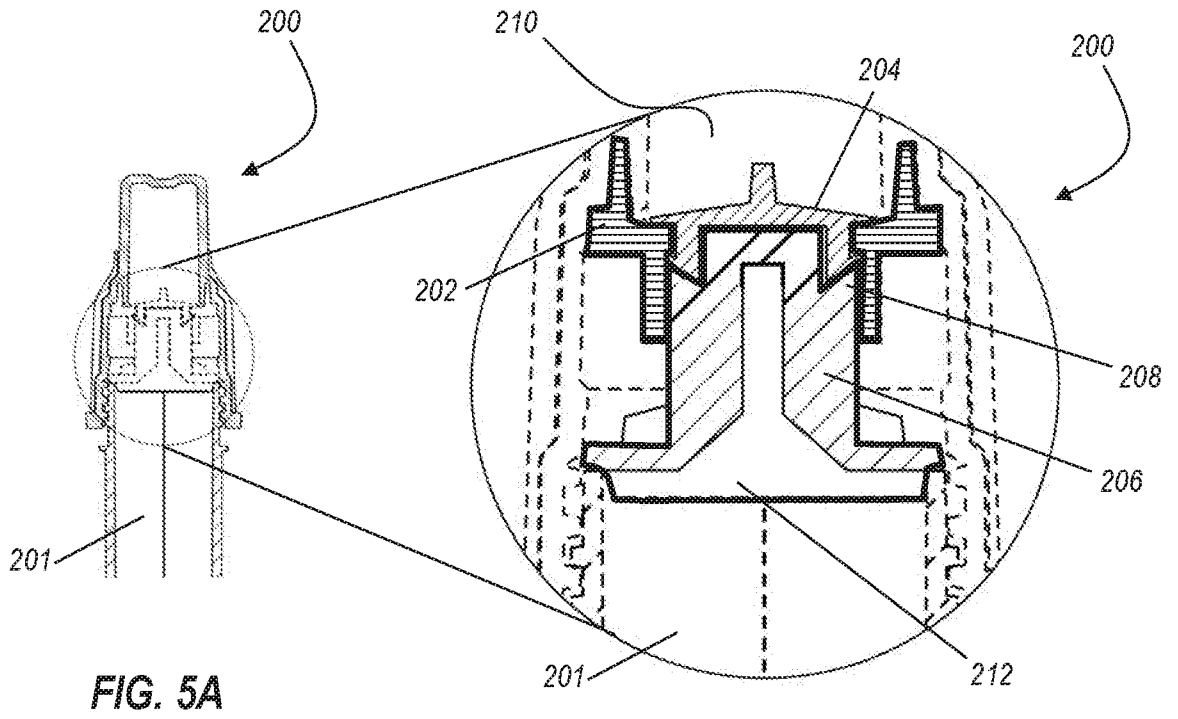


FIG. 4A

FIG. 4B



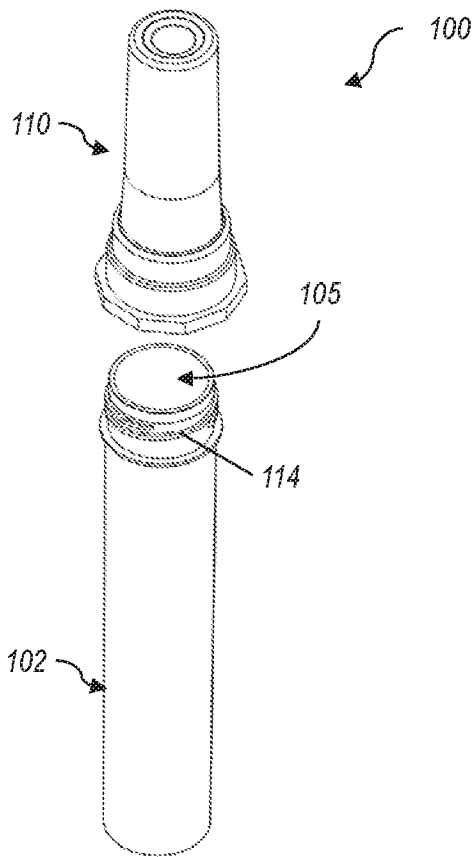


FIG. 1A