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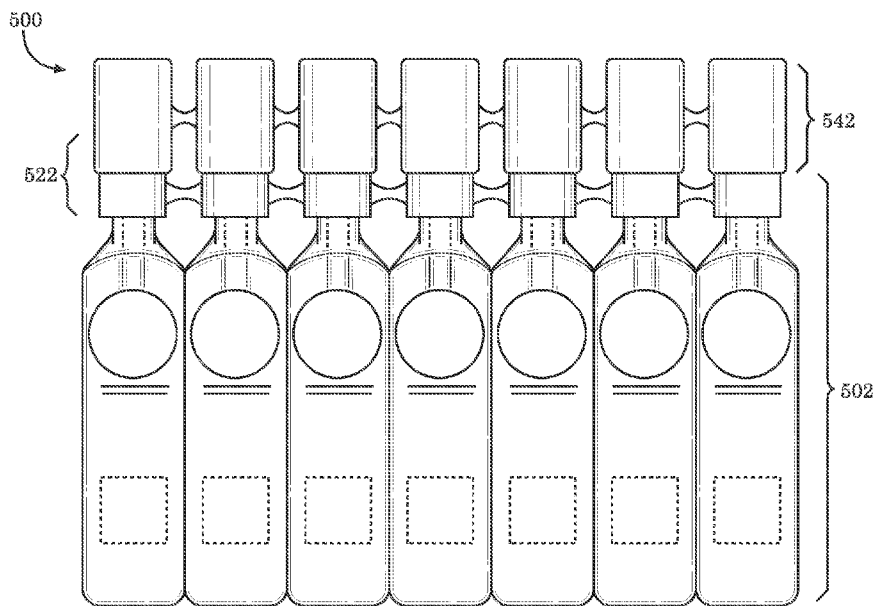


FIG. 5A

(57) Abstract: A fluid delivery manifold system assembled and configured to allow delivery of a single dose of a therapeutic agent (e.g., vaccine, drug, medicament, etc.) from a Blow-Fill-Seal (BFS) vial to a patient. The delivery assembly generally includes a modular manifold design consisting of separately constructed components cooperatively arranged and coupled to one another. The modular manifold construction allows for rapid manufacturing reconfigurations of one or more components with minimal costs to create new delivery manifold configurations that meet specific needs (i.e., different modes of delivery depending on agent to be delivered, such as subcutaneous, intramuscular, intradermal, intravenous injection, spray, or droplet delivery).



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SYSTEMS AND METHODS FOR FLUID DELIVERY MANIFOLDS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims benefit and priority to, and is a non-provisional of: (i) U.S. Provisional Application Serial No. 62/587879 titled "DELIVERY SYSTEM" and filed on November 17, 2017, (ii) U.S. Provisional Application Serial No. 62/674565 titled "NFC-Enabled Drug Containing System and Associated Information Layer" and filed on May 21, 2018, and (iii) U.S. Provisional Application Serial No. 62/680116 titled "NFC-ENABLED DRUG CONTAINING SYSTEM AND ASSOCIATED INFORMATION LAYER" and filed on June 4, 2018; the contents of each of which are hereby incorporated by reference herein in their entirety.

BACKGROUND

[0002] Every year, millions of people become infected and die from a variety of diseases, some of which are vaccine-preventable. Although vaccination has led to a dramatic decline in the number of cases of several infectious diseases, some of these diseases remain quite common. In many instances, large populations of the world, particularly in developing countries, suffer from the spread of vaccine-preventable diseases due to ineffective immunization programs, either because of poor implementation, lack of affordable vaccines, or inadequate devices for administering vaccines, or combinations thereof.

[0003] Some implementations of immunization programs generally include administration of vaccines via a typical reusable syringe. However, in many situations, particularly in developing countries, the administration of vaccines occur outside of a hospital and may be provided by a non-professional, such that injections are given to patients without carefully controlling access to syringes. The use of reusable syringes under those circumstances increases the risk of infection and spread of blood-borne diseases, particularly when syringes, which have been previously used and are no longer sterile, are used to administer subsequent injections. For example, the World Health Organization (WHO) estimates that blood-borne diseases, such as Hepatitis and human immunodeficiency virus (HIV), are being transmitted due to reuse of such syringes, resulting the death of more than one million people each year.

[0004] Previous attempts at providing single-use or disposable injection devices to remedy such problems in the industry have achieved measurable success but have failed to adequately remedy the existing problems. Pre-filled, single-use injection devices manufactured via injection molding or Form-Fill-Seal (FFS) processes, such as the Uniject™ device available from the Becton, Dickinson and Company of Franklin Lakes, NJ, for example, while offering precise manufacturing tolerances in the range of two thousandths of an inch (0.002-in; 50.8 μm) to four thousandths of an inch (0.004-in; 101.6 μm) – for hole diameters in molded parts, require separate sterilization processes (e.g., gamma radiation) that are not compatible with certain fluids, provide production rates limited to approximately nine thousand (9,000) non-sterile units per hour, and can be provided to an end-user for

approximately one dollar and forty cents (\$1.40) per dose/unit.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] An understanding of embodiments described herein and many of the attendant advantages thereof may be readily obtained by reference to the following detailed description when considered with the accompanying drawings, wherein:

FIG. 1 is a front view of BFS vial package according to some embodiments;

FIG. 2 is a front view of a fluid delivery manifold according to some embodiments;

FIG. 3 is a front view of a safety cap manifold according to some embodiments;

FIG. 4 is a front view of a safety cap manifold according to some embodiments;

FIG. 5A and FIG. 5B are front and cross-sectional views of a fluid delivery manifold system according to some embodiments;

FIG. 6A, FIG. 6B, FIG. 6C, FIG. 6D, FIG. 6E, FIG. 6F, FIG. 6G, and FIG. 6H are top-front perspective, top, bottom, left, right, front, back, and cross-sectional views of a fluid delivery hub according to some embodiments;

FIG. 7A and FIG. 7B are cross-sectional views of a fluid delivery manifold system according to some embodiments;

FIG. 8A and FIG. 8B are cross-sectional views of a fluid delivery manifold system according to some embodiments; and

FIG. 9 is a flow diagram of a method according to some embodiments.

DETAILED DESCRIPTION

I. Introduction

[0006] Embodiments of the present invention provide systems and methods for fluid delivery manifolds that overcome the drawbacks of current delivery devices and methods. For example, the delivery system of some embodiments may include a Blow-Fill-Seal (BFS) package coupled to a fluid delivery manifold and/or a safety cap manifold. In some embodiments, an administration member such as a needle may be selectively actuated by application of force to the fluid delivery manifold and/or a safety cap manifold, causing the administration member to pierce a fluid reservoir of at least one BFS vial of the BFS package. Utilization of such systems that employ BFS vials and/or a fluid delivery manifold may be advantageous and may address various shortcomings of previous systems.

[0007] BFS vials may, for example, offer a less expensive alternative to vials or devices created via other manufacturing techniques. In some embodiments, BFS vials (e.g., due to the nature of the BFS manufacturing

process) may not require separate sterilization (e.g., an may accordingly be compatible with a wider array of fluids), may provide enhanced production rates of approximately thirty thousand (30,000) sterile/aseptic units per hour, and/or may be provided to an end-user for approximately forty-five cents (\$0.45) per dose/unit. In some embodiments, these advantages may come with an attendant drawback of reduced manufacturing tolerances. BFS processes may, for example, offer less precise manufacturing tolerances in the range of five hundredths of an inch (0.05-in; 1.27 mm) to fifteen hundredths of an inch (0.15-in; 3.81 mm) – for linear dimensions, e.g., in accordance with the standard ISO 2768-1 “General tolerances for linear and angular dimensions without individual tolerance indications” published by the International Organization for Standardization (ISO) of Geneva, Switzerland (November 15, 1989).

[0008] According to some embodiments, a single-dose, disposable, and/or non-refillable fluid delivery device may be provided despite the presence of the less precise manufacturing tolerances of the BFS vials, by utilization of the systems and methods described herein.

II. Fluid Delivery Manifold Systems

[0009] Referring initially to FIG. 1, for example, a front view of BFS vial package 102 according to some embodiments is shown. The BFS vial package 102 may, for example, comprise and/or define a plurality of individual-dose BFS vials 104a-g joined, coupled, and/or formed together, e.g., as depicted. In some embodiments, and as illustrated with respect to a first one of the plurality of BFS vial 104a, the first BFS vial 104a may comprise and/or define a first or proximate end 104a-1 and a second or distal end 104a-2. Disposed therebetween, according to some embodiments, may be a first BFS vial body 106a. In some embodiments, each BFS vial 104a-g may be coupled (e.g., during and/or as a by-product of a BFS formation process) to any adjacent BFS vial 104a-g via the respectively-adjacent BFS bodies 106a-g. The connected series of seven (7) BFS vials 104a-g depicted in FIG. 1 may, for example, be formed together via a single, seven-compartment BFS mold or die (not shown) during a BFS formation process. In some embodiments, fewer or more BFS vials 104a-g may comprise and/or define the BFS vial package 102, as is or becomes known or practicable.

[0010] According to some embodiments, each BFS vial 104a-g may comprise and/or define various features such as features molded, formed, cut, glued, and/or otherwise coupled thereto. As depicted in FIG. 1 for example, the first BFS vial 104a may comprise a first vial neck 108a (e.g., at or near the distal end 104a-2) upon which various mating features are formed (or otherwise coupled). In some embodiments, the first vial neck 108a may comprise a first or distal exterior radial flange 108a-1 and/or a second or proximate exterior radial flange 108a-2. According to some embodiments, either of the radial flanges 108a-1, 108a-2 and/or a separate mating feature (not shown) on or of the first vial neck 108a may comprise a tab or other radial protrusion that permits indexed mating of the first vial neck 108a with various other components (not shown in FIG. 1). In some embodiments, each of the BFS vials 104a-g may comprise and/or define a fluid reservoir 110a-g, e.g., disposed and/or formed on each respective vial

body 106a-g thereof. According to some embodiments, each fluid reservoir 110a-g may store, house, and/or accept a single dose of fluid such as one or more medications, vaccines, solutions, and/or other therapeutic, restorative, preventative and/or curative agents. In some embodiments, a nitrogen bubble (not shown) may be disposed in the fluid reservoirs 110a-g to facilitate expelling of all of the fluid in the case that the fluid reservoirs 110a-g are squeezed and/or compressed by a user (not shown).

[0011] Radially inward compressive force applied to a first fluid reservoir 110a of the first BFS vial 104a may, for example, cause the first fluid reservoir 110a to collapse radially inward, forcing the fluid stored therein into a fluid channel 112a disposed in the first vial neck 108a. The first vial neck 108a may comprise a tube or passage, for example, that but for a fluid seal 112a-1 disposed at the distal end 104a-2, would form an opening at the distal end 104a-2 through which the fluid may flow when expelled from the first fluid reservoir 110a. In some embodiments, the first vial body 106a may comprise and/or define a flat or grip portion 114a disposed between the first fluid reservoir 110a and the proximate end 104a-1 of the first BFS vial 104a. The grip portion 114a may, for example, comprise a flat element that permits axial force to be applied to the first BFS vial 104a without causing such axial force to be applied to the first fluid reservoir 110a (e.g., for engaging an administering element (not shown) as described herein).

[0012] In some embodiments, the BFS vial package 102 may comprise an indicia imprinting thereon (and/or therein) and/or upon each individual BFS vial 104a-g (e.g., on the grip portion 114a of the first BFS vial 104a). Exemplary indicia may include, but is not limited to, lot number, expiration date, medication information (e.g., type, quantity, etc.), a security stamp (color changing temperature sensor to provide indication of whether BFS vials 104a-g have or have not been maintained at required temperature), as well as a dosage and/or measurement line provided on each BF vial 104a-g. While seven (7) BFS vials 104a-g are depicted in FIG. 1 as being coupled to and/or comprising the BFS vial package 102, fewer or more BFS vials 104a-g may be coupled to the BFS vial package 102 as is or becomes desirable and/or practicable.

[0013] According to some embodiments, the BFS vial package 102 and/or one or more of the BFS vials 104a-g may comprise and/or be coupled to one or more electronic devices 116a-g. The electronic devices 116a-g may comprise, for example, one or more passive inductive, Radio Frequency IDentification (RFID), Near-Field-Communication (NFC), processing, power storage, and/or memory storage devices. In some embodiments, the electronic devices 116a-g may store, process, receive, and/or transmit various data elements such as to track geographical movement of the BFS vial package 102 and/or to verify or confirm that a particular BFS vial 104a-g should be utilized for administration to a particular recipient.

[0014] In some embodiments for example, in the case that a user (whether a healthcare worker, a patient who is self-injecting or a friend or family member injecting a patient) is about to inject a fluid agent utilizing the first BFS vial 104a that comprises a first electronic device 116a such as an NFC chip, the user may first open an appropriate app on his/her mobile device (not shown) and tap (or bring into proximity) the first BFS vial 104a and/or the first

electronic device 116a to the mobile device to initiate communications therebetween. This may allow, in some embodiments, the app to verify the injection by verifying and/or authenticating one or more of the following: (i) that the fluid is the correct fluid agent the patient is supposed to be receiving (e.g., based on a comparison of fluid data stored by the first electronic device 116a and patient information stored in a separate memory device, e.g., of the user's mobile device); (ii) that the injection is being administered within an appropriate window of time (e.g., by comparing a current time and/or date to a time and/or date stored and/or referenced by data of the first electronic device 116a); (iii) that the first BFS vial 104a and/or fluid therein has not been compromised and/or is not expired. According to some embodiments, any of the foregoing may be verified based on records of the patient stored in the app on the mobile device and/or accessible to the app via the internet or a cloud-based system and/or data stored in the first electronic device 116a. In some embodiments, in the case that the required (or desired) verifications are processed successfully, the user may be authorized to perform the injection (e.g., an approval indicator may be output to the user via a screen of the app). The user may be motivated to only inject upon receiving the approval via the app because the user may only receive rewards via the app if he/she performs approved injections. In some embodiments, the user may also be requested to upload a photo of the first BFS vial 104a and/or the injection site (not shown) after the injection (e.g., to finalize qualification for a reward and/or to qualify for an additional reward). According to some embodiments, a reward may be provided to the user via the user's mobile device, e.g., in response to receiving data descriptive of the administration of the fluid and/or the use of the first BFS vial 104a.

[0015] In some embodiments, fewer or more components 104a-g, 104a-1, 104a-2, 106a-g, 108a, 108a-1, 108a-2, 110a-g, 112a, 112a-1, 114a-g, 116a-g and/or various configurations of the depicted components 104a-g, 104a-1, 104a-2, 106a-g, 108a, 108a-1, 108a-2, 110a-g, 112a, 112a-1, 114a-g, 116a-g may be included in the BFS vial package 102 without deviating from the scope of embodiments described herein. In some embodiments, the components 104a-g, 104a-1, 104a-2, 106a-g, 108a, 108a-1, 108a-2, 110a-g, 112a, 112a-1, 114a-g, 116a-g may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the BFS vial package 102 (and/or portion and/or component 104a-g, 104a-1, 104a-2, 106a-g, 108a, 108a-1, 108a-2, 110a-g, 112a, 112a-1, 114a-g, 116a-g thereof) may be utilized in accordance with the method 900 of FIG. 9 herein, and/or portions thereof.

[0016] Turning now to FIG. 2, a front view of a fluid delivery manifold 222 according to some embodiments is shown. The fluid delivery manifold 222 may, for example, be configured to mate with a BFS vial package (not shown; such as the BFS vial package 102 of FIG. 1 herein). In some embodiments, the fluid delivery manifold 222 may comprise a plurality of fluid delivery hubs 224a-g, each, e.g., configured to mate with a BFS vial (not shown; such as the BFS vials 104a-g of FIG. 1 herein). According to some embodiments, one or more of the fluid delivery hubs 224a-g, such as a first one of the fluid delivery hubs 224a, may comprise and/or define a first or proximate end 224a-1 and a second or distal end 224a-2. In some embodiments, the first fluid delivery hub 224a may comprise

and/or define a first interior volume 224a-3 comprising one or more internal features such as a first or proximate radial channel 224a-4 and/or a second or distal radial channel 224a-5. According to some embodiments, the fluid delivery hubs 224a-g may comprise hub bodies 226a-g, e.g., a first hub body 226a of the first fluid delivery hub 224a being disposed between the first and second ends 224a-1, 224a-2 thereof. In some embodiments, the hub bodies 226a-g may be substantially cylindrical.

[0017] According to some embodiments, the hub bodies 226a-g may comprise and/or define seats 228a-g. As depicted in FIG. 2, for example, the first hub body 226a may comprise a first seat 228a disposed or formed on an upper surface at the distal end 224a-2 of the first hub body 226a. In some embodiments, the first seat 228a may be in communication with the first interior volume 224a-3 via a bore 228a-1 disposed therebetween. The bore 228a-1 may, for example, allow for passage of an administration member (not shown) coupled to provide fluid (e.g., toward the distal end 224a-2) from a BFS vial (not shown in FIG. 2) coupled and/or disposed in the first interior volume 224a-3. According to some embodiments, the seats 228a-g may be sized and/or configured to accept, couple to, and/or mate with a seal, washer, stopper, and/or other element (not shown) disposed therein.

[0018] In some embodiments, the hub bodies 226a-g may be joined together to adjacent hub bodies 226a-g via one or more hub connectors 230. The hub connectors 230 and the hub bodies 226a-g may be formed together as a result of a BFS manufacturing process, for example, such as by being extruded from the same plastic and/or polymer material acted upon by a single BFS mold or die. According to some embodiments, the hub connectors 230 may be configured to be easily removed from the hub bodies 226a-g such as by incorporating perforations, stress points, and/or break points that are designed to shear, tear, or sever in response to certain applied forces. The first fluid delivery hub 224a may be separated from an adjacent second fluid delivery hub 224b, for example, in response to a rotational or twisting force being applied to the joint or juncture where a hub connector 230 is coupled to the first hub body 226a (and/or a second hub body 226b). In some embodiments, a designed stress or break point may be disposed at the juncture with the hub bodies 226a-g, in the middle of a length of the hub connectors 230, or as is or becomes desirable and/or practicable. In such a manner, for example, the fluid delivery manifold 222 may be quickly and easily manufactured as a single part while allowing the individual fluid delivery hubs 224a-g to be selectively removed with minimal effort, as is known in the plastic manufacturing arts.

[0019] According to some embodiments, fewer or more components 224a-g, 224a-1, 224a-2, 224a-3, 224a-4, 224a-5, 226a-g, 228a-g, 228a-1, 230 and/or various configurations of the depicted components 224a-g, 224a-1, 224a-2, 224a-3, 224a-4, 224a-5, 226a-g, 228a-g, 228a-1, 230 may be included in the fluid delivery manifold 222 without deviating from the scope of embodiments described herein. In some embodiments, the components 224a-g, 224a-1, 224a-2, 224a-3, 224a-4, 224a-5, 226a-g, 228a-g, 228a-1, 230 may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the fluid delivery manifold 222 (and/or portion and/or component 224a-g, 224a-1, 224a-2, 224a-3, 224a-4, 224a-5, 226a-g, 228a-g, 228a-1, 230 thereof) may be utilized in accordance with the method 900 of FIG. 9 herein, and/or portions

thereof.

[0020] Turning now to FIG. 3, a front view of a safety cap manifold 342 according to some embodiments is shown. In some embodiments, the safety cap manifold 342 may be configured to mate with a fluid delivery manifold (not shown) such as the fluid delivery manifold 222 of FIG. 2 herein. The safety cap manifold 342 may, for example, comprise a plurality of safety caps 344a-g each being configured to mate with a respective fluid delivery hub (not shown) such as the fluid delivery hubs 224a-g of FIG. 2 herein. In some embodiments, one or more of the safety caps 344a-g, such as a first one of the safety caps 344a, may comprise and/or define a first or proximate end 344a-1 and a second or distal end 344a-2. In some embodiments, the first safety cap 344a may comprise and/or define a first lower void 344a-3. According to some embodiments, the safety caps 344a-g may comprise safety cap bodies 346a-g, e.g., a first safety cap body 346a of the first safety cap 344a being disposed between the first and second ends 344a-1, 344a-2 thereof. In some embodiments, the safety cap bodies 346a-g may be substantially cylindrical.

[0021] According to some embodiments, the safety cap bodies 346a-g may comprise and/or define upper voids 348a-g. As depicted in FIG. 3, for example, the first safety cap body 346a may comprise a first upper void 348a disposed, formed, and/or open at (or closed at) the distal end 344a-2 of the first safety cap body 346a. In some embodiments, the first upper void 348a may be in communication with the first lower void 344a-3 via a passage 348a-1 disposed therebetween. The passage 348a-1 may, for example, allow for passage of an administration member (not shown) housed and/or retained by a fluid delivery hub (not shown) disposed and/or coupled within the first lower void 344a-3.

[0022] In some embodiments, the safety cap bodies 346a-g may be joined together to adjacent safety cap bodies 346a-g via one or more cap connectors 350. The cap connectors 350 and the safety cap bodies 346a-g may be formed together as a result of a BFS (or other) manufacturing process, for example, such as by being extruded and/or injected from the same plastic and/or polymer material acted upon by a single BFS (or other) mold or die. According to some embodiments, the cap connectors 350 may be configured to be easily removed from the safety cap bodies 346a-g such as by incorporating perforations, stress points, and/or break points that are designed to shear, tear, or sever in response to certain applied forces. The first safety cap 344a may be separated from an adjacent second safety cap 344b, for example, in response to a rotational or twisting force being applied to the joint or juncture where a cap connector 350 is coupled to the first safety cap body 346a (and/or a second safety cap body 346b). In some embodiments, a designed stress or break point may be disposed at the juncture with the safety cap bodies 346a-g, in the middle of a length of the cap connectors 350, or as is or becomes desirable and/or practicable. In such a manner, for example, the safety cap manifold 342 may be quickly and easily manufactured as a single part while allowing the individual safety caps 344a-g to be selectively removed with minimal effort, as is known in the plastic manufacturing arts.

[0023] According to some embodiments, fewer or more components 344a-g, 344a-1, 344a-2, 344a-3, 346a-g, 348a-g, 348a-1, 350 and/or various configurations of the depicted components 344a-g, 344a-1, 344a-2, 344a-3,

346a-g, 348a-g, 348a-1, 350 may be included in the safety cap manifold 342 without deviating from the scope of embodiments described herein. In some embodiments, the components 344a-g, 344a-1, 344a-2, 344a-3, 346a-g, 348a-g, 348a-1, 350 may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the safety cap manifold 342 (and/or portion and/or component 344a-g, 344a-1, 344a-2, 344a-3, 346a-g, 348a-g, 348a-1, 350 thereof) may be utilized in accordance with the methods 900 of FIG. 9 herein, and/or portions thereof.

[0024] Referring now to FIG. 4, a front view of a safety cap manifold 442 according to some embodiments is shown. In some embodiments, the safety cap manifold 442 may be configured to mate with a fluid delivery manifold (not shown) such as the fluid delivery manifold 222 of FIG. 2 herein. The safety cap manifold 442 may, for example, comprise a plurality of safety caps 444a-g each being configured to mate with a respective fluid delivery hub (not shown) such as the fluid delivery hubs 224a-g of FIG. 2 herein. In some embodiments, one or more of the safety caps 444a-g, such as a first one of the safety caps 444a, may comprise and/or define a first or proximate end 444a-1 and a second or distal end 444a-2. In some embodiments, the first safety cap 444a may comprise and/or define a first lower void 444a-3 (e.g., having a first diameter) and/or a first upper void 444a-4 (e.g., having a second diameter) in communication therewith. According to some embodiments, the safety caps 444a-g may comprise safety cap bodies 446a-g, e.g., a first safety cap body 446a of the first safety cap 444a being disposed between the first and second ends 444a-1, 444a-2 thereof. In some embodiments, the safety cap bodies 446a-g may be conically shaped and/or may comprise a plurality of shaped portions.

[0025] As depicted in FIG. 4 for example, the first safety cap body 446a may comprise a lower body portion 446a-1 that is cylindrically-shaped with a first outside diameter and an upper body portion 446a-2 that is cylindrically-shaped with a second outside diameter that is smaller than the first outside diameter. According to some embodiments, a smooth transition of the outside surface of the first safety cap body 446a between the first and second outside diameters may define a tapered body portion 446a-3 between the lower body portion 446a-1 and the upper body portion 446a-2. In some embodiments, the upper body portion 446a-2 may be frustoconically-shaped and/or may define therein the upper void 444a-4. The upper void 444a-4 and/or the upper body portion 446a-2 may, for example, allow for passage of an administration member (not shown) housed and/or retained by a fluid delivery hub (not shown) disposed and/or coupled within the first lower void 444a-3.

[0026] According to some embodiments, the first safety cap body 446a may comprise and/or define an exterior flange 446a-4. The exterior flange 446a-4 may, for example, be formed and/or defined by the intersection of the upper body portion 446a-2 and the lower body portion 446a-1 (and/or the tapered body portion 446a-3), e.g., having a radial depth based on the difference between the first and second outside diameters thereof. In some embodiments, the exterior flange 446a-4 and/or the tapered body portion 446a-3 may be utilized to apply axial forces on the first safety cap 444a, e.g., to effectuate activation of a fluid delivery system (not shown) as described herein.

[0027] In some embodiments, the safety cap bodies 446a-g may be joined together to adjacent safety cap bodies 446a-g via one or more cap connectors 450. The cap connectors 450 and the safety cap bodies 446a-g may be formed together as a result of a BFS (or other) manufacturing process, for example, such as by being extruded and/or injected from the same plastic and/or polymer material acted upon by a single BFS (or other) mold or die. According to some embodiments, the cap connectors 450 may be configured to be easily removed from the safety cap bodies 446a-g such as by incorporating perforations, stress points, and/or break points that are designed to shear, tear, or sever in response to certain applied forces. The first safety cap 444a may be separated from an adjacent second safety cap 444b, for example, in response to a rotational or twisting force being applied to the joint or juncture where a cap connector 450 is coupled to the first safety cap body 446a (and/or a second safety cap body 446b). In some embodiments, a designed stress or break point may be disposed at the juncture with the safety cap bodies 446a-g, in the middle of a length of the cap connectors 450, or as is or becomes desirable and/or practicable. In such a manner, for example, the safety cap manifold 442 may be quickly and easily manufactured as a single part while allowing the individual safety caps 444a-g to be selectively removed with minimal effort, as is known in the plastic manufacturing arts.

[0028] According to some embodiments, fewer or more components 444a-g, 444a-1, 444a-2, 444a-3, 444a-4, 446a-g, 446a-1, 446a-2, 446a-3, 446a-4, 450 and/or various configurations of the depicted components 444a-g, 444a-1, 444a-2, 444a-3, 444a-4, 446a-g, 446a-1, 446a-2, 446a-3, 446a-4, 450 may be included in the safety cap manifold 442 without deviating from the scope of embodiments described herein. In some embodiments, the components 444a-g, 444a-1, 444a-2, 444a-3, 444a-4, 446a-g, 446a-1, 446a-2, 446a-3, 446a-4, 450 may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the safety cap manifold 442 (and/or portion and/or component 444a-g, 444a-1, 444a-2, 444a-3, 444a-4, 446a-g, 446a-1, 446a-2, 446a-3, 446a-4, 450 thereof) may be utilized in accordance with the methods 900 of FIG. 9 herein, and/or portions thereof.

[0029] Turning now to FIG. 5A and FIG. 5B, front and cross-sectional views of a fluid delivery manifold system 500 according to some embodiments are shown. The fluid delivery manifold system 500 may comprise, for example, a BFS vial package 502 comprising a plurality of individual BFS vials 504a-g. Features of the BFS vials 504a-g are described in representative detail by referring to a first one of the BFS vials 504a (e.g., the left-most BFS vial 504a-g of the BFS vial package 502). According to some embodiments, the first BFS vial 504a may comprise a first or proximate end 504a-1 and a second or distal end 504a-2 between which is disposed a first vial body 506a. In some embodiments, each BFS vials 504a-g may comprise a vial body 506a-g that may be coupled to any adjacent vial body 506a-g in the BFS vial package 502 and/or may be coupled to and/or define various features. With reference to the first BFS vial 504a, for example, the first vial body 506a may comprise, define, and/or be coupled to a first vial neck 508a having a first or distal radial flange 508a-1 and/or a second or proximate radial flange 508a-2 formed and/or coupled thereto.

[0030] According to some embodiments, each BFS vial 504a-g may comprise a fluid reservoir 510a-g in communication with a respective fluid passage 512a-g (e.g., a first fluid passage 512a of the first BFS vial 504a being disposed in (or formed by) the first vial neck 508a). With reference to the first BFS vial 504a, for example, fluid may be stored in (e.g., injected into during an aseptic BFS manufacturing process) a first fluid reservoir 510a and/or the first fluid passage 512a and may be prevented from existing the first BFS vial 504a by a first fluid seal 512a-1 disposed at a distal end of the fluid passage 512a. In some embodiments, the BFS vials 504a-g may comprise grip portions 514a-g and/or electronic devices 516a-g (e.g., embedded and/or formed within the BFS vials 504a-g).

[0031] In some embodiments, the fluid delivery manifold system 500 may comprise a fluid delivery manifold 522 coupled to the BFS vial package 502. The fluid delivery manifold 522 may comprise, for example, a plurality of fluid delivery hubs 524a-g, each fluid delivery hub 524a-g being coupled to a respective one of the BFS vials 504a-g. Features of the fluid delivery hubs 524a-g are described in representative detail by referring to a first one of the fluid delivery hubs 524a (e.g., the left-most fluid delivery hub 524a-g of the fluid delivery manifold 522). The first fluid delivery hub 524a may comprise, according to some embodiments, a first or proximate end 524a-1 and a second or distal end 524a-2 and/or may comprise and/or define a first interior volume 524a-3. In some embodiments, the first interior volume 524a-3 may comprise one or more internal mating features such as a first or proximate radial channel 524a-4 and/or a second or distal radial channel 524a-5. According to some embodiments, the fluid delivery hubs 524a-g may comprise hub bodies 526a-g, e.g., a first hub body 526a of the first fluid delivery hub 524a being disposed between the first and second ends 524a-1, 524a-2 thereof. In some embodiments, the hub bodies 526a-g may be substantially cylindrical.

[0032] As shown in the cross-section of FIG. 5B, the first vial neck 508a may be inserted into the first interior volume 524a-3 by an amount that aligns first radial flange 508a-1 with the proximate radial channel 524a-4. In some embodiments, engagement and/or insertion of the first vial neck 508a into the first interior volume 524a-3 may cause the first vial neck 508a of the first BFS vial 504a (and/or the first radial flange 508a-1 thereof) to compress radially inward and/or may cause the first hub body 526a to expand radially outward (e.g., elastically), to allow continued advancement of the first BFS vial 504a into the first interior volume 524a-3, e.g., in accordance with a tight fit and/or interference fit engagement. According to some embodiments, the radial pressure exerted by forcing the first vial neck 508a of the first BFS vial 504a into the first interior volume 524a-3 may impart a radial spring effect to the first radial flange 508a-1 (or a portion thereof) such that when axial advancement aligns the first radial flange 508a-1 with the corresponding proximate radial channel 524a-4, the first radial flange 508a-1 (or a portion thereof) may spring radially outward and into the corresponding proximate radial channel 524a-4, thereby reducing and/or removing the radial pressure exerted thereon by the difference between an diameter of the first interior volume 524a-3 and an outside diameter and/or radial extents of the first radial flange 508a-1. In such a manner, for example, each BFS vial 504a-g may be snapped into each respective fluid delivery hub 524a-g.

[0033] According to some embodiments, the hub bodies 526a-g may comprise and/or define seats 528a-g. As depicted in FIG. 5B, for example, the first hub body 526a may comprise a first seat 528a disposed or formed on an upper surface at the distal end 524a-2 of the first hub body 526a. In some embodiments, the first seat 528a may be in communication with the first interior volume 524a-3 via a bore 528a-1 disposed therebetween. In some embodiments, the hub bodies 526a-g may be joined together to adjacent hub bodies 526a-g via one or more hub connectors 530. In such a manner, for example, the fluid delivery manifold 522 may be mated with or coupled to the BFS vial package 502 (e.g., as part of a manufacturing assembly process).

[0034] In some embodiments, the fluid delivery manifold system 500 may comprise a safety cap manifold 542 coupled to the fluid delivery manifold 522. The safety cap manifold 542 may comprise, for example, a plurality of safety caps 544a-g, each safety cap 544a-g being coupled to a respective one of the fluid delivery hubs 524a-g. Features of the safety caps 544a-g are described in representative detail by referring to a first one of the safety caps 544a (e.g., the left-most safety cap 544a-g of the safety cap manifold 542). The first safety cap 544a may comprise, according to some embodiments, a first or proximate end 544a-1 and a second or distal end 544a-2 and/or may comprise and/or define a lower void 544a-3, e.g., open at the proximate end 544a-1. In some embodiments, the lower void 544a-3 may comprise one or more internal mating features (not shown) such as to mate to corresponding features (also not shown) on an outside surface of the first fluid delivery hub 524a to which the first safety cap 544a is coupled.

[0035] According to some embodiments, the first safety cap 544a may comprise a first cap body 546a disposed between the first and second ends 544a-1, 544a-2 thereof. In some embodiments, the first cap body 546a may be substantially cylindrical. In some embodiments, the safety caps 544a-g may comprise and/or define upper voids 548a-g. The first safety cap 544a may comprise a first upper void 548a open at the distal end 544a-2, for example, and/or in communication with the first lower void 544a-3, e.g., via a first passage 548a-1. In some embodiments, the cap bodies 546a-g may be joined together to adjacent cap bodies 546a-g via one or more cap connectors 550. In such a manner, for example, the safety cap manifold 542 may be mated with or coupled to the fluid delivery manifold 522 (e.g., as part of a manufacturing assembly process).

[0036] In some embodiments, the mated safety caps 544a-g and fluid delivery hubs 524a-g may house and/or retain needles or administration members 560a-g (e.g., for at least one of subcutaneous, intramuscular, intradermal, and intravenous injection) and/or seals 570a-g. As shown with respect to the first BFS vial 504a, the first fluid delivery hub 524a, and the first safety cap 544a coupling, for example, a first administration member 560a may extend from within the interior volume 524a-3 (e.g., proximate to the first fluid seal 512a-1) of the first fluid delivery hub 524a, through the bore 528a-1 and the first seat 528a and into the lower void 544a-3 of the first safety cap 544a. According to some embodiments, within the lower void 544a-3 of the first safety cap 544a the first administration member 560a may pass through and/or be coupled to a first seal 570 (e.g., an annular rubber seal) and pass through the passage 548a-1 of the first safety cap 544a and into the first upper void 548a thereof. In

some embodiments, the upper void 548a may be closed at the distal end 544a-2, e.g., to prevent accidental access to the first administration member 560a. According to some embodiments, the axial length of the first safety cap 544a and/or the axial depth or extent of the first upper void 548a may be substantially longer than the length of the first administration member 560a exposed in the first upper void 548a and/or the upper void 548a may otherwise not need to be closed at the distal end 544a-2.

[0037] According to some embodiments, any coupled set of BFS vials 504a-g, fluid delivery hubs 524a-g, and safety caps 544a-g may be configured to be easily removed from the fluid delivery manifold system 500 such as by incorporating perforations, stress points, and/or break points that are designed to shear, tear, or sever in response to certain applied forces. Rotational or twisting force applied to the coupled first BFS vial 504a, first fluid delivery hub 524a, and first safety cap 544a may, for example, generate stresses (i) along a coupling between the first vial body 506a and an adjacent second vial body 506b, (ii) within the hub connector 530 connecting the first fluid delivery hub 524a and an adjacent second delivery hub 524b, and/or (iii) within the cap connector 550 connecting the first safety cap 544a and an adjacent second safety cap 544b. Reduced cross-sectional area at one or more of these various connections may be designed to fail in response to experiencing such stresses, thereby permitting a single-dose BFS vial 504a-g, fluid delivery hub 542a-g, and safety cap 544a-g unit to be easily and selectively removed from the fluid delivery manifold system 500.

[0038] While a certain style of safety cap 544a-g is depicted in FIG. 5A and FIG. 5B, it should be understood that different styles and/or configurations of safety caps 544a-g (e.g., as described herein) may be utilized without deviating from the scope of some embodiments. According to some embodiments, the fluid delivery manifold system 500 may be depicted in FIG. 5A and FIG. 5B in a first, assembled, and/or non-activated state. As depicted, for example, the administration members 560a-g have not yet been engaged to puncture the BFS vials 504a-g to permit release and/or administration of the fluid stored in the fluid reservoirs 510a-g. In some embodiments, an axial compressive force may be applied to the safety caps 544a-g and/or the fluid delivery hubs 524a-g in one direction and the grip portions 514a-g in an opposite direction, to urge the BFS vials 504a-g further into the fluid delivery hubs 524a-g and cause the administration members 560a-g to pierce the respective BFS vials 504a-g. In some embodiments, such an activation may be accomplished for single BFS vial 504a-g at a time or activation may be effectuated for multiple BFS vials 504a-g at one time, e.g., as permitted by the structural configurations, alignment, and engagement of the BFS vial package 502, the fluid delivery manifold 522, and the safety cap manifold 542.

[0039] In some embodiments, fewer or more components 502, 504a-g, 504a-1, 504a-2, 506a-g, 508a, 508a-1, 508a-2, 510a-g, 512a-g, 514a-g, 516a-g, 522, 524a-g, 524a-1, 524a-2, 524a-3, 524a-4, 524a-5, 526a-g, 528a-g, 528a-1, 530, 542, 544a-g, 544a-1, 544a-2, 544a-3, 546a, 548a-g, 548a-1, 550, 560a-g, 570a-g and/or various configurations of the depicted components 502, 504a-g, 504a-1, 504a-2, 506a-g, 508a, 508a-1, 508a-2, 510a-g, 512a-g, 514a-g, 516a-g, 522, 524a-g, 524a-1, 524a-2, 524a-3, 524a-4, 524a-5, 526a-g, 528a-g, 528a-1, 530, 542,

544a-g, 544a-1, 544a-2, 544a-3, 546a, 548a-g, 548a-1, 550, 560a-g, 570a-g may be included in the fluid delivery manifold system 500 without deviating from the scope of embodiments described herein. In some embodiments, the components 502, 504a-g, 504a-1, 504a-2, 506a-g, 508a, 508a-1, 508a-2, 510a-g, 512a-g, 514a-g, 516a-g, 522, 524a-g, 524a-1, 524a-2, 524a-3, 524a-4, 524a-5, 526a-g, 528a-g, 528a-1, 530, 542, 544a-g, 544a-1, 544a-2, 544a-3, 546a, 548a-g, 548a-1, 550, 560a-g, 570a-g may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the fluid delivery manifold system 500 (and/or portion and/or component 502, 504a-g, 504a-1, 504a-2, 506a-g, 508a, 508a-1, 508a-2, 510a-g, 512a-g, 514a-g, 516a-g, 522, 524a-g, 524a-1, 524a-2, 524a-3, 524a-4, 524a-5, 526a-g, 528a-g, 528a-1, 530, 542, 544a-g, 544a-1, 544a-2, 544a-3, 546a, 548a-g, 548a-1, 550, 560a-g, 570a-g thereof) may be utilized in accordance with the method 900 of FIG. 9 herein, and/or portions thereof.

[0040] Turning now to FIG. 6A, FIG. 6B, FIG. 6C, FIG. 6D, FIG. 6E, FIG. 6F, FIG. 6G, and FIG. 6H, top-front perspective, top, bottom, left, right, front, back, and cross-sectional views of a fluid delivery hub 624 according to some embodiments are shown. The fluid delivery hub 624 may comprise, for example, a first or proximate end 624-1 and a second or distal end 624-2 and/or may define an interior volume 624-3 (e.g., open at the proximate end 624-1). In some embodiments, the interior volume 624-3 may comprise and/or define one or more mating features (e.g., on an inside surface of the fluid delivery hub 624) such as a first or proximate radial channel 624-4 and/or a second or distal radial channel 624-5. According to some embodiments, the channels 624-4, 624-5 may be beveled and/or rounded, as shown, to facilitate entry and exit of corresponding mating flanges (not shown) thereof. In some embodiments, a lower edge of one or more of the channels 624-4, 624-5 may comprise a right-angle or other angular profile (not shown) such that a corresponding mating feature may readily enter the channel 624-4, 624-5 from the proximate end 624-1 but may be impeded from exiting the channel 624-4, 624-5 (e.g., from backing out) toward the proximate end 624-1. In such a manner, for example, a BFS vial (not shown) with a corresponding mating feature(s) may be easily inserted into the interior volume 624-3 but may be locked therein once engaged, e.g., to prevent attempted reuse of the fluid delivery hub 624.

[0041] According to some embodiments, the interior volume 624-3 may be defined by a hub body 626 such as a cylindrical shape as-depicted. In some embodiments, the fluid delivery hub 624 (and/or the hub body 626 thereof) may comprise and/or define a seat 628. The seat 628 may comprise, for example, a depression, indent, and/or counter-sink feature disposed on a top surface of the hub body 626 at the distal end 624-2. In some embodiments, the seat 628 may comprise a void or volume that is in communication with the interior volume 624-3 via a bore 628-1. According to some embodiments, the fluid delivery hub 624 (and/or the hub body 626 thereof) may comprise a hub connector 630 that may, for example, comprise an element molded and/or coupled to the hub body 626 and operable to be coupled to an adjacent fluid delivery hub (not shown). In some embodiments, the hub connector 630 may comprise a portion of a connective element that connected the hub body 626 to and adjacent hub body and then was selectively severed to remove the fluid delivery hub 624, e.g., from a fluid delivery manifold (not

shown) such as the fluid delivery manifolds 222, 522, of FIG. 2, FIG. 5A, and/or FIG. 5B herein.

[0042] In some embodiments, fewer or more components 624-1, 624-2, 624-3, 624-4, 624-5, 626, 628, 628-1, 630 and/or various configurations of the depicted components 624-1, 624-2, 624-3, 624-4, 624-5, 626, 628, 628-1, 630 may be included in the fluid delivery hub 624 without deviating from the scope of embodiments described herein. In some embodiments, the components 624-1, 624-2, 624-3, 624-4, 624-5, 626, 628, 628-1, 630 may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the fluid delivery hub 624 (and/or portion and/or component 624-1, 624-2, 624-3, 624-4, 624-5, 626, 628, 628-1, 630 thereof) may be utilized in accordance with the method 900 of FIG. 9 herein, and/or portions thereof.

[0043] Turning now to FIG. 7A and FIG. 7B, cross-sectional views of a fluid delivery manifold system 700 according to some embodiments are shown. In some embodiments, the fluid delivery manifold system 700 may be depicted in various states of activation in FIG. 7A and FIG. 7B. In FIG. 7A, for example, the fluid delivery manifold system 700 may be depicted in a first or unengaged state while in FIG. 7B the fluid delivery manifold system 700 may be depicted in a second or engaged state. According to some embodiments, a user (not shown) may progress the fluid delivery manifold system 700 from the first state to the second state by selective application of axial force that ultimately causes a fluid to be delivered to a recipient (not shown; e.g., a therapeutic and/or medical fluid to be delivered to a patient).

[0044] According to some embodiments, the fluid delivery manifold system 700 may comprise a BFS vial neck 708 having a first or distal exterior radial flange 708-1 and a second or proximate exterior radial flange 708-2. In some embodiments, a fluid (not explicitly shown) may reside in and/or travel through a fluid passage 712 within the BFS vial neck 708 and/or may be contained by a fluid seal 712-1. The fluid seal 712-1 may be integral to the BFS vial neck 708 such as by being formed during a BFS manufacturing process together with the BFS vial neck 708 or may comprise a separate element coupled to seal the BFS vial neck 708 and attendant fluid passage 712 thereof.

[0045] In some embodiments, the fluid delivery manifold system 700 may comprise a fluid delivery hub 724 coupled to the BFS vial neck 708. The BFS vial neck 708 may, for example, be at least partially inserted into an interior volume 724-3 defined by the fluid delivery hub 724, e.g., as shown in FIG. 7A. According to some embodiments, the BFS vial neck 708 may have been inserted to a first position within the interior volume 724-3 as shown in FIG. 7A, such that the first radial flange 708-1 engages with and/or becomes seated in a first or proximate radial channel 724-4 disposed on an inside surface of the interior volume 724-3. As depicted in FIG. 7B, continued advancement of the BFS vial neck 708 into the interior volume 724-3 may cause the first radial flange 708-1 to disengage with and/or move out of the first radial channel 724-4 and travel along the inside surface of the interior volume 724-3 until it becomes engaged with and/or seated in a second or distal radial channel 724-5 (as shown in FIG. 7B). Upon achieving such a second and/or additional level of insertion into the interior volume 724-3, in some embodiments the second radial flange 708-2 may become engaged with and/or seated in the first radial channel

724-4 (also as shown in FIG. 7B). In such a manner, for example, at the first state shown in FIG. 7A the BFS vial neck 708 may be secured to the fluid delivery hub 724 at a first position (e.g., via engagement of the first radial flange 708-1 with the first radial channel 724-4; e.g., a transport, assembly, and/or pre-engagement position) while at the second state shown in FIG. 7B the BFS vial neck 708 may be secured to the fluid delivery hub 724 at a second position (e.g., via engagement of the first radial flange 708-1 with the second radial channel 724-5 and engagement of the second radial flange 708-2 with the first radial channel 724-4; e.g., an engagement position). In some embodiments, the interior volume 724-3 (and/or the channels 724-4, 724-5 thereof) may be formed and/or defined by a hub body 726. According to some embodiments, the hub body 726 may comprise and/or define a seat 728 disposed opposite to the interior volume 724-3 and/or a bore 728-1 extending between the seat 728 and the interior volume 724-3.

[0046] In some embodiments, the fluid delivery manifold system 700 may comprise a safety cap 744 defining a lower void 744-3 into which the hub body 726 is at least partially inserted and/or disposed (e.g., as shown in FIG. 7A). The lower void 744-3 may comprise an inside diameter equivalent to (or slightly smaller than) an outside diameter of the hub body 726, for example, such as permitting for a desired fit therebetween. According to some embodiments, the lower void 744-3 may be defined by a cap body 746 that may, for example, be cylindrically-shaped. In some embodiments, the safety cap 744 (and/or cap body 746 thereof) may comprise and/or define an upper void 748 in communication with the lower void 744-3 via a passage 748-1.

[0047] According to some embodiments, the fluid delivery manifold system 700 may comprise an administration member 760 (such as a needle or tube; e.g., a needle having a length in the ranges of (i) 0.5 mm to 4 mm, (ii) 4 mm to 15 mm, or (iii) 15 mm to 30 mm) having a first or proximate end 760-1 and a second or distal end 760-2. In some embodiments, the administration member 760 may be hollow and/or may otherwise define a fluid channel 760-3 extending from the first end 760-1 to the second end 760-3. In some embodiments, the administration member 760 may pass through and/or be coupled to a seal 770 disposed in the lower void 744-3. The seal 770 may comprise, for example, an annular rubber or thermoplastic element that may be deformable or pliable. According to some embodiments, either or both of the first end 760-1 and the second end 760-2 of the administration member 760 may comprise a tip, point, prong, blade, and/or other feature and/or configuration, such as to pierce the fluid seal 712-1 (e.g., in the case of the first end 760-1) or pierce an administration surface (such as skin; not shown; e.g., in the case of the second end 760-2).

[0048] In some embodiments, and as depicted in FIG. 7A, at the first or disengaged state of the fluid delivery manifold system 700 the first end 760-1 of the administration member 760 may be disposed in the interior volume 724-3 of the fluid delivery hub 724 and the second end 760-2 of the administration member 760 may be disposed in the upper void 748 of the safety cap 744. The administration member 760 may pass through, for example, each of the bore 728-1 (and the seat 728), the seal 770, and the passage 748-1. According to some embodiments, axial force may be applied to transition the fluid delivery manifold system 700 to the second or engaged state of FIG. 7B

where the first end 760-1 of the administration member 760 has pierced the fluid seal 712-1 and is disposed within the fluid passage 712 of the BFS vial neck 708 and where the seal 770 is seated in, engaged with, and/or coupled to the seat 728. In such a manner, for example, the fluid delivery manifold system 700 may be engaged to provide the fluid from the fluid passage 712, through the fluid channel 760-3, and into a recipient (not shown). In some embodiments, the safety cap 744 may be removed to expose the administration member 760 and/or the second end 760-2 thereof for administration of the fluid. According to some embodiments, axial force (downward, as-oriented in FIG. 7A and FIG. 7B) may cause the seal 770 to deform and/or compress into the seat 728. Axial force applied to the safety cap 744 may cause the cap body 746 (and/or the ceiling of the interior volume 724-3) to act upon the seal 770 and urge the seal 770 axially downward (e.g., as depicted transitioning from FIG. 7A to FIG. 7B). In some embodiments, once the seal 770 contacts the seat 728 it may be forced therein and/or may be deformed or compressed into the seat 728.

[0049] According to some embodiments, upon the seal 770 achieving a degree of compression and/or deformation, force may be transferred to the hub body 726, causing the first radial flange 708-1 of the BFS vial neck 708 to unseat and/or disengage from the first radial channel 724-4, allowing the fluid delivery hub 724 to progress to further envelope the BFS vial neck 708 (e.g., the BFS vial neck 708 advancing further into the interior volume 724-3). In some embodiments, the BFS vial neck 708 may comprise a plastic and/or polymer having a higher degree of compressibility than that of the fluid delivery hub 724, such that the progression of the radial flanges 708-1, 708-2 along the inside walls of the interior volume 724-3 may cause a radially inward compression and/or deformation of the flanges 708-1, 708-2. In some embodiments, such compression may be elastic such that upon encountering an increased interior diameter at the location of either of the channels 724-4, 724-5 the flanges 708-1, 708-2 may spring back radially outward to seat within the channels 724-4, 724-5. According to some embodiments, the seal 770 may be affixed and/or coupled to the administration member 760 such that axial force applied to the seal 770 causes the administration member 760 to move (e.g., as depicted in FIG. 7A and FIG. 7B).

[0050] In some embodiments, fewer or more components 708, 708-1, 708-2, 712, 712-1, 724, 724-3, 724-4, 724-5, 726, 728, 728-1, 744, 744-3, 746, 748, 748-1, 760, 760-1, 760-2, 760-3, 770 and/or various configurations of the depicted components 708, 708-1, 708-2, 712, 712-1, 724, 724-3, 724-4, 724-5, 726, 728, 728-1, 744, 744-3, 746, 748, 748-1, 760, 760-1, 760-2, 760-3, 770 may be included in the fluid delivery manifold system 700 without deviating from the scope of embodiments described herein. In some embodiments, the components 708, 708-1, 708-2, 712, 712-1, 724, 724-3, 724-4, 724-5, 726, 728, 728-1, 744, 744-3, 746, 748, 748-1, 760, 760-1, 760-2, 760-3, 770 may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the fluid delivery manifold system 700 (and/or portion and/or component 708, 708-1, 708-2, 712, 712-1, 724, 724-3, 724-4, 724-5, 726, 728, 728-1, 744, 744-3, 746, 748, 748-1, 760, 760-1, 760-2, 760-3, 770 thereof) may be utilized in accordance with the method 900 of FIG. 9 herein, and/or portions thereof.

[0051] Referring now to FIG. 8A and FIG. 8B, cross-sectional views of a fluid delivery manifold system 800 according to some embodiments are shown. In some embodiments, the fluid delivery manifold system 800 may be depicted in various states of activation in FIG. 8A and FIG. 8B. In FIG. 8A, for example, the fluid delivery manifold system 800 may be depicted in a first or unengaged state while in FIG. 8B the fluid delivery manifold system 800 may be depicted in a second or engaged state. According to some embodiments, a user (not shown) may progress the fluid delivery manifold system 800 from the first state to the second state by selective application of axial force that ultimately causes a fluid to be delivered to a recipient (not shown; e.g., a therapeutic and/or medical fluid to be delivered to a patient).

[0052] According to some embodiments, the fluid delivery manifold system 800 may comprise a BFS vial neck 808 having a first or distal exterior radial flange 808-1 and a second or proximate exterior radial flange 808-2. In some embodiments, a fluid (not explicitly shown) may reside in and/or travel through a fluid passage 812 within the BFS vial neck 808 and/or may be contained by a fluid seal 812-1. The fluid seal 812-1 may be integral to the BFS vial neck 808 such as by being formed during a BFS manufacturing process together with the BFS vial neck 808 or may comprise a separate element coupled to seal the BFS vial neck 808 and attendant fluid passage 812 thereof.

[0053] In some embodiments, the fluid delivery manifold system 800 may comprise a fluid delivery hub 824 coupled to the BFS vial neck 808. The BFS vial neck 808 may, for example, be at least partially inserted into an interior volume 824-3 defined by the fluid delivery hub 824, e.g., as shown in FIG. 8A. According to some embodiments, the BFS vial neck 808 may have been inserted to a first position within the interior volume 824-3 as shown in FIG. 8A, such that the first radial flange 808-1 engages with and/or becomes seated in a first or proximate radial channel 824-4 disposed on an inside surface of the interior volume 824-3. As depicted in FIG. 8B, continued advancement of the BFS vial neck 808 into the interior volume 824-3 may cause the first radial flange 808-1 to disengage with and/or move out of the first radial channel 824-4 and travel along the inside surface of the interior volume 824-3 until it becomes engaged with and/or seated in a second or distal radial channel 824-5 (as shown in FIG. 8B). Upon achieving such a second and/or additional level of insertion into the interior volume 824-3, in some embodiments the second radial flange 808-2 may become engaged with and/or seated in the first radial channel 824-4 (also as shown in FIG. 8B). In such a manner, for example, at the first state shown in FIG. 8A the BFS vial neck 708 may be secured to the fluid delivery hub 824 at a first position (e.g., via engagement of the first radial flange 808-1 with the first radial channel 824-4; e.g., a transport, assembly, and/or pre-engagement position) while at the second state shown in FIG. 8B the BFS vial neck 808 may be secured to the fluid delivery hub 824 at a second position (e.g., via engagement of the first radial flange 808-1 with the second radial channel 824-5 and engagement of the second radial flange 808-2 with the first radial channel 824-4; e.g., an engagement position). In some embodiments, the interior volume 824-3 (and/or the channels 824-4, 824-5 thereof) may be formed and/or defined by a hub body 826. According to some embodiments, the hub body 826 may comprise and/or define a seat 828 disposed opposite to the interior volume 824-3 and/or a bore 828-1 extending between the seat 828 and the

interior volume 824-3.

[0054] In some embodiments, the fluid delivery manifold system 800 may comprise a safety cap 844 defining a lower void 844-3 into which the hub body 826 is at least partially inserted and/or disposed (e.g., as shown in FIG. 8A) and/or an upper void 844-4. The lower void 844-3 may comprise an inside diameter equivalent to (or slightly smaller than) an outside diameter of the hub body 826, for example, such as permitting for a desired fit therebetween. According to some embodiments, the lower void 844-3 may be defined by a cap body 846 that may, for example, be comprise a lower body portion 846-1 having a first exterior diameter and an upper body portion 846-2 having a second exterior diameter. According to some embodiments, in the case that the second exterior diameter is smaller than the first exterior diameter, the cap body 846 may comprise and/or define (e.g., at a transition between the lower cap body 846-1 and the upper cap body 846-2) an exterior flange 846-4. In some embodiments, the upper void 844-4 may be defined within the upper body portion 846-2 and the lower void 844-3 may be defined within the lower body portion 846-1.

[0055] According to some embodiments, the fluid delivery manifold system 800 may comprise an administration member 860 (such as a needle or tube) having a first or proximate end 860-1 and a second or distal end 860-2. In some embodiments, the administration member 860 may be hollow and/or may otherwise define a fluid channel 860-3 extending from the first end 860-1 to the second end 860-3. In some embodiments, the administration member 860 may pass through and/or be coupled to a seal 870 disposed in the lower void 844-3. The seal 870 may comprise, for example, an annular rubber or thermoplastic element that may be deformable or pliable. According to some embodiments, either or both of the first end 860-1 and the second end 860-2 of the administration member 860 may comprise a tip, point, prong, blade, and/or other feature and/or configuration, such as to pierce the fluid seal 812-1 (e.g., in the case of the first end 860-1) or pierce an administration surface (such as skin; not shown; e.g., in the case of the second end 860-2).

[0056] In some embodiments, and as depicted in FIG. 8A, at the first or disengaged state of the fluid delivery manifold system 800 the first end 860-1 of the administration member 860 may be disposed in the interior volume 824-3 of the fluid delivery hub 824 and the second end 860-2 of the administration member 860 may be disposed in the upper void 848 of the safety cap 844. The administration member 860 may pass through, for example, each of the bore 828-1 (and the seat 828), the seal 870, and the passage 848-1. According to some embodiments, axial force may be applied (e.g., to the exterior flange 846-4) to transition the fluid delivery manifold system 800 to the second or engaged state of FIG. 8B where the first end 860-1 of the administration member 860 has pierced the fluid seal 812-1 and is disposed within the fluid passage 812 of the BFS vial neck 808 and where the seal 870 is seated in, engaged with, and/or coupled to the seat 828. In such a manner, for example, the fluid delivery manifold system 800 may be engaged to provide the fluid from the fluid passage 812, through the fluid channel 860-3, and into a recipient (not shown). In some embodiments, the safety cap 844 may be removed to expose the administration member 860 and/or the second end 860-2 thereof for administration of the fluid. According to some

embodiments, axial force (downward, as-oriented in FIG. 8A and FIG. 8B) may cause the seal 870 to deform and/or compress into the seat 828. Axial force applied to the safety cap 844 (e.g., to the exterior flange 846-4 thereof) may cause the cap body 846 (and/or the ceiling of the interior volume 824-3) to act upon the seal 870 and urge the seal 870 axially downward (e.g., as depicted transitioning from FIG. 8A to FIG. 8B). In some embodiments, once the seal 870 contacts the seat 828 it may be forced therein and/or may be deformed or compressed into the seat 828.

[0057] According to some embodiments, upon the seal 870 achieving a degree of compression and/or deformation, force may be transferred to the hub body 826, causing the first radial flange 808-1 of the BFS vial neck 808 to unseat and/or disengage from the first radial channel 824-4, allowing the fluid delivery hub 824 to progress to further envelope the BFS vial neck 808 (e.g., the BFS vial neck 808 advancing further into the interior volume 824-3). In some embodiments, the BFS vial neck 808 may comprise a plastic and/or polymer having a higher degree of compressibility than that of the fluid delivery hub 824, such that the progression of the radial flanges 808-1, 808-2 along the inside walls of the interior volume 824-3 may cause a radially inward compression and/or deformation of the flanges 808-1, 808-2. In some embodiments, such compression may be elastic such that upon encountering an increased interior diameter at the location of either of the channels 824-4, 824-5 the flanges 808-1, 808-2 may spring back radially outward to seat within the channels 824-4, 824-5. According to some embodiments, the seal 870 may be affixed and/or coupled to the administration member 860 such that axial force applied to the seal 870 causes the administration member 860 to move (e.g., as depicted in FIG. 8A and FIG. 8B).

[0058] In some embodiments, fewer or more components 808, 808-1, 808-2, 812, 812-1, 824, 824-3, 824-4, 824-5, 826, 828, 828-1, 844, 844-3, 844-4, 846, 846-1, 846-2, 846-4, 860, 860-1, 860-2, 860-3, 870 and/or various configurations of the depicted components 808, 808-1, 808-2, 812, 812-1, 824, 824-3, 824-4, 824-5, 826, 828, 828-1, 844, 844-3, 844-4, 846, 846-1, 846-2, 846-4, 860, 860-1, 860-2, 860-3, 870 may be included in the fluid delivery manifold system 800 without deviating from the scope of embodiments described herein. In some embodiments, the components 808, 808-1, 808-2, 812, 812-1, 824, 824-3, 824-4, 824-5, 826, 828, 828-1, 844, 844-3, 844-4, 846, 846-1, 846-2, 846-4, 860, 860-1, 860-2, 860-3, 870 may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. In some embodiments, the fluid delivery manifold system 800 (and/or portion and/or component 808, 808-1, 808-2, 812, 812-1, 824, 824-3, 824-4, 824-5, 826, 828, 828-1, 844, 844-3, 844-4, 846, 846-1, 846-2, 846-4, 860, 860-1, 860-2, 860-3, 870 thereof) may be utilized in accordance with the method 900 of FIG. 9 herein, and/or portions thereof.

III. Fluid Delivery Manifold Methods

[0059] FIG. 9 is a flow diagram of a method 900 according to some embodiments. The method 900 may, for example, illustrate an exemplary use of the various fluid delivery manifold systems and/or components thereof, as described herein. In some embodiments, the method 900 may comprise multiple related and/or consecutive processes such as actions associated with a first process "A" and a second process "B". According to some

embodiments, the different processes "A", "B" may be performed by different entities and/or at different times and/or locations. The process diagrams and flow diagrams described herein do not necessarily imply a fixed order to any depicted actions, steps, and/or procedures, and embodiments may generally be performed in any order that is practicable unless otherwise and specifically noted. While the order of actions, steps, and/or procedures described herein is generally not fixed, in some embodiments, actions, steps, and/or procedures may be specifically performed in the order listed, depicted, and/or described and/or may be performed in response to any previously listed, depicted, and/or described action, step, and/or procedure.

[0060] According to some embodiments, the first process "A" may comprise a manufacturing and/or assembly process. In some embodiments, the first process "A" and/or the method 900 may comprise assembling a BFS vial package with a fluid delivery manifold, at 902. A plurality of BFS vials connected in a package may be mated with corresponding fluid delivery hub members that are also interconnected, for example. According to some embodiments, the assembling may include an aligning of the respective BFS vials (or necks thereof) with individual fluid delivery hub components and applying a first axial force to cause mating of the BFS vials and fluid delivery hubs.

[0061] In some embodiments, the method 900 may comprise coupling a plurality of administration members (e.g., needles, droppers, nozzles) and respective fluid seals to the fluid delivery manifold, at 904. Each fluid delivery hub may comprise a bore in which an administration member is inserted, for example. According to some embodiments, the method 900 may comprise assembling a safety cap manifold with the fluid delivery manifold, at 906. In some embodiments, the assembling may include an aligning of the respective fluid delivery hubs with individual safety caps and applying a second axial force to cause mating of the fluid delivery hubs and the safety caps. According to some embodiments, a plurality of interconnected safety caps may be aligned, for example, and engaged with the fluid delivery hubs of the fluid delivery manifold. According to some embodiments, the coupling and/or mating of the safety caps with the fluid delivery hubs may cause the administration members and/or fluid seals to become encapsulated, retained, and/or restricted. In some embodiments, each administration member and each fluid seal may be housed within a respective safety cap and/or between the safety cap and a respective fluid delivery hub. In some embodiments, the assembly and coupling actions may occur in an aseptic environment, such as part of an aseptic BFS manufacturing process that also forms, fills, and seals the BFS vials.

[0062] According to some embodiments, the second process "B" may comprise an administration process. In some embodiments, the second process "B" and/or the method 900 may comprise activating a unit of the fluid delivery manifold system, at 908. A third axial force may be applied to axially compress a unit comprising a mated pairing of a BFS vial, a fluid delivery hub, an administration member, a seal, and a safety cap, for example, thereby causing an activation thereof. The third axial force may cause the administration member to pierce a seal of the BFS vial, for example, and/or may cause the fluid seal to become seated and/or coupled to the fluid delivery hub. According to some embodiments, the activating may comprise removing the unit from the respective package and

manifolds, such as by application of a twisting, shear, and/or rotational force thereto (e.g., with respect to the other units of the assembled fluid delivery manifold system).

[0063] In some embodiments, the method 900 may comprise removing the safety cap of the unit, at 910. Axial separation force may be applied to separate the safety cap from the fluid delivery hub of the unit, for example, exposing the administration member such as a needle, nozzle, dropper, or the like. According to some embodiments, the method 900 may comprise administering a dose of fluid, at 912. The administration element of the unit may be engaged with a patient, for example, and a collapsible and/or integral reservoir of the BFS vial may be squeezed (e.g., via application of inward radial force) to force fluid therefrom. According to some embodiments, the fluid may be forced in an antegrade axial direction such that it displaces a valve flap of a one-way valve, thereby allowing the fluid to proceed axially into the administration element and be delivered to the patient. In some embodiments, the method 900 may comprise replacing the safety cap, at 914. According to some embodiments, the method 900 may comprise disposing of the unit, at 916. In such a manner, for example, a low-cost, easily transported and more easily manufactured, assembled, and stored fluid delivery system may be provided that allows unskilled users to administer and/or self-administer various fluids such as medical and/or therapeutic substances.

IV. Rules of Interpretation

[0064] Throughout the description herein and unless otherwise specified, the following terms may include and/or encompass the example meanings provided. These terms and illustrative example meanings are provided to clarify the language selected to describe embodiments both in the specification and in the appended claims, and accordingly, are not intended to be generally limiting. While not generally limiting and while not limiting for all described embodiments, in some embodiments, the terms are specifically limited to the example definitions and/or examples provided. Other terms are defined throughout the present description.

[0065] Numerous embodiments are described in this patent application, and are presented for illustrative purposes only. The described embodiments are not, and are not intended to be, limiting in any sense. The presently disclosed invention(s) are widely applicable to numerous embodiments, as is readily apparent from the disclosure. One of ordinary skill in the art will recognize that the disclosed invention(s) may be practiced with various modifications and alterations, such as structural, logical, software, and electrical modifications. Although particular features of the disclosed invention(s) may be described with reference to one or more particular embodiments and/or drawings, it should be understood that such features are not limited to usage in the one or more particular embodiments or drawings with reference to which they are described, unless expressly specified otherwise.

[0066] Devices that are in communication with each other need not be in continuous communication with each other, unless expressly specified otherwise.

[0067] A description of an embodiment with several components or features does not imply that all or even any of

such components and/or features are required. On the contrary, a variety of optional components are described to illustrate the wide variety of possible embodiments of the present invention(s). Unless otherwise specified explicitly, no component and/or feature is essential or required.

[0068] Further, although process steps, algorithms or the like may be described in a sequential order, such processes may be configured to work in different orders. In other words, any sequence or order of steps that may be explicitly described does not necessarily indicate a requirement that the steps be performed in that order. The steps of processes described herein may be performed in any order practical. Further, some steps may be performed simultaneously despite being described or implied as occurring non-simultaneously (e.g., because one step is described after the other step). Moreover, the illustration of a process by its depiction in a drawing does not imply that the illustrated process is exclusive of other variations and modifications thereto, does not imply that the illustrated process or any of its steps are necessary to the invention, and does not imply that the illustrated process is preferred.

[0069] The present disclosure provides, to one of ordinary skill in the art, an enabling description of several embodiments and/or inventions. Some of these embodiments and/or inventions may not be claimed in the present application, but may nevertheless be claimed in one or more continuing applications that claim the benefit of priority of the present application. Applicants intend to file additional applications to pursue patents for subject matter that has been disclosed and enabled but not claimed in the present application.

[0070] It will be understood that various modifications can be made to the embodiments of the present disclosure herein without departing from the scope thereof. Therefore, the above description should not be construed as limiting the disclosure, but merely as embodiments thereof. Those skilled in the art will envision other modifications within the scope of the invention as defined by the claims appended hereto.

[0071] While several embodiments of the present disclosure have been described and illustrated herein, those of ordinary skill in the art will readily envision a variety of other means and/or structures for performing the functions and/or obtaining the results and/or one or more of the advantages described herein, and each of such variations and/or modifications is deemed to be within the scope of the present disclosure. More generally, those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will depend upon the specific application or applications for which the teachings of the present disclosure is/are used.

[0072] Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the disclosure described herein. It is, therefore, to be understood that the foregoing embodiments are presented by way of example only and that, within the scope of the appended claims and equivalents thereto, the disclosure may be practiced otherwise than as specifically described and claimed. The present disclosure is directed to each individual feature, system, article, material, kit, and/or method described herein. In addition, any combination of two or more such features, systems, articles, materials, kits,

and/or methods, if such features, systems, articles, materials, kits, and/or methods are not mutually inconsistent, is included within the scope of the present disclosure.

[0073] All definitions, as defined and used herein, should be understood to control over dictionary definitions, definitions in documents incorporated by reference, and/or ordinary meanings of the defined terms.

[0074] The indefinite articles "a" and "an," as used herein in the specification and in the claims, unless clearly indicated to the contrary, should be understood to mean "at least one."

[0075] The phrase "and/or," as used herein in the specification and in the claims, should be understood to mean "either or both" of the elements so conjoined, i.e., elements that are conjunctively present in some cases and disjunctively present in other cases. Other elements may optionally be present other than the elements specifically identified by the "and/or" clause, whether related or unrelated to those elements specifically identified, unless clearly indicated to the contrary.

[0076] Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

[0077] The terms and expressions which have been employed herein are used as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding any equivalents of the features shown and described (or portions thereof), and it is recognized that various modifications are possible within the scope of the claims. Accordingly, the claims are intended to cover all such equivalents.

[0078] Various modifications of the invention and many further embodiments thereof, in addition to those shown and described herein, will become apparent to those skilled in the art from the full contents of this document, including references to the scientific and patent literature cited herein. The subject matter herein contains important information, exemplification and guidance that can be adapted to the practice of this invention in its various embodiments and equivalents thereof.

What is claimed is:

1. A fluid delivery manifold system for delivery of a fluid agent, the fluid delivery manifold system comprising:
 - a blow-fill-seal (BFS) package comprising a plurality of individual BFS vials coupled together, each BFS vial containing a single dose of a fluid agent and each BFS vial comprising a neck having at least one mating feature disposed on an exterior surface thereof;
 - a fluid delivery manifold comprising a plurality of fluid delivery hubs coupled together, each fluid delivery hub defining an interior volume having one or more mating features disposed on an interior surface therein, and each of the one or more mating features being coupled to a corresponding at least one mating feature of one of the BFS vial necks:
 - a safety cap manifold comprising a plurality of safety caps coupled together, each safety cap defining a void in which one of the fluid delivery hubs is disposed;
 - a plurality of fluid seal elements, each fluid seal element being retained between one of the safety caps and a respective fluid delivery hub; and
 - a plurality of administration members, each administration member being coupled to one of the fluid seal elements.
2. The fluid delivery manifold system of claim 1, wherein each fluid delivery hub comprises a seal seat operable to accept one of the fluid seals in the case that axial compressive force is applied to a respective BFS vial and safety cap, urging the respective one of the fluid seals into the seal seat.
3. The fluid delivery system of claim 1, wherein at least one of the administration members comprises a needle for at least one of subcutaneous, intramuscular, intradermal, and intravenous injection of the fluid agent into a recipient.
4. The fluid delivery system of claim 3, wherein the needle comprises a length in the range of 0.5 mm to 4 mm.
5. The fluid delivery system of claim 3, wherein the needle comprises a length in the range of 4 mm to 15 mm.
6. The fluid delivery system of claim 3, wherein the needle comprises a length in the range of 15 mm to 30 mm.
7. The fluid delivery manifold system of claim 1, wherein at least one of the BFS vials comprises an electronic device storing data descriptive of the fluid agent.

8. The fluid delivery manifold system of claim 7, wherein the electronic device comprises a Near-Field-Communication (NFC) device.
9. The fluid manifold system of claim 8, wherein the NFC device is operable to facilitate processing of data defining the geographical movement of the at least one BFS vial.
10. The fluid manifold system of claim 8, wherein the NFC device is operable to facilitate processing of data that allows a verification that the at least one BFS vial is authorized for administration to a particular recipient

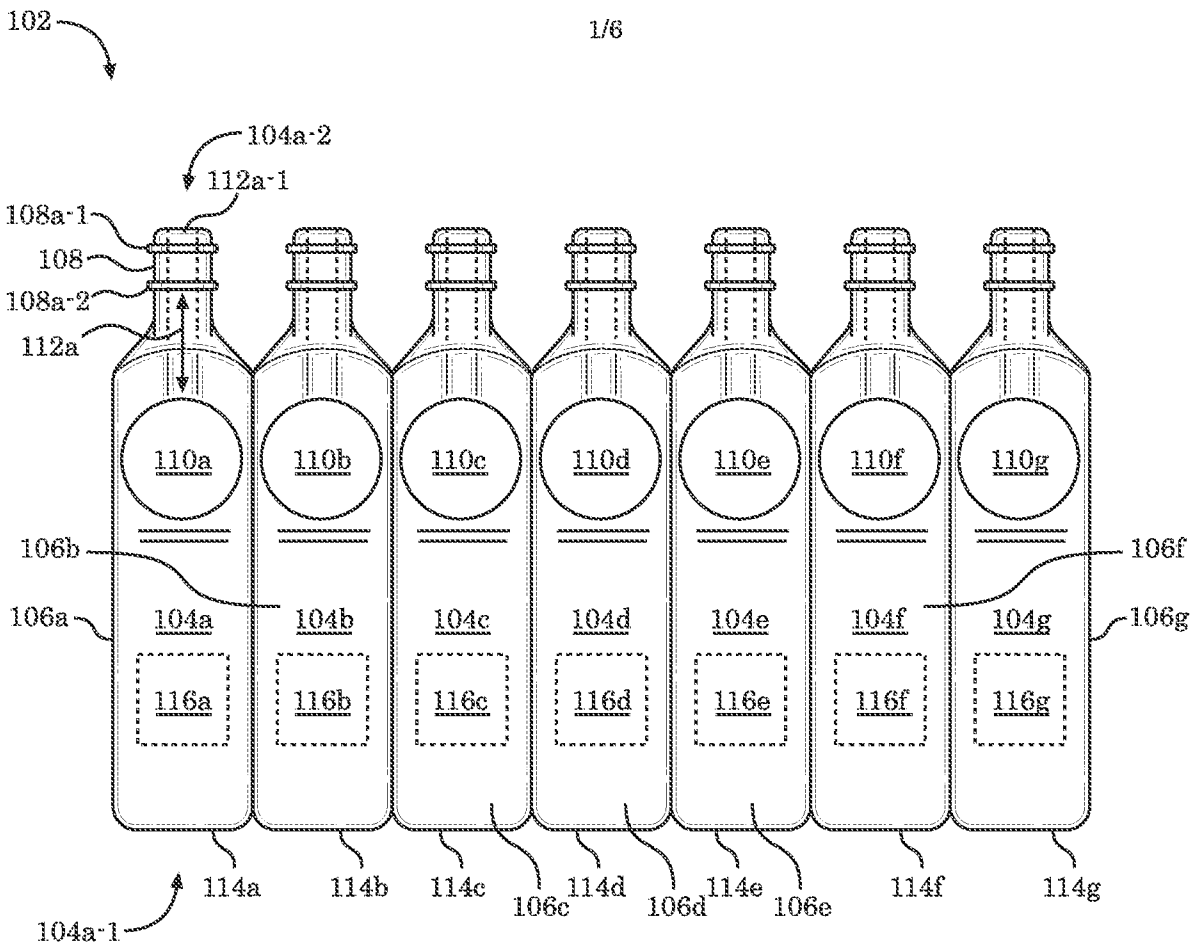


FIG. 1

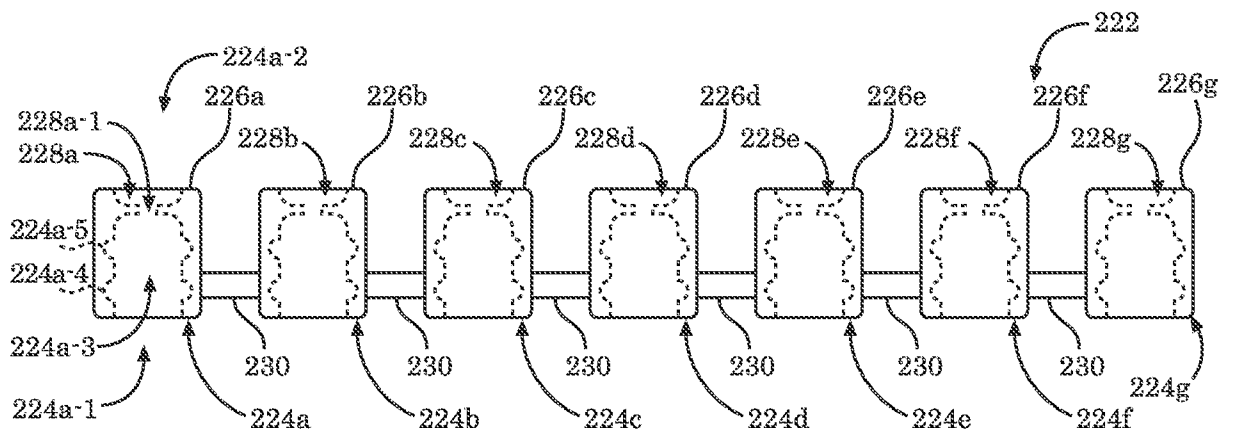


FIG. 2

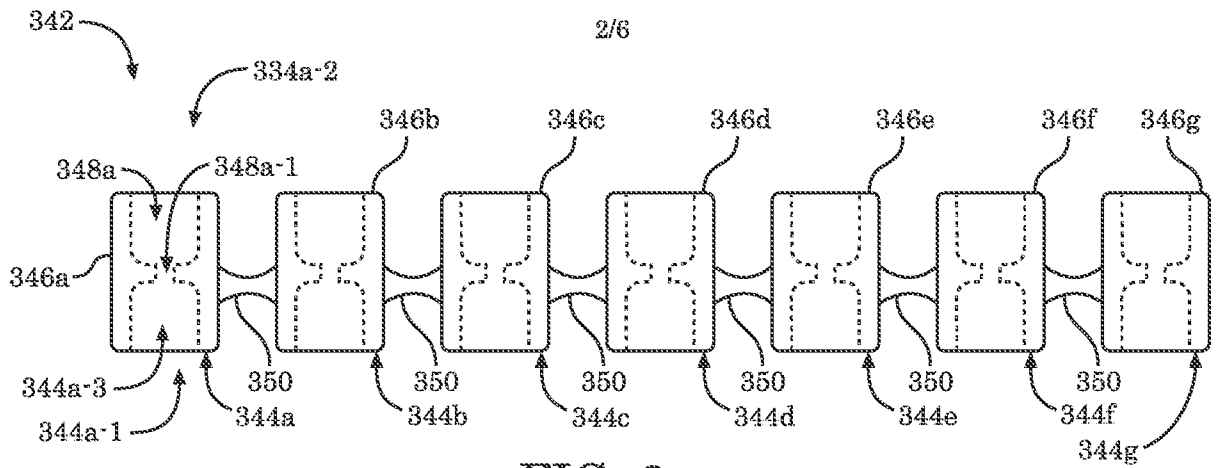


FIG. 3

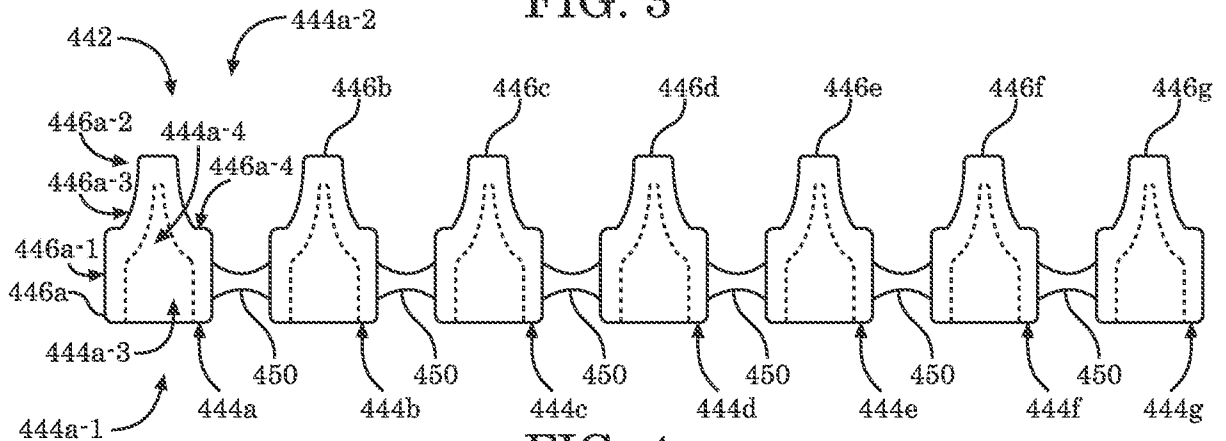


FIG. 4

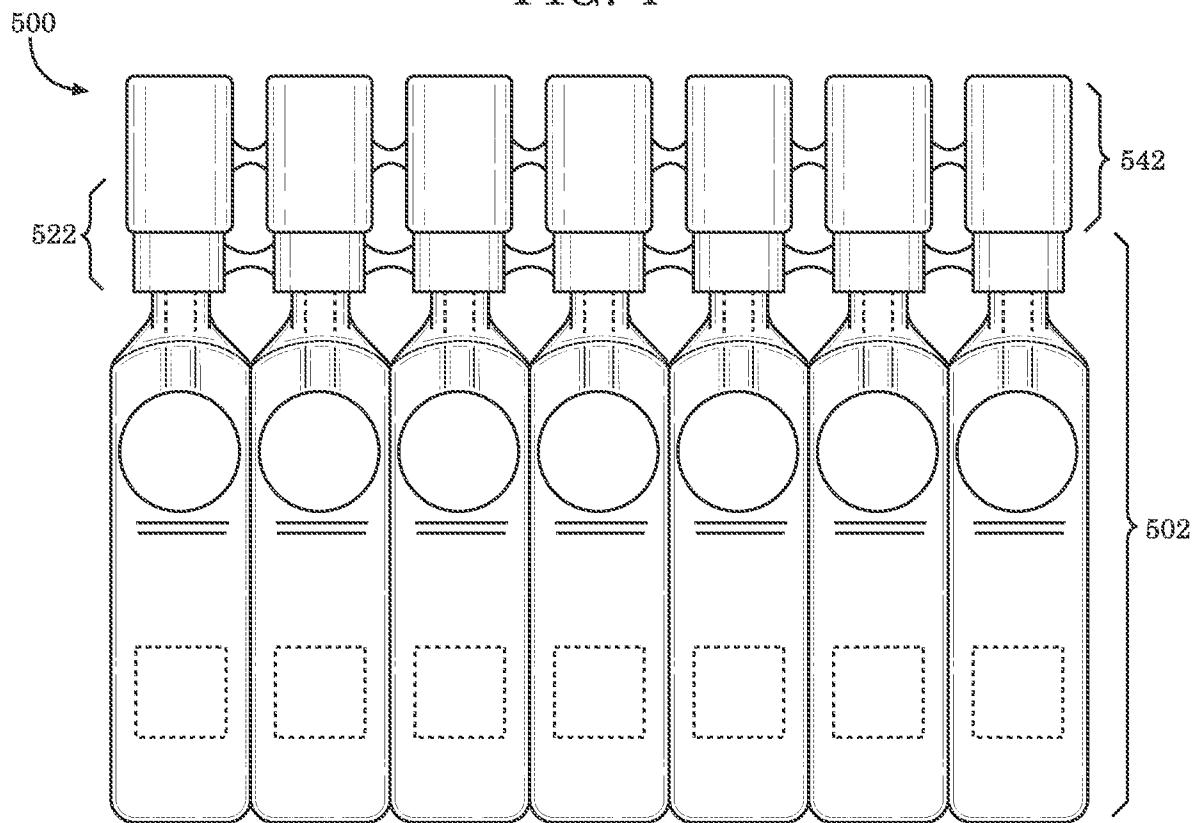
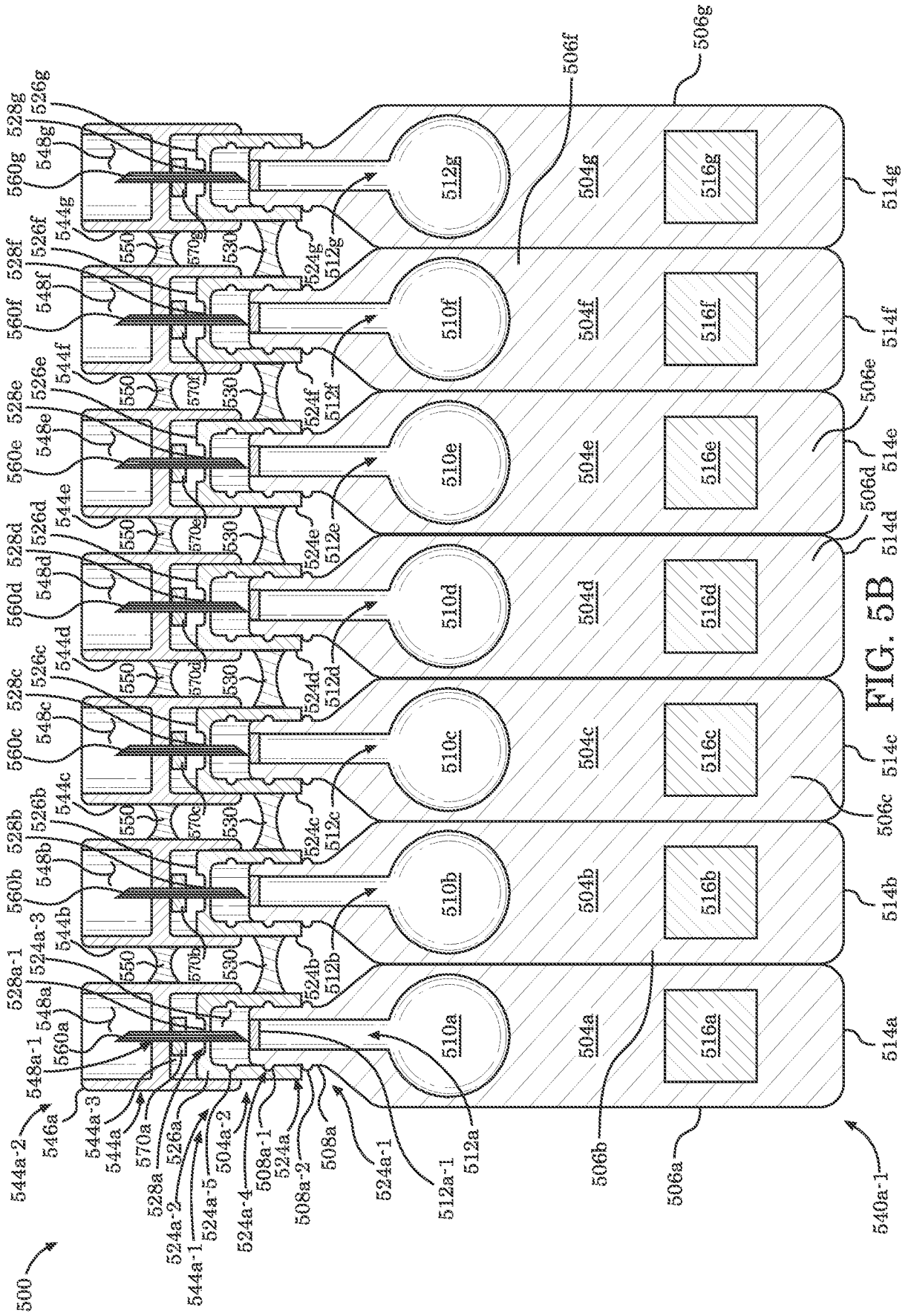


FIG. 5A



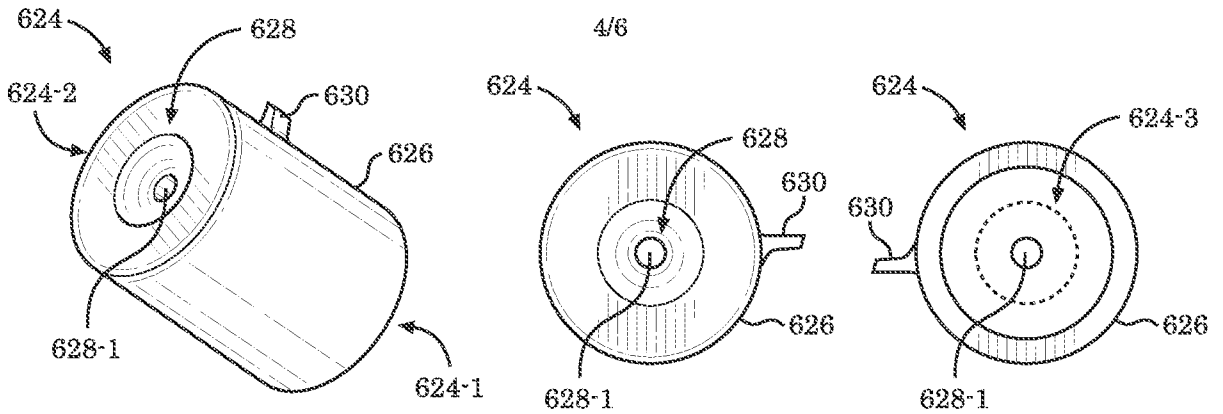


FIG. 6A

FIG. 6B

FIG. 6C

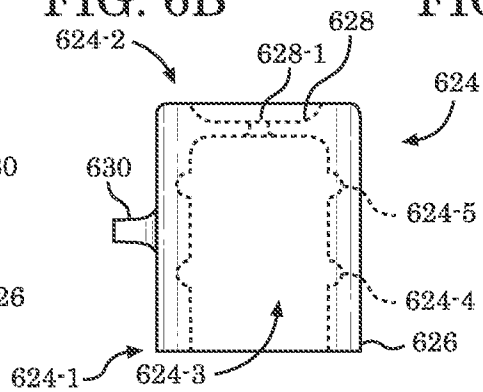
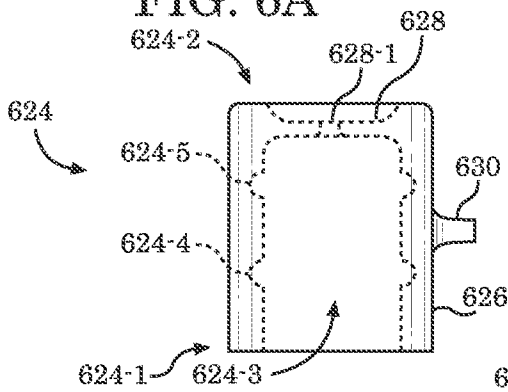


FIG. 6D

FIG. 6E

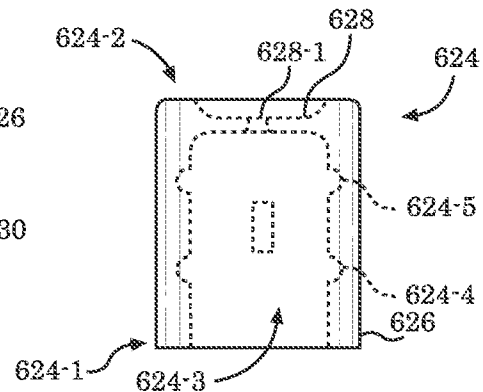
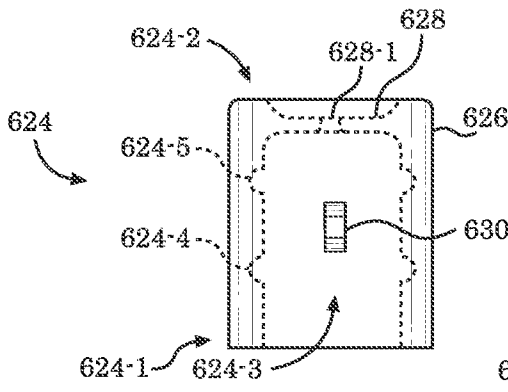


FIG. 6F

FIG. 6G

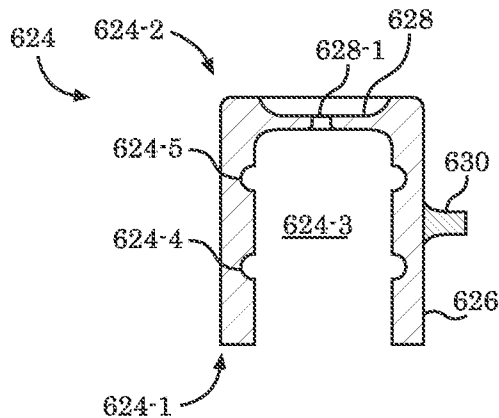


FIG. 6H

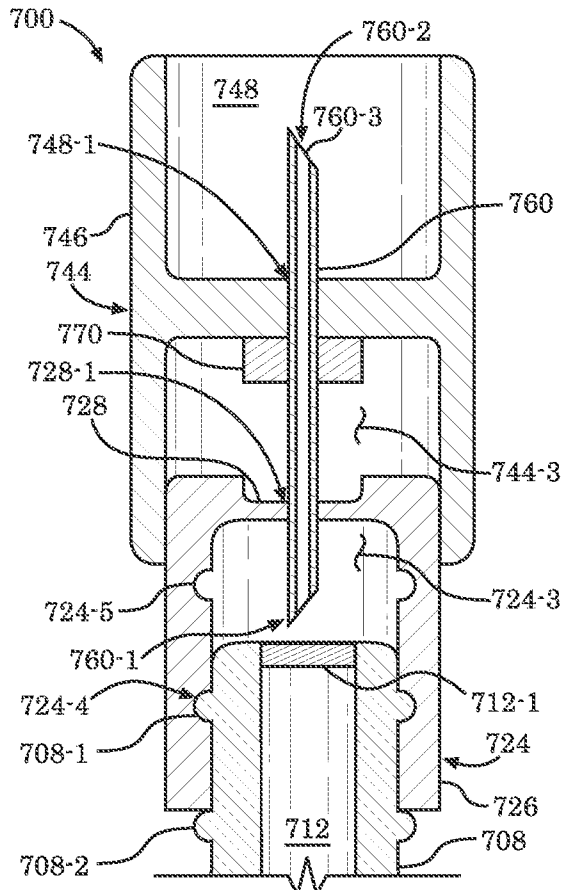


FIG. 7A

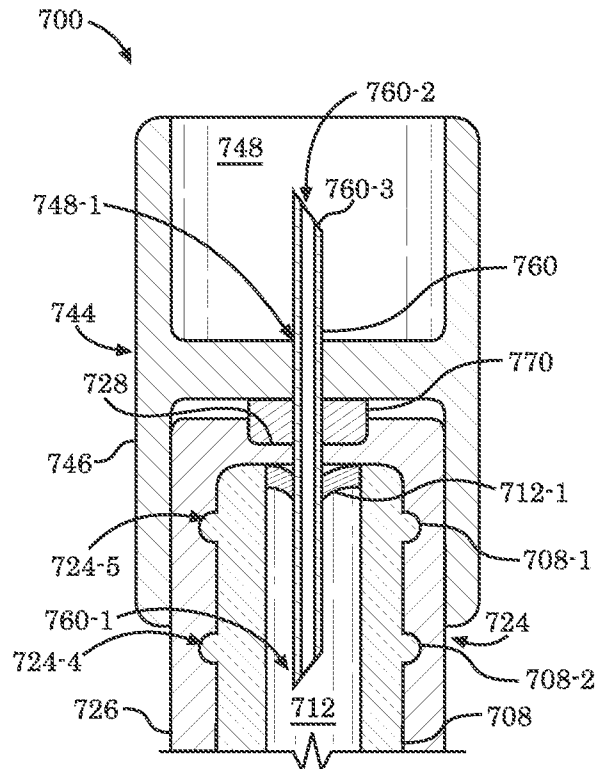


FIG. 7B

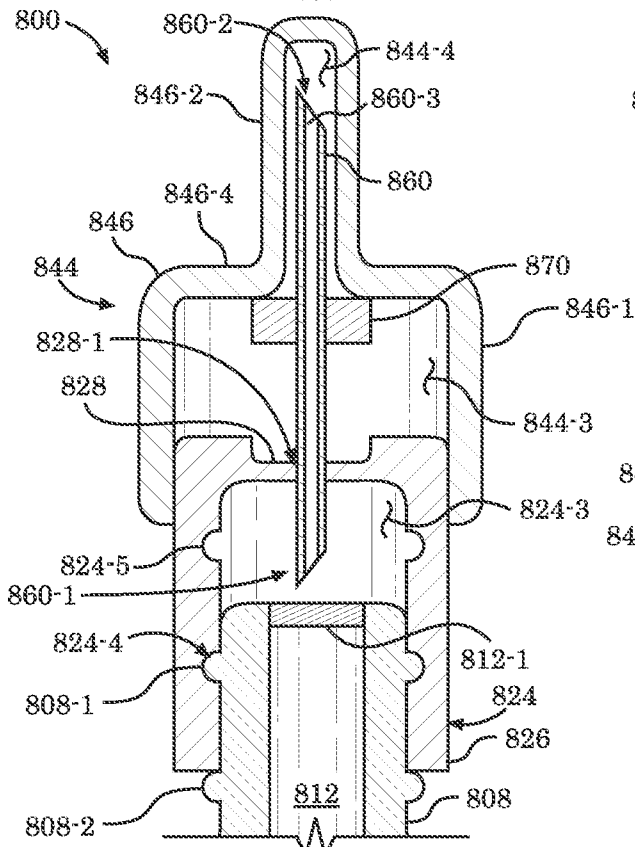


FIG. 8A

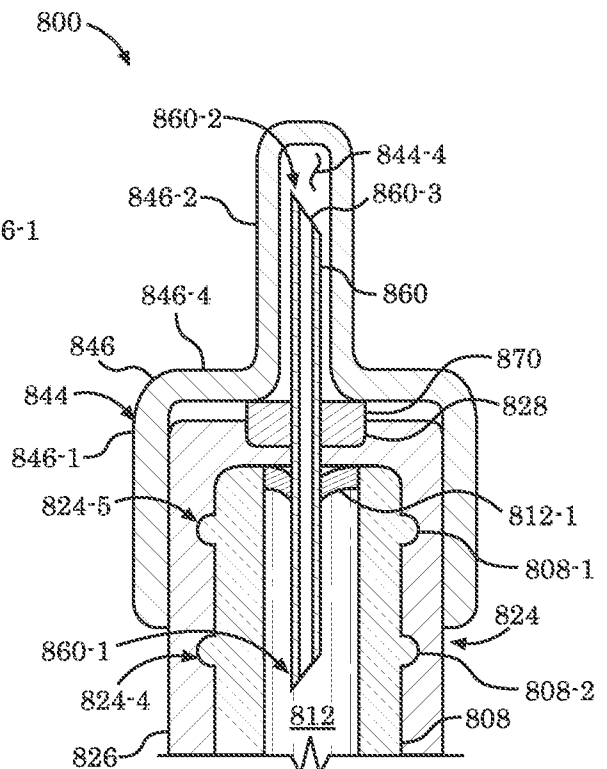


FIG. 8B

900 →

6 / 6

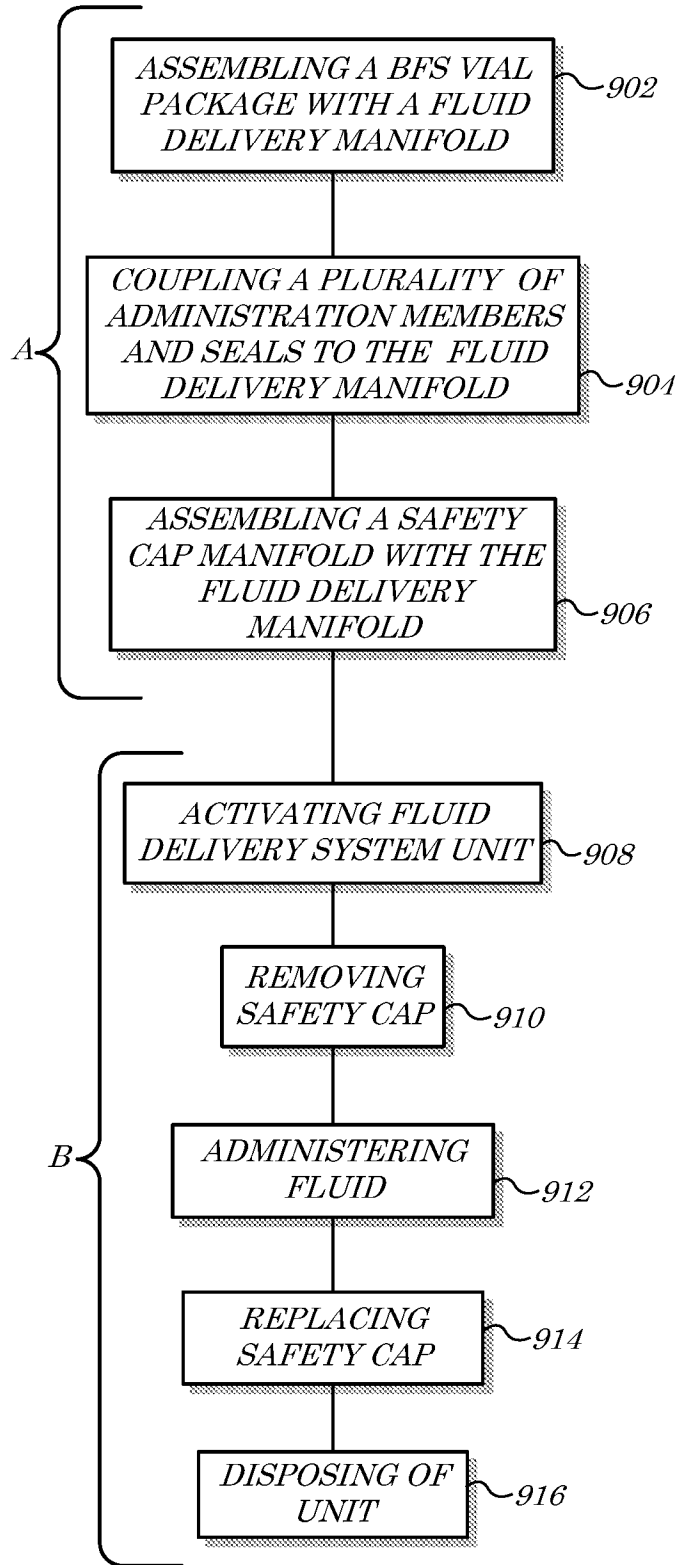


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2018/061696

A. CLASSIFICATION OF SUBJECT MATTER		
<i>A61M 5/19 (2006.01)</i> <i>A61M 5/32 (2006.01)</i> <i>A61J 1/06 (2006.01)</i> <i>A61M 5/28 (2006.01)</i>		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
A61M 5/28, A61J 1/06, B01L 3/02, B29C 49/20, A61M 5/19, 5/32		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
PatSearch (RUPTO Internal), USPTO, PAJ, Espacenet, Information Retrieval System of FIPS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2001/043799 A1 (BIODOME et al.) 21.06.2001, fig. 1, 6-8	1-10
A	US 2011/0224640 A1 (SANOFI-AVENTIS DEUTSCHLAND GMBH) 15.09.2011	1-10
A	WO 1997/010156 A1 (BIODOME et al.) 20.03.1997	1-10
A	WO 1998/025660 A1 (KIM HAN WOOK et al.) 18.06.1998	1-10
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search		Date of mailing of the international search report
14 February 2019 (14.02.2019)		07 March 2019 (07.03.2019)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37		Authorized officer R. Fedorova Telephone No. 8(495) 531-64-81