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SYSTEMS AND METHODS FOR PRE-FILLED MEDICAL DELIVERY ASSEMBLIES

Abstract

A pre-filled medical delivery assembly comprising a blow-fill-seal (BFS) bottle with a collapsible reservoir, a neck portion, and a side flange, an administration assembly comprising a collar with a mounting socket with an interior seat into which the neck portion is axially inserted, a needle hub coupled to a double-ended needle comprising a piercing end within the mounting socket and an administration end. A needle shield covers the needle after use and includes a shield base, a shield element, and a hinge flexibly connecting the shield base and the shield. The shield base further comprises at least one circumferential notch that couples to at least one side flange of the BFS bottle.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a Continuation Application of PCT Application No. PCT/US22/40006, filed Aug. 10, 2022 in the name of Price et al. and titled SYSTEMS AND METHODS FOR PRE-FILLED MEDICAL DELIVERY ASSEMBLIES, which PCT Application claims benefit and priority under 35 U.S.C. § 119 (e) to, and is a Non-provisional of, U.S. Provisional Patent Application No. 63/231,688 filed on Aug. 10, 2021 and titled “SYSTEMS AND METHODS FOR PRE-FILLED MEDICAL DELIVERY ASSEMBLIES”. Each of these Applications is hereby incorporated by reference herein in its entirety and for all purposes.

BACKGROUND

[0002] Applicant has previously developed various single-use, single-dose, pre-filled and/or disposable medical injection devices and systems, such as ones utilizing a fluid container manufactured in accordance with a Blow-Fill-Seal (BFS) manufacturing process and mated to one or more components comprising an administration member for injecting a fluid (e.g., a pharmacological agent) from the BFS container into a patient. Applicant's U.S. patent application Ser. No. 17/849,780 titled SYSTEMS AND METHODS FOR FLUID DELIVERY is one example of some embodiments of such injection devices and systems. Such injection devices and systems may benefit from certain safety features (e.g., a needle shield) to prevent or minimize sharps injury. Applicant has previously described some embodiments of such safety features in PCT Patent Application No. PCT/US21/042671 titled SYSTEMS AND METHODS FOR PRE-FILLED MEDICAL DELIVERY ASSEMBLIES. Additional benefits may be achieved by providing additional or alternate safety features for such injection devices.

SUMMARY

[0003] In one embodiment, a pre-filled medical delivery assembly has a blow-fill-seal (BFS) bottle with a collapsible reservoir, a neck portion, and a mounting flange formed on the neck portion, a needle hub having a collar with a mounting socket with an interior seat into which the mounting flange is axially mated, and a double-ended needle attached to the needle hub with a piercing end within the mounting socket and an administration end. A cap is removably attached to the needle hub and covers the administration end of the needle. A needle shield covers the needle after use and includes a shield base, a shield element, and a hinge flexibly connecting the shield base and the shield. The needle hub further comprises a fully seated position on the pre-filled medical delivery assembly which causes the piercing end of the double-ended needle to pierce a seal of the BFS bottle.

[0004] In another embodiment, a medical administration assembly includes a collar having a first end defining a mounting socket comprising an interior seat operable to accept an exterior flange of a blow-fill-seal (BFS) bottle that is axially mated, and a second end defining a hub socket having internal threads. A needle hub includes at least one thread cooperatively mated with the external threads of the collar to a first degree of advancement and is coupled to a double-ended needle disposed through the needle hub. A cap covers an administration end of the needle and includes an interior key to drive the needle hub to advance the at least one external thread of the needle hub to a second degree of advancement with respect to the internal threads of the hub socket of the collar. A needle shield covers the administration end of the needle after use and includes a shield base coupled to the medical administration assembly, a shield element, and a hinge element flexibly connecting the shield base and the shield element. Advancement of the threads to the second degree of advancement causes a piercing end of the double-ended needle to pierce a seal of the collar.

Description

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:

[0006] FIG. 1A, FIG. 1B, FIG. 1C, FIG. 1D, FIG. 1E, and FIG. 1F are various views of a needle shield for a pre-filled medical delivery assembly according to some embodiments;

[0007] FIG. 2A, FIG. 2B, FIG. 2C, FIG. 2D, FIG. 2E, and FIG. 2F are various views of the needle shield for a pre-filled medical delivery assembly coupling according to some embodiments; and

[0008] FIG. 3A and FIG. 3B are various views of a pre-filled medical delivery assembly according to some embodiments.

DETAILED DESCRIPTION

I. Introduction

[0009] Embodiments of the present disclosure provide systems and methods for pre-filled medical delivery assemblies that overcome drawbacks of current delivery devices and methods. For example, the pre-filled medical delivery assemblies of some embodiments may include a Blow-Fill-Seal (BFS) vial or bottle coupled to a specialized collar that facilitates coupling of an administration member (e.g., a needle) to the BFS vial. In some embodiments, such a pre-filled medical delivery assembly may be selectively actuated by application of rotational and/or axial force to a cap covering the administration member, causing the administration member to axially advance and pierce a reservoir of the BFS vial. Utilization of such systems that employ BFS vials may be advantageous and may address various shortcomings of previous systems. In still other embodiments, the collar may be integral with or pre-attached to the administration member before assembling to the BFS vial.

[0010] BFS vials may, for example, offer a less expensive alternative to typical 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., may accordingly be compatible with a wider array of fluids and/or liquids), may provide enhanced production rates of sterile/aseptic units per hour, and/or may be provided to an end-user for significantly lower per dose/unit costs. In some embodiments, these advantages may come with an attendant drawback of reduced manufacturing tolerances and other disadvantages of utilizing a “soft” plastic (e.g., having a Shore/Durometer “D” hardness of between 60 and 70). 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 (Nov. 15, 1989) and/or may not be readily adaptable to form certain mating features such as standardized threads. In some embodiments, these drawbacks and/or the deficiencies of prior systems may be advantageously addressed by specific features, configurations, and/or components as described hereinafter.

[0011] Further, in some embodiments it may be desired to dispose of the cap once removed from the needle before use of the pre-filled medical assembly. In such an embodiment, a separate needle shield may be attached to the pre-filled medical assembly and rotated, flipped, and/or otherwise engaged with or on to the needle (e.g., from the side) after use to cover the needle in preparation for disposal.

II. Pre-Filled Medical Delivery Assemblies-Needle Shield Attached to Mounting Collar

[0012] Referring initially to FIG. 1A, FIG. 1B, FIG. 1C, FIG. 1D, FIG. 1E, and FIG. 1F, various views of a pre-filled medical delivery assembly **100** according to some embodiments are shown. In

some embodiments, the pre-filled medical delivery assembly **100** may comprise various inter-connected and/or modular components such as a BFS vial **110** comprising and/or defining a vial neck **112**, a seal **114**, a mounting flange **116**, a vial flange **118**, a collapsible reservoir **120**, a dispensing reservoir **122**, and/or an identification area **124**. According to some embodiments, the pre-filled medical delivery assembly **100** may comprise an administration (e.g., injection) module or component **130** that is manufactured, assembled, and/or provided as a separate unit from the BFS vial **110**. In some embodiments, the administration component **130** may comprise a mounting collar **132** which itself comprises, is coupled to, and/or defines various features and/or elements. The mounting collar **132** and/or the administration assembly **130** may, for example, be maintained as a closed and/or sterile component via a seal **134** (e.g., a foil, wax, paper, and/or other thin, pierceable, tear-able, and/or removable object or layer coupled to the mounting collar **132** and/or the administration component **130**; not shown) that seals an interior volume or socket (not separately labeled) of the mounting collar **132**, disposed at a first end thereof.

[0013] According to some embodiments, the mounting collar **132** may comprise one or more coupling or mounting features such as one or more axial slits or slots **136**, an internal seat (not shown) that corresponds to and is the inverse of the mounting flange **116** of the BFS vial **110** to mount the collar **132** to the BFS vial **110** in the case that the neck **112** of the BFS vial **110** is inserted into the mounting collar **132** and/or the administration component **130**, a puncture seal **140**, and/or external threads **142**. It should be known that while external threads **142** are depicted in the figures, the mounting collar **132** could comprise internal threads and/or other mating features without deviating from the scope of the disclosure. In some embodiments, the mounting collar **132** may comprise and/or define an exterior flange **144** (e.g., a radial flange) that is operable to receive, mate with, and/or otherwise engage with a needle hub **150**. The mounting collar **132** may include the slot(s) **136** on at least one side. The slot(s) **136** fits over and receives the vial flange **118**, preventing the mounting collar **132** from rotating on the BFS vial **110** once attached. In some embodiments, the BFS vial **110** includes two vial flanges **118** on either side of the BFS vial **110** (as depicted), and the mounting collar **132** includes two slots **136** on opposite sides to receive two bottle or vial flanges **118** (e.g., terminal portions thereof; also as depicted).

[0014] In some embodiments, the needle hub **150** may couple to the mounting collar **132** via internal threads (within the needle hub **150**, not shown) thereof that correspond to and/or mate with the threads **142** of the mounting collar **132**. It should be known that while internal threads on the needle hub are described, the needle hub **150** may comprise external threads and/or other mating features that mate with internal threads and/or other corresponding mating features of the mounting collar **132** without deviating from the scope of the disclosure. According to some embodiments, the needle hub **150** may comprise, couple to and/or house a needle, canula, and/or other administration member **170**, and/or a cap **180** (e.g., selectively engaged and/or coupled to the needle hub **150** to shroud, house, and/or protect the administration member **170**). According to some embodiments, the pre-filled medical delivery assembly **100** may include a modular design consisting of separately constructed components **110**, **132**, **150**, **170**, **180** cooperatively arranged and coupled to one another.

[0015] In some embodiments, the collapsible reservoir **120** may be filled (fully or partially) with a fluid such as a liquid or other agent (not separately shown) to be delivered, e.g., to a patient (not shown). According to some embodiments, the liquid may be injected into the BFS vial **110** in a sterile environment during manufacture via a BFS process and sealed within the BFS vial **110** via the seal **114**. The seal **114** may comprise a portion of the molded BFS vial **110** for example that is configured to be pierced to expel the liquid, e.g., such as by providing a flat or planar piercing surface and/or by being oriented normal to an axis of the BFS vial **110** (and/or the pre-filled medical delivery assembly **100**). In some embodiments, the seal **114** may comprise a foil, wax, paper, and/or other thin, pierceable object or layer coupled to the BFS vial **110**. In some embodiments, the neck **112** of the BFS vial **110** may comprise the mounting flange **116** such as,

e.g., the “doughnut”-shaped exterior flange depicted. The mounting flange **116** may, for example, provide a radially elastic mating surface that is operable to provide a selective engagement or fit within the socket of the administration component **130**.

[0016] In some embodiments, the administration assembly **130** may include a needle shield **200**. The needle shield **200** may include an attachment base **220**, which may comprise a ring-shaped, annular, or “c”-clamp style base that fits around the mounting collar **132**, but may be any shape to fit around any element of the pre-filled medical delivery assembly **100** such as the BFS bottle **110**. In an embodiment, the attachment base **220** includes a flexible locking tab **222** that corresponds to the slot **136** of the mounting collar **132**. As depicted in the section view of FIG. **1D**, the flexible locking tab **222** fits into a space between the top of the vial flange **118** and the top of the slot **136**. The flexible locking tab **222** may be angled such that in use, as the attachment base **220** is slid over the mounting collar **132** and the flexible locking tab **222** is urged outwardly toward the body of the attachment base **220** and minimizes resistance to the sliding movement. Once the flexible locking tab **222** passes the top of the slot **136**, it is urged (e.g., by inherent and/or elastic spring and/or otherwise inward radial force) toward the space within the slot **136**. According to some embodiments, an interior diameter of the base **220** is less than the width of the bottle flange **118**, preventing the attachment base **220** from sliding past the vial flange **118** (up in the orientation of the view of FIG. **1D**). If urged in the opposite direction (down in the orientation of FIG. **1D**), a tip of the locking tab **222** may interfere with a slot surface **136-1** at the base of the slot **136** and prevent the attachment base **220** from being removed in a direction away from the BFS vial **110**. [0017] In still other embodiments, the attachment base **220** may be located on the mounting collar **132** and held in place by the needle hub **150**. The attachment base **220** may fit over the threads **142** of the mounting collar **132** and register against the flange **144** of the mounting collar **132**. The needle hub **150** may then attach to the mounting collar **132** and capture the attachment base **220** between a bottom portion of the needle hub **150** and the flange **144**.

[0018] According to some embodiments, a hinge **218** of the needle shield **200** may comprise a thin, flexible hinge that is the same material as the base **220** and a shield element **224**, and may be molded with and/or integral to the needle shield **200**. This is typically referred to as a “living hinge”, and allows the rigid base **220** and shield element **224** to rotate with respect to one another with minimal friction and wear. The living hinge **218** may be described as a purposeful fault line at a predetermined point in the material such that the needle shield **200** doesn't fail after repeated bending between shipping, administration, and covering positions (described below). Molding a living hinge **218** with, between, and/or connecting the attachment base **220** and the shield element **224** of the needle shield **200** reduces manufacturing complexity and assembly tolerance stacks that could lead to mismatches between the needle shield **200** and the administration member **170**. Typical types of living hinges include a straight or flat living hinge which is simply a straight, thin portion of the material that provides a convenient area for hinging action, a butterfly living hinge that urges pieces into the open or closed positions, a child safe hinge which includes features designed to make it child resistant, and a double or triple living hinge which include multiple portions of a hinge all working together. The living hinge **218** allows the shield element **224** to fold in an infinite number of positions in about one hundred and eighty (180) degrees with respect to the administration assembly **130**. This freedom of placement of the shield element **224** allows the administration assembly **130** to be placed in a shipping position such that the administration assembly may be packaged and shipped in the most convenient and efficient way possible, an administration position whereby the needle shield is conveniently located to allow the administration of the fluid, and a covering position whereby the administration element **170** is captured within the locating/restraining elements **202** and **204**, all without the hinge **218** failing and keeping the shield **224** located correctly. While the hinge **118** is depicted as a living hinge, other types, configurations, and/or quantities of hinges may be utilized in some embodiments.

[0019] According to some embodiments, the fluid (e.g., a liquid) in the BFS vial **110** may pass

between the collapsible reservoir **120** and a connected dispensing reservoir **122**. In some embodiments, a juncture, valve, and/or passage (not separately labeled) between the dispensing reservoir **122** and the collapsible reservoir **120** may restrict flow such that the liquid may readily enter one of the dispensing reservoir **122** and the collapsible reservoir **120** but may not readily return to the other reservoir **120**, **122**. Such a constriction may in some embodiments, provide various advantages in fluid retention and/or administration. In some embodiments, the constriction may not be necessary or desirable, such as in the case that the collapsible reservoir **120** and the dispensing reservoir **122** are formed and/or combined as a single, unobstructed reservoir, e.g., a single reservoir (not shown).

[0020] In some embodiments, the pre-filled medical delivery assembly **100** may include a modular design consisting of separately constructed components **110**, **130** cooperatively arranged and coupled to one another. As depicted in FIG. **1C**, for example, the BFS vial **110** and the administration component **130** may be manufactured, packaged, shipped, stored, and/or provided as separate components. In such a manner, the administration component **130** may not need to be stored or shipped in accordance with often restrictive requirements imposed on medicaments and may accordingly reduce the amount of space required for such specialized storage and/or shipping. The administration component **130** may also or alternatively be manufactured, stored, and/or shipped in advance (e.g., at a first time) while the BFS vial **110** that is pre-filled with the liquid may be manufactured, stored, and/or shipped at a later time (e.g., a second time). In some embodiments, the delay between the first time and the second time may be lengthy without causing determinantal effects, as the administration component **130** may be stored, in some embodiments, indefinitely. In such a manner, units of the administration component **130** may be provided to be on-hand in advance of the availability and/or arrival of the BFS vial **110**, reducing supply chain constraints in the case of proactive administration component **130** procurement.

[0021] According to some embodiments, the components **110**, **130** may be coupled, e.g., in the field and/or in situ, to provide an active pre-filled (e.g., injectable) medical delivery device or may be coupled during an automated and/or remote assembly process. The BFS vial **110** and the administration component **130** may be provided as separate units that are coupled together by a user that administers an injection to a patient, for example, or may be pre-assembled and/or coupled to reduce the number of administration steps required for the administration user (e.g., nurse, doctor, patient, etc.). According to some embodiments, the administration component **130** (and/or the mounting collar **132** thereof) may be axially engaged to couple with the BFS vial **110** via application of a mating axial force. The administration component **130** (and/or the mounting collar **132** thereof) may be urged onto the neck **112** of the BFS vial **110**, for example, such that the cooperatively shaped internal seat (e.g., an interior groove or channel) accepts the mounting flange **116**, thereby removably coupling the BFS vial **110** and the administration component **130** (and/or the mounting collar **132** thereof). In some embodiments, the internal seat (and/or other interior features) and/or the mounting flange **116** may be shaped such that uncoupling of the BFS vial **110** and the administration component **130** (and/or the mounting collar **132** thereof) is mechanically prohibited. In some embodiments, the mounting flange **116** may be shaped as an axially elongated rounded exterior flange (e.g., the “doughnut” shape as depicted) and/or the internal seat may comprise a cooperative and/or mirrored axially elongated rounded interior groove or track. According to some embodiments, the one or more slots **136** such as the mirrored axial slits depicted may engage with the vial flange **118** (and/or portions of the BFS vial **110**) such that rotation of the administration component **130** (and/or the mounting collar **132** thereof) with respect to the BFS vial **110** is restricted in the case that they are coupled.

[0022] In some embodiments the neck **112** of the BFS vial **110** may be urged and/or forced into the socket of the mounting collar **132** until the mounting flange **116** becomes seated in (and/or coupled to or mated with) the internal seat (e.g., a seated position). In such a manner, the seal **114** may be advantageously positioned adjacent to the puncture seal **140**. According to some embodiments, the

mounting flange **116** may be configured as the doughnut shape (as depicted) to provide various advantages to the pre-filled medical delivery assembly **100**. The axial elongation of the mounting flange **116** may, for example, provide for a smooth, uniform, and/or less forceful mating process that is less likely to deform the soft plastic neck **112** of the BFS vial **110** and/or may provide for a lengthened mating surface that is more likely to prevent leakage of the liquid. In some embodiments, the mounting flange **116** and the cooperatively shaped and sized internal seat (not shown) may permit simple, effective, and/or economic attachment of the administration component **130** to the BFS vial **110**.

[0023] In some embodiments, the BFS vial **110** and the administration component **130** (and/or the mounting collar **132** thereof) may be axially mated and/or otherwise coupled without utilization of the mounting flange **116**. The mounting flange **116** may, for example, not be included or may not be utilized. According to some embodiments, the mating may be effectuated, as depicted in FIG. **1E**, be seating and/or engagement of the vial flange **118** within the slot **136**. In some embodiments a single slot **136** and vial flange **118** coupling may be utilized, a pair of slots **136** and vial flange **118** couplings (as depicted) may be utilized, or more slots **136** and vial flange **118** couplings may be utilized (e.g., three (3) or more). In some embodiments, the coupling/mating of the slot(s) **136** and vial flange(s) **118** may comprise an interference, tapered, elastic deformation, and/or other fit that securely (and/or removably) couples the BFS vial **110** and the administration component **130** (and/or the mounting collar **132** thereof)—e.g., whether or not the mounting flange **116** is present and/or utilized.

[0024] In some embodiments, the needle hub **150** may be coupled to the mounting collar **132** via engagement of the external threads **142** of the mounting collar **132** with the internal threads of the needle hub **150** (and/or otherwise coupled and/or mated). In some embodiments, the internal threads may correspond and cooperate with the external threads **142** such that they may be rotationally and/or removably coupled. According to some embodiments, the administration component **130** may be provided with the mounting collar **132** and the needle hub **150** partially engaged (e.g., with the threads being partially coupled). In some embodiments, the partial engagement (or first engagement state) may cause the administration member **170** (e.g., a second or proximal end thereof) to be positioned adjacent to (and/or in contact with) the puncture seal **140** of the mounting collar **132**. In such a first engagement state, the administration component **130** may be coupled to the BFS vial **110**, but the BFS vial **110** (and/or the puncture seal **140**) have not yet been punctured and/or breached by the administration member **170**. In some embodiments, such as in the case that the mating of the BFS vial **110** and the administration component **130** (and/or the mounting collar **132** thereof) is effectuated between the slot(s) **136** and vial flange(s) **118**, the slot(s) **136** and vial flange(s) **118** may comprise one or more indexing and/or staging features (e.g., tabs, depressions, protrusions, shaped features, etc.) that provide for the multiple axial engagement states.

[0025] According to some embodiments the needle hub **150** may couple to and/or retain the administration member **170**. The administration member **170** may be inserted into and/or through the needle hub **150**, for example, such that it comprises a first or administration end extending axially distal from the BFS vial **110** and a second or piercing end disposed within the needle hub **150**. In some embodiments, the administration end and/or a distal portion of the administration member **170** may be housed, shrouded, and/or covered by the cap **180**. According to some embodiments, the cap **180** may be configured to house the administration member **170** and to removably couple to the mounting collar **132** (e.g., by fitting over an external portion thereof and/or by engaging with the external flange **144**).

[0026] According to some embodiments, the mounting collar **132** and needle hub **150** combination may be utilized to couple and/or mate the administration member **170** with the BFS vial **110** to provide a mechanism via which the administration member **170** may be coupled to the soft plastic BFS vial **110** in a reliable manner. Due to the nature of the BFS plastic and/or process and/or the

small form-factor of the BFS vial **110**, for example, providing standard external threads (not shown) directly on the neck **112** may not be a viable option for it would result in an imprecise, unreliable, and/or non-water tight coupling (i.e., the threads would be deformable even if they could be properly manufactured to within the desired tolerances, which itself is not a likely result) between the BFS vial **110** and, e.g., the needle hub **150**.

[0027] In some embodiments, the administration member **170** may include a needle shaped and/or sized for at least one of subcutaneous, intramuscular, intradermal, and intravenous injection of the liquid agent into the patient. For ease of explanation and description, the figures and the description herein generally refer to the administration member **170** as a needle or canula. However, it should be noted that, in other embodiments, the administration member **170** may include a nozzle (not shown) configured to control administration of the liquid agent to the patient. The nozzle may include a spray nozzle, for example, configured to facilitate dispersion of the liquid agent into a spray. Accordingly, a needle hub **150** fitted with a spray nozzle may be particularly useful in the administration of a liquid agent into the nasal passage, for example, or other parts of the body that benefit from a spray application (e.g., ear canal, other orifices). In other embodiments, the nozzle may be configured to facilitate formation of droplets of the liquid agent. Thus, a needle hub **150** including a droplet nozzle may be useful in the administration of a liquid agent by way of droplets, such as administration to the eyes, topical administration, and the like.

[0028] As generally understood, the liquid or drug (e.g., stored in the BFS vial **110** and/or one or more of the reservoirs **120**, **122** thereof) agent may include any type of agent to be injected into a patient (e.g., animal such as a mammal, either human or non-human) and capable of producing an effect (alone, or in combination with an active ingredient). Accordingly, the agent may include, but is not limited to, a vaccine, a drug, a therapeutic agent, a medicament, a diluent, and/or the like. According to some embodiment, either or both of the liquid agent and the active ingredient (i.e., the drug agent and/or components thereof) may be tracked, monitored, checked for compatibility with each other, etc., such as by utilization of electronic data storage devices (not shown) coupled to the various modules or components such as the BFS vial **110** (e.g., at, on, or in the identification area **124**) and/or the administration component **130**.

[0029] According to some embodiments, the mounting collar **132**, the needle hub **150**, the needle shield **200**, and/or the cap **180** may be composed of a medical grade material. In some embodiments, the mounting collar **132**, the needle hub **150**, the needle shield **220**, and/or the cap **180**, may be composed of a thermoplastic polymer or other “hard” plastic (e.g., greater than 80 on the Rockwell “R” scale), including, but not limited to, polybenzimidazole, acrylonitrile butadiene styrene (ABS), polystyrene, polyvinyl chloride, or the like. In some embodiments, the pre-filled medical delivery assembly **100** may be advantageously manufactured (in mass quantities) in separate parts or portions, namely, at least the “soft” plastic BFS vial **110** portion (e.g., a “first” piece) and the “hard” plastic administration component **130** (e.g., the “second” piece), with such different plastic parts/portions being selectively coupled to administer a medication to a patient.

[0030] According to some embodiments, the pre-filled medical delivery assembly **100** may be advanced from the first engagement state to a second engagement state where the administration member **170** has pierced the BFS vial **110** and the liquid therein may readily be expressed through the administration member **170** (e.g., and into a patient). The partial engagement of the mounting collar **132** and the needle hub **150** (e.g., with the threads being partially coupled and/or with the slot(s) **136** and vial flange(s) **118** being partially engaged) may, for example, be transitioned to a more advanced, fully, or completely advanced state by application of a rotational (and/or an axial) force to the cap **180**. In some embodiments, the more advanced and/or full engagement may cause the administration member **170** (e.g., the second or proximal end thereof) to advance through the puncture seal **140** of the mounting collar **132** and through the seal **114** of the BFS vial **110**. In such a manner, for example, the continued rotational engagement of the threads (and/or axial engagement of the administration member **170**) may cause the administration member **170** (e.g.,

the second or proximal end thereof) to open a liquid pathway between the BFS vial **110** (e.g., and/or the neck **112**, and/or reservoirs **120**, **122** thereof) and the first or distal end of the administration member **170**. In some embodiments, the cap **180** may be utilized as a rotational and/or axial force driver to transfer rotational force to the needle hub **150** to cause the advancement of the engagement of the threads (and, e.g., the puncturing of the puncture seal **140** and the seal **114** of the BFS vial **110**).

[0031] In some embodiments, the administration component **130** may comprise and/or be coupled to the needle shield **200**. The needle shield **200** may comprise, for example, the shield base **220** that is mounted on and/or around the mounting collar **132** (and/or the neck **112** of the BFS vial **110**).

According to some embodiments, the shield base **220** may comprise and/or be coupled to the hinge element **218** and/or may comprise one or more mounting features **202**, **204**, **206**. The hinge element **218** may flexibly couple the shield base **220** to the shield element **224**, for example, the shield element **224** comprising a molded and/or shaped element configured to be pushed on the side of the shield element **224** to selectively cover the administration member **170**. In some embodiments, the shield element **224** may comprise and/or define a shield volume or space (not separately labeled) that is sized and/or shaped to accept and/or house the administration member **170**. In some embodiments such as depicted in FIG. **1F**, the shield space may comprise, define, and/or house a first mounting feature or needle keeper **202** (e.g., in the case that the administration member **170** comprises a needle and/or canula), a second mounting feature or locating element **204**, and/or a third mounting feature or needle hub keeper **206**. In some embodiments, the needle keeper **202** may comprise and/or define a retention barb **210** and/or a retention space **212** that are configured to accept and/or retain a first or distal end of the administration member **170**. According to some embodiments, the locating element **204** may comprise and/or define locating barbs **214** that engage with a second portion of the administration member **170** such as to guide the administration member **170** to be in alignment with a shield axis **226**. In some embodiments, the needle hub keeper **206** may comprise and/or define a shaped locator element **216** that may, for example, be cooperatively shaped to align a portion of the needle hub **150** with the shield axis **226**. In some embodiments, such as depicted in FIG. **1E**, the needle shield **200** and/or the shield base **220** thereof may comprise and/or define a seat or notch **228** that aligns with, accepts, and/or mates with a portion (e.g., a terminus and/or extent) of the vial flange **118**. In such a manner, for example, the needle shield **200** may be indexed and/or mated with the vial flange **118**, thereby aligning and/or coupling the needle shield **200** with/to the BFS vial **110**. In some embodiments, the shield base **220** may be restrained and/or retained by being sandwiched between the vial flange **118** seated in the notch **228** (which prevents axial movement in a first direction) and the needle hub **250** (that prevents axial movement in a second and opposite direction). According to some embodiments, the pre-filled medical delivery assembly **100** may include a modular design consisting of separately constructed components **110**, **130**, **132**, **150**, **170**, **180**, **200** cooperatively arranged and coupled to one another.

[0032] In some embodiments, fewer or more components **110**, **112**, **114**, **116**, **118**, **120**, **122**, **124**, **130**, **132**, **136**, **140**, **142**, **144**, **150**, **170**, **180**, **200**, **202**, **204**, **206**, **208**, **210**, **212**, **214**, **216**, **218**, **220**, **222**, **224**, **226**, **228** and/or various configurations of the depicted components **110**, **112**, **114**, **116**, **118**, **120**, **122**, **124**, **130**, **132**, **136**, **140**, **142**, **144**, **150**, **170**, **180**, **200**, **202**, **204**, **206**, **208**, **210**, **212**, **214**, **216**, **218**, **220**, **222**, **224**, **226**, **228** may be included in the pre-filled medical delivery assembly **100** without deviating from the scope of embodiments described herein. In some embodiments, the components **110**, **112**, **114**, **116**, **118**, **120**, **122**, **124**, **130**, **132**, **136**, **140**, **142**, **144**, **150**, **170**, **180**, **200**, **202**, **204**, **206**, **208**, **210**, **212**, **214**, **216**, **218**, **220**, **222**, **224**, **226**, **228** may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein. According to some embodiments, the pre-filled medical delivery assembly **100** may comprise the mounting flange **116** but not the collapsible reservoir **120**. In some embodiments, the pre-filled medical delivery assembly **100** may comprise the mounting flange **116** but not the

dispensing reservoir **122**. According to some embodiments, the administration component **130** may be provided without (and/or separately from) the BFS vial **110**. In some embodiments, the puncture seal **140** may not be included and/or the mounting collar **132** and the needle hub **150** may comprise an integrated and/or unitary molded and/or constructed element. In some embodiments, the needle shield **200** may be integrated with the mounting collar **132**, the needle hub **150**, and/or otherwise with the administration component **130**.

[0033] Referring now to FIGS. 2A, 2B, 2C, 2D, 2E, and 2F, in some embodiments, a needle shield **200** may include any or all of three locating/restraining elements **202**, **204**, **206** disposed within and/or formed in a shield element **224** that is coupled to a shield base **220**. A locating/restraining element or retention member **202** may, in some embodiments, be configured to couple to, restrain, and/or accept a canula/needle (not shown). A second locating/restraining element or locating element **204** may comprise a feature that facilitates alignment of the canula/needle within the needle shield **200**. A third locating element **206** may be a coarse locator that includes a half-cylinder locator **216** that fits around the needle hub **150** (e.g., a portion thereof) and ensures that the needle shield **200** is located properly with respect to the length of the canula/needle (e.g., the administration member **170** of FIG. 1C herein) and that a tip **208** fits over the top (e.g., a piercing end or point) of the canula/needle. According to some embodiments, the locating element **204** is located between the locating/restraining elements **202** and **206** and may include a pair of locating barbs **214**. The locating barbs **214** may be centered along a shield axis (not shown; e.g., the shield axis **226** of FIG. 1F herein) to capture an intermediate portion of the canula/needle and locate the needle shield **200** more finely than the locating element **206**. The barbs **214** may be placed and/or configured (e.g., as axial cylindrical elements as shown) such that the canula/needle easily fits within the barbs **214** but requires some force to remove the canula/needle. The retention member **202** may include a retention barb **210** and a retention space **212**. The retention barb **210** may be shaped such that the canula/needle is able to easily slide past the retention barb **210** and into the retention space **212**, but removal of the canula/needle requires more force to push the retention barb **210** back upon itself to open and allow the canula/needle to release from the retention space **212**. According to some embodiments, the needle shield **200** and/or the. In some embodiments, the needle shield **200** and/or the shield base **220** thereof may comprise one or more locking tabs **222** disposed on and/or projecting radially inward from an interior surface of the shield base **220**. According to some embodiments, the needle shield **200** and/or the shield base **220** thereof may comprise and/or define one or more notches **228** disposed and/or formed in a radial circumference of the shield base **220**. In some embodiments, the notch(es) **228** may be radially aligned with the one or more locking tabs **222**.

[0034] In some embodiments, fewer or more components **202**, **204**, **206**, **208**, **210**, **212**, **214**, **216**, **218**, **220**, **222**, **224**, **228** and/or various configurations of the depicted components **202**, **204**, **206**, **208**, **210**, **212**, **214**, **216**, **218**, **220**, **222**, **224**, **228** may be included in the needle shield **200** without deviating from the scope of embodiments described herein. In some embodiments, the components shield base **220** may attach or couple to a BFS bottle (not shown; e.g., the BFS vial **110** of FIG. 1A herein). Some embodiments may include the restraining element **202** but not the locating/restraining elements **204** and **206**. Some embodiments may include the locating/restraining element **204** but not the locating/restraining elements **202** and **206**. In some embodiments, the needle shield **200** is provided as a separate element from an administration component (not shown; e.g., the administration component **130** of FIG. 1A herein) and attaches to a pre-filled medical delivery assembly as a third module thereof. In these embodiments, the BFS bottle and the administration component may be assembled to one another independently, and the needle shield **200** may be coupled to the medical delivery assembly by either sliding the shield base **220** up over the BFS bottle or over the top of a cap thereof, into its coupled position.

[0035] Referring now to FIG. 3A and FIG. 3B, side and partial assembly views of a pre-filled medical delivery assembly **300** according to some embodiments are shown. The pre-filled medical

delivery assembly **300** may comprise similar features and/or configurations and/or may be similar to the other assemblies described herein. The pre-filled medical delivery assembly **300** may comprise and/or define, for example, a BFS vial **310** coupled to an administration assembly **350** (comprising a mounting collar **332** and cap **380**), and/or a needle shield **390**. In some embodiments, the needle shield **390** may comprise and/or define a shield base **392**, a hinge element **392-1**, and/or a shield element **396** (e.g., defining and/or comprising a shield space; not separately labeled). In some embodiments, the shield base **392** may comprise a circular and/or annular ring or collar through which a portion of the BFS vial **310** may pass and/or be mounted. According to some embodiments, the shield base **392** may be sized and/or shaped to snap onto and/or house (i) a neck of the BFS vial **310** (not separately labeled) (ii) a portion of the BFS vial **310** disposed between a compressible chamber of the BFS vial **310** (not separately labeled) and a neck of the BFS vial **310**, and/or (iii) the administration assembly **350**. In some embodiments, the shield base **392** may be sized and/or shaped to snap onto and/or house the mounting collar **332** (e.g., similar to the pre-filled medical delivery assembly **100** and the needle shield **220** of FIG. 1A, FIG. 1B, FIG. 1C, FIG. 1D, FIG. 1E, and FIG. 1F herein).

[0036] In such a manner, for example, the shield base **392** may be selectively and/or removably coupled to the BFS vial **310** and/or the mounting collar **332**. According to some embodiments, the shield base **392** may be coupled to and/or comprise the hinge element **392-1** that may connect and/or link the shield base **392** to the shield element **396**. In such a manner, for example, in the case that the shield base **392** is coupled to and/or mounted on the BFS vial **310** (and/or the mounting collar **332**), the shield element **396**, by virtue of the connection via the hinge element **392-1** may also be coupled to the BFS vial **310**. The hinge element **392-1** may comprise any type, configuration, and/or quantity of hinge and/or elastic connector between the shield base **392** and the shield element **396** that permits the shield base **392** and the shield element **396** to be selectively positioned in a plurality of different orientations with respect to each other. In the case where the hinge element **392-1** comprises a pin and socket hinge (e.g., as shown), for example, the hinge element **392-1** may comprise a first pin and/or socket attached to (and/or integral to) the respective shield base **392** and a second and corresponding socket and/or pin attached to (and/or integral to) the shield element **396** and may permit repositioning about one or more of such elements (e.g., about an axis of connection thereof; not separately labeled).

[0037] According to some embodiments, the shield base **392** may be integrated with (or into) the mounting collar **332**. The mounting collar **332** may, for example, comprise and/or define the hinge element **392-1** that rotatably couples to the shield element **396**. In some embodiments, the shield base **392** may comprise and/or define one or mounting features (e.g., tabs, sockets, projections, detents, apertures, etc.; not separately labeled) that are configured to mate with corresponding mounting features (not shown) of one or more of the BFS vial **310** and the mounting collar **332**.

[0038] In some embodiments, the coupling of the BFS vial **310** and the administration assembly **350** (and/or the mounting collar **332** thereof) may be configured to explicitly permit free rotation (e.g., about a common axis) of the BFS vial **310** with respect to the administration assembly **350** (and/or the mounting collar **332** thereof).

[0039] In some embodiments, fewer or more components **310**, **332**, **350**, **380**, **390**, **392**, **392-1**, **396** and/or various configurations of the depicted components **310**, **332**, **350**, **380**, **390**, **392**, **392-1**, **396** may be included in the pre-filled medical delivery assembly **300** without deviating from the scope of embodiments described herein. In some embodiments, the components **310**, **332**, **350**, **380**, **390**, **392**, **392-1**, **396** may be similar in configuration and/or functionality to similarly named and/or numbered components as described herein.

III. Pre-filled Medical Delivery Methods

[0040] In some embodiments, various methods and/or processes may be performed and/or implemented to utilize a BFS vial and/or bottle filled with a single dose of medicament to administer the single dose to a patient/target. In some embodiments, a method may cause a BFS

vial to be coupled to an administration component that is engaged to puncture the BFS vial and then may be utilized to inject (or otherwise administer) the medicament to the patient/target. The methods and/or processes (and/or diagrams and/or flow diagrams thereof) 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.

[0041] In practice, for example, some or all of the following procedures may be followed to utilize a pre-filled medical delivery assembly to administer a medication (and/or other liquid) to a patient/target. In some embodiments, the area of injection may be cleaned and/or otherwise prepared. A neck and/or a seal of the BFS vial (e.g., a “first” part and/or component) may be cleaned (e.g., utilizing an alcohol wipe) to prepare the BFS vial for coupling to an administration component and/or assembly. In some embodiments, a “second” part and/or component comprising a pre-packaged mounting collar/coupling, needle hub (with an administration member), cap, and/or needle shield may comprise a seal that maintains an internal volume/liquid passage in a sterile state and the seal may be removed to prepare for the coupling to the BFS vial. According to some embodiments, the administration assembly may be axially aligned with the neck of the BFS vial and the neck may be inserted into the mounting collar and/or through a base member of the needle shield to engage a mounting flange with a cooperatively shaped interior mating feature. According to some embodiments, the administration component (and/or the mounting collar and/or the needle shield thereof) may “click” or snap onto the BFS vial.

[0042] According to some embodiments, the needle hub may, as a component of a pre-packaged “second” part/administration assembly for example, be only partially engaged with (e.g., partially threaded onto) the mounting collar. Only a portion of the threads may be engaged, for example, such that the “second” part is at least loosely or partially coupled as a single object/assembly but the administration member is not advanced axially enough to pierce the BFS vial in the case that the “second” part/assembly is mated with the BFS vial. In such a manner, for example, a user may couple the “first” and “second” parts and then selectively engage the administration member to puncture the BFS vial (e.g., by application of rotational force to advance the threads/mating thereof and/or by application of axial force that causes the administration member to pierce the BFS vial).

[0043] In some embodiments, a user may hold the mounting collar with one hand/fingers and thread (e.g., continue threading) the needle hub fully into the mounting collar by applying rotational force to the cap. The cap may comprise an internal key that engages with the one or more stop and/or drive features of the needle hub, for example, to transfer the rotational force to the needle hub and accordingly advance the mating of the threads. As the threading/mating advances, a second or piercing end of the administration member may be axially advanced to pierce through the mounting collar (e.g., a seal portion thereof) and/or through the seal of the BFS vial, thereby activating the pre-filled medical delivery assembly. In some embodiments, the stop/drive features may be shaped to comprise one or more surfaces that engage with the internal key of the cap in the case that the cap is rotated in a clockwise direction but may comprise an opposing surface or feature that permits (and/or forces) the internal key to disengage with the stop/drive features in the case that the cap is rotated in a counter-clockwise direction. In such a manner, for example, a user may readily couple (or complete the coupling of) the needle hub and the mounting collar but may be prevented from utilizing the cap to unscrew or decouple the needle hub and the mounting collar. In some embodiments, the internal key may be configured to accept a threshold amount of torque before a designed failure so that the user may readily tighten the threads but any attempt to overtighten will result in separation or destruction of the internal key, thereby preventing the cap from further functioning as a driver of the mating process and accordingly preventing

overtightening of the mating between the needle hub and the mounting collar. In some embodiments, an audible “click” or other sound of the failure of the internal key may comprise a designed indication to the user that the pre-filled medical delivery assembly is properly and/o fully assembled/activated. In some embodiments, the user may also or alternatively hold the mounting collar with one hand/fingers and push (e.g., axially) the mounting collar onto the BFS vial, causing the administration member to pierce the BFS vial axially (e.g., with or without rotation).

[0044] According to some embodiments, the cap may be removed to reveal the administration member and/or a first or administration end thereof. In some embodiments, the administration member (e.g., the administration end thereof) may be inserted into the patient and a collapsible reservoir of the BFS vial may be squeezed (e.g., receive an application of radially inward force), thereby expelling the liquid through the administration member and into the patient. In some embodiments, the administration member may be withdrawn from the patient and/or a needle shield (e.g., coupled to and/or part of the administration component/assembly) may be selectively moved (e.g., flipped and/or rotated) into position to cover the administration member/needle. As depicted herein, for example, a needle shield that is coupled to either or both of the BFS vial and the administration component/assembly may be selectively flipped up (e.g., from a first, transport, or storage position) to cover, retain, and/or mate with the administration member/needle (e.g., in a second or safety position). According to some embodiments, the first position may be between one hundred and eighty degrees (180°) and ninety degrees (90°) offset from the second position (e.g., along a particular axis and/or within a particular plane). The pre-filled medical delivery assembly may then be properly disposed of. While the mounting collar and the needle hub are generally described and depicted as separate couplable objects, in some embodiments they may be manufactured (e.g., molded) as a single object or piece or may comprise additional pieces or parts.

IV. Additional Embodiments

[0045] In some embodiments, a needle shield may comprise a support base defining a passage therethrough and comprising one or more protrusions within the passage, such protrusions extending radially inward from an inside surface of the support base. According to some embodiments, the support base may also or alternatively comprise one or more notches disposed on a radial circumference thereof. In some embodiments, the one or more notches may align radially (e.g., be positioned at the same points along the circumference) with the one or more protrusions. According to some embodiments, the support base may be coupled to and/or comprise a hinge element that couples the support base to a shield element comprising and/or defining an elongated voided and/or space. In some embodiments, the shield element may comprise a first alignment feature formed within the space at a first distance from the hinge, a second alignment feature formed within the space at a second distance from the hinge, and/or a third alignment feature formed within the space at a third distance from the hinge. According to some embodiments, the first alignment feature may comprise a shaped protrusion that is shaped to accept and/or mate with a portion of a needle hub. In some embodiments, the second alignment feature may comprise a pair of shaped protrusions that are configured to accept a first portion of a needle and guide the first portion of the needle to be in alignment with a central axis of the shield element. According to some embodiments, the third alignment feature may comprise a catch feature that is configured to accept and retain a second portion of the needle (and/or guide the second portion of the needle to be in alignment with the central axis of the shield element). In some embodiments, the pair of shaped protrusions of the second alignment feature may comprise a pair of cylindrical and/or rounded protrusions that are curved toward the central axis. According to some embodiments the hinge may comprise a living hinge. According to some embodiments, the notch may be shaped and/or configured to accept and/or retain a flange of a BFS vial.

V. Rules of Interpretation

[0046] 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.

[0047] 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.

[0048] Devices that are in communication with each other need not be in continuous communication with each other, unless expressly specified otherwise.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.”

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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.

Claims

1. A pre-filled medical delivery assembly, comprising: a blow-fill-seal (BFS) vial defining a collapsible reservoir, a neck portion, and at least one vial flange formed adjacent to the neck portion; a mounting collar comprising (i) a first end comprising a mounting socket comprising an interior seat into which the neck portion of the BFS vial is inserted, (ii) a second end comprising a collar mating feature, and (iii) at least one axial slot extending axially from the first end and toward the second end; a needle hub comprising at least one hub mating feature cooperatively mated with the collar mating feature; a double-ended needle disposed through and coupled to the needle hub and comprising a piercing end housed within the needle hub and an administration end distal from the needle hub; a cap removably attached to the needle hub and covering the administration end of

the needle; and a needle shield comprising a shield base coupled to the mounting collar, a shield element, and a hinge element flexibly connecting the shield base and the shield element, wherein the shield element comprises a retention element having a retention barb configured to capture the administration end of the double-ended needle within a retention space of the retention element, and wherein the shield base comprises at least one internal radial protrusion that engages with the at least one axial slot.

2. The pre-filled medical delivery assembly of claim 1, wherein the shield base comprises an annular element through which the mounting collar is inserted.
 3. The pre-filled medical delivery assembly of claim 1, wherein the shield base further comprises at least one circumferential notch that couples to the at least one vial flange.
 4. The pre-filled medical delivery assembly of claim 1, wherein the at least one vial flange is disposed within the at least one axial slot.
 5. The pre-filled medical delivery assembly of claim 1, wherein the shield element of the needle shield further comprises a locating element disposed further from the administration end of the double-ended needle than the retention barb, the locating element having a pair of locating barbs configured to capture an intermediate portion of the double-ended needle.
 6. The pre-filled medical delivery assembly of claim 1, wherein the shield base is retained between the at least one vial flange and the needle hub.
 7. The pre-filled medical delivery assembly of claim 1, wherein the collar is integral with the needle hub.
 8. A medical administration assembly, comprising: a collar having a first end defining a mounting socket comprising an interior seat operable to accept an exterior flange of a blow-fill-seal (BFS) vial that is axially mated, and a second end defining a hub socket comprising a collar mating feature; a needle hub comprising at least one hub mating feature cooperatively mated with the collar mating feature, the needle hub being coupled to a double-ended needle disposed through the needle hub; a needle shield comprising a shield base coupled to the collar, a shield element, and a hinge element flexibly connecting the shield base and the shield element, wherein the shield element comprises a retention element having retention barb configured to capture the administration end of the double-ended needle within a retention space of the retention element, and wherein the shield base further comprises at least one circumferential notch that couples to at least one vial flange of the BFS vial.
 9. The medical administration assembly of claim 8, wherein the shield element is rotated about the hinge element and coupled with the administration end of the needle after the cap is removed.
 10. The medical administration assembly of claim 8, further comprising a removable needle hub seal covering an opening of the mounting socket.
 11. The medical administration assembly of claim 8, wherein the collar is integral with the needle hub.
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