

TITLE

VIAL ADAPTERS

TECHNICAL FIELD

THIS INVENTION relates to connectors of the type used in the handling and administration of parenterally-administered fluids. More particularly, this invention relates to a vial adapter having a sharp cannula for piercing a vial closure, a shroud protecting an operator from inadvertent puncture by the sharp cannula and enabling removable connection to a vial, and a connector opposite the sharp cannula for connection to a device for fluid flow.

BACKGROUND

Access ports for injecting fluid into or removing fluid from a system, such as a drug vial, are well known and widely used. Conventional injection sites in drug vials generally involve a pierceable rubber stopper formed of an elastomeric material such as butyl rubber or the like, placed in the opening of the vial. A closure, typically formed of metal, is crimped over the rubber stopper and the flange of the vial to positively hold the stopper in place in the opening of the vial. The closure has an outer size, known as a "finish size." The closure also has an opening, or access port, through which the stopper and the vial opening may be accessed. A sharp cannula is inserted into the access port piercing the rubber stopper to position the distal, open end of the cannula past the rubber stopper to make fluid connection with the interior of the vial. Such a configuration is useful when reconstituting a powder (i.e., adding a diluent or a liquid substance to a powder to make a solution, emulsion, or the like). A growing number of drug therapies are preferably stored and/or transported in a powder form and, accordingly, require reconstitution or mixing into a liquid substance prior to injection and delivery into a patient.

Adapters have been found useful in that they can adapt the sharpened cannula that is placed into fluid communication with the vial to the connection device of another fluid container or fluid delivery device such as a syringe. For example, the adapter may include a female Luer fitting opposite the sharpened cannula to receive the nozzle of a syringe. Luer connection systems are a standard way of attaching syringes, catheters, hubbed needles, IV tubes, and the like to each other. Luer connections consist of conical/tubular male and female interlocking components slightly tapered to hold together better. Luer connections can either be a "luer slip",

which are luer connections with a simple pressure or twist fit, or luer connections can be a "luer lock", which can have an additional outer rim of threading allowing them to be more secure. The "adapter" therefore adapts the vial to the syringe, or adapts the sharpened cannula to the Luer-shaped nozzle of the syringe.

5 It has also been found useful to provide a means to attach or anchor the adapter to the vial to hold it in place while fluid communication between the vial and another device proceeds so that inadvertent disengagement of the adapter from the vial does not occur. For example, the adapter may have two arms that engage the neck or flange of the vial and hold the adapter in place on the vial. Other means include a shroud that
10 fits around the outside of the vial closure and snaps onto the vial closure under the crimped retaining cap thereby grasping the vial neck flange and the underside of the closure.

 However, some of the existing adapters available today suffer from various shortcomings. For example, most adapters are designed to function only on a single
15 vial closure finish size. These adapters do not securely attach to vial closures with diameters smaller or larger than vial closure finish sizes they are primarily molded to fit. They are therefore not usable on vials of other sizes. In addition, some vial adapters do not adequately protect an operator from inadvertent puncture of the operator's skin by the sharpened cannula of the adapter. The shroud or vial engagement device does
20 not extend completely over the sharpened cannula, thus exposing operators to possible puncture.

 Accompanying this limitation of functioning with only a single size of vial, a further consideration is the expense to hospitals or other medical facilities caused by having to stock numerous types and sizes of adapters. Vials of many flange sizes and
25 closure sizes are available and are frequently found in medical care facilities. Typically a hospital must stock a variety of adapters to be assured of having the correct adapter available that will properly interconnect with the multiple vial closures that exist. If a hospital must maintain a stock of adapters for each possible size of closure, a logistical problem as well as increased expense can result. Two common sizes of vial closures
30 are 13 mm vial closures and 20 mm vial closures. Reducing the number of adapters that must be stocked in a hospital can significantly lessen the problems with stocking the correct sizes and can reduce expenses.

Certain vial adapters exist that can accommodate multiple sizes of vial closure finishes. Such adapters generally utilize an adapter skirt having a plurality of longitudinal slits. The skirt may have a flare configuration to accept vials of multiple sizes, with the longitudinal slits creating flexible arms. When the cannula is inserted through a cap of a vial, interior aspects of the flexible arms are configured to engage with the vial beneath the cap of the vial. Therefore, the adapter is retained in position on the vial, and because the arms are flexible, the adapter can be retained on vials having different vial closure diameters. However, a practical way to accommodate a range of vial finish sizes, including the large vial finish sizes which are increasingly common in industry, is needed. Hence, those concerned with the development of medical adapters have recognized the need for a single adapter that is usable with vials of different sizes.

United States patent No. US 2010/0179506 discloses a vial adapter element for use in a drug mixing system including a body, a vial connection port extending from the body, a hollow vial puncturing spike that protrudes into the vial connection port and is in fluid communication with a syringe-adapter-element connection port that extends from the body, and a plurality of resilient tongues spaced around an inner wall of the body, the tongues being located in gaps formed in the inner wall of the body.

United States patent No. US 2011/0160701 discloses an apparatus for removal of premixed drugs or reconstitution of lyophilized drugs and for the injection of the reconstituted drug into the patient. The apparatus includes a syringe assembly and an adapter assembly that can be removably connected to a medicament container containing a premixed drug or lyophilized medicament.

United States patent No. US 2011/0022023 discloses a withdrawal spike unit comprising a withdrawal spike component and an integrally formed adapter component that is adapted to couple with a vial in a safe and secure manner. The integral formation of the component parts makes fully automated manufacture and assembly of assemblies comprising such a withdrawal spike unit coupled to a vial possible.

United States patent No. US 2010/0204679 discloses a mixing and injection apparatus including a needle and a needle base, a syringe attachment element and a mixing chamber

engagement assembly including a needle chamber surrounding the needle and a first liquid conduit portion, sealed from the needle chamber and a mixing chamber engagement portion including a second liquid conduit portion communicating with the first liquid conduit portion and configured for communication with a mixing chamber;; the syringe attachment element and the needle base being configured to permit liquid communication between an interior of the syringe and the first liquid conduit portion when the syringe attachment element and the needle base are in the first relative engagement orientation and to permit liquid communication between an interior of the syringe and the needle when the syringe attachment element and the needle base are in the second relative engagement orientation, axially separated from the first relative orientation along the injection axis.

WO 2011/057335 discloses a replaceable needle assembly provided for a retractable, prefilled syringe comprising a barrel having a mounting member and a plunger, whereby the retractable needle can be replaced by a user without affecting the retraction mechanism. The replaceable needle assembly comprises a needle fitted to a retractable needle mount and a needle retainer. The needle mount is removably, screw-threadedly mountable to the mounting member of the barrel. The needle retainer comprises a plurality of fingers that releasably engage the retractable needle to thereby prevent inadvertent retraction of the retractable needle before engagement by the plunger. The plunger comprises a plunger seal comprising an outer member and an inner member that engages the needle for spring-driven retraction. At the end of retraction, a lock is formed between the plunger and barrel to prevent re-use of the syringe.

SUMMARY

In a broad form, the invention is directed to a vial adapter for interconnecting a vial and a fluid delivery device. In one form, the vial adapter is for interconnecting vials having a variety of different closure sizes to said fluid delivery device. In a further or alternative form, the vial adapter is for interconnecting a vial and a fluid delivery device in the form of a safety syringe, wherein the vial adapter minimizes the risk of inadvertently activating a safety mechanism of the safety syringe.

In an aspect, the invention provides a vial adapter as claimed in claim 1.

5 The latitudinal apertures may be slits, windows, slots, cutouts or other apertures that extend laterally within the shroud. Suitably, each flexion arm is a lateral flexion arm. The length and/or number of the latitudinal apertures and/or flexion arms is preferably selected for engaging a vial closure within a broad range of sizes (e.g.diameters). Conveniently, the length of each of the flexion arms is such that when the adapter engages a relatively smaller diameter vial closure, at least one of the flexion

arms contacts and deforms to engage the smaller vial closure. Typically, the flexion arms are capable of deformation. Suitably, each of the flexion arms is capable of elastic deformation or plastic deformation. In at least one embodiment, the flexion arms comprise a narrowed segment at which the gross deformation takes place.

5 Advantageously, the flexion arms may deflect laterally under elastic deformation as a result of a force directed axially through a center line of the vial adapter. For example, such an arrangement may allow the flexion arms to engage (e.g., snap under) a retaining cap surrounding a seal in the vial closure. Each flexion arm may further comprise a gripping aspect that facilitates engaging and/or retaining the vial in fluid
10 communication with the vial closure.

In one embodiment, the base of the adapter housing comprises an outer surface and an inner surface. Suitably, at least part of the cannula extends or projects from the inner surface. Conveniently, in at least one embodiment the shroud extends from the base to surround a sharp tip of the cannula to thereby protect an operator of the vial
15 adapter from inadvertent puncture by the tip of the cannula.

One or more embodiments of the vial adapter may further include a distal flare extending or projecting from the shroud. In use, the distal flare extends or projects outwardly from a distal end of the shroud. Said flare may be useful in aiding a user to attach the vial adapter to a vial closure. Suitably, the flare is dimensioned so as to be
20 readily gripped or otherwise handled by the user.

In another embodiment, the vial adapter further comprises a collar. Suitably the collar is located at a proximal portion of the adapter housing. Typically, the collar facilitates connection of a syringe to the vial adapter by being adapted to receive the end of a barrel of a syringe for connection to the vial adapter. This prevents the syringe
25 from wobbling while the user is depressing or withdrawing the syringe plunger. According to this embodiment, optionally the angles of the interior surface of the vial adapter may be selected to promote an audible “snap” when the vial adapter is connected to the vial.

In at least one embodiment, a connector extends or projects from the adapter
30 housing, preferably from the base. In use, the connector extends or projects proximally from the base. The connector may comprise a Luer-slip, Luer-lock or any other connection type used in the art to connect the vial adapter to another fluid vial, a container or to a fluid delivery device. The connector may contain the female or the

male components of the connection type, including the Luer-type connection, such that it is capable of interfacing and/or engaging the corresponding syringe or other fluid delivery device. The connector may comprise an interior aperture or pass-through permitting fluid flow to and/or from a fluid delivery device through the cannula of the vial adapter to the vial closure. In at least one embodiment, the connector may further comprise a gasket, washer, O-ring, seal, or other similar component, such as an elastomeric gasket or O-ring. Such gaskets may assist, for example, in providing a tight connection between corresponding components of the connector of the vial adapter and the fluid delivery device and/or vial. The gaskets may similarly be utilized to minimize “dead space”, i.e., space within a component that may fill with fluid, to ensure that substantially all of the desired fluid transfer occurs between the components and devices.

As will be evident from the foregoing, in some embodiments the vial adapter of the present invention may be used to interconnect a vial and a fluid delivery device, such as a syringe, for fluid transfer between the vial and the fluid delivery device. Preferably, the vial adapter is utilized to connect between a vial and a safety syringe. Safety syringes are syringes which have integrated needle safety mechanisms to prevent accidental needle sticks and undesirable reuse of the syringe. By way of example, the safety syringes may be those which utilize the needle safety mechanisms as described in International Publication WO2006/119570, International Publication WO2006/108243, International Publication WO2009/003234, International Publication WO2011/057335 and/or International Publication WO2011/075760, although without limitation thereto. In some embodiments, the safety syringes may be “retractable” syringes that utilize a needle retraction safety mechanism which activates at the end of plunger travel or depression (i.e., at the end of fluid delivery). In some particular embodiments, the retractable needle may be replaceable, such as described for example in International Publication WO2011/057335.

Advantageously, to prevent premature activation of the needle retraction safety mechanism of the safety syringe, one or more embodiments of the vial adapter of the present invention may further comprise a conduit tip. Typically, the conduit tip projects from the connector. Preferably, in use the conduit tip projects proximally from the connector. The conduit tip may be attachable to the connector or may be integrally formed or otherwise preformed with the connector. The conduit tip may comprise a

protrusion which prevents or inhibits activation of a safety mechanism of the safety syringe. The conduit tip may have one or more internal apertures that permit fluid flow through the conduit tip. Typically, at least part of the cannula is in fluid communication with the conduit tip. This arrangement allows fluid communication
5 between the vial, the cannula and the conduit tip.

Accordingly, another aspect of the invention provides a vial adapter for interconnecting a vial comprising a closure having a seal and a safety syringe, said vial adapter comprising an adapter housing having a base, a shroud extending or projecting from the base which is capable of releasably engaging and/or retaining the vial closure,
10 a cannula extending or projecting from the base for penetrating said seal to thereby establish fluid communication between the vial and the vial adapter and a conduit tip which prevents or inhibits activation of a safety mechanism of the safety syringe.

Typically, the conduit tip projects or extends from the connector. In use, the conduit tip projects or extends proximally from the connector. The conduit tip may be
15 attachable to the connector or may be integrally formed or unitary with the connector. The conduit tip suitably comprises a protrusion which prevents or inhibits activation of a safety mechanism of the safety syringe. Preferably, the safety syringe is a retractable syringe that comprises a needle retraction mechanism, as hereinbefore described.

The conduit tip may have one or more internal apertures that permit fluid flow
20 through the conduit tip. Typically, at least part of the cannula is in fluid communication with the conduit tip. This arrangement allows fluid communication between the vial, the cannula and the conduit tip.

In at least one embodiment, the shroud further comprises one or a plurality of latitudinal apertures within at least one of which resides a flexion arm connected at one
25 end to the shroud, as hereinbefore described. Suitably, flexion arms are capable of engaging and/or retaining the vial adapter on the vial closure. Preferably, the length and/or number of the latitudinal slits and/or flexion arms is capable of releasably engaging and/or retaining a vial closure within a broad range of sizes (e.g., diameters). Each flexion arm may comprise a gripping aspect, as hereinbefore described.

30 In an alternative embodiment, the shroud comprises one or a plurality of longitudinal slits, wherein longitudinal arms respectively reside between adjacent slits, each connected at one end to the shroud. Suitably, the longitudinal arms are capable of engaging and/or retaining the vial adapter on the vial closure. Preferably, the

longitudinal arms are deformable. The longitudinal arms may be capable of elastic or plastic deformation.

In yet another aspect, the invention provides a method of transferring fluid from a vial comprising a closure having a seal to a fluid delivery device, said method
5 including the step of releasably connecting a vial adapter to the closure of the vial and to a fluid delivery device by fitting lateral arms of the vial adapter to the closure so that the vial adapter is in fluid communication with said fluid delivery device.

Suitably, the method further includes the step of transferring fluid between the vial and said fluid delivery device. Suitably, the vial adapter is as hereinbefore
10 described according to the aforementioned aspects. Preferably, the fluid delivery device is a safety syringe such as hereinbefore described.

A further aspect of the invention provides a method of transferring fluid from a vial comprising a closure having a seal to a fluid delivery device comprising a safety mechanism, said method including the step of inserting a conduit tip of a vial adapter
15 into said fluid delivery device so that the vial adapter is in fluid communication with said fluid delivery device.

Suitably, the method further includes the step of transferring fluid between the vial to said fluid delivery device. Suitably, insertion of the conduit tip of the vial adapter into said fluid delivery device avoids or prevents activation of the safety
20 mechanism. Suitably, the vial adapter is as hereinbefore described according to any of the aforementioned aspects comprising said conduit tip. Preferably, the fluid delivery device is a safety syringe comprising a needle retraction mechanism, such as hereinbefore described.

In a yet further aspect, the invention provides a kit comprising at least one vial
25 adapter of any of the aforementioned aspects and at least one fluid delivery device, or individual components thereof. In one embodiment, the fluid delivery device is a safety syringe. In one particular embodiment, the safety syringe comprises a barrel, plunger and a retractable needle. Preferably, according to this embodiment the kit provides a plurality of retractable needles, each of a different size or gauge. Optionally,
30 the retractable needle (or each retractable needle) is a replaceable retractable needle.

Other features and advantages of the present invention will become apparent from the following detailed description of preferred embodiments which, taken in

conjunction with the accompanying drawings, illustrate by way, of example the principles of the invention.

Throughout this specification, unless otherwise indicated, "comprise," "comprises," and "comprising," or related terms such as "includes" or "consists of,"
 5 are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers.

The use of the terms "a" and "an" and "the" and "at least one" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless
 10 otherwise indicated herein or clearly contradicted by context. The use of the term "at least one" followed by a list of one or more items (for example, "at least one of A and B") is to be construed to mean one item selected from the listed items (A or B) or any combination of two or more of the listed items (A and B), unless otherwise indicated herein or clearly contradicted by context.

15 BRIEF DESCRIPTION OF THE DRAWINGS

The following non-limiting embodiments of the invention are described herein with reference to the following drawings, wherein:

FIG. 1A is an isometric view of a prior art vial adapter and a vial;

FIG. 1B is a sectional view of a prior art vial adapter and a vial;

20 FIG. 2A is an isometric view of a vial adapter according to an embodiment of the present invention;

FIG. 2B is a cross-sectional side view of the vial adapter shown in FIG. 2A;

FIG. 3A is a side view of a vial adapter, according to at least one embodiment of the present invention, when connected to vial on one end and a syringe having a luer-type

25 connection on the other end;

FIG. 3B is a cross-sectional side view of the vial adapter, vial, and syringe having a luer-type connection shown in FIG. 3A;

FIG. 3C is an isometric view of the vial adapter shown in FIG. 3A;

FIG. 3D is an cross-sectional isometric view of the vial adapter shown in FIG. 3C;

30 FIG. 4A is an isometric view of a vial adapter comprising a conduit tip;

FIG. 4B is a cross-sectional side view of the vial adapter shown in FIG. 4A;

FIG. 5A is an isometric view of a vial adapter having a distal flare;

FIG. 5B is a sectional view of the vial adapter of FIG. 5B;

FIG. 6 is a side view of another embodiment of a vial adapter;

FIG. 7 is an isometric view of a vial adapter comprising a collar;

FIG. 8 is a cross-sectional view of a vial adapter in fluid communication with a vial and a syringe;

5 FIG. 9A is an isometric view of an alternative embodiment of a vial adapter comprising a conduit tip;

FIG. 9B is a sectional view of the embodiment shown in FIG. 9A; and

FIG. 10 shows an isometric view of a kit for drug storage, preparation, and/or delivery which includes a vial adapter.

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DETAILED DESCRIPTION

As will be described further below, embodiments of the present invention may include one or more additional components which may be considered standard components in the industry of medical devices. The components, and embodiments containing such components, are within the contemplation of the present invention and are to be understood as falling within the breadth and scope of the present invention. Reference to “proximal” or “proximally” in respect of a recited element means that in operation or use, the element projects, extends, is located or oriented towards or closer to an operator or user. Reference to “distal” or “distally” in respect of a recited element means that in operation or use, the element projects, extends is oriented or located away from an operator or user.

Embodiments of vial adapter 100 of the invention will be described in the context of a syringe, such as a safety syringe having a safety mechanism in the form of a retractable needle (*i.e.* a retractable syringe). It will be appreciated that the vial adapter may facilitate fluid transfer from a vial to the syringe to thereby reconstitute a powdered, dried, desiccated, dehydrated or otherwise solid substance in the syringe or may facilitate transfer of fluid from the syringe to the vial to thereby reconstitute a powdered, dried, desiccated, dehydrated or otherwise solid substance in the vial. In the latter case, the reconstituted fluid substance is then drawn back into the syringe for subsequent delivery, as is well understood in the art.

30 For initial reference, FIG. 1A shows an isometric view of an example of a prior art vial adapter 200 and vial 300. FIG. 1B shows a sectional view of prior art vial adapter 200. Vial 300 comprises container 310 closure 320 to which is fitted rubber seal 330 and crimped metal retainer 340. Vial adapter has housing 210 with

longitudinal slits 211 and longitudinal arms 212 for connection to vial closure 310, the longitudinal slits 211 and longitudinal arms 212 forming a generally “flower petal” shaped vial adapter 200. This configuration defines cavity 314 that fits over vial closure 320, enabling and longitudinal arms 212 to engage crimped metal retainer 340 fitted to vial closure 310. Cannula 230 has sharp tip 231 capable of piercing rubber seal 320 of vial 300. Connector 240 has bore 242 capable of fluid communication with internal aperture 232 of cannula 230. Connector 240 comprises luer 241 which is connectable to a syringe having a compatible luer connection (not shown) to thereby establish fluid communication between vial 300, vial adapter 200 and syringe (not shown). Vial adapter 200 may be convenient for vial closures 320 of one particular size but not for others. It is also noted that longitudinal slits 211 and longitudinal arms 212 extend into, and completely through, skirt portion 213, thereby complicating manufacture. Additionally or alternatively, vial adapter 200 does not function to prevent premature activation of safety mechanisms that may be part of a syringe or other fluid delivery device to which vial adapter 200 may be connected.

Certain embodiments of the present invention provide vial adapter 100 which is capable of connecting to vial closures 320 of various diameters and sizes. One such embodiment of vial adapter 100 of the present invention is shown in FIG. 2A and has a relatively uniform external profile (compared to that described in FIG. 1) while enabling connection to vial closures 320 of various sizes and diameters. FIG. 2B is a cross-sectional side view of vial adapter 100. Vial adapter 100 has housing 110 having base 120 and shroud 130 extending or projecting distally therefrom comprising latitudinal slits or windows 131 having respective flexion arms 132 which are permitted to deform, flex, or otherwise distort (at least temporarily and/or partially). Flexion arms 132 are respectively hingedly connected to shroud 130 through end 133. Flexion arms 132 respectively further comprise gripping aspect 134 which comprises gripping surface 135 (best seen in FIG. 2B) which can engage a vial closure, such as by the gripping crimped metal retainer shown in FIG 1A. The number of latitudinal slits or windows 131 and respective flexion arms 132 may be readily varied, but in this embodiment two latitudinal slits or windows 131 and respective flexion arms 132 are provided. Additionally, while the latitudinal slits or windows 131 and respective flexion arms 132 are shown in a counter-clockwise configuration, they may readily be manufactured and utilized in a clockwise configuration while remaining within the

embodiments of the present invention. Furthermore, as shown in Figs. 3A-3D, the latitudinal slits or windows 131 and respective flexion arms 132 are substantially latitudinal in function but may have a diagonal aspect or configuration for, for example, aesthetics. Connector 140 extends or projects proximally from outer surface 121 of base 120 and comprises bore 142 and luer 141 whereby a fluid delivery device such as a syringe having a compatible luer connection (shown, for example, in Figs. 3A-3B, and 10) may be connected to connector 140.

Cannula 150 comprises distal portion 153 which projects or extends substantially axially from inner surface 121 of base 120 and resides within internal cavity 114 of shroud housing 110. Cannula 150 further comprises internal aperture or pass-through 152 in fluid communication with bore 142 of connector to permit fluid flow between a vial closure and connector 140. It will be appreciated that shroud 130 extends from base 120 to surround a sharp tip of the cannula to thereby protect an operator of the vial adapter from inadvertent puncture by sharp tip 151 of cannula 150.

The connector may comprise a Luer-slip, Luer-lock or any other connection type used in the art to connect the vial adapter to another fluid vial, a container or to a fluid delivery device. The connector may contain the female or the male components of the connection type, including the Luer-type connection, such that it is capable of interfacing and/or engaging the corresponding syringe or other fluid delivery device. The connector may comprise an interior aperture or pass-through permitting fluid flow to and/or from a fluid delivery device through the cannula of the vial adapter to the vial closure. FIG. 3A is a side view of a vial adapter, according to at least one embodiment of the present invention, when connected to vial on one end and a syringe having a luer-type connection on the other end. FIG. 3B is a cross-sectional side view of the embodiment shown in FIG. 3A. As shown, the connector 140 of vial adapter 100 contains a luer-type connection. The connector 140 may be utilized to connect vial adapter 100 to a fluid delivery device, such as syringe 400. The vial adapter 100 may also be connected to vial 300, to facilitate fluid transfer between vial 300 and syringe 400, or *vice versa*.

FIG. 3C provides an isometric view of the vial adapter shown in FIG. 3A, while FIG. 3D provides a cross-sectional isometric view of the vial adapter shown in FIG. 3C. In at least one embodiment, as shown in FIGS. 3C-3D, the connector may further comprise a gasket 180. Gasket 180 may be a gasket, washer, O-ring, seal, or

other similar component, such as an elastomeric gasket or O-ring. Such gaskets may assist, for example, in providing a tight connection between corresponding components of the connector 140 of vial adapter 100 and the fluid delivery device 400 and/or vial 300. The gaskets may similarly be utilized to minimize “dead space”, i.e., space within a component that may fill with fluid, to ensure that substantially all of the desired fluid transfer occurs between the components and devices.

FIG. 4A is an isometric view and FIG. 4B is a sectional view of an embodiment of vial adapter 100 similar to that shown in FIGS. 2A and 2B, but further comprising conduit tip 160 which permits fluid flow between a fluid delivery device, such as a safety syringe, and a vial closure with an at least reduced risk of premature activation of the syringe safety mechanism (e.g., needle retraction mechanism). Conduit tip 160 has a generally stepped configuration comprising shoulders 161A, B and projection 162. Internal bore 163 is in fluid communication with internal aperture or pass-through 151 of cannula 150 and comprises outlet port 164.

FIG. 5A is an isometric view of vial adapter 100 and FIG 4B is a sectional view of vial adapter 100 according to an embodiment having distal flare 170. Distal flare 170 may be useful in aiding a user in attaching vial adapter 100 to a vial closure. In the embodiment shown in FIG. 5B, conduit tip 160 may be fitted to connector 140 by way of deformable hook arms 166A, B engaging recesses 143A, B in connector 140. Fluid communication between cannula 150 and conduit tip 160 is established by end portion 165 of conduit tip 160 fitting into internal aperture or pass-through 151 in proximal portion 154 of cannula 150 so that bore 163 is in fluid communication with internal aperture or pass-through 151 of cannula 150. In an alternative embodiment, connector 140 and conduit tip 160 may be an integrally-formed or otherwise pre-formed structure.

Latitudinal slits or windows 131 and flexion arms 132, may take a number of shapes and/or configurations while remaining within the scope and contemplation of the present invention. For example, FIG. 6 is a side view of another embodiment of vial adapter 100, having a more rounded latitudinal slit or window 131 by curvilinear edge 135.

FIG. 7 shows an embodiment of vial adapter 100 wherein housing 110 comprises collar 115 which is substantially annular and encloses connector 140. Collar 115 comprises lip 116 and is integrally formed with, and projects from, outer surface

121 of base 120 and may be suitably dimensioned to facilitate connection of a syringe to vial adapter 100 by being adapted to receive the end or nose of a barrel of the syringe for connection to vial adapter 100. This may facilitate a better connection between the syringe and the vial adapter and/or prevent a syringe from wobbling while the user is depressing or withdrawing the syringe plunger. An additional variation in this embodiment is that the angles of the interior surface of the vial adapter, for example at surfaces 134 and/or 135, may be adjusted to promote an audible “snap” when vial adapter 100 is connected to vial 300.

FIG. 8 shows an exemplary embodiment of vial adapter 100 in fluid communication with vial 300 and retractable syringe 400. Vial 300 comprises container 310 closure 320, to which rubber seal 330 and crimped metal retainer 340 are fitted. In this embodiment, retractable syringe 400 is of a type described in WO2011/057335 having a replaceable needle assembly. It will be appreciated that this embodiment of retractable syringe 400 is for illustrative purposes only and that vial adapter 100 can be used with a variety of different syringes such as hereinbefore described. In FIG. 8, tip 151 of cannula 150 penetrates rubber seal 330 of vial 300 and lateral flexion arms 131 engage vial closure by, for example, clampingly engaging crimped metal retainer. Gripping aspects 134 fit under crimped metal retainer 340. Syringe 400 comprises barrel 410, barrel adapter 420 comprising female thread 421, needle seal 430 having needle aperture 431 and plunger 440 having plunger member 441 and plunger seal 450 that comprises needle-engaging member 451. Although not shown, plunger 440 is of the type which comprises an internally-housed, compressed spring, whereby a release mechanism allows spring decompression to drive needle retraction. In FIG. 8, the replaceable needle assembly (not shown) has been screw-threadedly removed from female thread 421 of barrel adapter 420. Conduit tip 160 penetrates aperture 431 in needle seal 430 which normally accommodates the retractable needle body (not shown) and prevents depression or travel of plunger 440 to a point where the release mechanism is activated and spring decompression can occur (such as fully described in WO2011/057335). Accordingly, fluid 118 can be transferred from syringe 400 to vial 300 or *vice versa* by way of bore 163 of conduit tip 160 and internal aperture or pass-through 151 of cannula 150, to thereby reconstitute a solid substance (not shown) in the vial or the syringe. Once reconstitution has occurred, the mixed fluid is drawn back into the syringe 400. Vial

adapter 300 and syringe 400 are disconnected and the replaceable needle assembly is screwed into syringe barrel adapter 420. Additionally or alternatively, fluid 118 can be transferred from syringe 400 to vial 300 or *vice versa* by way of bore 163 of conduit tip 160 and internal aperture or pass-through 151 of cannula 150, to thereby mix with a liquid substance (not shown) in the vial or the syringe. Once mixing has occurred, the mixed fluid is drawn back into the syringe 400. Vial adapter 300 and syringe 400 are disconnected and the replaceable needle assembly is screwed into syringe barrel adapter 420. In the embodiment shown in FIG. 8, cannula 150 and conduit tip 160 are separate components. Alternatively, it is contemplated that cannula 150 and conduit tip 160 could be a single, unitary or integrally-formed structure.

An alternative embodiment of vial adapter 1100 is shown in FIGS 9A and 9B. FIG. 9A is an isometric view of vial adapter 1100 and FIG 9B is a sectional view of adapter 1100. Adapter 1100 comprises housing 1110 having shroud 1130 extending or projecting distally therefrom and conduit tip 1190 projecting from connector 1140 on outer surface 1121 of base 1121, essentially as hereinbefore described. Conduit tip 1160 comprises projection 1162 and internal bore 1163 which permits fluid flow between a fluid delivery device, such as syringe 400 shown in FIG. 8, and a vial closure without risk of premature safety activation, as hereinbefore described. In this embodiment, housing 1120 of vial adapter 1100 comprises shroud 1130 comprising a plurality of longitudinal slits 1131 and longitudinal arms 1132. While longitudinal arms 1132 are capable of elastic deformation to thereby engage or capture a vial closure (or a crimped metal retainer fitted to the vial closure), this embodiment is more suited to vials of a particular size (e.g., diameter) or relatively narrow range of sizes while providing the conduit tip 1160 to prevent or avoid premature activation of syringe safety mechanisms.

It will be appreciated that conduit tip, cannula, base and shroud, connection port, and other components of the vial adapter may be separate or unified components which provide multiple functions. For example and as described previously, the conduit tip and cannula may be separate or a unified, integrally-formed component that functions to prevent retraction activation, the cannula to pierce the sealing membrane of the vial closure and provide a fluid conduit between the fluid container or fluid conduction device and the vial closure. The unified conduit tip and cannula may also be attached to the connector and/or the base and shroud of the vial adapters. In at least

one embodiment described in, conduit tip is a separate component attached to the remaining components of vial adapter. In another embodiment the cannula and the connection port are pre-formed aspects on opposing surfaces of base, from which the shroud also extends; while the tip is a separate component connected to the connection port. A range of assembly configurations can be achieved with the components of the vial adapters described herein. Such configurations provide various manufacturing and assembly advantages, and can be adjusted to meet a range of needs while providing the same general functionality of the resulting vial adapters.

Other embodiments provide a kit 1000 which may comprise one or more vial adapters 100 wherein vial adapter 100 is fully assembled or where one or more vial adapters are provided with separate components to be assembled by the user, such as hereinbefore described and shown in FIG. 10. Kits 1000 may further comprise a syringe such as retractable syringe 400 and one or more retractable needle assemblies 500 either as fully assembled or separate components (e.g., separate barrel, needle assembly, and plunger components). The kits 1000 may further comprise a vial 300. The vial 300 may have container 310 and a vial seal, such as elastomeric, permeable vial seal 301, that may be pierced by the vial adapter 100. The syringe 400 may also have an elastomeric seal, such as tip cap 401, that may be removed to connect syringe 400 to vial adapter 100 at connector 140 of vial adapter 100. The vial adapter thus facilitates a connection between the vial and the syringe to permit fluid flow, such as through the conduit tip 160. Some syringes 400, particularly non-retractable syringes, may utilize a vial adapter that does not require the conduit tip 160 shown in FIG. 10, or a conduit tip 160 at all (as shown in FIGS. 2A and 2B). After fluid transfer from the vial 300 to the syringe 400, vial adapter 100 may be disconnected and a needle assembly, such as a retractable needle assembly 500, may be attached to the syringe 400 for drug delivery to a user. The needle assemblies 500 shown in FIG. 10 are enclosed in needle cap 550.

It will be appreciated that the foregoing description provides examples of the disclosed vial adapter and method of use. However, it is contemplated that other embodiments or implementations may differ in detail from the foregoing examples. All references to the disclosure or examples thereof are intended to reference the particular example being discussed at that point and are not intended to imply any limitation as to the scope of the disclosure more generally. All language of distinction and

disparagement with respect to certain features is intended to indicate a lack of preference for those features, but not to exclude such from the scope of the disclosure entirely unless otherwise indicated.

5 Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context.

10 Accordingly, this disclosure includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the disclosure unless otherwise indicated herein or otherwise clearly contradicted by context.

CLAIMS

1. A vial adapter (100, 1100) for interconnecting a fluid delivery device (400) that is a safety syringe (400); and a vial (300) having a closure (320) having a seal (330); said vial adapter comprising an adapter housing (110, 1110). having a base (120), a
5 shroud (130, 1130) extending or projecting from the base and a cannula (150) extending or projecting from the base for penetrating said seal to thereby establish fluid communication between the vial and the vial adapter, wherein the shroud comprises one or a plurality of latitudinal apertures (131, 1131) within at least one of which resides a lateral flexion arm (132) connected at one end to the shroud, each
10 lateral flexion arm capable of engaging and/or retaining the vial closure (320); the vial adapter further comprising a conduit tip (160, 1160) in fluid communication with the cannula (150), the conduit tip further comprising a projection (162, 1162) for preventing or inhibiting inadvertent activation of the safety mechanism of the safety syringe (400).
- 15 2. The vial adapter (100, 1100) of Claim 1, wherein the latitudinal apertures (131, 1131) are, or comprise, slits, windows, slots or cutouts.
3. The vial adapter (100, 1100) of Claim 1 or Claim 2, comprising a plurality of latitudinal apertures (131, 1131) that each comprises a lateral flexion arm (132).
4. The vial adapter (100, 1100) of any preceding claim, wherein each lateral
20 flexion arm (132) is capable of elastic deformation or plastic deformation.
5. The vial adapter (100, 1100) of any preceding claim, wherein each lateral flexion arm (132) further comprises a gripping aspect (134).
6. The vial adapter (100, 1100) of any preceding claim, wherein each lateral
25 flexion arm (132) comprises a snapping aspect to provide audible and/or tactile feedback to the user that the vial adapter is securely attached.
7. The vial adapter (100, 1100) of any preceding claim, wherein the shroud (130, 1130) projects or extends from the base to surround the cannula (150) to protect an operator of the vial adapter from inadvertent puncture by the cannula.
- 30 8. The vial adapter (100, 1100) of any preceding claim which comprises a flare (170) extending or projecting outwardly from a distal end of the shroud (130, 1130).

9. The vial adapter (100, 1100) of any preceding claim, further comprising a connector (140, 1140) which facilitates releasably connecting the vial adapter to said fluid delivery device.

10. The vial adapter (100, 1100) of any preceding claim, which further comprises a
5 gasket (180) internally within the connector (140, 1140) of the vial adapter (100), wherein the gasket minimizes dead space between the vial adapter and the fluid delivery device.

11. The vial adapter (100, 1100) of any preceding claim, which further comprises a collar that at least partly surrounds a connector, wherein the connector facilitates
10 releasably connecting the vial adapter to said fluid delivery device (400).

12.

The vial adapter (100, 1100) of Claim 11, wherein the conduit tip (160) is attachable to the connector (140, 1140).

or is integrally formed with the connector.

13. The vial adapter (100, 1100) of any one of Claims 1-12, wherein the conduit tip
15 is configured to penetrate an aperture in a needle seal of the safety syringe which normally accommodates a retractable needle body and to prevent depression or travel of a plunger of the safety syringe to a point where the safety mechanism is activated.

14. A method of transferring fluid from a vial (300) comprising a closure (320) to a
20 fluid delivery device (400), said method including the step of connecting a vial adapter (100, 1100) according to any one of Claims 1-13 to the closure of the vial and to a safety syringe, and fitting the one or plurality of lateral flexion arms (132) of the vial adapter to the closure so that the vial adapter is in fluid communication with said safety syringe .

25 15. A kit comprising at least one vial adapter (100, 1100) according to any one of Claims 1-13 and at least one safety syringe, or individual components thereof.