Abstract: According to some embodiments of the present disclosure, an adaptor configured to couple with a sealed vial can include a connector interface. The adaptor can include one or more access channels (e.g., passages). In some cases the one or more access channels are in fluid communication with the connector interface. The adaptor can include a piercing member. The piercing member can include a regulator channel. The adaptor can include a regulator assembly. The regulator assembly can include a first regulator inlet. In some cases, the regulator includes a second regulator inlet. One or more of the first and second regulator inlets can include a filter configured to filter fluid passing into and/or out of the respective regulator inlets. One or more valves can be positioned between the first and second regulator inlets and the piercing member.

FIG. 3
Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(H))

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(Hi))

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PRESSURE-REGULATING VIAL ADAPTORS

RELATED APPLICATIONS

[0081] This application claims the benefit of U.S. Provisional Patent Application No. 62/014,872, filed on June 20, 2014, and entitled "Pressure-Regulating Vial Adaptors," the entire contents of which are incorporated by reference herein and made part of this specification.

SUMMARY

[0082] According to some embodiments of the present disclosure, an adaptor configured to couple with a sealed vial can include a connector interface. The adaptor can include one or more access channels (e.g., passages). In some cases the one or more access channels are in fluid communication with the connector interface. The adaptor can include a piercing member. The piercing member can include a regulator channel. The adaptor can include a regulator assembly. The regulator assembly can include a first regulator inlet. In some cases, the regulator includes a second regulator inlet. One or more of the first and second regulator inlets can include a filter configured to filter fluid passing into and/or out of the respective regulator inlets. One or more valves can be positioned between the first and/or second regulator inlets and the piercing member.

[0003] According to some variants, an adaptor configured to couple with a sealed vial can include a connector interface. In some embodiments, the adaptor includes an access channel. The access channel can be in fluid communication with the connector interface, in some cases, the adaptor includes a regulator assembly. The regulator assembly can include a first regulator inlet. The first regulator inlet can be in fluid communication with an ambient environment surrounding the adaptor. In some embodiments, the regulator assembly includes a first regulator lumen. In some cases, the regulator assembly includes a second regulator inlet. The second regulator inlet can be in fluid communication with the ambient environment. In some cases, the regulator assembly includes a second regulator lumen. In some embodiments, the regulator assembly includes a first filter. The first filter can be capable of fluid communication with the first regulator lumen. In some embodiments, the first filter is configured to filter fluid passing into the first
regulator lumen. The regulator assembly can include a second filter. The second filter can be in fluid communication with the second regulator lumen. In some embodiments, the second filter is configured to filter fluid passing from the second regulator lumen and into the ambient environment. In some embodiments, the regulator assembly includes a regulator valve. The regulator valve can be in fluid communication with the first regulator lumen. In some embodiments, the regulator valve is configured to permit passage of fluid from the ambient environment into the first regulator lumen. In some cases, the regulator valve is configured to prevent passage of fluid from within the vial to the first filter. The adaptor can include a piercing member. The piercing member can include a proximal end and a distal end. In some embodiments, the distal end comprises a piercing tip. In some cases, the adaptor includes a regulator channel. The regulator channel can be positioned at least partially within the piercing member. In some embodiments, the regulator channel includes a first regulator channel opening in fluid communication with the first regulator lumen. In some embodiments, the adaptor can be used in conjunction with a sealed vial.

[0004] In some embodiments, the regulator valve comprises a valve stem and/or a flap portion. In some cases, the flap portion comprises a concave side and/or a convex side. In some embodiments, the first regulator lumen and the second regulator lumen are in fluid communication with each other. In some configurations, the regulator valve is positioned in a plug portion. In some cases, the plug portion can be inserted into the regulator lumen. In some embodiments, the plug portion is flexible. In some embodiments, the plug portion is retained within the regulator lumen (e.g., by a friction fit). In some cases, a cap portion limits the extent to which the plug portion is inserted into the regulator lumen. In some embodiments, the first filter is positioned in the plug portion. In some cases, the first filter is positioned within the first regulator lumen. In some embodiments, the second filter is positioned within the second regulator lumen. In some cases, the first and second filters are positioned along a common line. In some embodiments, the common line is generally perpendicular to the regulator channel. In some cases, the regulator valve is positioned along the common hue.

[0005] According to some variants, a method of manufacturing a vial adaptor can include providing a connector interface. In some embodiments, the
The method includes providing an access channel. The access channel can be in fluid communication with the connector interface. The method can include providing a regulator assembly. The regulator assembly can include a first regulator inlet. The first regulator inlet can be in fluid communication with an ambient environment surrounding the adaptor. In some cases, the regulator assembly includes a second regulator inlet. The second regulator inlet can be in fluid communication with the ambient environment. The regulator assembly can include a first filter. The first filter can be configured to filter fluid passing into the vial adaptor. In some embodiments, the regulator assembly includes a second filter. The second filter can be configured to filter fluid passing from the vial adaptor into the ambient environment. In some cases, the regulator assembly includes a regulator valve. The regulator valve can be configured to permit passage of fluid from the ambient environment into the vial adaptor. In some embodiments, the regulator valve is configured to inhibit passage of fluid from within the vial to the first filter. The method can include providing a piercing member. The piercing member can include a proximal end and a distal end. In some cases, the distal end includes a piercing tip. In some embodiments, the method includes providing a regulator channel. The regulator channel can be positioned at least partially within the piercing member. In some embodiments, the regulator channel includes a first regulator channel opening. In some cases, the regulator channel is in fluid communication with the second filter and/or with the regulator valve. In some embodiments, the first and second regulator inlets are provided along a common line that is generally perpendicular to the regulator channel. In some cases, the regulator valve is providing along the common line. In some embodiments, the regulator valve is configured to prevent passage of fluid from within the vial to the first filter. In some cases, the regulator valve comprises a valve stem and/or a flap portion. In some embodiments, the flap portion has a concave side and/or a convex side.
BACKGROUND

Field

Certain embodiments disclosed herein relate to adaptors for coupling with medicinal vials, and components thereof, and methods to contain vapors and/or to aid in regulating pressures within medicinal vials.

Description of Related Art

It is a common practice to store medicines or other medically related fluids in vials or other containers. In some instances, the medicines or fluids so stored are iherapeut ic if injected into the bloodstream, but harmful if inhaled or if contacted by exposed skin. Certain known systems for extracting potentially harmful medicines from vials suffer from various drawbacks.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are depicted in the accompanying drawings for illustrative purposes, and should in no way be interpreted as limiting the scope of the embodiments. In addition, any features of different disclosed embodiments can be combined to form additional embodiments, which are part of this disclosure,

Figure 1 schematically illustrates a system for removing compounds from and/or injecting compounds into a vial,

Figure 2 schematically illustrates another system for removing compounds from and/or injecting compounds into a vial.

Figure 2A schematically illustrates another system for removing compounds from and/or injecting compounds into a vial.

Figure 2B schematically illustrates another system for removing compounds from and/or injecting compounds into a vial.

Figure 3 is a top perspective view of a vial adaptor.

Figure 4 is a front plan view of the vial adaptor of Figure 3.

Figure 5 is a right plan view of the vial adaptor of Figure 3.

Figure 6 is a left plan view of the vial adaptor of Figure 3.

Figure 7 is a front cross-sectional view of the vial adaptor of Figure 3.

Figure 8 is a close up front cross-section view of the regulator valve of Figure 3.
[0019] Figure 9 is a top right perspective cross-section view of the vial adaptor of Figure 3.

[0020] Figure 10 is a top left perspective cross-section view of the vial adaptor of Figure 3.

[0021] Figure 11 is a front cross-sectional view of another embodiment of a vial adaptor.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS

[0022] Figure 1 is a schematic illustration of a container 10, such as a medicinal vial, that can be coupled with an accessor 28 and a regulator 30. In certain arrangements, the regulator 38 allows the removal of some or all of the contents of the container 18 via the accessor 28 without a significant change of pressure within the container 10. In some embodiments, the regulator 30 can include one or more portions of any of the example regulators shown and/or described in international Patent Publication Number WO 2013/025946, titled PRESSURE-REGULATING VIAL ADAPTORs, filed August 16, 2012, the entire contents of which are incorporated by reference and made part of this specification. Every individual structure, component, feature, or step that is illustrated or described in any embodiment in this specification can be used alone or in combination with any other structure, component, feature, or step that is illustrated or described in any other embodiment in this specification. No structure, component, feature, or step in this specification is indispensable or essential, but rather can be omitted in some embodiments.

[0023] In general, the container 10 is hermetically sealed to preserve the contents of the container 10 in a sterile environment. The container 10 can be evacuated or pressurized upon sealing. In some instances, the container 10 is partially or completely filled with a liquid, such as a drug or other medical fluid. In such instances, one or more gases can also be sealed in the container 10. In some instances, a solid or powdered substance, such as a lyophilized pharmaceutical, is disposed in the container 10.

[0024] The accessor 28 generally provides access to contents of the container 10 such that the contents may be removed or added to. In certain arrangements, the accessor 20 includes an opening between the interior and exterior of the container 10. The accessor 20 can further comprise a passageway between the
interior and exterior of the container 10. In some configurations, the passageway of
the accessor 20 can be selectively opened and closed, in some arrangements, the
accessor 20 comprises a conduit extending through a surface of the container 10.
The accessor 20 can be integrally formed with the container 10 prior to the sealing
thereof or introduced to the container 10 after the container 10 has been sealed.

[0025] In some configurations, the accessor 20 is in fluid communication
with the container 10, as indicated by an arrow 21. In certain of these
configurations, when the pressure inside the container 10 varies from that of the
surrounding environment, the introduction of the accessor 20 to the container 10
causes a transfer through the accessor 20. For example, in some arrangements, the
pressure of the environment that surrounds the container 10 exceeds the pressure
within the container 10, which may cause ambient air from the environment to
ingress through the accessor 20 upon insertion of the accessor 20 into the container
10. In other arrangements, the pressure inside the container 10 exceeds that of the
surrounding environment, causing the contents of the container 10 to egress through
the accessor 20.

[0026] In some configurations, the accessor 20 is coupled with an
exchange device 40. In certain instances, the accessor 20 and the exchange device 40
are separable, in some instances, the accessor 20 and the exchange device 40 are
integrially formed. The exchange device 40 is configured to accept fluids and/or gases
from the container 10 via the accessor 20, to introduce fluids and/or gases to the
container 10 via the accessor 20, or to do some combination of the two. In some
arrangements, the exchange device 40 is in fluid communication with the accessor
28, as indicated by an arrow 24. In certain configurations, the exchange device 40
comprises a medical instrument, such as a syringe.

[0027] In some instances, the exchange device 40 is configured to remove
some or all of the contents of the container 10 via the accessor 28. In certain
arrangements, the exchange device 40 can remove the contents independent of
pressure differences, or lack thereof, between the interior of the container 10 and
the surrounding environment. For example, in instances where the pressure outside
of the container 10 exceeds that within the container 10, an exchange device 40
comprising a syringe can remove the contents of the container 10 if sufficient force is
exerted to extract the plunger from the syringe. The exchange device 40 can
similarly introduce fluids and/or gases to the container 10 independent of pressure
differences between the interior of the container 10 and the surrounding
environment.

[0028] In certain configurations, the regulator 30 is coupled with the
container 15. The regulator 38 generally regulates the pressure within the container
18. As used herein, the term "regulate," or any derivative thereof, is a broad term
used in its ordinary sense and includes, unless otherwise noted, any active,
affirmative, or positive activity, or any passive, reactive, respondent,
accommodating, or compensating activity that tends to effect a change. In some
instances, the regulator 30 substantially maintains a pressure difference, or
equilibrium, between the interior of the container 10 and the surrounding
environment. As used herein, the term "maintain," or any derivative thereof, is a
broad term used in its ordinary sense and includes the tendency to preserve an
original condition for some period, with some small degree of variation permitted as
may be appropriate in the circumstances. In some instances, the regulator 30
maintains a substantially constant pressure within the container 10. In certain
instances, the pressure within the container 10 varies by no more than about 1 psi,
no more than about 2 psi, no more than about 3 psi, no more than about 4 psi, or no
more than about 5 psi. In still further instances, the regulator 30 equalizes pressures
exerted on the contents of the container 10. As used herein, the term "equalize," or
any derivative thereof, is a broad term used in its ordinary sense and includes the
tendency for causing quantities to be the same or close to the same, with some small
degree of variation permitted as may be appropriate in the circumstances. In certain
configurations, the regulator 30 is coupled with the container 10 to allow or
encourage equalization of a pressure difference between the interior of the container
18 and some other environment, such as the environment surrounding the container
10 or an environment within the exchange device 40. In some arrangements, a single
device comprises the regulator 30 and the accessor 20. In other arrangements, the
regulator 30 and the accessor 20 are separate units.

[0029] The regulator 30 is generally in communication with the container
10, as indicated by an arrow 31, and a reservoir 50, as indicated by another arrow
35. In some configurations, the reservoir 50 comprises at least a portion of the
environment surrounding the container 10. In some cases, the reservoir 50 is the ambient environment surrounding the container 10.

[0030] In certain embodiments, the regulator 3D provides fluid communication between the container 10 and the reservoir SO. In certain of such embodiments, the fluid in the reservoir 50 (e.g., in the surrounding environment) includes mainly gas so as not to appreciably dilute liquid contents of the container 10. In some arrangements, the regulator 30 comprises a filter to purify or remove contaminants from the gas or liquid entering the container 18, thereby reducing the risk of contaminating the contents of the container 10. In certain arrangements, the filter is hydrophobic such that air can enter the container 18 but fluid cannot escape therefrom. In some configurations, the regulator 30 comprises an orientation-actuated or orientation-sensitive check valve which selectively inhibits fluid communication between the container 10 and the filter. In some configurations, the regulator 30 comprises a check valve which selectively inhibits fluid communication between the container 10 and the filter when the valve and/or the container 10 are oriented so that the regulator 30 is held above (e.g., further from the floor than) the regulator 30.

[0031] As schematically illustrated in Figure 2, in certain embodiments, the accessor 20, or some portion thereof, is located within the container 10. As detailed above, the accessor 20 can be integrally formed with the container 10 or separate therefrom. In some embodiments, the regulator 30, or some portion thereof, is located outside the container 10. In some arrangements, the regulator 30 is integrally formed with the container 10. It is possible to have any combination of the accessor 20, or some portion thereof, entirely within, partially within, or outside of the container 10 and/or the regulator 30, or some portion thereof, entirely within, partially within, or outside of the container 10.

[0032] In certain embodiments, the accessor 20 is in fluid communication with the container 10. In further embodiments, the accessor 20 is in fluid communication with the exchange device 40, as indicated by the arrow 24.

[0033] The regulator 38 can be in fluid or non-fluid communication with the container 10. In some embodiments, the regulator 30 is located entirely outside the container 10. In some embodiments, the regulator 30 is in communication, either fluid or non-fluid, with the reservoir SO, as indicated by the arrow 35.
[0034] As schematically illustrated in Figure 2A, in certain embodiments, the accessor 20, or some portion thereof, can be located within the container 10. In some embodiments, the accessor 20, or some portion thereof, can be located outside the container 10. In some embodiments, a valve 25, or some portion thereof, can be located outside the container 18. In some embodiments, the valve 25, or some portion thereof, can be located within the container 10. In some embodiments, the regulator 30 is located entirely outside the container 18. In some embodiments, the regulator 30, or some portion thereof, can be located within the container 10. It is possible to have any combination of the accessor 20, or some portion thereof, entirely within, partially within, or outside of the container 18 and/or the valve 25, or some portion thereof, entirely within, partially within, or outside of the container 18. It is also possible to have any combination of the accessor 20, or some portion thereof, entirely within, partially within, or outside of the container 10 and/or the regulator 30, or some portion thereof, entirely within, partially within, or outside of the container 10.

[0035] The accessor 20 can be in fluid communication with the container 10, as indicated by the arrow 21. In some embodiments, the accessor 20 can be in fluid communication with the exchange device 40, as indicated by the arrow 24.

[0036] In certain embodiments, the regulator 30 can be in fluid or non-fluid communication with a valve 25, as indicated by the arrow 32. In some embodiments, the valve 25 can be integrally formed with the container 10 or separate therefrom. In some embodiments, the valve 25 can be integrally formed with the regulator 38 or separate therefrom. In certain embodiments, the valve 25 can be in fluid or non-fluid communication with the container 10, as indicated by the arrow 33.

[0037] In some embodiments the regulator 30 can be in fluid or non-fluid communication with the reservoir 50 (e.g., the ambient surroundings), as indicated by the arrow 35A.

[0038] According to some configurations, the regulator 30 can comprise a filter. In some embodiments, the filter can selectively inhibit passage of liquids and/or contaminants between the valve 25 and the reservoir 50. In some embodiments, the Alter can selectively inhibit passage of liquids and/or contaminants between the reservoir 50 and the valve 25,
In some embodiments, the valve 25 can be a one-way check valve. In some embodiments, the valve 25 can be a two-way valve. According to some configurations, the valve 25 can selectively inhibit liquid communication between the filter and/or reservoir and the container 10.

As illustrated in Figure 2B, the regulator 30 can include a non-valved fluid connection 32A between the container 10, the regulator 38, and the reservoir 50. In some embodiments, the non-valved fluid connection is a second inlet/outlet between the regulator 30 and the reservoir 58. The second inlet/outlet can be filtered. For example, a hydrophobic and/or antimicrobial filter can be positioned in the regulator 30 between the second outlet and the container 10.

In certain embodiments, the adaptor 100 (e.g., a vial adaptor) comprises a piercing member 120, a cap connector 130, a connector interface 140, and a regulator assembly ISO. Further details and examples regarding some embodiments of piercing members 120, cap connectors 130, and connector interfaces 148 are provided in U.S. Patent Application Publication No. 2809/0216212, the entirety of each of which is incorporated herein by reference and is made a part of this specification. For clarity, a vial is not illustrated. The adaptor 100 can mate with the vial in a similar manner as illustrated and described in U.S. Patent Application No. 14/179,475, filed February 12, 2014, the entirety of which is incorporated herein by reference and is made a part of this specification. For example, when the adaptor 100 is mated with the vial, the piercing member 120 extends through a septum of the vial into the interior of the vial.

In some embodiments, such as in the illustrated embodiment, the cap connector 130 comprises a central portion 132 (that can be curved) and one or more tabs 134 (which can be opposing) attached to the central portion 132. Each of the tabs 134 can be supported at a proximal end of the tab 134 by the central portion 132 of the body portion 388. As shown, the distal end of the tabs 134 can each be unrestrained so as to allow the tab to deflect outward. As used herein the term, "proximal," or any derivative thereof, refers to a direction along the axial length of the piercing member 120 that is toward the connector interface 148; the term "distal," or any derivative thereof, indicates the opposite direction.

The cap connector 130, including the central portion 132 and tabs 134, can help removably secure the vial adaptor 180 to the outside surface of the vial.
and can help facilitate the removal of the vial adaptor 100 from the vial. In some embodiments, the cap connector 130 comprises only one tab 134, as opposed to a pair of opposing tabs 134, the single tab being configured to removably secure the vial adaptor 300 to the outside surface of the vial and to facilitate the removal of the vial adaptor 100 from the vial. The single tab 134 can be of any suitable configuration, including those set forth herein.

[0044] As illustrated in Figures 3-5, the connector interface 140 can have an interface centerline 142. The interface centerline 142 can extend substantially through a center of the connector interface 148 generally perpendicular to a proximal opening of the connector interface 140. In some embodiments, the interface centerline 142 extends through a substantial centerline of the piercing member 120. In some embodiments, the interface centerline 142 is perpendicular to the top of a vial to which the vial adaptor 100 is coupled.

[0045] As illustrated in FIGURE 4, the regulator assembly 150 can include a regulator centerline 152. The regulator centerline 152 can extend substantially through the center of the regulator assembly 150. For example, in some embodiments, the regulator assembly 150 has a generally cylindrical shape, and the regulator centerline 152 extends through a central axis of the cylindrical regulator assembly 150. In some embodiments, the regulator assembly 150 does not have a straight configuration, and the centerline of the regulator assembly 150 is not a straight line. The regulator centerline 152 can be approximately perpendicular to the interface connector 140, as illustrated in Figure 4. In some embodiments, the regulator centerline 152 extends at an oblique angle to the connector centerline 142. In some embodiments, the regulator centerline 152 intersects the connector centerline 142.

[0046] Referring to Figures 4 and 5, the regulator assembly 150 can include a first regulator inlet 154. The piercing member 120 can include a piercing tip 122. The piercing tip can be configured to pierce a septum or other seal of a vial to which the vial adaptor 100 is coupled. As illustrated in Figure 4, the regulator assembly 150 can include a second regulator inlet 156. In some embodiments, a flow inhibitor, such as a valve or a hinged door (not shown), is connected to the second regulator inlet 156. The flow inhibitor can be configured to inhibit or prevent passage of fluids and/or solids into or out from the inlet 156 when the hinged door is
in a closed position. In some embodiments, the flow Inhibitor can be transitioned to an opened position by a user of the vial adaptor 100. One or more of the first regulator inlet 154 and the second regulator inlet 156 can be positioned along the regulator centerline 152. In some embodiments, both the first and second regulator inlets 154, 156 are positioned substantially collinear with each other, in some cases (not illustrated), the first regulator inlet 154 is positioned at an oblique, or non-collinear, or perpendicular angle with respect to the second regulator inlet 156. In some such cases, both the first and second regulator inlets 154, 156 are positioned on axes generally perpendicular to the interface centerline 142.

[0847] As illustrated in Figure 7, the connector interface 140 can be in fluid communication with an access channel 142. The access channel 142 can extend into the vial when the vial adaptor 1835 is coupled to the vial. In some embodiments, the access channel extends through the regulator assembly 158. The access channel 142 can have an access channel wall 144. The access channel wall 144 can inhibit or prevent fluid communication between the access channel 142 and the regulator assembly 158 (e.g., within the regulator assembly 158). The access channel 142 can extend from a proximal end at the connector interface 140 to a distal access aperture 146, at or near a distal end of the piercing member 120. The access channel 142 can provide fluid communication between a device (e.g., a syringe) coupled to the connector Interface 140 and an interior of the vial or other container to which the vial adaptor 108 is coupled.

[0048] Referring to Figure 7, the regulator assembly 150 can include a regulator housing 158. The regulator housing 158 can have a generally cylindrical shape, a generally rectangular shape, or some other shape. In some embodiments, the regulator housing 158 spans the access channel wall 142. In some cases, the regulator housing 158 is positioned only on one side of the access channel wall 142.

[0049] The regulator housing 158 can comprise a first regulator lumen 160. In some embodiments, the first regulator lumen 160 extends between the first regulator inlet 154 and the access channel wall 142. As illustrated, the first regulator lumen 160 can be in fluid communication with a regulator channel 162. The regulator channel 162 can extend at least partially through the piercing member 120. For example, the regulator channel 162 can extend between the first regulator lumen 160 and a distal regulator aperture 164. The distal regulator
aperture 164 can be positioned at or near the piercing tip 122 of the piercing member 120. In some embodiments, the regulator channel 162 extends substantially parallel to the interface centerline 142.

[0050] In some embodiments, the regulator housing 158 comprises a second regulator lumen 182. The second regulator lumen 182 can extend between the second regulator inlet 156 and the access channel wall 142. In some cases, the second regulator lumen 182 is in fluid communication with one or more of the first regulator lumen 160 and the regulator channel 162. For example, as illustrated in Figure 9, the first and second regulator lumens 160, 182 can be connected via a connecting channel 184. In some embodiments, the connecting channel 184 spans the access channel wall 142. As shown in Figure 7, the first and second regulator lumens 160, 182 and/or the regulator valve 186 can be positioned along a common line that is generally perpendicular to the regulator channel 162.

[0051] As illustrated in Figure 7, a regulator cap 166 can be positioned in or on the first regulator inlet 154. The regulator cap 166 can include a plug portion 168 configured to mate with or otherwise couple with the regulator housing 158. The plug portion 168 can be constructed from a flexible or semi-flexible material. In some embodiments, the plug portion 168 is constructed from a rigid or semi-rigid material. The plug portion 168 can be friction-fit with the regulator housing 158 (such as within the first regulator lumen 160, as illustrated in Figure 7), adhered thereto, or otherwise fastened to the regulator housing 158. As shown in Figure 7, the first filter can be positioned in the plug portion 168. The regulator cap 166 can include a cap portion 170. The cap portion 170 can be configured to limit the extent to which the plug portion 168 may be inserted into the regulator housing 158. For example, the cap portion 170 can have a cross-sectional width (e.g., a diameter) greater than the cross-sectional widths of the plug portion 168 and/or of the first regulator lumen 160.

[0052] In some embodiments, the plug portion 168 includes a hollow interior. The hollow interior of the plug portion 168 can comprise a first filter chamber 172. The first filter chamber 172 can be configured to receive a first filter 174. The first filter 174 can be adhered to or otherwise affixed to an interior of the plug portion 168 within the filter chamber 172. The filter 174 can inhibit or prevent passage of liquid and/or microbials past the filter 174. For example, the filter 174...
can be hydrophobic and/or antimicrobial, in some embodiments, as shown in Figure 7, the first filter 174 can be capable of fluid communication with the first regulator lumen 160. In some embodiments, the first filter 174 is positioned within the first regulator lumen 160 outside of the hollow interior of the plug portion 168 (e.g., outside of the first filter chamber 172).

[0053] As illustrated in Figure 7, the second regulator inlet 156 can include a second filter chamber 176. The second filter chamber 176 can receive a second filter 178. The second filter 178 can be hydrophobic and/or antimicrobial. In some embodiments, the second filter chamber includes a filter seat 188. The filter seat 180 can be configured to inhibit or prevent accidental adherence of the filter 178 to one or more surfaces of the interior of the first regulator lumen 160. As illustrated, the second filter chamber 176 can be a portion of the second regulator lumen 182. In some embodiments, as shown in Figure 7, the second filter 178 can be in fluid communication with the second regulator lumen 182.

[0054] As illustrated in Figures 7-10, the regulator assembly 180 can include a regulator valve 186. As shown in Figure 7, the regulator valve 186 can be in fluid communication with the interior of the vial adaptor (e.g., with the first regulator lumen 160) and the regulator valve can be configured to permit passage of fluid from the ambient environment into the first regulator lumen. The regulator valve 186 can be configured to inhibit or prevent fluid flow into and/or out of the vial via the regulator channel 162. In some embodiments, as shown in Figure 7, the regulator valve can be configured to prevent passage of fluid from within the vial to the first filter. In some embodiments, the regulator valve 186 is positioned in a fluid path between the first regulator inlet 154 and the distal regulator aperture 164. In some cases, the regulator valve 186 is positioned in a fluid path between the second regulator inlet 156 and the distal regulator aperture 164. In some embodiments, the regulator valve 186 is positioned at least partially within the regulator channel 162. In some cases, all or a portion of the regulator valve 186 is positioned within the first regulator lumen 160. The regulator valve 186 can be configured to transition between an opened configuration and a closed configuration. In some cases, the regulator valve 186 permits fluid flow in one or more directions between the distal regulator aperture 164 and the first and/or second regulator inlets 154, 156 when the regulator valve 186 is in the opened configuration. For example, the regulator valve
186 can be positioned and configured to operate as a one-way valve to permit fluid flow from the first regulator inlet 154 to the distal regulator aperture 164, but not from the distal regulator aperture 164 to the first regulator inlet 154, when the regulator valve 186 is in the opened configuration. In some embodiments, the regulator valve 186 inhibits or prevents fluid flow past the regulator valve 186 when the regulator valve 186 is in the closed configuration.

[0055] The regulator valve 186 can include a valve body 188. The valve body 188 can be configured to releasably mate with or fixedly mate with a valve seat 195. In some embodiments, at least a portion of the valve body 188 comprises an elastomeric, resilient, and/or flexible material. For example, the valve body 188 can be injection molded using an elastomeric material.

[0056] The valve body 188 can include a flap portion 191. The flap portion 191 can have a concave side 191a and a convex side 191b. In some embodiments, the flap portion 191 can have a generally circular shape, rectangular shape, oval shape, or other suitable shape. The flap portion 191 can extend outward from (e.g., radially outward with respect to the regulator centerline 152) a hub portion 189 of the valve body 186. In some embodiments, the flap portion includes a lip portion 193. The lip portion 193 can be positioned at or near a periphery of the flap portion 191.

[0057] In some embodiments, as shown, the flap portion 191 can be configured to produce a restoring force when the flap portion 191 is temporarily moved away from its natural concave or convex configurations (e.g., such as when the flap portion 191 is caused to become substantially flat, or less concave or less convex than in its natural position, or to essentially reverse its natural concave or convex sides) to bias the flap portion 191 back to its original shape and/or orientation. In some embodiments of this configuration, the flap portion 191 can temporarily permit the passage of fluid flow that exceeds a threshold pressure from the concave side of the flap portion 191 toward the convex side of the flap portion 191, but the flat portion 191 can resist, impede, or prevent the passage of fluid flow from the convex side of the flap portion 191 toward the concave side of the flap portion, even at extremely high pressure within the context of a vascular medical product.
[0058] In some embodiments, the valve seat 190 includes a valve stem 194. The valve stem 194 can have a first end 194a and a second end 194b. The valve stem 194 can extend from the flap portion 191 (e.g., from the concave side 191a of the flap portion 191). For example, the first end 194a can be connected to the hub portion 189 of the valve body 188 and the second end 194b of the valve body 188 can be spaced from the hub portion 189. The valve stem 194 can include a valve anchor 196. The valve anchor 196 can be, for example, one or more protrusions (e.g., an annular protrusion) or other features configured to inhibit accidental de-coupling between the valve body 188 and the valve seat 190. In some embodiments, the valve anchor 196 is positioned at or near the second end 194b of the valve stem 194.

[0059] In some cases, the valve seat 190 is formed as a portion of the regulator cap 166. As illustrated in Figures 7-10, the valve seat 190 can comprises a separate component configured to mate with or otherwise connect with the regulator cap 166. For example, the valve seat 190 can include a mating portion 198. The mating portion 198 can be configured to mate with the plug portion 168 of the regulator cap 166. In some embodiments, an outer cross-section of the mating portion 198 can be sized and shaped to substantially match an inner cross-section of the plug portion 168. In some embodiments, the mating portion 198 of the valve seat 190 is friction-fit to the plug portion 168. In some embodiments, adhesives or other mating materials are used to mate the mating portion 198 to the plug portion 168. The valve seat 190 can include a stop portion 200. The stop portion 200 can be configured to limit the extent to which the mating portion 198 is inserted into or over the plug portion 168. For example, the stop portion 280 can have a larger cross-sectional area than the mating portion 198.

[0060] The stop portion 200 or some other portion of the valve seat 190 or of the regulator cap 166 can include a seat aperture 202. The seat aperture 202 can have a cross-sectional shape configured to receive at least a portion of the valve stem 194. The stop portion 280 can have a thickness (e.g., as measured substantially parallel to the regulator centerline 1S2 in Figure 7) such that the valve stem 194 and/or other portions of the valve body 188 are elastically deformed when the valve stem 194 is mated with the seat aperture 202. For example, the thickness of the stop portion 208 can be greater than a distance between the valve anchor 196 and the lip portion 193 of the valve body 188 when the valve body 188 is in a non-deformed
configuration. In some embodiments, the lip portion 193 of the valve body 188 is deflected away from the valve anchor 196 when the valve stem 194 is mated with the seat aperture 202. Deflection of the lip portion 193 away from the valve anchor 196 can bias the lip portion 193 toward the stop portion 200. Contact between the lip portion 193 and the stop portion 200 of the valve seat 190 can form a seal to inhibit or prevent fluid flow through the valve seat 190 past the flap portion 191 of the valve body 188. In some embodiments, deflection of the lip portion 193 away from the valve anchor 196 can bias the regulator valve 186 to the closed configuration.

[0061] In some embodiments, the valve stem 194 includes a flexibility-increasing feature. For example, the valve stem 194 can include a cored portion 284. The cored portion 204 can increase the compressibility of the valve stem 194. In some embodiments, the cored portion 204 can increase a sealing force between the valve stem 194 and the seat aperture 202. For example, the cored portion 204 can facilitate insertion of a valve stem 194 having a larger width (e.g., diameter) than would otherwise be capable of insertion into the seat aperture 202.

[0062] As illustrated in Figure 9, the valve seat 190 (e.g., the cap portion 200 of the valve seat 190) can include one or more valve channels 206. The valve channels 206 can facilitate fluid communication between the first regulator inlet 154 and the regulator valve 186. For example, the one or more valve channels 206 can facilitate fluid communication between the filter chamber 172 and the flap portion 191 of the regulator valve 186. In some embodiments, each of the one or more valve channels 206 is positioned within the periphery of the flap portion 191 of the regulator valve 186 (e.g., radially inside of the contact area between the lip portion 193 and the stop portion 200). In some embodiments, space between the valve stem 194 and the seat aperture can facilitate fluid communication between the filter chamber 172 and the flap portion 191 of the regulator valve 186.

[0063] The regulator assembly 158 can be configured to regulate pressure within the vial when compounds (e.g., liquids, gases, and/or solids) are introduced into or withdrawn from the vial. For example, introduction of a compound into the vial via the access channel 142 can increase the pressure within the vial. The regulator assembly ISO can be configured to release at least a portion of the excess pressure (e.g., the pressure above ambient pressure) by, for example, releasing gas from the vial through the second regulator inlet 156 via the regulator channel 162.

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As shown in Figure 7, the second filter 178 can be configured to filter fluid passing from the second regulator lumen 182 into the ambient environment.

[0064] In some cases, the regulator assembly 150 can be configured to relieve pressure deficits within the vial. For example, withdrawing compounds from the vial via the access channel 142 can decrease the pressure within the vial. Decreased pressure within the vial can create a vacuum in the first regulator lumen 165 and/or in the second regulator lumen 176. The regulator assembly 150 can be configured to introduce ambient air (e.g., filtered ambient air) into the vial when a vacuum is created in the first and/or second regulator lumens 160, 176. For example, the regulator assembly 130 can draw ambient air into the vial via the second regulator inlet 156, through second filter 178, and/or through the regulator channel 162. In some cases (e.g., when the second regulator inlet 156 is partially or fully blocked or clogged), creation of a vacuum in the first regulator lumen 160 between the regulator valve 186 and the regulator channel 162 can create a pressure differential across the flap portion 191 of the regulator valve 186. For example, the pressure on the side of the flap portion 191 in communication with the first regulator inlet 154 can be approximately ambient pressure while the pressure on the side of the flap portion 191 in communication with the regulator channel 162 can be below ambient pressure. The regulator valve 186 can be configured to release the seal between the lip portion 193 of the flap portion 191 and the stop portion 200 of the valve seat 190 when the pressure differential across the flap portion 191 exceeds a threshold value (e.g., a cracking pressure). In some cases, the cracking pressure of the flap portion 191 can be greater than or equal to about 0.1 psi and/or less than or equal to about 5 psi. Release of the seal between the lip portion 193 of the flap portion 191 and the stop portion 208 of the valve seat 190 can transition the regulator valve 186 to an opened configuration. Transitioning the regulator valve 186 to the opened configuration can permit passage of air (e.g., filtered air) from the ambient surroundings into the vial. Introducing air from the ambient surroundings into the vial can increase the pressure within the vial and can reduce the pressure differential across the flap portion 191 of the regulator valve 186. Many variations are possible.

[0065] In some embodiments, the regulator valve 186 is configured to operate independent of the orientation of the valve adaptor 100. For example, the
regulator valve 186 can be configured to operate in substantially the same manner whether the connector Interface 148 is oriented above or below the piercing tip 122 of the piercing member 120. In some embodiments, the regulator valve 186 is configured to inhibit or prevent wetting of the first filter 174 from liquid within the vial. As explained above, the regulator valve 186 can operate as a one-way valve to permit fluid passage from the first regulator inlet 154 to the vial when the cracking pressure on the flap portion 191 of the regulator valve 186 is reached. Maintaining the first filter 174 in a dry condition can permit use of a small (e.g., small diameter) filter in the first filter chamber 172.

[0066] Figure 11 illustrates an embodiment of a vial adaptor 1100 that can have any components or portions of any other vial adaptors disclosed herein. In some embodiments, the vial adaptor 1100 includes a connector interface 1140 and a piercing member 1120 in partial communication with the connector interface 1140. In some embodiments, the vial adaptor 1100 includes a regulator assembly 1150. As illustrated, the vial adaptor 1100 can be configured to regulate pressure within vial introduction of compounds to and/or withdrawal of compounds from the vial. Some numerical references to components in Figure 11 are the same as or similar to those previously described for the vial adaptor 100 (e.g., piercing member 1120 v. piercing member 120). It is to be understood that the components can be the same in function or are similar in function to previously-described components. The adaptor 1100 of Figure 11 shows certain variations to the adaptor 100 of Figures 1-10. As illustrated in Figure 11, the regulator cap 1166 and valve seat 190 can form a unitary component. In some cases, the valve seat aperture 1200 can be positioned on the plug portion 1168 of the regulator cap 1166.

[0067] As illustrated in the figures of this application, including in Figure 7, a pressure-regulating vial adaptor can be manufactured using any suitable manufacturing process that provides any or all of the components that are illustrated and/or described in this specification, either alone or in combination with one or more other components that are illustrated and/or described in this specification.

[0068] For expository purposes, the term "horizontal" as used herein is defined as a plane parallel to the plane or surface of the floor of the area in which the device being described is used or the method being described is performed,
regardless of its orientation. The term "floor" floor can be Interchanged with the term "ground." The term "vertical" refers to a direction perpendicular to the horizontal as just defined. Terms such as "above," "below," "bottom," "top," "side," "higher," "lower," "upper," "over," and "under," are defined with respect to the horizontal plane.

[0069] The terms "approximately", "about", "generally" and "substantially" as used herein represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", "generally," and "substantially" may refer to an amount that is within less than 10% of the stated amount.

[0070] Although the vial adaptor has been disclosed in the context of certain embodiments and examples, it will be understood by those skilled in the art that the vial adaptor extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the embodiments and certain modifications and equivalents thereof. For example, some embodiments do not include a second regulator inlet 156 and, instead, regulate pressure within the vial via the first regulator inlet 154. Accordingly, it is intended that the scope of the vial adaptor herein-disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.
THE FOLLOWING IS CLAIMED:

1. An adaptor configured to couple with a sealed vial, the adaptor comprising:
   a connector interface;
   an access channel in fluid communication with the connector interface;
   a regulator assembly comprising:
      a first regulator inlet in fluid communication with an ambient environment surrounding the adaptor;
      a first regulator lumen;
      a second regulator inlet in fluid communication with the ambient environment;
      a second regulator lumen;
      a first filter capable of fluid communication with the first regulator lumen and configured to filter fluid passing into the first regulator lumen;
      a second filter in fluid communication with the second regulator lumen and configured to filter fluid passing from the second regulator lumen and into the ambient environment; and
      a regulator valve in fluid communication with the first regulator lumen, the regulator valve configured to permit passage of fluid from the ambient environment into the first regulator lumen, and the regulator valve configured to prevent passage of fluid from within the vial to the first filter;
   a piercing member comprising a proximal end and a distal end, the distal end comprising a piercing tip; and
   a regulator channel positioned at least partially within the piercing member and comprising a first regulator channel opening in fluid communication with the first regulator lumen.

2. The combination of the adaptor of Claim 1 and the sealed vial.

3. The adaptor of Claim 1 in which the regulator valve comprises a valve stem and a flap portion.
4. The adaptor of Claim 3, wherein the flap portion comprises a concave side and a convex side.

5. The adaptor of Claim 1, wherein the first regulator lumen and the second regulator lumen are in fluid communication with each other.

6. The adaptor of Claim 1, wherein the regulator valve is positioned in a plug portion that is inserted into the regulator lumen.

7. The adaptor of Claim 6, wherein the plug portion is flexible.

8. The adaptor of Claim 7, wherein the plug portion is retained within the regulator lumen by a friction fit.

9. The adaptor of Claim 7, wherein a cap portion limits the extent to which the plug portion is inserted into the regulator lumen,

10. The adaptor of Claim 9, wherein the first filter is positioned in the plug portion.

11. The adaptor of Claim 1, wherein the first filter is positioned within the first regulator lumen.

12. The adaptor of Claim 11, wherein the second filter is positioned within the second regulator lumen.

13. The adaptor of Claim 1, wherein the first and second filters are positioned along a common line that is generally perpendicular to the regulator channel.

14. The adaptor of Claim 13, wherein the regulator valve is positioned along the common line.

15. A method of manufacturing a vial adaptor comprising the steps of:
providing a connector interface;
providing an access channel in fluid communication with the connector interface;
providing a regulator assembly comprising:
   a first regulator inlet in fluid communication with an ambient environment surrounding the adaptor;
   a second regulator inlet in fluid communication with the ambient environment;
   a first filter configured to filter fluid passing into the vial adaptor;
a second filter configured to filter fluid passing from the vial adaptor into the ambient environment; and

a regulator valve configured to permit passage of fluid from the ambient environment into the vial adaptor, and the regulator valve configured to inhibit passage of fluid from within the vial to the first filter;

providing a piercing member comprising a proximal end and a distal end, the distal end comprising a piercing tip; and

providing a regulator channel positioned at least partially within the piercing member and comprising a first regulator channel opening, the regulator channel being in fluid communication with the second filter and the regulator valve.

16. The method of Claim 15, in which the first and second regulator inlets are provided along a common line that is generally perpendicular to the regulator channel.

17. The method of Claim 16, in which the regulator valve is providing along the common line.

18. The method of Claim 15, wherein the regulator valve is configured to prevent passage of fluid from within the vial to the first filter.

19. The method of Claim 15, wherein the regulator valve comprises a valve stem and a flap portion.

20. The method of Claim 19, wherein the flap portion has a concave side and a convex side.
FIG. 1
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61J 1/20 (2015.01)
CPC - A61J 1/20 (2015.07)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61J 1/00, 1/05, 1/20, 1/22 (2015.01)
USPC - 128/6/12; 137/798; 855; 141/18, 329; 206/438; 215/228, 247; 220/694; 222/478; 251/303; (Continued below)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

CPC - A61J 1/00, 1/05, 1/20, 1/22 (2015.07) (keyword delimited)
USPC - (Continued) 604/403, 405, 406, 407, 411, 414..415

Electronic database consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Google Scholar, Google, YouTube.

Search terms used: vial, adaptor, adapter, lap, valve, needle, puncture, pierce, flex, resilient, bend, elastic, filter

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
</table>

Further categories of cited documents:

“A” document defining the general state of the art which is not considered to be of particular relevance

“E” earlier application or patent but published on or after the international filing date

“L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

“O” document referring to an oral disclosure, use, exhibition or other means

“P” document published prior to the international filing date but later than the priority date claimed.

Date of the actual completion of the international search

11 August 2015

Date of mailing of the international search report

31 AUG 2015

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