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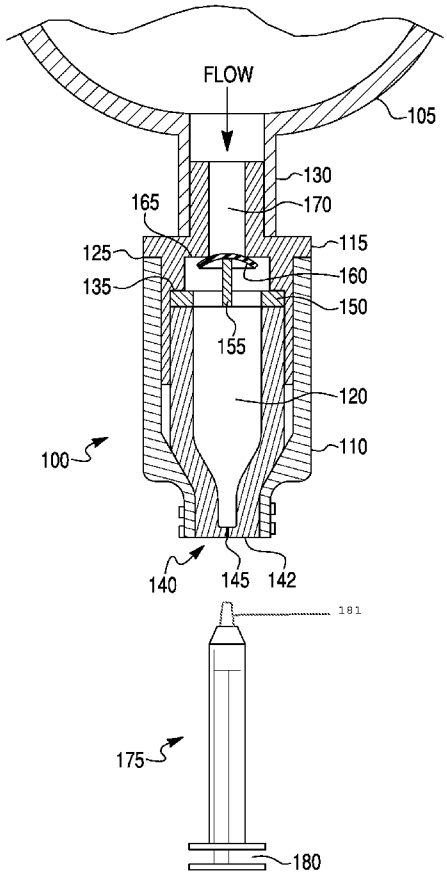
[Continued on next page]

(54) Title: FLEXIBLE MULTI-USE CONTAINER, SYSTEM AND METHOD OF MANUFACTURE

Fig. 1



(57) Abstract: The disclosed embodiments provide a valve structure that is hermetically sealed to a lower flange formed on an IV bag to form a one-way outlet accessible with a luer tip syringe that does not have a needle. The valve structure can include a piston in combination with a disc or disc valve. The piston can have a slit septum or opening allowing access to an interior surface of the piston. The disc valve is typically in a closed position that prevents injections or other incursions into the bag, thus preserving the integrity and sterility of the bag contents.

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FLEXIBLE MULTI-USE CONTAINER, SYSTEM AND METHOD OF MANUFACTURE

This application claims priority under 35 U.S.C. No. 61/943,023, filed on February 21, 2014, the disclosure of which is incorporated herein by reference in its entirety.

Field

[0001] The presently disclosed subject matter relates to a multi-use container for the storage and administration of solutions, and more particularly, to a combination multi-use, multi-compartment container and one-way dispensing valve assembly for aspirating or otherwise removing fluids from the container.

BACKGROUND

[0002] One of the most widely used methods of medical therapy involves the intravenous (IV) infusion of liquid medicaments and/or nutrients into the bloodstream of a patient. This is commonly referred to as intravenous infusion therapy and typically the entire contents of an IV container are infused into a patient during a single procedure. Conventional IV containers include IV bags or bottles which can contain the liquid to be infused into the patient.

[0003] When the IV container is a bag, a rigid, hollow, sharpened IV spike is typically pushed into the bag port to establish a pathway for fluid communication through which the liquid can flow out of the bag. The spike, in turn, is typically connected to or formed integrally with an inlet port of a small, elongated, transparent hollow container familiarly referred to as a "drip chamber," with the fluid pathway of the spike in fluid communication with the inlet port of the drip chamber. An IV line is typically connected to an outlet port (which usually is located below the inlet port) of the drip chamber. A flow control clamp (such as a roller clamp or other suitable flow regulating device) can be engaged with the IV line, and a medical technician can manipulate the flow control clamp to squeeze the IV line and thereby regulate fluid flow through the IV line. To establish a path for fluid communication from the IV container to the patient, a sharp needle is connected to the IV line to puncture the patient. Together, the drip chamber with outlet tube and clamp is referred to as an "IV set."

[0004] Typically, the bag or bottle is elevated above the patient to establish a positive pressure head to force the fluid that is within the bag or bottle through the drip chamber into the patient. Because the drip chamber is transparent, a medical technician can view the medicament as it passes (normally by dripping) through the drip chamber to aid the medical technician in

establishing a predetermined flow rate of medicament into the patient as the medical technician adjusts the roller clamp on the IV line. This IV set can also be used with a pump or fluid delivery system. Conventional IV sets that utilize a needle and catheter can be problematic because they raise the risk of needle stick injuries and contamination of the IV fluid.

[0005] Conventional IV containers, including IV bags also are typically intended for a single use due to the risk of contamination of the IV fluid. Multi-dose administration of medication is typically performed using glass vials having elastomeric stoppers that require fluid to be withdrawn using a syringe and a needle. These systems also raise the risk of needle sticks and glass breakage. Furthermore, fluids in a glass vial are premixed and thus have shorter shelf life than unmixed medications.

SUMMARY

[0006] In view of the foregoing characteristics of and problems with conventional IV containers, the disclosed embodiments provide a multi-compartment, multi-use container that allows for drug reconstitution and safe access for multi-use applications. Multi-use applications can also be referred to as multi-dose applications that allow withdrawing medication for periodic administration to a single patient from a single container until the container is empty or until the need no longer exists for the bag contents. The terms multi-use container, multi-dose container multi-use bag, multi-dose bag and IV bag can be used interchangeably based on the intended use of the container. In one embodiment of the disclosed subject matter, the multi-dose container is a multi-compartment plastic bag having a one-way, needle free, aspiration valve. In accordance with the disclosed embodiments, the multi-compartment bag can separate one component, such as a drug, from another component, such as a diluent.

[0007] The disclosed embodiments include a multi-compartment plastic bag that can be segmented or partitioned into a plurality, e.g., two, three or more, chambers separated by at least one peelable seal. The peelable seals are rupturable so as to facilitate the mixing of the contents between the various chambers. For example, rupturing a peelable seal could allow the contents of the chambers to safely mix without exposure to the environment or being contacted by

humans. A chamber can be larger than the other chamber(s) or each chamber can be of equal or substantially similar dimensions or volume. A first chamber, which can be the larger chamber, can contain a liquid diluent(s) while the other chamber(s) can contain an active pharmaceutical ingredient (API), which can be a dry powder, liquid, or gas. Another chamber can be empty and define or form a buffer space or region that separates the drug from a delivery set port.

[0008] The disclosed embodiments further include a valve structure that is hermetically sealed to a lower flange formed on the plastic bag to form a one-way outlet accessible with a luer tip syringe that does not have a needle. In accordance with an embodiment of the disclosed subject matter, the valve structure can include a piston in combination with a disc or disc valve. In this embodiment, the piston can have a slit septum or opening allowing access to an interior surface of the piston. Also, in this embodiment, the disc valve is typically in a closed position. This normally closed position prevents injections into the bag, thus preserving the integrity of the bag contents.

[0009] Thus, the exemplary valve structure can be used for aspirating fluid from a container such as an intravenous fluid bag. In one embodiment, the valve structure partially opens when the luer tip of a syringe is inserted into the slit septum. In this embodiment, the valve structure fully opens when the syringe plunger is pulled back, creating a negative pressure on the opening and the normally closed valve disc. In particular, when a syringe is attached to a lower portion of the valve structure and the syringe plunger is withdrawn, a negative pressure is created and increases the relative pressure forcing the disc to further flex away from a valve seat (shoulder). When the negative pressure created by the syringe plunger is released, the disc returns to its normally closed position with a top surface of the disc and the shoulder forming an annular seal. When a full or partially full syringe is attached to the dispensing valve assembly, it is difficult and/or impossible to empty the contents of the syringe into a container through the valve. Positive pressure applied by the syringe plunger will only contribute to a tighter seal between the top surface of the disc and the valve shoulder.

[0010] The disclosed valve structure and multi-dose container combination prevents fluid

seepage if the bag is dropped or squeezed excessively. In most cases, positive pressure on the bag would open the normally closed disc valve. However, the addition of a slit septum adds an additional barrier to leakage. The slit septum also provides additional contamination protection by providing a surface that can easily be cleaned with an alcohol wipe.

[0011] Thus, the disclosed embodiments provide a one-way dispensing valve assembly for aspirating fluid, which allows for withdrawal of fluid from a container, but does not allow flow of fluid back into the same or different container. The disclosed subject matter also provides a one-way aspiration valve that prevents the introduction of contaminants and infectants back into the original receptacle, such as an IV bag. The exemplary one-way dispensing valve assembly for aspirating fluid can prevent alteration and dilution of the fluid in an original container by preventing the reintroduction of an unused portion of the fluid back into the original container. The disclosed embodiments further provide a one-way dispensing valve assembly for aspirating fluid into a syringe (without needle).

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The disclosed subject matter of the present application will now be described in more detail with reference to exemplary embodiments of the apparatus, system, and method, given by way of example, and with reference to the accompanying drawings, in which:

[0013] Fig. 1 is a cross-sectional view of a one-way, needle free, aspiration valve in communication with a lower portion of a multi-dose container in accordance with an embodiment of the disclosed subject matter;

[0014] Fig. 2 is a perspective view of a spacer in accordance with an embodiment of the disclosed subject matter; and

[0015] Fig. 3 is a perspective view of a multi-compartment bag and valve structure in accordance with an embodiment of the disclosed subject matter.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0016] This application incorporates by reference the entire disclosures of the following commonly assigned patents and patent applications: U.S. Patent Nos. 5,944,709; 6,198,106;

6,165,161; 6,203,535; 5,910,138; 5,928,213; 6,468,377; 6,117,123; 6,846,305; 6,764,567; 6,996,951; U.S. Provisional Application No. 61/872,833; and U.S. Provisional Application No. 61/909,034.

[0017] Fig. 1 shows a cross-sectional view of an embodiment of a valve structure 100 in fluid communication with multi-dose container 105. The valve structure 100 of this embodiment is generally cylindrical in shape, however, it should be understood that the valve structure 100 can be any number of shapes including, but not limited to a square, rectangular, etc. The valve structure 100 allows one-way, multi-use access to the contents of the container 105 without the use of a needle. The valve structure 100 includes a housing 110 and a connector 115. The connector 115 includes a first shoulder 135 and a second shoulder 165. As shown in Fig. 1, a portion of the connector 115 is fitted within an internal surface (inner wall) of the housing 110 so that a first passageway 120 and a second passageway 170 are formed. The connector 115 can be held within the housing 110 through a variety of mechanisms, such as through friction fitting. Alternately, the connector 115 can be coupled to the housing 110 through a sonic weld formed at a welding point 125, or by a separate device such as a clamp or pin, etc. The connector 115 is configured to be in fluid communication with a bag port 130 formed on a lower surface of the container 105. This allows fluid communication to occur between an interior of the valve structure and the contents of the container. The disclosed embodiments also contemplate the connector 115 being formed integrally with the bag port 130. In this embodiment, the bag port 130 is formed as a portion of the valve structure 100.

[0018] Fig. 1 also shows a piston 140 formed within the first passageway 120. The piston 140 has a first end that terminates at a slit septum 142. As shown in Fig. 1, a slit 145 is formed through the slit septum 142 that allows access to the first passageway 120. A portion of an opposing end of the piston 140 can be in communication with an inner surface of the connector 115. Fig. 1 also shows a spacer 150 formed between an opposing end of the piston 140 and the first shoulder 135 of the connector 115. The spacer 150 also includes a rib portion 155 formed across opposing circumferential surfaces of the spacer 150. The exemplary spacer 150 of Fig. 1

has a generally circular (cylindrical) shape and the rib portion 155 is generally triangular in shape and extends in a direction parallel to a central axis of the opening of the spacer 150.

[0019] Fig. 1 also shows a resilient valve disc 160 that separates the first passageway 120 from the second passageway 170. The valve disc 160 can be made from a number of resilient materials, such as a silicone elastomer, in a variety of suitable thicknesses. As described above, the rib portion 155 is shown as a triangular base, but can be any shape that will accommodate a bottom surface of valve disc 160 and help provide a seal between a top surface of the valve disc 160 and the second shoulder 165 (also referred to as a valve seat 165). Fig. 1 also shows a syringe 175 having a plunger 180. The syringe can be configured such that its tip 181 can be inserted into the first passageway 120 via the slit 145 of the slit septum 142.

[0020] In the normally closed position, valve disc 160 is partially flexed by the rib portion 155 against the valve seat 165 to form an annular seal. During aspiration, the valve disc 160 is further flexed and separated from valve seat 165 by a drop in differential pressure of the first passageway 120 relative to the second passageway 170. This differential pressure or pressure drop can be realized by inserting the tip of the syringe 175 into the first passageway 120 and then pulling back the syringe plunger 180. As valve disc 160 is flexed away from valve seat 165, the annular seal is broken to permit fluid flow from the second passageway 170 to first passageway 120, typically in a downward or lateral direction. When the pulling action of the syringe is stopped, valve disc 160 returns to its original, normally closed position with the top surface of the disc 160 in contact with valve seat 165, thereby renewing the seal and preventing flow in either direction. Specifically, flow from the syringe 175 and from the first passageway 120 back into the bag 105 is prevented to avoid contamination of the remaining contents of the bag 105.

[0021] In one embodiment, the top of rib 155 is substantially co-planar with the valve seat 165. This spatial relationship creates a seal between the disc 160 and the valve seat 165 for a variety of disc thicknesses.

[0022] The slit 145 formed on the bottom surface 142 of the piston 140 is capable of receiving the luer tip of the syringe 175. When a luer tip 181 of the syringe 175 is inserted into the slit

145, the valve structure 100 is partially opened. The valve structure 100 fully opens when, as described above, the plunger 180 of the syringe 175 is pulled back creating a negative pressure within the first passageway 120 and thus opening the normally closed disc 160.

[0023] The disclosed valve closure combination, e.g., the disc 160 and the slit 145, prevents fluid seepage if the bag is dropped or squeezed excessively. Typically, positive pressure on the bag would open a normally closed disc, but the addition of a septum creates additional protection against leakage and adds an additional layer of contamination protection by providing a surface that can be easily cleaned with an alcohol wipe.

[0024] The piston 140 can be configured of relatively elastic material (elastic at least with respect to the housing 110 and the connector 115) such that when a reduced pressure exists in the first passageway 120, the piston 140 allows the spacer 150 and disc 160 to move downward against the elastic force of the piston 140 material to thus unseat the disc from the valve seat 165 and open the valve 100. When pressure is normalized between chambers 120 and 170, the elastic return force of the piston 140 allows the spacer 150 and disc 160 to return to the normally closed state where the disc 160 mates with the valve seat 165. Alternatively, a separate elastic or spring structure can be provided between the spacer and the piston 140 (or other location) to provide the elastic force for opening and closing the disc 160 relative to the valve seat 165.

[0025] Fig 2 shows a close-in view of the rib portion 155 and spacer 150. The embodiment of Fig. 2 shows the spacer 150 having a circular shape so that it can be held within the exemplary valve structure 100. In the embodiment of Fig. 2, the spacer 150 and rib portion 155 are formed so that the rib portion 155 is fitted or molded integrally within the spacer 150. It should be noted that the disclosed embodiments also contemplate other shapes and configurations for both the rib portion 155 and the spacer 150, depending on the geometry of the associated valve structures. The spacer 150 and valve disc 160 are shown as being separately formed structures. However, it is contemplated that the spacer and valve disc 160 can be formed as a unitary structure rather than as separate components. Also, the shape of the valve disc 160 could be changed depending upon the shape of the valve structure 100. In addition, it is contemplated that the rib portion 155

can be formed in various alternative configurations, such as a cone with various apertures, openings or windows running along the conically extending surface, as well as various other shapes that serve to space the valve disc 160 while permitting fluid to flow through the rib portion 155 and spacer 150.

[0026] Fig. 3 shows a multi-compartment bag 300 that can be used with the valve structure 100 described above. The multi-compartment bag 300 can be formed from a generally planar front sheet 12 and an opposing generally planar back or rear sheet (not shown). The front sheet 12 and rear sheet can be constructed of a single layer of flexible material or multi-layer laminates of flexible material.

[0027] The front sheet 12 and rear sheet forming the container 300 can be provided separately and disposed opposing each other along a common plane. The sheets can then be sealed together along a common peripheral edge 16 with a permanent seal. The sealed common peripheral edge 16 extends around the entire periphery of the container 300 and cooperates with a first peelable seal 25 to form a first chamber 17. The peripheral seal may vary in configuration and width, and can be formed by heat sealing, vibration welding, etc. An opening 18 can be provided on a top surface of the container 300 which allows the container to be mounted, hung from, or otherwise attached to, for example, a support stand. Alternatively, the front sheet 12 and rear sheet (not shown) may be formed from a single film sheet which is folded-over and the edges sealed together by any known or later developed sealing process.

[0028] In the exemplary embodiment of Fig. 3, the bag 300 is partitioned into three separate chambers: a first or upper chamber 17; a second or intermediate chamber 19; and, a third or lower chamber 20, each of which can be sterile, depending on the intended application of the bag 300. The upper and intermediate chambers 17 and 19 are separated from one another by a first peelable seal 25, while the intermediate and lower chambers 19 and 20 are separated from one another by a second peelable seal 26. In other embodiments of the disclosed subject matter, a peelable seal can only be provided between the upper chamber 17 and the intermediate chamber 19. In these embodiments, the seal between the intermediate chamber 19 and the lower chamber

20 can be rupturable through the application of a hydraulic force caused by a user forcing the contents of the upper and intermediate chambers 17 and 19 into the lower chamber 20.

[0029] A "peelable" seal, as the term is used herein, is a seal which is sufficiently durable to allow normal handling of the container without inadvertent or unintentional rupturing of the seal (resulting in the contents of the compartments mixing unintentionally), while also allowing the seal to rupture easily when intended and desired. The seal is ruptured using hydraulic pressure applied by manipulating or squeezing the container/bag. Once the seal is intentionally ruptured, the contents from adjacent chambers 17 and 19 can be mixed together and eventually dispensed from the container. The peelable seal can be formed by partially melting together the polymeric material present in the adjoining interior faces of the front and back sheets. The seal is obtained by, for example, a heat sealing process wherein heat and pressure is applied to a localized area with varying times, temperatures, and pressures which will be described in greater detail below. Rupturing the peelable seal can allow the contents of the chambers to safely mix without exposure to the environment or being contacted by a human. It should also be understood that one chamber can be larger than the other chamber(s) or each chamber can be of equal of substantially similar dimensions or volume.

[0030] In one application for the container/bag 300, the upper compartment 17 is filled with a liquid diluent and the intermediate compartment 19 is filled with a medicament, such as an active pharmaceutical ingredient, or other nutritional or supplemental ingredient intended to be received intravenously or ingested by the user or patient and which can be provided in any form, including a liquid, gel, gas, or solid form. The lower compartment 20 can function as a security interface for an outlet port 30 and remains empty until the container is ready to be used. In this embodiment, the upper chamber 17 can contain a liquid diluent(s) while the intermediate chamber 19 can contain the medicament, active pharmaceutical ingredient (API), nutritional ingredient, or other supplemental ingredient, any of which can be either a dry powder, gel, solid or a liquid.

[0031] As shown in Fig. 3, the outlet port 30 extends downwardly and includes a nozzle

configured to engage the valve structure 100. As described above, the syringe 180 (Fig. 1) is configured to be inserted into the bottom section of the valve structure 100 via the slit 145 (Fig. 1). In use, a medical professional can mix the contents of the upper chamber 17 and the intermediate chamber 19 hydraulic force to open the peelable seal allowing the contents of the upper and intermediate chambers 17 and 19 to mix. Continued fluid pressure opens the final seal allowing the mixture to enter chamber 20. In this manner, the contents of the container are ready to be dispensed.

[0032] As described earlier, when a luer tip of the syringe 175 (Fig. 1) is inserted into the slit 145 (Fig. 1), the valve structure 100 is partially opened. The valve structure 100 fully opens when, as described above, the plunger 180 (Fig. 1) of the syringe 175 (Fig. 1) is pulled back creating a negative pressure within the first passageway 120 and thereby opening the normally closed disc 160 (Fig. 1). In this condition, fluid will flow from bag 300 through first and second passageways 170 (Fig. 1) and 120 (Fig. 1) into both the first passageway 120 and syringe 175 (Fig. 1).

[0033] A method for aspirating a fluid from a multi-dose container is also disclosed, and can include: providing the container along with a one way valve located adjacent a septum; inserting a syringe into the septum of the one way valve, the syringe including a plunger and a housing and not including a needle; and withdrawing the plunger from the housing of the syringe to cause a negative pressure within the septum and thereby drawing fluid from the container into at least one of the septum and the syringe.

[0034] As describe above, the valve structure 100, the piston 140 and the spacer 150 of Fig. 1 can have a generally cylindrical shape. However, these components can be formed in other shapes, including a rectangular shape, a square shape, etc. The valve structure 100 and its components can be made of a variety of materials, including various plastics and elastomers. For example, the housing 110, the connector 115 and the spacer 155 can be formed from a hard plastic material, such as but not limited to polypropylene, polycarbonate and the like. The piston 140 can be formed from various materials, including but not limited to elastomers. In one

embodiment, the piston 140 is formed of a resilient material having a relative hardness that is less than the relative hardness of the housing 110, the connector 115 and the spacer 155. The valve disc 160 can be made from a number of resilient materials, such as a silicone elastomer, in a variety of suitable thicknesses.

[0035] The slit 145 in the septum 142 can also have a variety of shapes. In the depicted embodiment, the slit 145 is shown as a straight line. However, it is possible for the slit 145 to be shaped as a cross, an arc, a sine wave, a star, an asterisk, or other shape. The slit 145 can be specially configured to match with the shape of a luer tip of the syringe 175. Moreover, if the luer tip of the syringe 175 is shaped as a cross, the slit 145 can also be formed as a cross to tightly seal with the luer tip when the syringe 175 is inserted in the septum 142. Additionally, the slit 145 could be replaced with a frangible hinged portion that partially tears away to allow the syringe 175 to be inserted into the septum 142, but remains attached at a hinge portion such that the frangible portion does not float away or become entrained in the fluid in the passageway 120. The slit 145 can extend from an area outside of the septum 142 all the way through the septum 142 to the first passageway 120 such that resiliency of the material that makes up the septum 142 causes the slit 145 to remain closed to separate the first passageway 120 from an area outside the valve 100. Alternatively, the slit 145 can extend only partially through the septum. In this case, it will be necessary to forceably rupture the slit 145 with the syringe 175 (or other device) to allow the syringe access to the first passageway 120.

[0036] The septum 142 described above is not limited to a slit piston, but can also be configured to function as a needleless, luer-activated valve. One such example is the type of septum disclosed in United States Patent 5,439,451 to Collinson, which teaches castellations on top, thereby allowing the fluid to flow around the piston instead of through the piston. Another alternate embodiment could be a piston having a slit and internal cannula as disclosed in United States patent 6,113,068, wherein the syringe moves the piston inward thereby exposing the cannula via the slit, which would allow the fluid to pass through the cannula and out of the valve.

[0037] In the above description and the claims that follow, words descriptive of orientation

(upper, bottom, etc.) are provided to clarify the disclosed subject matter. They refer to the orientation shown in the drawings. However, it should be understood that the disclosed valve may be used in any orientation.

[0038] Since the disclosed subject matter is subject to modifications and variations, it is intended that the foregoing description and the accompanying drawings shall be interpreted as illustrative of only one form of the disclosed embodiments, whose scope is to be measured by the following claims. In addition, the disclosure and teachings in all of the above-described related art patent documents are herby incorporated in their entireties by reference.

Claims:

1. An aspiration valve device comprising:

a housing body having a first passageway therethrough;

a connector body having a second passageway therethrough, the connector body including a first seat and a second seat, at least a portion of the connector body formed within the first passageway;

a piston body formed within the first passageway, the piston body including a septum disposed at a first end of the piston body; and

a flexible valve disc having a top surface, the flexible valve disc mounted between the housing body and the connector body, wherein the housing body, the connector body and the flexible valve disc form a one-way valve,

wherein the top surface of the disc forms an annular seal with the second seat of the connector body.

2. The aspiration valve device according to claim 1, including a spacer formed between the first shoulder of the connector body and the piston body.

3. The aspiration valve device according to claim 1, wherein the piston body is configured such that a fluid pressure drop in the first passageway increases a relative pressure in the second passageway such that the disc is flexed away from the second shoulder and allows fluid from the second passageway into the first passageway.

4. The aspiration valve device according to claim 1, wherein the housing body and the connector body are formed as a single unitary structure.

5. The aspiration valve device according to claim 1, wherein the septum of the piston body includes a slit defined therein.

6. The aspiration valve device according to claim 1, further comprising:
a flexible bag configured to be removably attached to the connector body.

7. The aspiration valve device according to claim 6, wherein the flexible bag includes multiple chambers separated by peelable seals such that the contents of the flexible bag can be selectively mixed at a desired time.

8. The aspiration valve device according to claim 7, further comprising:
a syringe configured to mate with the septum in the piston body.

9. The aspiration valve device according to claim 6, further comprising:
a syringe configured to mate with the septum in the piston body.

10. The aspiration valve device according to claim 1, further comprising:
a syringe configured to mate with the septum in the piston body.

11. The aspiration valve device according to claim 1, wherein the piston body is made from an elastic material and the housing body is made from a material that is relatively inelastic as compared to the elastic material of the piston body.

12. The aspiration valve device according to claim 11, wherein the connector body and the housing body are a single integral structure.

13. The aspiration valve device according to claim 1, further comprising:
a spacer located between the piston body and the valve disc, the spacer including at least one opening that allows fluid flow to pass therethrough.

14. The aspiration valve device according to claim 13, wherein the piston body includes a cylinder made from a relatively elastic material, and the spacer is located at an end of the piston body and configured to maintain the valve disc in a first closed state when a first pressure exists in the first passageway and to allow the valve disc to move to a second open state when a second pressure lower than the first pressure exists in the first passageway.

15. An aspiration valve device comprising:

a housing defining a first passageway and a second passageway, the housing including a connector opening at an end of the second passageway located at a connector end of the housing, and the housing including an outlet opening at an end of the first passageway located at an outlet end of the housing;

a valve structure located between the first passageway and the second passageway; and

an elastomeric structure located within the first passageway and relatively more elastic than the housing, the elastomeric structure configured to bias the valve structure towards a closed state where the valve structure does not permit fluid to flow between the first passageway and second passageway, the elastomeric structure also including a port structure located adjacent the outlet end of the housing and configured to be connected to a source of negative pressure.

16. The aspiration valve device of claim 15, further comprising a spacer structure located between the valve structure and the elastomeric structure, wherein the elastomeric structure is configured as a cylinder to define a flow path therethrough, and the valve structure and spacer are located at a first end of the cylinder, and the port structure is configured as a septum located at a second opposite end of the cylinder.

17. An aspiration kit comprising:

a housing body having a first passageway and second passageway;

a valve separating the first passageway from the second passageway;

a piston body located in the first passageway, the piston body including a septum disposed at a first end of the piston body; and

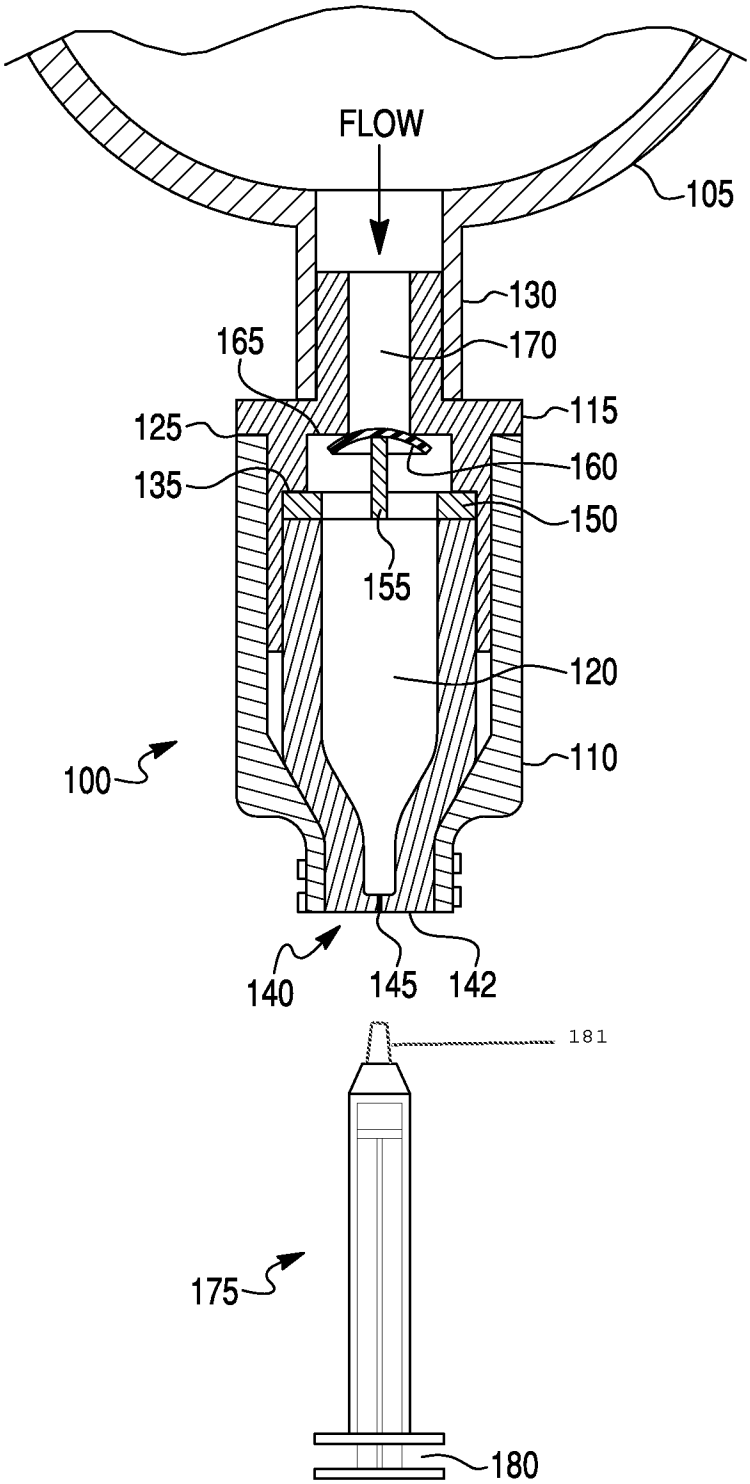
a syringe having a luer tip with no needle and configured to mate with the septum.

18. The kit of claim 6, further comprising:

a flexible dose container.

19. The kit of claim 6, wherein the septum of the piston body includes a slit defined therein.

Fig. 1


FLOW
105
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180

Fig. 2

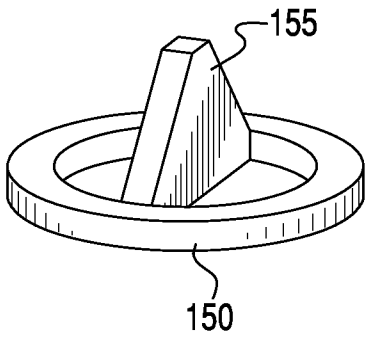
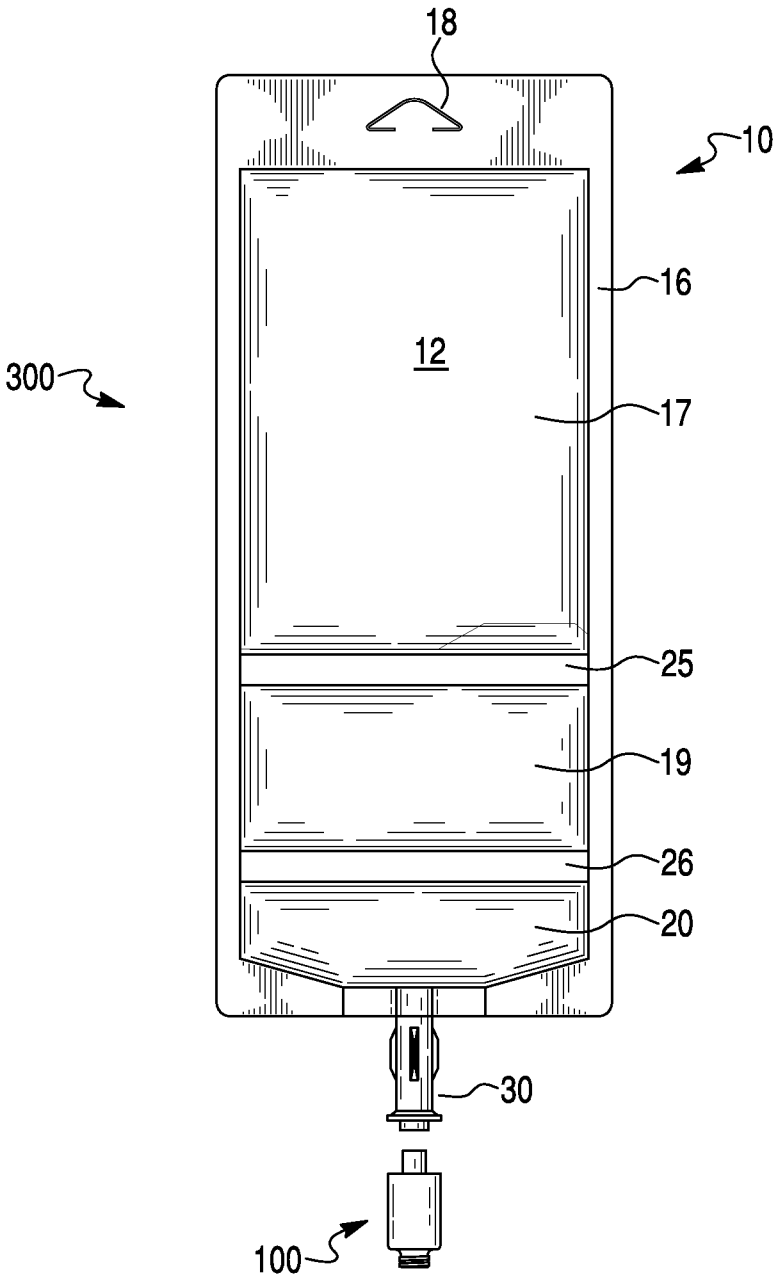

155
150

Fig. 3



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/16930

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14, directed to an aspiration valve device having a connector body.

Group II: Claims 15-16, directed to an aspiration valve device having a elastomeric structure with a port structure.

Group III: Claims 17-19, directed to an aspiration kit having a syringe with a luer tip.

----Continued on Supplemental Page---

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/16930

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/00 (2015.01)
CPC - A61M 39/24
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)
CPC: A61M 39/24 IPC(8): A61M 5/00 (2015.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/247 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Patents; Google
Search Terms Used: slit, septum, disc, disk, valve, integral, monolithic, unitary, intravenous, i.v., aspiration, reflux, check, bag, peelable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0249723 A1 (FANGROW JR.) 30 September 2010 (30.09.2010) fig 57, 58, para [0129], [0135], [0153], [0312], [0314]	1-3, 5-6, 9-14
Y		4, 7-8
Y	US 5,618,268 A (RAINES et al) 08 April 1997 (08.04.1997) fig 2A, 2B, col 9, ln 51-53	4
Y	US 2004/0068960 A1 (SMITH et al) 15 April 2004 (15.04.2004) abstract, para [0153]	7-8

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier 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
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 June 2015 (23.06.2015)	14 JUL 2015

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/16930

Continuation of Box III: Observations where unity of invention is lacking

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a connector body having a second passageway therethrough, the connector body including a first seat and a second seat, at least a portion of the connector body formed within the first passageway, not required by the claims of Groups II or III.

The invention of Group II includes the special technical feature of the elastomeric structure also including a port structure located adjacent the outlet end of the housing and configured to be connected to a source of negative pressure, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a syringe having a luer tip with no needle and configured to mate with the septum, not required by the claims of Groups I or II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical features of a housing body having a first passageway and second passageway; and a valve separating the first passageway from the second passageway;. However, this shared technical feature do not represent a contribution over prior art as being anticipated by US 2010/0249723 A1 (FANGROW JR.), which teaches a housing body (1322, 1324) having a first passageway (top open end of 1322) and second passageway (bottom open end of 1324, fig 57); and a valve (1330) separating the first passageway from the second passageway (fig 57).

Groups I and III additionally share the common technical feature of a piston body located in the first passageway, the piston body including a septum disposed at a first end of the piston body. However, this shared technical feature does not represent a contribution over prior art as being anticipated by Fangrow Jr., which teaches a piston body (1326) located in the first passageway, the piston body including a septum (fig 58 shows 1328 protruding out of piston, septum inherent) disposed at a first end of the piston body (fig 57, 58).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

NOTE: Claims 18-19 improperly depend from claim 6. It is assumed that claims 18-19 are dependent upon claim 17.