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Intravenous fluid bag with an integrated valve having a seal with a compressed state that permits fluid flow into the bag and a relaxed state preventing fluid flow

Abstract

An intravenous fluid bag comprising: a primary chamber configured to retain a liquid; a valve in fluid communication with the primary chamber, the valve including a housing, a spike element, and a seal, with the housing surrounding the seal, which surrounds the spike element; the spike element having a first end culminating in a tip, a second end having an inner conduit, and one or more through holes between the tip and the second end in fluid communication with the inner conduit forming part of a continuous liquid passageway in fluid communication with the primary chamber; the seal having a relaxed state preventing fluid flow through the valve, and the seal having a compressed state through which the through holes of the spike element extend allowing fluid flow from a source external the intravenous fluid bag, through the through holes, through the inner conduit, and into the primary chamber.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This Application is a continuation of application Ser. No. 15/938,953 filed on 28 Mar. 2018 (now U.S. Pat. No. 11,129,771), the entirety of which is incorporated herein by reference in its entirety.

FIELD OF THE DISCLOSURE
(1) The present disclosure generally relates to an intravenous fluid bag.
BACKGROUND OF THE DISCLOSURE

(2) An intravenous fluid bag sometimes includes an injection port. The injection port allows for another fluid, which can contain a medicament, to be injected into the intravenous fluid bag. The injection port sometimes requires a metal needle to pierce the injection port to inject the medicament-containing fluid into the intravenous fluid bag. The use of metal needles can cause injury, can damage the intravenous fluid bag, and can require special disposal processes.

BRIEF SUMMARY OF THE DISCLOSURE

(3) According to a first aspect of the present disclosure, an intravenous fluid bag includes a primary chamber configured to retain a liquid. A valve is in fluid communication with the primary chamber. The valve includes a housing, a spike element, and a seal, with the housing surrounding the seal, which surrounds the spike element. The spike element includes a first end culminating in a tip, a second end having an inner conduit, and one or more through holes between the tip and the second end in fluid communication with the inner conduit forming part of a continuous liquid passageway in fluid communication with the primary chamber. The second end is disposed closer to the primary chamber than the tip. The seal includes a first end, a second end, and a seal cap at the first end. The seal includes a relaxed state in which the seal forms a liquid tight seal over the through holes preventing fluid flow through the valve. The seal includes a compressed state through which the tip and the through holes of the spike element extend allowing fluid flow from a source external the intravenous fluid bag, through the through holes, through the inner conduit, and into the primary chamber.

(4) Embodiments of the first aspect of the invention can include any one or a combination of the following features: a plastic sleeve surrounds a length of the housing of the valve and holds the valve in place; the primary chamber is formed of plastic that is contiguous with the plastic sleeve that surrounds the housing of the valve; a plastic sleeve surrounds the inner conduit of the spike element of the valve and holds the valve in place; the primary chamber is formed of plastic that is contiguous with the plastic sleeve that surrounds the inner conduit of the spike element of the valve; the inner conduit has an outer surface that is cylindrical; the housing includes a hollow interior that surrounds the tip of the spike element; the inner conduit of the spike element is not in fluid communication with the hollow interior of the housing when the seal is in the relaxed state; the housing has an outer surface and threads extending from the outer surface configured to couple with a syringe; the one or more through holes are 18 gauge in size or larger; the first end of the seal has a flat external surface not covered by the housing; the housing has a first end that is open forming an opening; the first end of the housing at the opening and the flat external surface of the seal are flush; the seal forms a conically shaped cavity in which the tip of the spike element is disposed when the seal is in the relaxed state; the seal includes a plurality of ringed wall portions that collapse when the seal moves from the relaxed state to the compressed state; the seal cap includes a piercing through which the tip and the through holes of the spike element extend when the seal is in the compressed state; when the seal is in the relaxed state, the piercing is closed and does not permit the flow of fluid through the seal cap; and an antimicrobial coating including a silane quaternary ammonium ion or salt thereof.

(5) According to a second aspect of the present disclosure, a method of introducing a second liquid into an intravenous fluid bag that contains a first liquid includes presenting an intravenous fluid bag. A primary chamber retains at least the first liquid. A valve is in fluid communication with the primary chamber. The valve includes a housing, a spike element, and a seal, with the housing surrounding the seal, which surrounds the spike element. The spike element includes a first end culminating in a tip, a second end having an inner conduit, and one or more through holes between the tip and the second end in fluid communication with the inner conduit forming part of a continuous liquid passageway in fluid communication with the primary chamber. The second end is disposed closer to the primary chamber than the tip. The seal includes a first end, a second end, and a seal cap at the first end. The seal includes a relaxed state in which the seal forms a liquid tight seal over the through holes preventing fluid flow through the valve. The seal has a compressed

state through which the tip and the through holes of the spike element extend when the seal is in the compressed state allowing fluid flow from a source external the intravenous fluid bag, through the through holes, through the inner conduit, and into the primary chamber. A second liquid container includes a second liquid. A valve interaction portion includes a seal compression element surrounding a liquid outlet. The second liquid container includes a pressure inducing element. The seal of the valve of the intravenous fluid bag is compressed from the relaxed state into the compressed state with the seal compression element of the second liquid container. The second liquid is caused to flow from the second liquid container through the valve of the intravenous fluid bag and into the primary chamber of the intravenous fluid bag with the first liquid.

(6) Embodiments of the second aspect of the invention can include any one or a combination of the following features: the valve interaction portion of the second liquid container further comprising a thread receiver; the housing of the valve of the intravenous fluid bag has an outer surface and threads extending from the outer surface; compressing the seal of the valve of the intravenous fluid bag into the compressed state occurs while the thread receiver is receiving the threads of the housing of the valve of the intravenous fluid bag; the one or more through holes are 18 gauge in size or larger; the liquid outlet of the valve interaction portion of the second liquid container is 18 gauge in size or larger; the seal of the intravenous fluid bag including a plurality of ringed wall portions; compressing the seal of the valve of the intravenous fluid bag into the compressed state causes the plurality of ringed wall portions to collapse; moving the seal compression element away from the second end of the seal, thereby allowing the seal of the valve of the intravenous fluid bag to move to the relaxed state; the intravenous fluid bag further comprising an outlet port; and the method further comprising: causing the first liquid and the second liquid in the primary chamber of the intravenous fluid bag to exit the intravenous fluid bag through the outlet port.

(7) These and other features, advantages, and objects of the present disclosure will be further understood and appreciated by those skilled in the art by reference to the following specification, claims, and appended drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) In the drawings:

(2) FIG. **1** is a perspective view of an embodiment of an intravenous fluid bag, illustrating an inlet port and a valve in communication with the inlet port;

(3) FIG. **2** is a perspective view of the intravenous fluid bag of FIG. **1**, taken along cross-section II-II of FIG. **1**, illustrating a liquid within a primary chamber of the intravenous fluid bag;

(4) FIG. **3** is a perspective view of the valve of the intravenous fluid bag of FIG. **1**, illustrating a plastic sleeve of the inlet port attached to the valve, surrounding an outer surface of a spike element of the valve;

(5) FIG. **4** is a blown up side view of the valve of the intravenous fluid bag of FIG. **1**, illustrating a tip of the spike element being disposed in a seal of the valve, and the seal being disposed within a housing of the valve;

(6) FIG. **5** is a front view of a vertical cross-section of the valve of the intravenous fluid bag of FIG. **1**, illustrating the housing securing the valve and the spike element, and the spike element having an inner conduit in fluid communication with the primary chamber of the intravenous fluid bag and in fluid communication with through holes near the tip of the spike element, and the seal in a relaxed state blocking further fluid communication beyond the valve;

(7) FIG. **6** is similar to FIG. **5** but illustrates the seal in a compressed state allowing fluid flow from a source beyond the valve, through the through holes of the spike element, through the inner conduit thereof, and into the primary chamber of the intravenous fluid bag;

(8) FIG. **7** is a perspective view of a second liquid container with a seal compression element being inserted into the first end of the housing of the valve of the intravenous fluid bag of FIG. **1** in order to cause a second liquid in the second liquid container to flow through the valve and into the primary chamber of the intravenous fluid bag with the liquid already in the primary chamber of the intravenous fluid bag; and

(9) FIG. **8** is a front view of a vertical cross-section of the second liquid container coupled to the valve via a thread receiver receiving a thread of the housing, the top and through holes of the spike element within a liquid outlet of the second liquid container as the seal compression element forces the seal into the compressed state allowing a pressure inducing element of the second liquid container to force the second liquid out the liquid outlet, through the through holes and then the inner conduit of the spike element of the valve, and into the primary chamber of the intravenous fluid bag.

DETAILED DESCRIPTION

(10) For purposes of description herein, it is to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification are simply exemplary embodiments of the inventive concepts defined in the appended claims. Hence, physical characteristics relating to the embodiments disclosed herein are not to be considered as limiting, unless the claims expressly state otherwise.

(11) Referring now to FIGS. **1**-**2**, an intravenous fluid bag **10** includes a primary chamber **12** to retain a liquid **14**. A plastic material **16** forms the primary chamber **12**, but other materials may be suitable. The plastic material **16** is transparent to allow the contents (e.g., the liquid **14**) of the primary chamber **12** to be seen. The plastic material **16** need not be transparent however. The intravenous fluid bag **10** includes an aperture **18**, which allows the intravenous fluid bag **10** to be hung on a pole (not illustrated) during use. The intravenous fluid bag **10** further includes an outlet port **20**, which is covered by a removable cap **22**. The removable cap **22** can be removed, allowing a spike (not illustrated) to be inserted into the outlet port **20** so that the liquid **14** (any additional liquid added to the primary chamber **12**, as discussed below) of the intravenous fluid bag **10** can be administered to the patient (also not illustrated).

(12) The intravenous fluid bag **10** further includes an inlet port **24**. The inlet port **24** includes a valve **26**, which operates to selectively permit or deny fluid communication through the inlet port **24** into the primary chamber **12**. The valve **26** is in fluid communication with the primary chamber **12**. A plastic sleeve **28** (e.g., a tubular portion) surrounds a portion of the valve **26** to hold the valve **26** in place as a component of the intravenous fluid bag **10**. The plastic sleeve **28** is contiguous with the plastic material **16** that forms the primary chamber **12**.

(13) Referring now additionally to FIGS. **3**-**6**, the valve **26** includes a housing **30**, a spike element **32**, and a seal **34**. The seal **34** surrounds a portion of the spike element **32**. The housing **30** surrounds the seal **34**. The housing **30** encloses a portion of the seal **34** and the spike element **32** to function as the valve **26** in the manner set forth in U.S. Pat. Nos. 5,685,866 and 9,433,708, which are both incorporated herein by reference in their entireties.

(14) The spike element **32** has a tip **36** defining a first end and a second end **38** with an opening **40** into an inner conduit **42**. The spike element **32** has one or more through holes **44**, which are in fluid communication with the inner conduit **42**. The one or more through holes **44** are disposed between the tip **36** and the second end **38**, and can be disposed adjacent the tip **36** as illustrated in FIG. **5**. Because the one or more through holes **44** are in fluid communication with the inner conduit **42**, the one or more through holes **44** are part of a continuous liquid passageway, via the inner conduit **42** and the opening **40**, to the primary chamber **12** of the intravenous fluid bag **10**. The one or more through holes **44** can be any size, but can be 18 gauge in size or larger to allow adequate fluid flow from an external liquid container, such as a syringe (discussed further below). The second end **38** of the spike element **32** is disposed closer to the primary chamber **12** than the tip **36**. The spike element **32** has an outer surface **46** proximate the second end **38**, which the outer surface **46** can be

cylindrical as in the illustrated embodiment, but could be any desired shape.
(15) The seal **34** has a first end **48** and a second end **50**. The seal **34** has a seal cap **52** disposed at the first end **48**. The seal **34** naturally maintains a relaxed state **54** (FIG. **5**), but can be forced into a compressed state **55** (FIG. **6**). In the relaxed state **54** (FIG. **5**), the seal **34** forms a liquid tight seal over the one or more through holes **44** preventing fluid flow through the valve **26**, such as from the primary chamber **12** of the intravenous fluid bag **10** through the spike element **32** and beyond the valve **26**, or fluid flow in the opposite direction. The seal **34** has a generally hollow interior that forms a cavity **56**. A portion of the spike element **32** is disposed in the cavity **56** in the seal **34**. When the seal **34** is in the relaxed state **54**, the tip **36** of the spike element **32** is disposed in the cavity **56**. The cavity **56** can take a variety of shapes, such as the conical shape in the illustrated embodiment. The first end **48** of the seal **34** has an external surface **58**, which in the illustrated embodiment, is generally flat (planar). The seal **34** of the illustrated embodiment includes a plurality of ringed wall portions **60**. When the seal **34** is forced from the relaxed state **54** to the compressed state **55**, the plurality of ringed wall portions **60** collapse upon each other. The plurality of ringed wall portions **60** can function as a spring element that assists the seal **34** in returning to the relaxed state **54** from the compressed state **55** when the force upon the seal **34** is removed.
(16) The housing **30** has a first end **62**, a second end **64**, and a hollow interior **66**, within which the spike element **32** and the seal **34** are secured. The hollow interior **66** surrounds the tip **36** of the spike element **32** and, in the illustrated embodiment, the seal cap **52** of the seal **34**. Both the first end **62** and the second end **64** of the housing **30** are open forming openings **68**, **70**, respectively. The first end **62** of the housing **30** surrounds the seal cap **52** of the seal **34** at the opening **68** such that the first end **62** of the housing **30** at the opening **68** and the external surface **58** of the seal **34** are flush. When the seal **34** is in the relaxed state **54** (FIG. **5**), the inner conduit **42** of the spike element **32** is not in fluid communication with the hollow interior **66** of the housing **30**. In the relaxed state **54**, the seal **34** prevents fluid in the inner conduit **42** of the spike element **32** from flowing into the hollow interior **66** of the housing **30**. The housing **30** has an outer surface **72** that extends between the first end **62** and the second end **64**. The outer surface **72** can include threads **74** extending therefrom adjacent to the first end **62**. The threads **74** permit a device with matching thread receivers, such as a syringe (discussed further below), to be coupled to the valve **26** via the housing **30**.
(17) In the compressed state **55** (FIG. **6**), the tip **36** and the one or more through holes **44** of the spike element **32** extend through the seal cap **52**. The seal cap **52** can include a piercing **76** through the seal cap **52** from the external surface **58** through to the cavity **56**. The tip **36**, and the one or more through holes **44** of the spike element **32**, extend through the piercing **76** when the seal **34** transitions from the relaxed state **54** to the compressed state **55**. When the seal **34** is in the compressed state **55**, fluid can flow from a source external to the intravenous fluid bag **10**, through the one or more through holes **44** of the spike element **32**, through the inner conduit **42**, and into the primary chamber **12** of the intravenous fluid bag **10** to mix with the liquid **14** already in the primary chamber **12**. When the seal **34** is returned to the relaxed state **54**, the piercing **76** through the seal cap **52** closes and does not permit the flow of fluid through the seal cap **52**.
(18) As mentioned above, the plastic sleeve **28** surrounds a portion of the valve **26** to hold the valve **26** in place to control fluid flow into and out of the primary chamber **12** of the intravenous fluid bag **10**. For example, the plastic sleeve **28**, as in the illustrated embodiment, can surround the outer surface **46** of the spike element **32**. The plastic sleeve **28** can be heat shrunk over the outer surface **46**. As another possible alternative, the plastic sleeve **28** can surround a portion of the housing **30** of the valve **26**, such as the second end **64** of the housing **30**. Regardless, the plastic sleeve **28** can thus hold the valve **26** in place and form a liquid tight seal around the valve **26**.
(19) Referring now additionally to FIGS. **7-8**, the intravenous fluid bag **10**, including the valve **26**, can be utilized to introduce a second liquid **78** into the intravenous fluid bag **10**, which already contains the liquid **14**. As discussed above, the intravenous fluid bag **10** includes a primary

chamber **12** that retains the liquid **14**. It may be desirable to add the second liquid **78**, contained in a second liquid container **80**, into the intravenous fluid bag **10** to mix with the liquid **14**. The second liquid **78** can be medicine or otherwise have desirable properties such that it is desirable to add the second liquid **78** to the liquid **14** to administer intravenously the combined second liquid **78** and the liquid **14** to a patient (not illustrated). In addition to containing the second liquid **78**, the second liquid container **80** includes a valve interaction portion **82**. The valve interaction portion **82** includes a seal compression element **84** that surrounds a liquid outlet **86**. The second liquid container **80** further includes a pressure inducing element **88**.

(20) The seal compression element **84** of the second liquid container **80** is inserted into the opening **68** of the first end **62** of the housing **30** of the valve **26** of the intravenous fluid bag **10**, and pressed against the external surface **58** of the seal cap **52** of the seal **34**. The seal compression element **84** then compresses the seal **34** from the relaxed state **54** into the compressed state **55**. The tip **36** and the one or more through holes **44** of the spike element **32** are disposed within the liquid outlet **86** of the seal compression element **84**. The liquid outlet **86**, like the one or more through holes **44**, can be 18 gauge size or larger, but can also be smaller.

(21) The second liquid **78** is then caused to flow in a direction **87** from the second liquid container **80**, through the valve **26** of the intravenous fluid bag **10**, and into the primary chamber **12** of the intravenous fluid bag **10**. The second liquid **78** thus combines (mixes or potentially reacts) with the liquid **14**. The second liquid **78** can be so caused to flow in the direction **87** by imparting a force **90** on the pressure inducing element **88**. The pressure inducing element **88** forces the second liquid **78** into the liquid outlet **86**, through the one or more through holes **44** of the spike element **32**, through the inner conduit **42**, and into the primary chamber **12** of the intravenous fluid bag **10**.

(22) The valve interaction portion **82** of the second liquid container **80** can further comprise a thread receiver **92**. The thread receiver **92** is configured to receive the threads **74** extending from the outer surface **72** of the housing **30** of the valve **26**. Twisting the second liquid container **80** while the tip **36** of the spike element **32** of the valve **26** is disposed in the seal compression element **84** can cause the thread receiver **92** to receive the threads **74** of the housing **30**. Continued twisting of the second liquid container **80** can cause the seal compression element **84** to compress the seal **34** of the valve **26** into the compressed state **55**.

(23) When the second liquid **78** has been caused to enter the primary chamber **12** of the intravenous fluid bag **10**, the seal compression element **84** can be moved out of the opening **68** at the first end **62** of the housing **30** and away from the second end **50** of the seal **34**. Moving the seal compression element **84** in this manner allows the seal **34** to move from the compressed state **55** back to the natural relaxed state **54**. The combined liquid **14** with the second liquid **78** can then be administered intravenously to the patient by causing the liquid **14** and the second liquid **78** mixture (or reaction product, if the second liquid **78** and the liquid **14** react) in the primary chamber **12** of the intravenous fluid bag **10** to exit the intravenous fluid bag **10** through the outlet port **20**.

(24) Every and any component of the intravenous fluid bag **10** described herein, or any combination thereof, can be coated with an antimicrobial substance. The antimicrobial coating includes a silane quaternary ammonium ion or salt thereof. Preferred silane quaternary ammonium ions or salts thereof include 3-(trimethoxysilyl)propyldimethyloctadecyl ammonium ion, 3-(trimethoxysilyl)propyldimethyloctadecyl ammonium chloride, 3-(trihydroxysilyl)propyldimethyloctadecyl ammonium ion, or 3-(trihydroxysilyl)propyldimethyloctadecyl ammonium chloride. To impart the antimicrobial coating, the component or components of the intravenous fluid bag **10** can be coated with a solution including the silane quaternary ammonium ion or salt thereof, as described above. In addition to the silane quaternary ammonium ion or salt thereof, the solution can further include a solvent. A preferred solvent is isopropyl alcohol. The silane quaternary ammonium ion or salt thereof can comprise between 0.1 percent and 10 percent by weight of the solution. More preferably, the silane quaternary ammonium ion or salt thereof can comprise between 0.75 percent and 5 percent by

weight of the solution. Even more preferably, the silane quaternary ammonium ion or salt thereof can comprise between 1.9 percent and 2.1 percent by weight of the solution. As for the isopropyl alcohol, the isopropyl alcohol can comprise between 30 percent to 90 percent by weight of the solution. More preferably, the isopropyl alcohol can comprise between 55 percent and 65 percent by weight of the solution. An example preferable solution comprises (by weight) 60.0 percent isopropyl alcohol, 0.02 percent 3-(trimethoxysilyl)propyldimethyloctadecyl ammonium chloride, and 34.19 percent deionized water.

(25) It is to be understood that variations and modifications can be made on the aforementioned structure without departing from the concepts of the present disclosure, and further it is to be understood that such concepts are intended to be covered by the following claims unless these claims by their language expressly state otherwise.

Claims

1. A method of manufacturing an intravenous fluid bag comprising: heat shrinking a plastic sleeve, which is contiguous with a plastic material forming a primary chamber configured to retain a liquid, over an outer surface of a valve; wherein, after the heat shrinking, the plastic sleeve holds the valve in place and forms a liquid tight seal around the valve and the valve is in fluid communication with the primary chamber.

2. The method of claim 1, wherein the valve comprises a housing, a seal that the housing surrounds, and a spike element that the seal surrounds; and the spike element comprises the outer surface over which the plastic sleeve is heat shrunk.

3. The method of claim 2, wherein the housing comprises (i) an outer surface, different than the outer surface of the valve over which the plastic sleeve is heat shrunk, and (ii) threads extending from the outer surface of the housing that are configured to couple with a syringe.

4. The method of claim 2, wherein the spike element further comprises a first end culminating in a tip, a second end having an inner conduit, and one or more through holes between the tip and the second end in fluid communication with the inner conduit forming part of a continuous liquid passageway in fluid communication with the primary chamber, the second end being disposed closer to the primary chamber than the tip.

5. The method of claim 4, wherein the outer surface over which the plastic sleeve is heat shrunk is proximate the second end of the spike element.

6. The method of claim 4, wherein the one or more through holes of the spike element are 18 gauge in size or larger.

7. The method of claim 4, wherein the seal comprises (i) a first end, (ii) a second end, (iii) a seal cap at the first end, (iv) a relaxed state in which the seal forms a liquid tight seal over the through holes of the spike element preventing fluid flow through the valve, and (v) a compressed state in which the tip and the through holes of the spike element extend through the seal cap allowing fluid flow from a source external the intravenous fluid bag, through the through holes, through the inner conduit, and into the primary chamber.

8. The method of claim 7, wherein the housing includes a hollow interior that surrounds the tip of the spike element; and the inner conduit of the spike element is not in fluid communication with the hollow interior of the housing when the seal is in the relaxed state.

9. The method of claim 7, wherein the seal forms a conically shaped cavity in which the tip of the spike element is disposed when the seal is in the relaxed state.

10. The method of claim 7, wherein the seal comprises a plurality of ringed wall portions that collapse when the seal moves from the relaxed state to the compressed state.

11. The method of claim 7, wherein the seal cap comprises a piercing through which the tip and the through holes of the spike element extend when the seal is in the compressed state; and when the seal is in the relaxed state, the piercing is closed and does not permit flow of fluid through the seal

cap.
12. The method of claim 7, wherein the first end of the seal comprises a flat external surface not covered by the housing.
13. The method of claim 12, wherein the housing has a first end that is open forming an opening; and the first end of the housing at the opening and the flat external surface of the seal are flush.
14. The method of claim 1, wherein the outer surface is cylindrical.
15. The method of claim 1, wherein the intravenous fluid bag further comprises an antimicrobial coating, which comprises a silane quaternary ammonium ion or salt thereof.