PARENTERAL FLUID DELIVERY BAG WITH INTEGRAL LINE SET

FIELD OF THE INVENTION

The instant invention relates to drug delivery bags and, more specifically, to I.V. bags.

BACKGROUND OF THE INVENTION

The general I.V. bag is well known in the art. Such a bag has an envelope which contains a fluid. This fluid either contains a medicament or the bag is arranged to allow a medicament to be added to the fluid contained within the bag. These bags come equipped either with septa or some other docking means so as to allow a line set to be attached. To prevent air infiltration of the patient, the line set must then be purged or primed. Furthermore, after the medicament has been delivered to the patient, the line set must be flushed or purged before an additional or different medicament can be added. This is a time consuming procedure and, in this time of rising costs, any gain in efficiency of the staff is welcome.

U.S. Patent 3, 307, 549 to Zackheim discloses an enema bag which has an extended fluid chamber serving as an enema tube. This device does not contemplate either a fluid reservoir and extensible line set formed from two webs or a peelably releasable set as disclosed in the instant invention.

U.S. Patent 5, 466, 322 to Munsch describes an elongate plastic member, or tube, which is fused to an adjacent member and is subsequently peelable from an adjoining member. The invention does

not, however, disclose a bag and line set formed integral as in the instant invention.

According to one aspect of the invention there is provided bag means for parenteral administration of fluids, comprising a plurality of retaining means, each for retaining a fluid within its own bag and, integral with said fluid retaining means, extensible means for administering said fluid parenterally, wherein said extensible means provides fluid communication between said plurality of fluid retaining means to a single terminus.

Preferably the extensible means has the terminus remote from said plurality of means for retaining a fluid and there is a fitment adapted to be in parenteral fluid communication with a patient, said terminus being adapted to enter into fluid communication with said fitment.

In one embodiment of the invention, the terminus includes the fitment and has a frangible plug therewithin.

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In order that the invention may be more readily understood and put into practical effect, reference will now be made to the accompanying drawings in which:-

Fig. 1 is a plan view of a bag for administering fluids,

Fig. 2 is a perspective view of the bag shown in Fig. 1 with the integral inset deployed and the bag hanging in the preferred orientation for delivery of a fluid,

Fig. 3 is a perspective view of the drug introducer,

Fig. 4 is a perspective view of the introducer with a medicament bottle affixed,

Fig. 5 is a plan view of the bag of Fig. 1 in the pre-filled embodiment thereof,

Fig. 6 is a cross-sectional view of the line set of the bag of Fig. 1, and

Fig. 7 is a plan view of a dual bag for administering a fluid according to one embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in Figure 1, an assembly 1 is disclosed which is formed of a plurality of polymeric sheets 10 and 12 wherein the sheets can be of a polyvinylchloride, polyolefin or other flexible, liquid-tight, and biocompatible material.

The sheets are formed into a reservoir 20 capable of containing a medicament or a suitable diluent or other fluid. Reservoir 20 is defined by a plurality of welded seals 22, 24, 26, and 28 wherein the seals are operative to separate the reservoir 20 from the rest of the bag assembly 1.

Seals 22, 24, 26, and 28 are preferentially made by radio-frequency welding, but may be made by any other suitable process for making parenteral fluid delivery bags. The reservoir is further defined by a peripheral seal 30 which is formed about the outer edge of the bag assembly 1 and is operative to enclose the outer edges of reservoir 20 in cooperation with seals 22, 24, 26 and 28.

The perimeter seal 30 also defines, in cooperation with the first upper reservoir seal 24 and the second upper reservoir seal 28, a first hanging aperture 32 and a second hanging aperture 34 which are operative to engage a bag hanger 200, as shown in Figure 2, thereby orienting the bag assembly 1 correctly for administration of the fluid or medicament contained in, or introduced to, reservoir 20.

Line set 40 is formed integral with reservoir 20 and bag assembly 1, and is in fluid communication with reservoir 20 via port 41. The integral line set 40 is co-formed with bag 1 and is releasably attached thereto by a tearable seal 50. To deploy the line set 40, an operator, such as a nurse, would grasp the distal end 78 of the line set 40 and draw the distal end 78 away from the bag assembly 1, thereby

releasing the tear seal 50 of the line set 40 and drawing the line set 40 out of the line set aperture 42 defined by the bag web 60 to which the line set 40 is attached via tear seal 50.

In the pictured embodiment, line set 40 is spiral wound within web 60, and displays a continuous spiral tear seal 50. The instant invention contemplates a variety of line set layouts within web 60, including, but not limited to, sinusoidal or folded s-shaped arrangements when the line set 40 is undeployed.

Line set 40 is composed of a first envelope section 40A and a second envelope section 40B. In this embodiment the envelope sections are formed from sheets 10 and 12, out of which the rest of the bag assembly 1 is also formed.

In an embodiment, line set 40, consisting of envelopes 40A and 40B, is formed by sealing the first envelope 40A to the second envelope 40B forming fluid seal 52. Exterior to the fluid seal 52 is tear seal 50 as aforedescribed, thereby allowing deployment of line set 40 whilst maintaining integrity of the line set 40.

The distal end or terminus 79 of the line set 40 is fused or otherwise connected to an appropriate connector or fitment 80 which may be a septum, or luer fitting, or frangible connector, or some other connector or combination thereof suitable for intravenous delivery of fluids. Additionally, line set 40 is filled with fluid also resident in chamber 20, thereby eliminating the necessity of purging the line set of air as aforementioned.

Associated with the chamber 20, and in fluid communication therewith, is a fill port 85 through which fluid is introduced into the chamber 20. Fill port 85 is subsequently sealed by plug 88, thereby

closing off port 85 and fill tube 87. Alternatively, and preferred, the line set 40 may be used as a fill port prior to connecting the appropriate connector 80 to the line set 40. In an embodiment herein preferred, also associated with chamber 10, is a medicament introduction port 110 which is attached to bag 1 at support ring 100. Support ring 100 is formed with the rest of bag 1 and is operative to support introduction port 110 in a suitable position for administering a medicament from another container into chamber 20. In the preferred embodiment, introduction port 110 is a spike connector, wherein the spike connector 110 has a connector cup 112 in contact with support ring 100 and a cup bottom 114, the exterior side of which is in contact with the interior of chamber 20. Also associated with connector 110 is an interior spike 130, said spike 130 being in fluid communication with chamber 20 subsequent to opening frangible plug 132.

In operation, protective film 120 is removed exposing spike connector 130. A suitable medicament containing vial 136 is impaled on spike connector 130. Then frangible 132 is broken, allowing fluid communication between chamber 10 and the medicament containing vial 136, allowing the medicament in vial 136 to be introduced to a patient via line set 40.

In the alternate embodiment of the invention a first fluid containing bag 200 has wrapped therearound a substantially helically wound line set 210 which is in fluid communication with the bag 200 by means of a fluid orifice 212. The line set 210 joins a second drainage line set 214 at a wye-junction 216 wherein the second leg of the wye 218 is integral with a drainage line 220 which is helically wound about drainage bag 222 and is formed integral therewith. Drainage line 220 is in fluid communication with drainage bag 222 by

means of a drain orifice 224 at the proximal end 226 of the drain line 220.

The base of wye-junction 216 defines a common delivery and drain line 228, the distal end of which comprises an appropriate fitment 230. Inserted within the delivery line 228 and the drain line 220 are frangible plugs 232, 234 respectively which are operative to provide a unidirectional flow of fluid from the delivery bag 200 to the patient and subsequently from the patient into drain bag 222.

In operation in this embodiment of the invention an operator would deploy both the delivery line 210 and the drain line 220. The operator would then break the delivery line frangible plug 232 after connecting the fitment 230 to the patient thereby allowing fluid to flow from the delivery bag 200 to the patient. When the delivery therapy is complete, the operator would then break frangible plug 234 which is associated with drain line 220 thereby allowing fluid to drain from the patient into the receiving or drain bag 222.

The aforewritten detailed description is illustrative of the preferred embodiment of the instant invention and is not meant to present limitations on the instant invention aside from those in the claims appended hereto.

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Claims

1. Bag means for parenteral administration of fluids, comprising: a plurality of retaining means, each for retaining a fluid within its own bag and, integral with said fluid retaining means, extensible means for administering said fluid parenterally, wherein said extensible means provides fluid communication between said plurality of fluid retaining means to a single terminus.

2. Bag means according to claim 1, wherein said extensible means has said terminus remote from said plurality of means for retaining a fluid and there is a fitment adapted to be in parenteral fluid communication with a patient, said terminus being adapted to enter into fluid communication with said fitment.

3. Bag means according to claim 2 wherein said terminus includes said fitment.

4. Bag means according to claim 1, 2 or 3, wherein said terminus includes a frangible plug therewithin.

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ABSTRACT

A bag (200) for containing a fluid for parenteral administration has wrapped therearound a line set (210) in fluid communication with a fitment (230) which allows the fluid to flow from the delivery bag (20) to the patient. A second or drainage bag (222) is connected by line set (214) to the fitment (230) to receive fluid from the patient.

Figure 2