

- [54] ANTI-REFLUX DEVICE FOR URINARY COLLECTION BAGS
- [75] Inventors: **Bhupendra C. Patel, Elgin; John F. Dye, Barrington, both of Ill.**
- [73] Assignee: **The Kendall Company, Boston, Mass.**
- [22] Filed: **May 24, 1973**
- [21] Appl. No.: **363,614**
- [52] U.S. Cl. **128/275; 128/294; 128/DIG. 24; 137/525.1**
- [51] Int. Cl.²..... **A61F 5/44**
- [58] Field of Search **128/275, 294, 295, DIG. 24, 128/274; 137/525, 525.1**

3,716,055 2/1973 Schultze..... 128/275
 3,734,080 5/1973 Petterson et al. 128/2 F

Primary Examiner—**Kyle L. Howell**
 Attorney, Agent, or Firm—**Edward J. Scahill, Jr.**

[57] **ABSTRACT**

A flexible collection bag used for collecting urinary and other body fluid drainage, has a film or sheet flap valve laminate closing against the internal surface of the bag in response to positive pressures within the bag. The flap valve is located over the inlet opening of the bag, through which liquid passes for collection, and is a sheet of thin flexible material having all but its lower periphery sealed to the inside of the bag and the back support portion of the inlet opening, thus leaving a lower free flap portion below the inlet opening. The flap valve remains in a passive state; however, when the bag pressure exceeds the input or drain line pressure, the valve closes and remains closed until the bag pressure drops below the line pressure. The valve advantageously permits only a unidirectional flow to occur, thereby preventing any refluxing action of the bag contents from taking place therein.

2 Claims, 7 Drawing Figures

- [56] **References Cited**
- UNITED STATES PATENTS**
- 2,755,060 7/1956 Twyman..... 128/274 UX
- 3,477,438 11/1969 Allen et al..... 128/349 BV
- 3,525,357 8/1970 Koreski..... 128/274 UX
- 3,529,599 9/1970 Folkman et al..... 128/275
- 3,564,620 2/1971 Clark 128/295
- 3,586,041 6/1971 Monestere 128/295

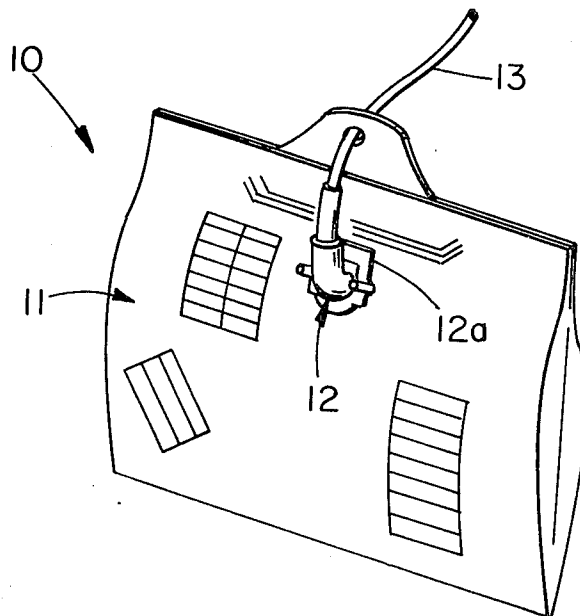


FIG 1

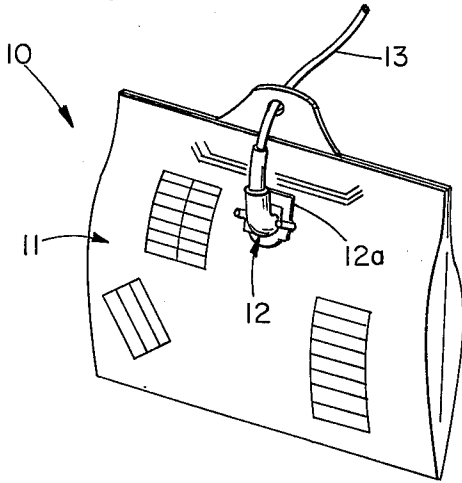


FIG 2

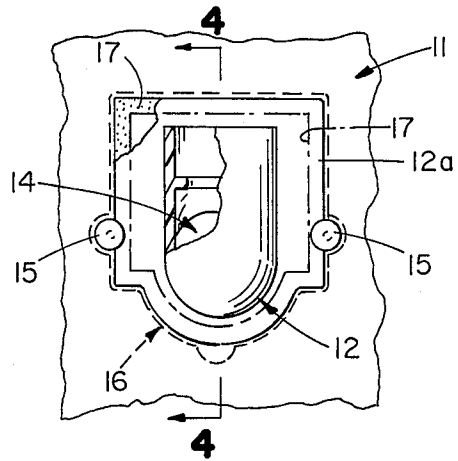


FIG 5

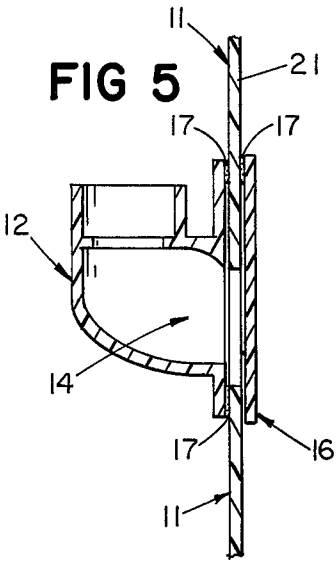


FIG 4

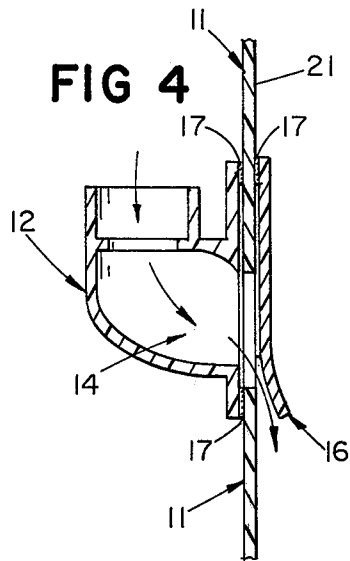


FIG 3

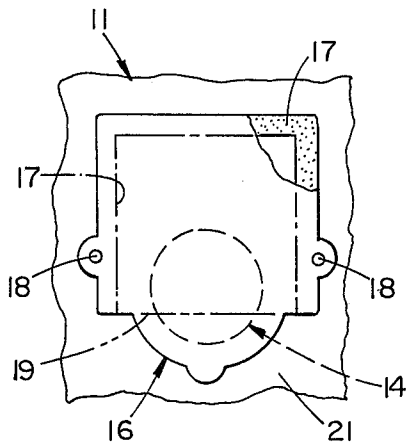


FIG 6

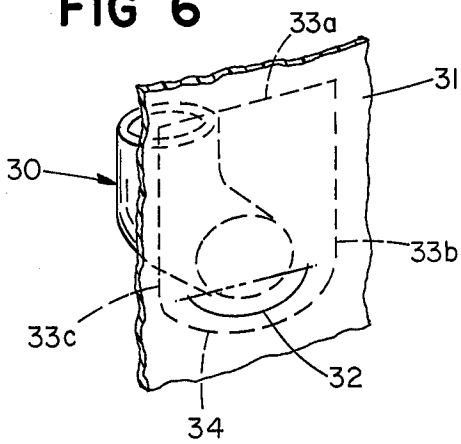
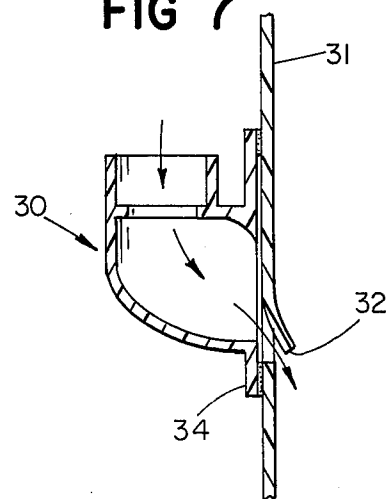


FIG 7



ANTI-REFLUX DEVICE FOR URINARY COLLECTION BAGS

BACKGROUND OF THE INVENTION

This invention relates to urinary collection bags, and more particularly to an anti-reflux device for a flexible walled urinary collection bag.

In the past, rigid type, urinary collection containers were used to collect body drainage fluids, and reflux was not a problem except for when the container was actually inverted. However, since the advent of disposable, flexible collection bags, the likelihood of reflux of the collected waste occurring and backing up into the drainage line, has increased significantly. Any external or internal pressure in any form, as well as inversion, can induce reflux.

Some of the more obvious consequences of reflux are as follows: an increase in pressure on the bladder, and if this increase were sudden, it could possibly result in trauma; the introduction of undesirable break-down products back to the area from which they were removed; any precipitates, mucus or the like forming in the large collection bag could be forced into the smaller inlet opening possibly blocking same; contamination of the drainage tubing at least as far as the reflux extends initially and then, later progressively contaminating the entire system through the retrograde migration of the seeded organisms. Prior art attempts to eliminate reflux problems in flexible, walled, body fluid collection bags have been many and varied, but have met with limited success.

Accordingly, an object of this invention is to provide a simple and economical means for preventing any refluxing action from taking place in flexible walled urinary collection bags.

It is another object of the present invention to provide an anti-reflux device for urinary collection bags that advantageously permits only a unidirectional flow of liquid to occur (flowing into the bag).

It is a further object of the present invention to provide an anti-reflux device for a urinary collection bag that simply consists of a flap valve that remains in a passive state until the bag pressure exceeds the input or drain line pressure, whereupon the valve closes and remains closed until the bag pressure falls below the line pressure.

SUMMARY OF THE INVENTION

A flexible urinary collection bag has an opening thereon and an inlet connector secured on the outside thereof and coinciding therewith that is covered on the inside by a flap valve that permits the passage of liquid into the bag but prevents reflux of the liquid from the bag back into the inlet connector or up into the tube. The flap valve is a film or sheet of flexible material cut to substantially the same size as the back support of the connector and is sealed to the inside of the bag, substantially covering the inlet opening, in such a manner that all but the lower periphery of the valve is sealed to the inside of the bag. The unsealed portion of the valve flexes outwardly when fluid passes from the connector into the bag, but when the bag pressure exceeds the input or drain line pressure, the valve closes and remains closed until the bag pressure drops below the line pressure. The valve advantageously permits only a unidirectional flow of liquid to occur, thereby preventing

any refluxing action of the bag contents from taking place therein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a drainage bag that utilizes the anti-reflux device of this invention;

FIG. 2 is a partially exposed front view of the inlet connector used in this invention;

FIG. 3 is a rear view of the flap valve of this invention secured to an inside wall of the drainage bag;

FIG. 4 is a cross-section of the connector of FIG. 2, showing the flap valve of this invention in its opened position;

FIG. 5 is a cross-section of the connector of FIG. 2, showing the flap valve of this invention in its closed position;

FIG. 6 is a perspective view of the connector and another embodiment of a flap valve of this invention; and

FIG. 7 is a cross-section of another embodiment of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a body fluid drainage bag 10, such as a urinary collection bag, having a tubular inlet connector 12 secured to an outside wall 11 of the bag 10. The bag 10 is composed of at least two sheets or walls of a flexible plastic material or the like, such as polyethylene, polyvinylchloride or the like, joined together at their peripheral edges. An inlet of drainage tube 13 is connected to the bag 10 through the inlet connector 12 and carries fluids from the body into the drainage bag 10. The inlet connector 12 is advantageously of molded flexible plastic material, but can be of any material known to those skilled in the art, and should be secured to a wall of the bag 10 so that it is leakproof and cannot be pulled away from the bag by hand. The connector 12 has a back support 12a of the same material as the inlet connector and is used to support the inlet connector 12 on the wall of the collection bag, as well as providing a somewhat rigid base for securing a flap valve on the back thereof. The back support 12a preferably has a generally U-shaped configuration for a more positive seal of the flap valve to the back support.

In FIGS. 2 and 3, the connector 12 includes a tubular elbow portion that has a round opening 14 therein that is aligned to an opening in the wall 11 by means of a first set of locator points 15 on the connector 12 and the opening on the wall itself. A flap valve 16 is secured to the inside of wall 11 so as to substantially coincide with the outline of the inlet connector 12, matching a second set of locator points or marks on the valve 16 with the first set of locator points on the connector 12. The flap valve 16 is sealed to the inside of wall 11 in a manner as to leave only its lower periphery, such as shown by dotted line 19, free to flex inwardly toward the bag interior. The flap valve 16 should be a thin film or sheet of flexible and resilient material (of substantially the same thickness as the bag material) such as vinyl materials, rubber elastomers or any thermoplastic or thermoset materials. The valve material should advantageously have a roughened or embossed surface on at least one side thereof to insure that there will be no sticking of the valve to the bag. If both the valve surface and bag surface were smooth, the possibility exists that upon exposure of same to any temperature increase such as during sterilization, the vinyl on vinyl surface

will become tacky and will stick together. For this reason, the valve surface should advantageously have an embossed surface of some kind. Also, the film valve must be flat, straight and stable at the temperatures used in processing, sterilizing and the like. The method of sealing may be by solvent, heat, impulse, R-F or by any other suitable means of achieving a strong and leakproof bond such as known to those skilled in the art. A flap valve of this structure will advantageously only permit the unidirectional flow of liquid into the bag 10.

FIGS. 4 and 5 show the flap valve 16 in both its opened and closed positions, respectively. In FIG. 4 it can be seen that fluids draining from the body through a drainage tube, such as 13 in FIG. 1, will flow, as shown by the arrows, into the round opening 14 within the inlet connector 12 and will continue to flow into the collection bag at 21 through the opening provided by the lower periphery of the flap valve 16 flexing in toward the interior of the bag. The flap valve 16 is held securely in place by means of the seal 17 so that only a relatively small opening remains through which the fluids may drain. However, when the bag pressure exceeds the input or drain line pressure, the flap valve 16 closes and remains closed against the inside of wall 11 as shown in FIG. 5. The valve 16 will not open again until the bag pressure drops below the line pressure, thereby prohibiting any refluxing of the waste drainage fluids into the connector or the drainage tube.

The round opening 14 of the inlet connector is constructed so that the fluids flowing therethrough will be concentrated at the lower periphery of the flap valve 16 that is free to flex inwardly into the bag interior. However, other advantageous structures for the inlet connector will occur to those skilled in the art, and may be used with the flap valve of this invention.

FIGS. 6 and 7 show another embodiment of this invention wherein the inlet connector 30 is securely attached to the wall 31 of the flexible collection bag. The wall 31 has a semi-circular slit 32 thereon that acts as a flap valve. It should be noted herein that the "flap valve" is simply the semi-circular slit 32, and is not a separate unit that is secured to collection bag wall 31. In this embodiment, the valve is reinforced on three sides at 33a, 33b and 33c by way of the inlet connector 30 being securely attached to the wall 31 in a position thereon, whereby the bottommost portion 34 of the inlet connector 30 lies concentric with, and just above the semicircular slit 32. In this manner, fluids can drain from the body entering the inlet connector, as shown by the arrows in FIG. 7, and continuing on down past the slit portion 32 and on into the collection bag. Care

should be exercised herein in positioning the inlet connector 30 as just described above. This invention offers ease of manufacture, simplicity of design, and an efficient anti-reflux device for collection bags, all at low cost.

The above-described specific embodiments of this invention have been set forth for the purpose of illustration. It will be apparent to those skilled in the art that various modifications may be made in the structure of this invention without departing from the principles of the invention as pointed out and disclosed herein. For that reason, it is not intended that the invention should be limited other than by the scope of the appended claims.

What is claimed is:

1. An anti-reflux device for a body fluid collection bag comprising:
 - a at least two flexible walls of a plastic material joined together at the peripheral edges thereof, one of said at least two walls having an opening on an upper portion thereof;
 - a tubular inlet connector comprising a back support and a tubular elbow portion attached thereto, said elbow portion having a generally circular opening therein that coincides with said opening on said wall, said circular opening being constructed so that fluids flowing therethrough will be concentrated at the lowermost portion thereof, said connector being secured to the exterior of said wall so that said circular opening is aligned with said wall opening;
 - a drainage tube for transporting body fluids to said bag being attached to said tubular inlet connector; and,
 - a flap valve consisting of a sheet of thin flexible material having substantially the same configuration as said back support and being secured to the interior of said wall having the opening thereon so as to substantially coincide with the outline of said inlet connector, said flap valve being secured in a manner that leaves only its lower periphery unsecured and free to flex inwardly toward said bag interior when fluid passes therethrough but to close when the bag pressure exceeds the drainage tube pressure, said lower periphery covering the lowest portion of said circular opening and extending slightly below it.
2. The anti-reflux device of claim 1 wherein said back support and said flap valve have at least two coinciding locator points thereon for correctly positioning and securing one to the other.

* * * * *

55

60

65