

Nov. 18, 1969

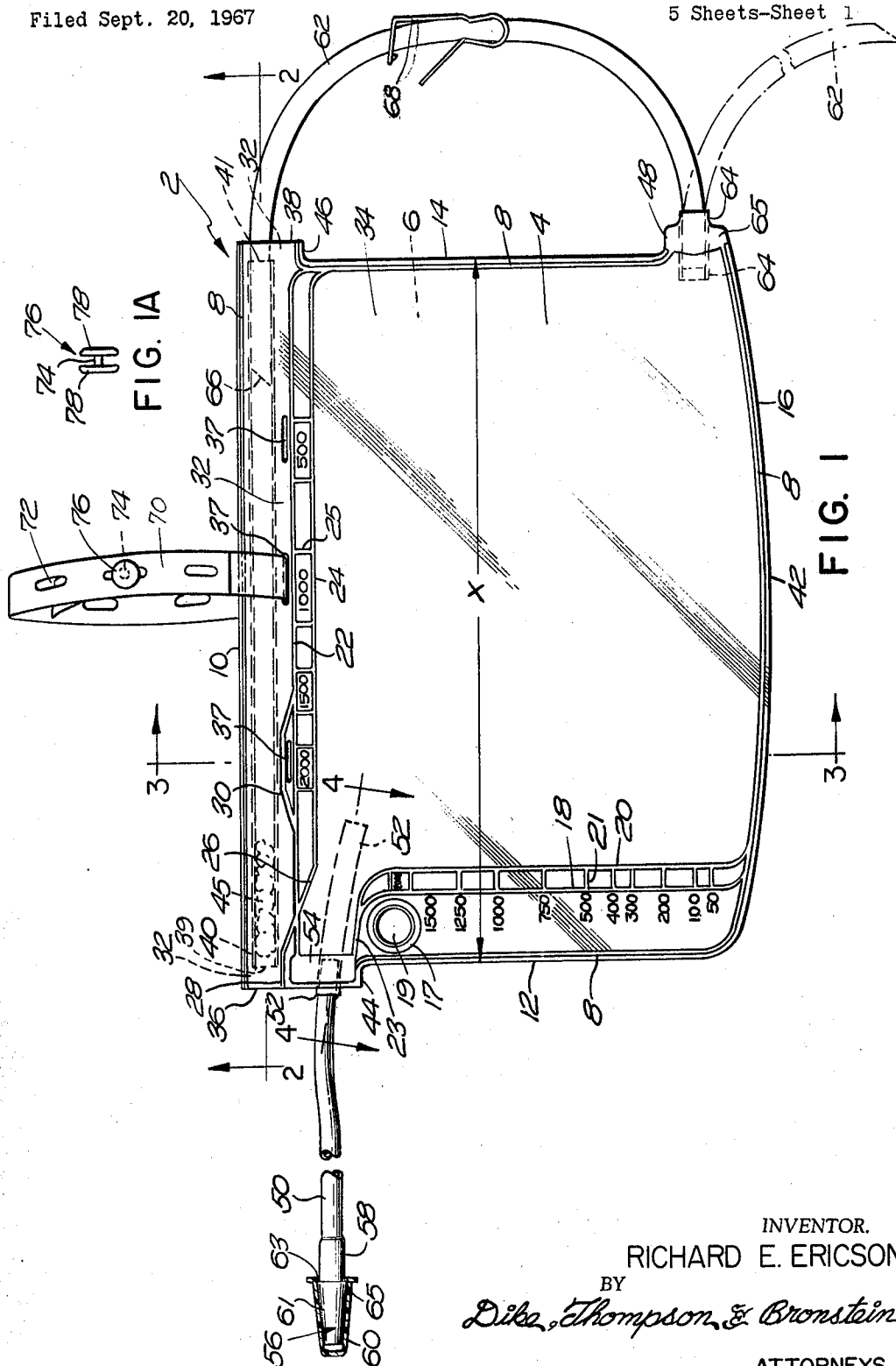
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3,478,743

CLOSED URINARY DRAINAGE SYSTEM

Filed Sept. 20, 1967

5 Sheets-Sheet 1



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CLOSED URINARY DRAINAGE SYSTEM

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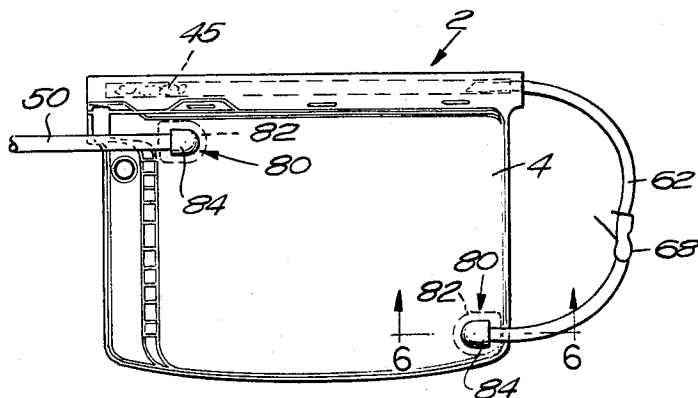


FIG. 5

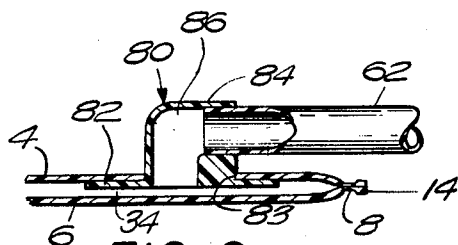


FIG. 6

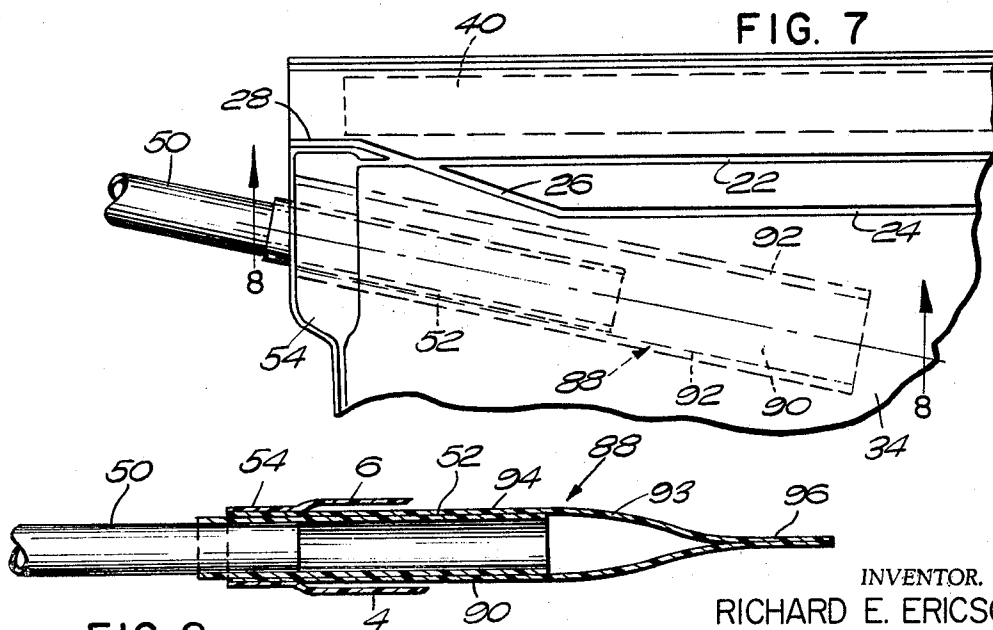


FIG. 8

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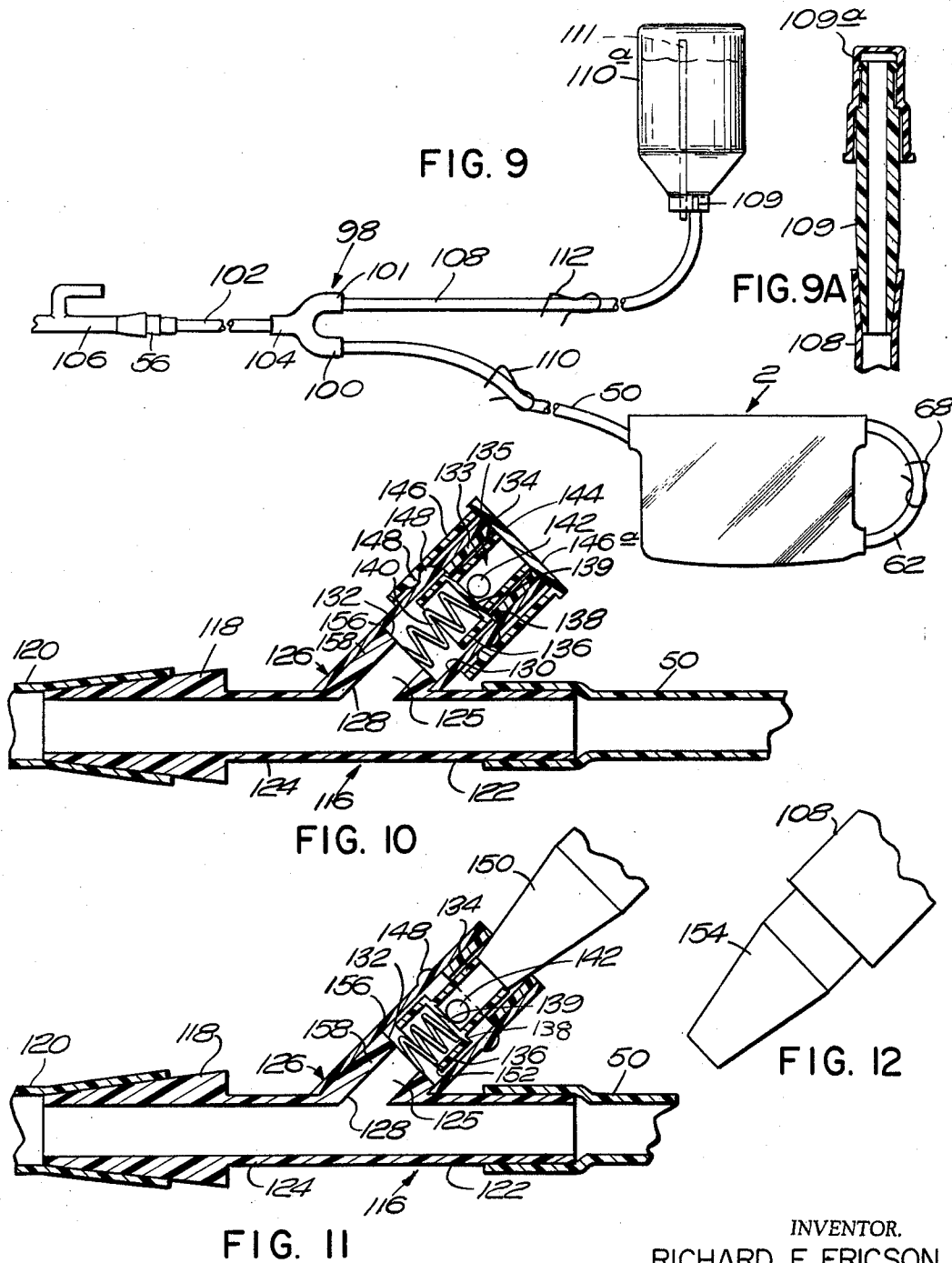
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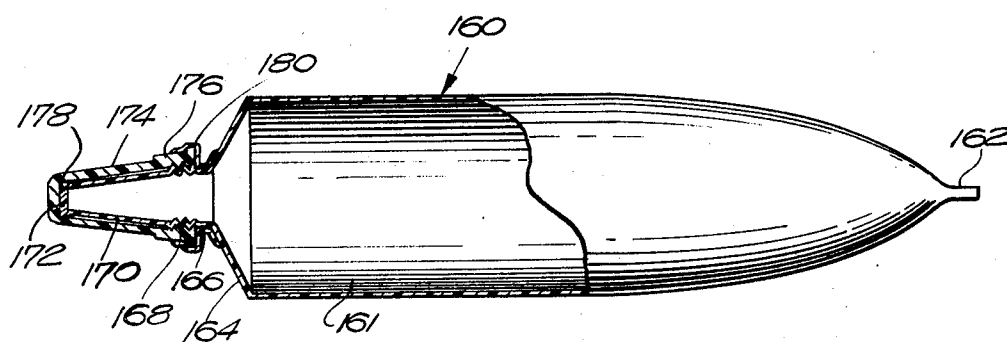
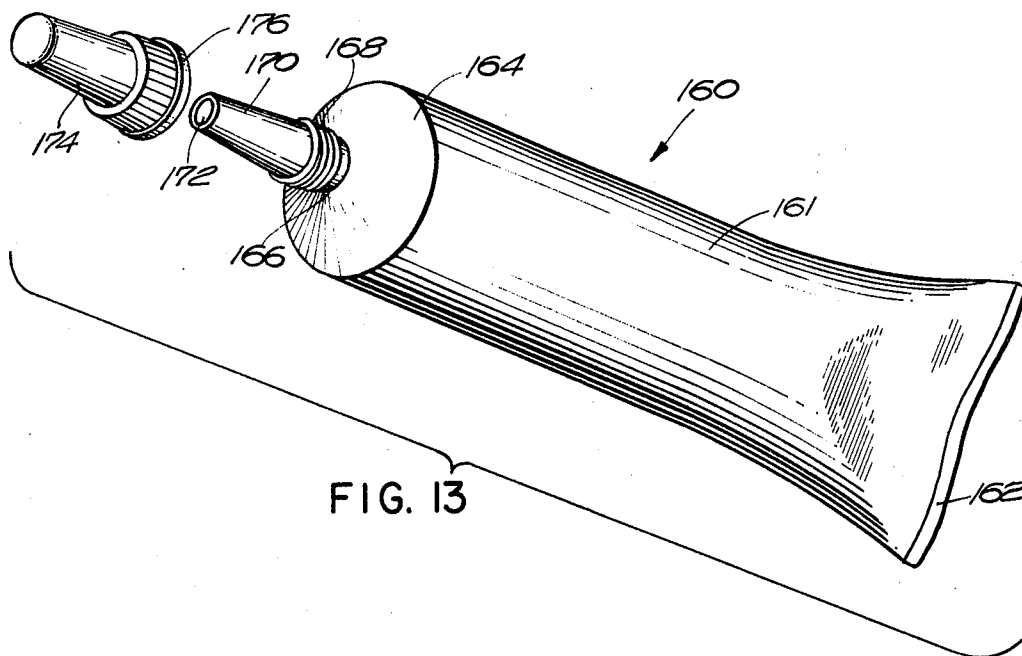
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CLOSED URINARY DRAINAGE SYSTEM

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32 Claims

ABSTRACT OF THE DISCLOSURE

A closed urinary drainage system comprising a disposable, plastic bag made up of a pair of flat, flexible, plastic sheet panels in back-to-back relation sealed along their peripheries, one panel being opaque, preferably white, and the other transparent or translucent. The bag is divided by a horizontal seal line into a lower drainage fluid chamber and an upper elongated pocket, which extends along the width of the top of the bag and which snugly receives a relatively rigid, hollow, stabilizing tube open at both ends. A flexible urinary drainage tube, for draining fluid into the upper part of the fluid chamber, and a flexible draw-off tube, for drawing off fluid from the lower part of the fluid chamber, are hermetically sealed to the upper and lower portions of the bag respectively. The draw-off tube loops laterally outwardly and upwardly and then laterally inwardly from the lower portion of the bag with its end being snugly but removably received in an open end of the stabilizing tube, the other end of such stabilizing tube being open to the atmosphere. A filter is located in the stabilizer tube spaced from the end of the draw-off tube. The fluid chamber is closed to the atmosphere except through the stabilizer tube, filter and draw-off tube. The filter within the stabilizing tube closes this route to micro-organisms. Accordingly, the system is a closed one. The bag may be suspended by means of a highly flexible, plastic hanging strap received in a slit in the bag immediately under the stabilizing tube, and the lower edge of the bag is bowed downwardly, with the lowermost portion being located opposite the slit for balance. The stabilizing tube stabilizes the bag against wrinkle and sag, provides a protective and convenient receptacle for the end of the draw-off tube to reduce danger of contamination thereof and functions with the draw-off tube as a filtered inlet for sterilizing gases and as an overflow.

The drainage tube may be provided with a branched fitting for connection with an irrigating tube connected to a source of irrigating fluid for closed system alternating irrigation and drainage.

The branch of the fitting for connection for irrigation, may be provided with a valve member biased to close seal position and adapted to be forced out of close position by insertion of the tip of an irrigating syringe or a rigid tubular adapter attached to the irrigation tube.

BRIEF SUMMARY OF THE INVENTION

The present invention relates to a closed urinary drainage system, and, particularly, to such a system which embodies (a) a disposable, flexible, plastic urinary drainage bag made up of a pair of flat, highly flexible, plastic sheet panels in back-to-back relation and hermetically sealed or otherwise closed along their peripheries, (b) a flexible urinary drainage tube for draining urinary fluid into the bag and (c) a flexible draw-off tube for drawing drainage fluid from the bag, both tubes being hermetically sealed to the upper and lower portions of the bag, respectively.

According to the present invention, the bag panels are

provided with an elongated seal area, extending along the width of the bag and spaced slightly below the upper sealed edge of the bag to divide the bag interior into a lower drainage fluid chamber and an upper, narrow, elongated, horizontal pocket extending the width of the bag, the drainage tube communicating with the upper portion of the chamber and the draw-off tube communicating with the lower portion of the chamber. A relatively rigid, hollow, plastic stabilizing tube, open at both ends, is snugly received within such pocket.

The draw-off tube loops upwardly from the lower portion of the bag with its end being snugly but removably received in an end of the stabilizing tube, the other end of the stabilizing tube being open to the atmosphere. A filter, such as a wad of cotton, is located in the stabilizing tube opposite the end of the draw-off tube. The free end of the drainage tube is provided with a catheter adapter with a sealed cap thereover so that the only ingress into the fluid chamber from the atmosphere is through the stabilizing tube, filter and draw-off tube.

The advantages of this arrangement are as follows:

(1) The system is a closed one, i.e., closed to micro-organisms, to thereby reduce the chances of contamination.

(2) The stabilizing tube stabilizes the bag against wrinkle or sag due to the unbalanced weight of the bag and/or its contents during use.

(3) In addition to performing the aforesaid stabilizing function, the stabilizing tube also provides a protective and convenient receptacle for the end of the draw-off tube to keep it free from contamination and to keep it from flopping around.

(4) Also, the stabilizing tube cooperates with the draw-off tube received therein to provide a filtered inlet for gas sterilizing the bag through the stabilizing tube, filter and draw-off tube. Although this provides a convenient route for sterilization, the filter closes this route to micro-organisms.

(5) In addition, the stabilizing tube, in cooperation with the draw-off tube received therein, also provides for overflow through the draw-off tube and stabilizing tube.

Also, according to the invention, one of the plastic bag panels is opaque, preferably white, and the other is transparent or translucent and has imprinted thereon volume graduations and quantities. This arrangement provides an important advantage in that the urine level and volume may be easily observed against the white background through the transparent panel. The white background, provided by the white panel, facilitates reading of urine level and volume even in poor light, and from an unfavorable angle, which are the usual conditions during drainage. Also, the white, opaque panel provides a modesty shield by turning the bag so that the opaque side faces the visitor.

Preferably, in accordance with the invention, the drainage bag is suspended by one or more highly flexible, plastic, hanging straps passing through one or more horizontally disposed slits in the bag under the stabilizing tube. The bottom edge of the bag is bowed downwardly with the lowermost portion being located directly under one slit, which is intermediate the side edges of the bag, to provide proper balance at the commencement, and during all stages, of drainage even with one strap suspension.

The present invention also contemplates placing in the drainage tube a multi-branch, hollow fitting, to one branch of which is sealed the drainage tube to the bag, to a second branch of which is connected a catheter adapter and to a third branch of which is sealed an end of an irrigation tube, the other end of which is provided with an adapter or cannula for connection with a source

of irrigating fluid. This arrangement permits alternating irrigation from the source of irrigating fluid and drainage to the drainage bag in a closed system. Appropriate external clamping may be provided for closing the drainage tube during irrigation and closing the irrigation tube during drainage.

Another aspect of the invention comprises such a fitting of novel construction in which the third branch, rather than being sealed to an irrigation tube, is provided with a closure valve normally biased to close position, but which may be moved to open position by insertion, in the end of the third branch, of the tip of an irrigating syringe or the tip of a rigid tubular adapter connected with an irrigation tube, which is in turn connected to a source of irrigating fluid, e.g. a flask of such fluid. Opening the valve opens communication between the syringe or irrigation tube and the catheter adapter to provide irrigation. Where a syringe is used, it is withdrawn from the third branch after irrigation, whereupon the aforesaid valve returns to close position, followed by drainage to the drainage tube. The syringe is refilled, the tip reinserted into the third branch and irrigation, followed by drainage, are repeated. Where an irrigation tube and flask of irrigating fluid are used, appropriate clamping is used for alternate irrigation and drainage. This type of fitting provides an extremely versatile and inexpensive system which can be used for drainage alone or for alternate irrigation and drainage with an irrigation syringe or other source of irrigating fluid.

The present invention also contemplates a novel source of irrigating fluid particularly adapted for use with the aforesaid valved fitting, comprising a flexible, disposable, transparent or translucent, tubular, sealed, plastic package in which such fluid is packaged for storage and shipment and which is provided with an integral externally tapered dispensing tip adapted to be inserted in the aforesaid third branch of the fitting to open the fitting valve, such package constituting a syringe bulb, with the dispensing tip constituting a tapered syringe tip through which the fluid can be dispensed from the package through such fitting by squeezing the main tubular portion or bulb. The tip is covered with a removable plastic cap sealed thereto by a tamper-proof seal. The package has the general shape of a large toothpaste tube, the outlet neck of which extends axially into the tapered syringe tip over which the cap is threaded.

Other objects and advantages of the invention will be apparent from the accompanying drawings and following detailed description thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a front view in elevation of a urinary drainage bag embodying the present invention, with the normal position of the draw-off tube being shown in full lines and the position of the draw-off tube during draw-off being shown in broken lines;

FIG. 1A is a view in elevation of the button for fastening the flexible hanging strap shown in FIG. 1;

FIG. 2 is a section taken along the line 2—2 of FIG. 1;

FIG. 3 is a section taken along the line 3—3 of FIG. 1;

FIG. 4 is a section taken along the line 4—4 of FIG. 1;

FIG. 5 is a reduced view like FIG. 1 showing an alternate manner in which the drainage and draw-off tubes may be connected to the drainage bag.

FIG. 6 is a section taken along the line 6—6 of FIG. 5;

FIG. 7 is a fragmentary view like FIG. 1 showing the upper left portion of the bag and a portion of the drainage tube provided with a flap or flutter valve for preventing accidental surge of drainage fluid back into the patient's urethra;

FIG. 8 is a section taken along the line 8—8 of FIG. 7;

FIG. 9 is a view in elevation of the drainage bag of FIG. 1 connected in a closed system by a multi-branch

fitting with a source of irrigating fluid for alternating irrigation and drainage;

FIG. 9A shows the adapter at the end of the irrigation tube of FIG. 9 for connecting the tube with a flask containing irrigating fluid;

FIG. 10 is an elevational view in section of a novel multi-branch fitting embodying the present invention, the fitting being shown connected to the drainage tube from the bag of FIG. 1 and with the spring biased closure valve in the third branch of the fitting closed;

FIG. 11 is a view like FIG. 10 with the closure valve forced to open position by insertion of the tip of an irrigating syringe into the third branch for irrigation;

FIG. 12 is a view in elevation of a rigid tubular adapter at the end of an irrigation tube for use with the fitting of FIGS. 10 and 11;

FIG. 13 is a view in perspective of a novel combined irrigating syringe and irrigating fluid package with cap removed particularly adapted for use with the valved fitting of FIGS. 10 and 11; and

FIG. 14 is a sectional view in elevation of the combined irrigating syringe and package shown in FIG. 13 with the cap sealed to the syringe tip.

DETAILED DESCRIPTION

With reference to the drawings, 2 represents a plastic, collapsible, urinary, drainage bag embodying the invention. It comprises a pair of flat, flexible, plastic, e.g. polyvinyl-chloride, sheet panels 4 and 6 (FIGS. 1 and 3) laid back to back against each other and heat sealed to each other along their margins at 8 to form a flat, collapsible bag having an upper edge 10, a pair of side edges 12 and 14 and a lower edge 16. The bag may also be made by folding a plastic sheet over on itself along a fold line and sealing along the free edges or may be made from a flattened plastic tube, the ends of which are sealed. The front panel 4 is transparent (or translucent) whereas the rear panel 6 is opaque and white. Panel 6 is formed from polyvinylchloride sheet material containing white pigments. The inside surface of each of the panels is embossed with a medium taffeta finish to thereby make the surface rough. This insures against adhering of the panels to each other due to chemicals or mucus in the urine.

The plastic panels 4 and 6 forming the left portion of the bag (as viewed in FIG. 1) have a pair of vertical, longitudinal, narrow, heat-sealed areas (lines) 18 and 20 which extend upwardly from the seal margin 8 of the lower bag edge 16 and turn horizontally outwardly and run together at 23 to the side edge 12 of the bag, as shown. The two vertical seal lines 18 and 20 have a plurality of vertically spaced, short, horizontal heat seal lines 21 therebetween. The panels forming the upper portion of the bag also have a pair of parallel, narrow, longitudinal, horizontal heat-sealed areas (lines) 22 and 24 extending along but spaced slightly from the upper edge 10 of the bag. Seal lines 22 and 24 extend from one side edge of the bag to the other. They turn downwardly close to side edge 14 and run into the seal margin 8 forming such edge, as shown. The upper seal line 22 extends horizontally straight to the seal margin of side edge 12 of the bag whereas the lower seal area 24 turns upwardly at an angle at 26 and then horizontally at 28 to side edge 12, as shown. Seal line 22 also has a branch 30 intermediate the ends thereof which extends upwardly at an angle from seal line 22, then horizontally and then downwardly at an angle into seal line 22. The two horizontal seal lines 22 and 24 have a plurality of spaced, short, vertical heat seal lines 25 therebetween. Between the vertical seal line 18 and the side edge 12, and within certain of the areas between the short, vertical seal lines 25 are imprinted numerals. These numerals are imprinted on the front panel 4 by the application of heat to the bag to seal the panels together at the numeral areas, as in the case of the seal lines 18, 20, 21, 22, 24 and

25 and the seal margins 8. The short, horizontal lines 21 are volume graduation lines and the numerals opposite such lines indicate the volume, e.g. in cubic centimeters, of liquid in the bag when it is located in the position shown in FIG. 1, whereas, the short, vertical lines 25 are volume graduation lines and the numerals adjacent thereto indicate the volume of liquid in the bag when the bag is turned 90° so that the side edge 14 becomes the lower edge. The bag can be used for drainage in either position. The aforesaid volume graduation lines and numerals are visible on the front transparent panel 4. A finger hole 19 extends through the bag at a location slightly below seal line 23 and between seal line 18 and the edge 12 of the bag. The primary purpose of the hole is to carry or hang the empty bag. The portion of the bag panels around the hole edge are sealed at 17.

The horizontal seal lines 22 and 24 divide the interior of the bag into a longitudinal, horizontal, upper pocket 32, extending along the top of the bag from side to side, and a lower urinary fluid chamber 34. The pocket 32 is open at its ends 36 and 38 (the side edges 12 and 14 not being sealed in these areas) and is formed by the upper sealed edge 10 and by the seal line 22, with its branch 30, to the right of seal line 26, together with the left portion of seal line 24 located above seal line 22, as shown in FIG. 1. The fluid chamber is formed by the lower sealed edge 16, by the sealed side edge 14, including the enlarged seal area 65 to be more fully described hereinafter, by the seal lines 20 and 23, by the horizontal seal line 24 and a small portion of the left end of seal line 22 to the left of seal line 26 and by the seal area 54 to be more fully described hereinafter. The aforesaid seal lines and numerals are made during the same heat sealing operation in which the margins of the panels are sealed at 8, 54 and 65, the seal area 17 also being formed at the same time and by the same operation.

Located slightly above the seal line 22 are a plurality of horizontally spaced, horizontal slits 37 extending through both panels of the bag, the panel areas adjacent the edges of the slits being heat sealed to strengthen them during the same sealing operation in which margin seals 8 are formed. The slits 37 and hole 19 are also formed in this same operation. The left-hand slit 37 is located between seal line 22 and its branch 30.

Tightly but removably received in the pocket 32 above slits 37 is a cylindrical, elongated, stabilizing tube 40 made of plastic, e.g. polystyrene, and open at both ends 39 and 41. The plastic of tube 40, and hence tube 40, are relatively rigid compared to the plastic bag 2. The length of the plastic stabilizing tube 40 is about the same as the width X of the bag proper from side to side, but is slightly less than the length of pocket 32, although it does not have to be. The fit between the stabilizing tube 40 and branch seal line 30 and between the tube 40 and the end portion 28 of seal line 24 is a snug one to ensure against the tube 40 accidentally sliding out of an open end of the pocket 32. However, because these snug areas are relatively small compared to the overall lengths of the pocket and stabilizing tube, the tube can be easily slid into position during assembly. It is noted that the sealed edges of the two right-hand slits 37 form reduced cross-sectional areas of pocket 32. The stabilizing tube in the drawings is .420" O.D. and .360" I.D. with a wall thickness of .060", but the dimensions are not critical. The maximum height of the bag shown in the drawings is 9½" but bag dimensions are not critical either.

It will be seen that the slits 37 are located immediately under the rigid stabilizing tube 40.

The lower edge 16 of the bag bows downwardly and outwardly, as shown, the lowest area 42 lying near the middle of the lower edge 16 directly below the middle slit 37.

The upper portions of the side edges 12 and 14 and the lower right portion of the side edge 14 extend laterally outwardly slightly at 44, 46 and 48, respectively, as

shown. The upper width of the bag shown in the drawings is 12¾ inches, the width X at the middle is 12 inches and the width in the area of extension 48 is 12½ inches, but these dimensions are not critical. The opposite ends of pocket 32 are located in extensions 44 and 46, as shown.

The end of a soft, flexible, transparent or translucent, plastic, e.g. polyvinylchloride, drainage tube 50 extends through the upper left side edge 12 of the bag at extension 44, into the fluid chamber 34 in an air-tight manner and at a slight angle, as shown. Actually, the end of tube 50 is hermetically sealed by solvent cement within the end of a soft, flexible, transparent, polyvinylchloride receptor tube 52 (see FIG. 4), which extends through the side edge of the bag between panels 4 and 6 at extension 44 into the fluid chamber. The edge portions of the panels 4 and 6 at extension area 44 are hermetically sealed around and to the periphery of receptor tube 52 by heat at seal area 54 during the same operation in which the seal margins 8 are formed. It is noted that seal area 54 is wider than the seal margins 8 to insure against breakage of the seal by the weight and manipulation of the drainage and receptor tube 50-52. The seal area 54 intersects the seal line 22 and the seal line 23, as shown, to form a continuous seal except through the drainage tube 50-52. The receptor tube 52, the walls of which are thinner than the drainage tube 50, extends laterally and downwardly at a slight angle, as shown, a substantial distance into the fluid chamber 34, e.g. 2 to 3 inches, in order to insure against the panels adhering to each other at the exit end of tube 52 to thereby block such exit end. It is noted that seal line 23 forms with the left portions of seal lines 22 and 24, a horizontal entry passage for receiving the tube 52. For convenience the combined tubes 50 and 52 will be sometimes hereinafter referred to as the drainage tube 50-52. The other end of drainage tube 50-52 is provided with a conventional plastic (polystyrene) catheter adapter 56, the shank 58 of which is sealed by solvent cement within the end of the drainage tube 50-52. The catheter adapter is covered by a conventional, flexible, plastic (polyethylene) adapter cap 60, the intumed snap rib 63 of which snaps over the shoulder 65 of the adapter and which is internally tapered along its axial dimension to provide an air-tight seal between its inner tapered surface and the outer tapered adapter surface 61 when the lip 63 of the cap is snapped over the shoulder 65 of the adapter.

The end of a soft, flexible, transparent, plastic, e.g. polyvinyl chloride, draw-off tube 62 extends between panels 4 and 6 through the lower right-side edge 14 of the bag into the fluid chamber at the extension 48. Actually, the end of tube 62 is hermetically sealed by solvent cement within a flexible, plastic (polyvinyl chloride), transparent receptor tube 64, corresponding to tube 52, which receptor tube 64 extends between panels 4 and 6 through the side edge of the bag at extension 48 into the fluid chamber 34, with the adjacent edge portions of the panels 4 and 6 being hermetically sealed by heat around and to the periphery of the receptor tube at the seal area 65 during the same operation in which seal margins 8 are formed. Seal areas 54 and 65 are really enlarged parts of the seal margin 8 forming the side edges 12 and 14, respectively. For convenience, the assembly of tubes 62 and 64 will be sometimes hereinafter referred to as the draw-off tube 62-64.

The other end of draw-off tube 62-64 is bevelled at 66.

The draw-off tube 62-64 is provided with a conventional metal or plastic clamp 68 external of the tube for closing and opening the tube for flow of fluid there-through.

Normally, the clamp 68 is open and the draw-off tube 62 loops laterally outwardly and upwardly and then laterally inwardly into the open end 41 of stabilizer tube 40, as shown, with the end portion thereof extending a substantial distance into the open end portion of the

stabilizer tube in which it is snugly received. The fit between the soft, flexible and compressible draw-off tube 62 and the more rigid stabilizer tube 40 is tight enough to provide a sealing effect therebetween and to prevent the draw-off tube from accidentally falling out of the stabilizer tube. However, the draw-off tube can be removed from the stabilizer tube and replaced therein when it is desired to draw off drainage fluid from the fluid chamber 34. The aforesaid sealing effect between draw-off tube and stabilizing tube is sufficient to substantially seal the system against the entry of air and is achieved by virtue of the flexibility and compressibility of the draw-off tube 62, the end of which is bevelled at 66 to facilitate insertion into the stabilizing tube. In this respect, the outer diameter of the draw-off tube 62 is made slightly larger than the inside diameter of the stabilizing tube so that slight compression of the draw-off tube occurs when it is inserted into the stabilizing tube to thereby achieve the aforesaid sealing effect.

The other end 39 of the stabilizer tube is open to the atmosphere. Located in the stabilizing tube 40 opposite the bevelled end 66 of the draw-off tube 62 is a filter 45, e.g. a wad of cotton, for filtering out micro-organisms from any air which might enter the fluid chamber 34 through stabilizer tube 40 and draw-off tube 62-64. Although the stabilizing tube 40 and draw-off tube 62-64 provide communication between the atmosphere and the fluid chamber 34 through the filter 45, the function thereof is not that of a vent during drainage since the passage provided thereby connects with the bottom of the fluid chamber 34 and not the top. Accordingly, the system of the present invention is a non-vented one.

The outside and inside diameters of drainage tube 50 in the drawings are $\frac{3}{32}$ inch and $\frac{3}{16}$ inch, respectively, with a wall thickness of .055 inch. It is very soft and flexible—65 durometer in the drawings—to insure against accidental kinking. The inside diameter of draw-off tube 62 shown in the drawings is the same as that of the drainage tube 50, but the wall thickness thereof is .040 inch within a softness of 75 durometer. However, the dimensions of these tubes are not critical; nor do they have any critical softness value, although it is highly desirable that the drainage tube be very soft and flexible.

During use, the bag is suspended or hung by one or more highly flexible, plastic, e.g. linearpolyethylene, straps 70, extending through one or more of the strap receiving slits 37, as shown, and having a plurality of elongated openings 72 spaced along the length thereof for receiving the shank 74 of the rigid plastic, cuff-link shaped button 76. The end portions of the strap 70 extend along each other and are adjustably and removably fastened together by the button 76, the shank of which extends through a hole 72 in one end portion and a hole 72 in the other end portion and is held therein by the two flanges 78 at either end of the shank. The button 76 can easily be removed and placed in the holes 72 because of the high flexibility of the strap. In the drawings, the drainage bag is hung by a single strap in the middle slit 37.

Preferably, the stabilizer tube 40 is colored but it need not be.

In use, the bag 2 is hung by strap 70 on, for example, the hospital bed frame with the bag hanging below the bed just above the floor. Because the bag 2 is relatively short in height (its width is substantially greater than its height), the bag does not drag on the floor. The increased width provides adequate fluid chamber volume. After the bag is hung on the bed, the catheter adapter 56 is connected to the catheter and the catheter is applied to the patient (or vice versa) to drain urinary fluid from the patient's bladder into the bag. Urinary fluid can be withdrawn from the bag at will by removing the end 66 of the draw-off tube 62 from the stabilizer tube 40, the flow through tube 62 being controlled by clamp 68.

The provision of a relatively rigid horizontal stabiliz-

ing tube along the top of the bag with the draw-off tube looping from the bottom of the bag into the end of the stabilizer tube are important features of the invention. With such an arrangement, the stabilizer tube performs the following useful functions:

(1) It stabilizes the highly flexible bag so that it will not wrinkle (wrinkling of the bag panels interferes with collection of fluid in the bag and may cause the panels to stick together) or sag due to the unbalanced weight of the bag (including the integrally attached drainage and draw-off tubes) and its contents; in effect, it provides the main support for the bag and holds the bag taut during drainage.

(2) It provides support for strap suspension by a single strap 70 or a plurality of straps without sag or wrinkling. In this respect, it is noted that the strap or straps extend directly under the relatively rigid stabilizing tube to thereby support the tube, which in turn supports the bag along its width. The bowed out contour of the lower edge 16 of the bag, with the lowest or outermost part 42 of the bow lying directly under the strap 70 in the middle slit 37, provides proper balance during all stages of drainage with one strap suspension, in which the one strap is located in the middle slit 37, as shown. It will be seen that during initial stages of drainage, the first flow of drainage fluid collects in the pocket formed by the bowed-out portion of the lower edge 16 directly under the single strap 70 to develop a fulcrum.

(3) It provides a protective and convenient receptacle for the end of the draw-off tube 62. This keeps the end of the draw-off tube free from contamination and keeps it from dangling from the bag.

(4) With the draw-off tube 62 received in the end thereof, which is the normal condition of the bag during use and as shown in the drawings, the stabilizing tube 40 functions as a filtered inlet for sterilizing the inside (fluid chamber 34) of the bag through the stabilizing tube 40 and draw-off tube 62-64. In this respect, these bags are sterilized by a gas, e.g. ethylene oxide. The procedure is to place the entire bag assembly, as shown in FIG. 1, in a conventional, thin, plastic film package or wrapper, e.g. polyethylene, in which it is marketed. The package is sealed except for one or more slits or nicks therein. The thus packaged bag is then placed in a chamber into which is flowed the sterilizing gas. The sterilizing gas flows into the film package through the slits and thence through the stabilizing tube 40, through the filter 45 and through the draw-off tube 62-64 into the fluid chamber 34 to thereby sterilize the system. Upon removal of the sterilized, packaged bag from the gas chamber, the cotton wad filter 45, although permitting the passage of sterilizing gas therethrough, closes the system to micro-organisms, to thereby prevent contamination of the draw-off tube and the fluid chamber 34 through the stabilizing tube and provide a closed system. In this respect, all the seals between the tubes and the bag and along the bag margins and between the drainage tube 50 and catheter adapter 56 are air-tight seals. The only portals of entry to the fluid chamber 34 are through the draw-off tube 62-64 and the drainage tube 50-52. However, the end and inner passage of the draw-off tube are sterile since the filter 45 closes to micro-organisms not only the fluid chamber 34 but also the end and inner passage of the draw-off tube 62-64, and the tight fit between the draw-off tube 62-64 and the stabilizing tube 40 prevents passage of air therebetween. The air-tight seal between the catheter adapter 56 and its cap 60 closes the catheter adapter and inner passage of the drainage tube 50-52 to micro-organisms. Hence the system is truly a closed one. The same is true when the catheter adapter is connected to the catheter during drainage.

(5) The stabilizing tube 40, with the draw-off tube 62 received therein, as shown in FIG. 1, provides for overflow through the draw-off and stabilizing tubes before the bladder is distended in the event that the bag is not emptied when it should be. Although the horizontal

stabilizing tube 40 is above the inlet end of drainage tube 50-52, it has been found that well before the liquid level reaches the end of tube 50-52, there is sufficient pressure above the liquid level in the bag coupled with the pressure of the liquid column in the bag to cause overflow through the draw-off tube 62-64 and stabilizing tube 40 and through the cotton filter 45. However, the aforesaid pressure above the liquid level at which overflow will occur is not great enough in magnitude to unduly distend the patient's bladder. This is an important advantage when it is remembered that the urine or irrigating fluid must not back up into or distend the patient's bladder and should not be permitted to reach the inlet end of the drainage tube 50.

It is also noted that by making the flexible draw-off tube long enough to be received within the stabilizing tube, it is relatively easy to handle when used to draw-off the urine, as compared to a relatively short draw-off tube.

The drainage tube 50 may have sealed therein a conventional plastic or glass drip chamber to indicate the flow rate of urine. The drip chamber may comprise a flexible or rigid transparent, enlarged plastic tube with the drainage tube from the catheter adapter extending into and through the top thereof and into the drip chamber to form the drip tube, the drainage tube from the drainage bag being sealed to the bottom of the drip chamber.

FIGS. 5 and 6 show a slight modification of the hermetic attachment of the drainage tube 50 and draw-off tube 62 to the bag. Instead of these tubes extending into receptor tubes which extend through the side edges of the drainage bag into the fluid chamber, as in FIGS. 1 to 4, each of them is attached to the bag by means of a plastic, e.g. polyvinylchloride, hollow elbow fitting 80, made up of a flat base 82, which extends upwardly into a 90° elbow portion 84. The fitting 80 has a 90° passage 86 therethrough, one end of which comprises an opening in and through the base 82. The flat base 82 is located in the fluid chamber 34, with its upper surface sealed, e.g. by heat sealing, to the inner surface of panel 4 forming the fluid chamber 34. The elbow portion 84 extends from the base 82 through a hole 83 in the panel 4 to expose the other outer end of the elbow passage 86 to the outside of the bag. The drainage tube 50 in one case and the draw-off tube 62 in the other, is solvent cemented into the exposed outer end of the 90° elbow passage 86. The circular heat seal between the outer surface of base 82 and the inner surface of panel 4 (made during the same operation in which the other aforementioned heat seals are made) prevents any flow of air therebetween. The two holes 83 in panel 4 are located in about the same position as the inner end of receptor tube 52 and the inner end of receptor tube 64, respectively. The bag and affiliated tubes are otherwise the same in construction as in FIGS. 1 to 4.

FIGS. 7 and 8 show a slight modification of the construction of FIGS. 1 to 4, such modification comprising a one-way flutter or flap valve 88 applied over the inner end portion of drainage tube 52, as shown. Flutter or flap valve 88 is made up of two superimposed, elongated, flat strips 90 and 94 of the same plastic sheet material as panels 4 and 6, the inner surfaces thereof being embossed like panels 4 and 6 and the rear strip 94 being white and opaque like panel 6, whereas the front strip 90 is transparent like panel 4. The flat surfaces of the strips 90 and 94 are parallel to the flat panels 4 and 6 and the strips are heat sealed in back-to-back relation along their longitudinal edges at 92. The left portion, as viewed in FIGS. 7 and 8, of the flutter valve 88 is located around the tube 52, as shown, with the right portion, as viewed in these figures, protruding a sufficient distance beyond the end of tube 52 at 93 so that the two strips 90 and 94 are collapsed against, and in intimate contact with, each other over substantial portions of their lengths at 96 to thereby permit flow of fluid from tube 52 into the fluid chamber 34 through the flutter valve but prevent substantial flow of fluid in an opposite direction from the fluid chamber

into tube 52. The left end portion of flutter valve 88 is located around the portion of tube 52 sealed between the side edge portions of panels 4 and 6 at seal area 54 and is heat-sealed to the outer periphery of such portion of tube 52 and to the panels 4 and 6 at seal area 54 to thereby secure the flutter valve in place on tube 52. This valve prevents surging of drainage fluid from the bag to the patient's bladder in the event that the bag with urine fluids therein should be elevated above the level of the bladder but does not provide an absolute seal.

Where it is desired to use a drip chamber in the drainage tube 50, the flap valve 88, instead of being secured to the inner end of the drainage tube within the drainage bag, may extend downwardly from the upper inlet tube of the drip chamber, to which the upper end of the flap valve is sealed, into the drip chamber to form a drip tube as well as a flap valve. Where the drip chamber comprises an enlarged heat-sealable, flexible, transparent, plastic tube pinched together and heat-sealed at its ends, the upper end of the flap valve may be heat sealed between the inlet tube and the top sealed edge portion of the drip chamber tube as in FIGS. 7 and 8.

FIG. 9 shows how the drainage bag 2 can be used in a closed system to alternately irrigate and drain a patient's bladder. A multi-branch hollow, plastic, e.g. polyvinyl chloride, fitting 98, e.g. a Y fitting, is located in the drainage tube 50, as shown. The end of drainage tube 50 from the bag 2 is sealed by solvent cementing into a branch 100 of the plastic fitting. An end of the transparent, flexible polyvinylchloride catheter tube 102 (part of drainage tube 50 in FIGS. 1 to 4) is sealed by solvent cementing into a second branch 104 of fitting 98, the other end of catheter tube 102 having solvent sealed therein the shank of catheter adapter 56, which is shown in FIG. 9 connected with a conventional two-way Foley catheter 106 (only partly shown). Sealed in the third branch 101 of the fitting 98 by solvent cementing is one end of a flexible, transparent irrigation tube 108 of the same material as tube 50, the other end of which is provided with a conventional, rigid tubular adapter 109 made of transparent rigid plastic, e.g. polystyrene, which adapter is inserted in a hole in the rubber stopper of a conventional irrigating fluid bottle 110a containing sterilized irrigating fluid, e.g. saline solution, for irrigating the bladder. Drainage tube 50 and irrigation tube 108 are each provided with a conventional metal or plastic clamp 110 and 112, respectively. By opening clamp 112 and closing clamp 110 and supporting the bottle 110a above the patient's bladder, irrigating fluid flows into the patient's bladder through irrigating tube 108 and fitting 98. Subsequently, by closing clamp 112 and opening clamp 110, the bladder may be drained into bag 2 through fitting 98 and drainage tube 50. In this way, alternating irrigation and drainage are provided with a closed system. The bag 2, tube 50, fitting 98, tube 102, catheter adapter 56, irrigating tube 108 and adapter 109 are sold as a disposable sterilized integral unit with the cap 60 (FIG. 1) located over the catheter adapter 56 as in FIG. 1 and with a conventional, internally tapered, resilient polyethylene cap 109a also pressed tightly over the adapter 109 in an air-tight manner. If desired, the clamp 110 can be omitted and the tube 50 pinched shut by hand during irrigation.

If desired, a disposable, collapsible, flexible, transparent or translucent and sterilized plastic bag (formed by a pair of flexible, plastic, e.g. polypropylene, sheet panels laid back to back against each other and sealed along their peripheries), such as that shown and described in U.S. Patent No. 3,306,327, can be used as a sterilized source of irrigation fluid instead of a bottle or flask 110a to avoid the necessity of a vent such as vent tube 111 in FIG. 9. In such case, the irrigation tube 108 may be attached to the spout of the bag of irrigating fluid by means of a spout cap to which the tube is sealed, as shown in the aforesaid patent, or the irrigation tube 108 may be permanently sealed to the spout of the plastic bag filled with sterilized irrigating fluid (i.e. by perma-

nently sealing the spout cap, shown in such patent, to the spout), with a conventional ball valve (of the type described in FIGS. 7 and 18 of U.S. Patent No. 3,328,255) being located in the irrigation tube where it joins the spout, so that the bag and irrigating fluid sealed therein form part of the disposable integral sterilized unit referred to above. When it is desired to use the unit, the ball valve is manipulated (from outside the system) out of the irrigation tube into the spout to open the tube for flow therethrough. Instead of polypropylene, the plastic bag containing the irrigating fluid may be made of other plastic materials which have a very low rate of water transmission, which are heat sealable, which are inert to the irrigating fluid and which will withstand autoclaving conditions, such as high density polyethylene or a copolymer of high density polyethylene and nylon.

The aforesaid closed system technique of alternately irrigating and draining with the construction of FIG. 9 has important advantages over the conventional way of doing this, which comprises first connecting, by a catheter adapter attached to an irrigating tube, a source of irrigating fluid to the catheter, to irrigate the bladder, followed by disconnecting the source of irrigating fluid from the catheter, followed by connecting, by another catheter adapter attached to a drainage tube, a drainage bag to the catheter to drain the bladder. The most important advantage of the FIG. 9 technique over this conventional technique, in addition to greater convenience and speed, is that the risk of contamination is substantially reduced.

FIGS. 10 and 11 show a novel multi-branch fitting 116 made integral with the catheter adapter 118 (shown in FIGS. 10 and 11 as being connected with the catheter 120), to permit use of the drainage bag 2 for drainage alone or for alternating drainage and irrigation either with an irrigating syringe (irrigation with an irrigating syringe is a conventional technique) or a source of irrigating fluid as in FIG. 9. The combined integral fitting and adapter 116-118 is made of a relative rigid plastic, e.g. polystyrene. The end of drainage tube 50 from drainage bag 2 (not shown in FIGS. 10 and 11) is solvent cemented over the end of branch 122 of the multi-branch fitting 116 with the catheter adapter 118 extending integrally from a second branch 124 of the fitting. The third branch 126 extends from the straight portion 122-124 of the fitting at an angle of about 45° and is made up of an inner branch stub 158, integral with portions 122 and 124 of the fitting, and a rigid polystyrene tube 156 cemented or press fitted in an air-tight manner over branch stub 158 and protruding beyond the end of such branch stub. The internal passage 125 in branch 126 has a reduced diameter inner portion 128, formed by branch stub 158, and an enlarged diameter outer portion 130 formed by tube 156, the juncture of the two forming a shoulder 132, which comprises the end of the branch stub. Pressed or cemented into the outer end portion of the enlarged passage portion 130 is a cylindrical closure ring 133 of rigid plastic, e.g. polystyrene. The interior passage of ring 133 forms an outer reduced diameter portion of the passage 125, so that the passage 125 may be considered as having a reduced diameter inner portion 128, an enlarged diameter intermediate portion 130 and a reduced diameter outer portion 133, the juncture of the intermediate enlarged diameter portion 130 and the outer reduced diameter portion 133 forming an internal shoulder which consists of the inner edge of ring 133.

Slidably received within ring 133 is an upper reduced diameter cylindrical portion 134 of a hollow valve member 135 of rigid plastic, e.g. polystyrene, the reduced diameter portion 134 extending integrally axially and inwardly into an enlarged diameter cylindrical portion 136, which is slidably received within the intermediate enlarged diameter portion 130 of passage 125 inwardly of the ring 133, the juncture of the reduced diameter portion 134 and the enlarged diameter portion 136 of

the valve member 135 forming an external valve shoulder 138. The outer diameter of portion 136 of valve 135 is sufficiently smaller than the diameter of enlarged passage portion 130 so that an annular space is provided therebetween for passage of fluid, as will be described hereinafter. An integral, internal cross wall 139 in valve member 135 separates the interiors of portions 134 and 136 so that fluid cannot pass axially through the valve member 135. Cross wall 139 forms with the cylindrical enlarged portion 136 an inverted cup in which is nested the outer end of a coil spring 140 biased between the shoulder 132 of branch 126 and the cross wall 139 of valve member 135 to urge the valve member 135 axially outwardly to a position in which the external valve shoulder 138 thereof engages the inner edge of the ring 133 to prevent the flow of fluid therebetween. This engagement also limits the outward movement of the valve member 135. This is the normal closed position of valve member 135. The cylindrical wall of portion 134 of valve member 135 has a port or hole 142 therein. When the valve member 135 is in its normal closed position, as shown in FIG. 10, the hole 142 is located wholly within ring 133. It may be seen that the inner edge of ring 133 functions as a valve seat for the valve surface formed by the valve shoulder 138 so that engagement of such shoulder 138 with such inner edge of ring 133 by spring 140, as shown in FIG. 10, closes the branch 126 against flow of fluid therethrough.

Branch 126 is provided with a flexible cap 144 made of polyethylene, the annular wall 146 of which fits snugly around the periphery of the outer end portion of tube 156 of the branch. The outer periphery of tube 156 and the internal surface of the cap wall 146 are provided with circumferentially extending snap ribs 148 which cooperate with each other to permit the cap 144 to be removably snapped into place and held on the outer end of the branch, as shown, with the inner surface of the end wall 146a of the cap pressed tightly against the outer edge of tube 156 and/or the outer edge of valve portion 134 to provide an air-tight seal.

With the arrangement of FIGS. 10 and 11, the bladder can be drained into the bag 2 in the normal manner through drainage tube 50. No leakage of drainage fluid occurs through branch 126 because the valve member 135 is closed. For the same reason, the system remains a closed one. However, if it is desired to irrigate and drain alternately, this may be done quite simply and conveniently in two ways as follows:

If it is desired to irrigate by means of an irrigating syringe, as is conventionally done, it is only necessary to remove cap 144 and insert the tapered syringe tip 150 (FIG. 11) into the branch 126. The edge of the syringe tip 150 engages the outer edge of portion 134 of valve member 135, as shown, and inward movement of the syringe tip slides the valve member 135 inwardly against the force of spring 140 to the open position shown in FIG. 11 in which (1) the shoulder 138 is moved inwardly away from the inner edge of ring 133 to permit the flow of fluid therebetween and (2) the hole 142 is moved inwardly of the closure ring 133 to uncover the hole, so that by squeezing the bulb of the syringe containing irrigating fluid, the irrigating fluid can now flow from the syringe tip into and through the cylindrical portion 134 of valve 135, through the hole 142, into the enlarged intermediate passage portion 130 and thence through the space between portion 136 of valve 135 and the passage wall of 130, through reduced passage portion 128, through branch 124 and catheter adapter 118 and into the bladder. When the valve member 135 is moved to this open position, engagement of the tapered periphery of the syringe tip 150 with the outer edge of branch 126, as shown in FIG. 11, prevents further inward movement of the syringe tip and the valve member 135 and also forms a seal to prevent leakage of any irrigating fluid which might escape from between the en-

gaged edge of the syringe tip and outer edge of valve portion 134 or which might pass from hole 142 axially outwardly between the periphery of valve portion 134 and the internal wall of ring 133. The dimensions of the reduced and enlarged diameter passage portions 128 and 130, respectively, of branch passage 125, the dimensions of the reduced and enlarged portions 134 and 136 of valve member 135, the dimensions of ring 133, and the dimensions and taper of the syringe tip 150 are such that the tapered tip 150 of the syringe engages the outer edge of branch 126 to prevent further inward movement of the syringe tip 150 and valve member 135 before the inner edge 152 of valve member 135 strikes the shoulder 132, to thereby ensure free flow of irrigating fluid between such edge 132 and such shoulder. The internal diameters of the edge of the syringe tip and the edge of the reduced diameter valve portion 134 are approximately the same to provide uninterrupted flow from the syringe tip into valve portion 134. During irrigation, the clamp on the drainage tube 50 is shut or the drainage tube is kinked shut by hand so that the irrigating fluid does not flow into the drainage bag. Upon emptying the syringe, it is withdrawn from the branch 126, whereupon the spring 140 returns the valve member 135 to closed position, as shown in FIG. 10. The bladder can then be drained into the drainage bag followed by further irrigation and drainage in the same way as desired.

If it is desired to irrigate the bladder from a flask containing irrigating fluid, as shown in FIG. 9, the end of the irrigating tube 108, shown in FIG. 9, opposite from the end connected to the flask 110a is provided with a rigid tubular, plastic adapter 154 (FIG. 12) having a tapered end portion of the same dimensions as the syringe tip 150. Such adapter 154 is normally capped in an air-tight conventional manner with a flexible polyethylene cap (not shown). When it is desired to irrigate, the adapter 109 of tube 108 is inserted into bottle 110a (after cap 109a is removed) and the rigid tubular adapter 154 at the other end of tube 108 is inserted (after its cap is removed) into the branch 126 in the same manner as the syringe tip 150 was inserted in the aforesaid description, to move the valve member 135 to open position, whereupon the clamp 112 (FIG. 9) is opened to irrigate, with drainage tube 50 being closed by clamp 110 or by kinking during such irrigation. Thereafter, clamp 112 is shut and clamp 110 is opened to provide drainage so that irrigation and drainage can be carried out alternately in a closed system.

The combined fitting 116 and catheter adapter 118 is quite inexpensive and simple to manufacture, the spring and valve member being first inserted into the passage 125 followed by pressing or cementing the ring 133 into place. All the parts are of molded plastic, e.g. polystyrene, except the spring.

It may be seen that the use of fitting 116 eliminates the necessity of alternately connecting and disconnecting the catheter adapters of drainage and irrigation tubes with the catheter to provide irrigation and drainage, as has been done in the past, and accordingly, reduces the risk of contamination in addition to increasing convenience and simplifying the procedure.

With such an arrangement, the integral assembly of bag 2, tube 50 and combined fitting and catheter adapter 116-118 are sold as a sterilized unit, with the cap 60 (FIG. 1) over the catheter adapter. The sterilized irrigation tube with the capped adapter 154 and the capped adapter 109 attached to opposite ends thereof is packaged in the same package with the aforesaid integral assembly. A sterilized irrigation syringe with its tip also capped may also be provided in the package.

An important advantage of the fitting 116 for drainage purposes is that, in the event during drainage, the catheter or catheter adapter or urethra or bladder opening becomes clogged with blood clots or other matter, the clots can be easily removed to clear the system without dis-

connecting the drainage bag from the catheter or removal of the catheter, simply by forcing water or saline solution into the catheter adapter through branch 126 by means of an irrigation syringe.

In the FIG. 9 embodiment, a conventional plastic or glass drip chamber may be provided in the irrigation tube 108. Such drip chamber may be made a part of the adapter 109 for insertion in the rubber stopper of the bottle or flask 110a. In such case, the lower end of the adapter is sealed to, and extends into, the top of the transparent drip chamber so as to protrude into the chamber as a drip tube, and the irrigation tube is sealed to the lower end of the chamber, the drip chamber being included as an integral part of the sterilized unit of drainage bag with affiliated tubes 50, 62 and 108, fitting 98 and catheter adapter 56.

FIGS. 13 and 14 show a novel, disposable combination irrigating fluid package and syringe 160 especially adapted for use with the fitting 116 of FIGS. 10 and 11.

The combined package and syringe 160 comprises a toothpaste tube-shaped cylindrical tube 161 made of a transparent or translucent, flexible, plastic, which is substantially impermeable to loss of irrigating fluid there-through as a water vapor over a long period of time (i.e., it has a very low water vapor transmission rate), which is highly inert to the irrigating fluid, in which migration of plasticizers does not occur, which can withstand autoclaving conditions and which is heat sealable to itself, such as polypropylene or high density polyethylene or a high density polyethylene nylon copolymer. One end of the tube 161 is pinched and sealed together by a planar heat seal at 162. The other end of tube 161 tapers inwardly at 164 into a threaded outlet neck 166, which is externally threaded at 168. The threaded portion 168 of neck 166 extends outwardly and axially into an externally tapered syringe tip 170 having the same dimensions as the syringe tip 150 in FIGS. 10 and 11, so that such syringe tip 170 is adapted to be inserted into the third branch 126 of the fitting 116 of FIGS. 10 and 11 into engagement with the outer edge of portion 134 of valve member 135 to force the valve member to its open FIG. 11 position, the tapered periphery of tip 170 engaging the edge of branch 126 well before the edge 152 of portion 136 of valve 135 engages shoulder 132.

Syringe tip 170 is provided with an elongated, externally and internally tapered cap 174 of rigid plastic, e.g. polystyrene, having a cylindrical, lower open end portion 176, which is internally threaded for threading on the threaded portion 168 of the neck 166 to thereby hold the cap 174 on and over the tip 170 with the edge 172 of the tip pressed against a compressible sealing disc 178 of compressible material, e.g. polyethylene or cork, cemented to the inner surface of the end wall of the cap to provide an air-tight and liquid-proof seal. A tamper- and air-proof "whiskey" seal between the cap 174 and syringe tip 170 of the filled package 160 is provided by heat shrinking a thin band 180 of heat shrinkable plastic, such as cellulose resin sold by Du Pont de Nemours under the trade name Cell-O-Seal, tightly around the periphery of the open enlarged end portion 176 of the cap and tightly around the adjacent periphery of the neck 166 and tapered portion 164 of the tubular package 161 to form an air-tight seal therebetween.

The capped tube 161 is filled with sterilized irrigating fluid, e.g. saline solution, the interior of the tube and the syringe tip 170 also being sterilized. Sterility is preserved by the tamper-proof whiskey seal 180. The filled, sterilized capped package is shipped and sold as such. When it is ready for use, it is necessary only to remove the cap 174, insert the syringe tip 170 into the branch 126 of the fitting 116 and squeeze the contents into the bladder to irrigate the same. Thus, the sterilized irrigating fluid is packaged for shipment and sale in the sterile syringe in which it is used. This sterile package is particularly useful with the fitting 116 to easily remove blood clots or other

matter which interfere with proper urinary drainage, as aforesaid. However, it can be used in the same manner as conventional irrigating syringes without fitting 116.

The inside diameter of tube 161 in FIGS. 13 and 14 is 1½ inches with a wall thickness of ⅛ inch. The length of the tube (exclusive of the neck) is 5½ inches and it holds 100 cc. of fluid. The length of the syringe tip beyond the threaded neck is ¾ inch and the external taper of the syringe tip is about 10°. The internal and external diameters of the edge of the syringe tip are ⅜" and ¼", respectively. However, the dimensions and capacity of the tube and syringe tip are not critical so long as the tube is large enough to hold a substantial charge of irrigating fluid and so long as the syringe tip can be inserted into the branch 126 of fitting 116 a limited distance to open valve 135, as aforesaid.

The combined syringe-package 160 shown in the drawings, including the tube 161, the threaded neck 166 and the syringe tip 170 was made by blow molding as one integral piece.

The tube 161 shown in the drawings has sufficient rigidity to hold its shape but is sufficiently flexible and yieldable to be easily squeezed by the fingers to eject the fluid. It is elastic enough to return to its normal shape after squeezing. The neck 166 and syringe tip 170 are more rigid than the tube 161.

After the tube, neck and syringe tip unit 161, 164, 166, 168 and 170 is blow molded, the large open end is sealed at 162 and the closed syringe tip end is cut to form the edge 172. Thereafter the tube is filled with irrigating fluid and is capped by cap 174, followed by sealing with the sealing band 180, followed finally by sterilization of the capped, filled package.

If desired, in the embodiments of FIGS. 9, 10 and 11, a one way disc or flap (e.g. like that shown in FIGS. 7 and 8) valve or ball check valve may be placed at the mouth of the branch 100 in FIG. 9 or the mouth of the branch 122 in FIG. 11 in order to prevent back flow of drainage fluid in the drainage tube 50 during irrigation or in the event that the drainage tube 50 and/or bag 2 is elevated above the patient's bladder. Such a valve may also be used in the FIG. 1 embodiment at the mouth of the shank 58 of the catheter adapter 56.

The present invention is not only useful for drainage from and irrigation to the bladder but also can be used for closed system drainage from and closed system irrigation to other body cavities.

It is not intended that the invention be limited to the constructions shown in the accompanying drawings and above description but only to those constructions which are claimed below and their equivalents.

I claim:

1. A closed system, flexible, plastic drainage bag comprising a pair of flexible, plastic sheet panels arranged in back-to-back relationship and closed along their peripheries to form the bag, the panels forming the upper portion of said bag being provided with means extending along but spaced from the upper edge of the bag to divide the bag interior into a lower drainage fluid chamber and an upper elongated horizontal pocket above said chamber, an elongated hollow stabilizing tube received in said pocket, said stabilizing tube being relatively rigid compared to said panels, a flexible drainage tube hermetically sealed to said bag for flow of drainage fluid into said chamber, a flexible draw-off tube hermetically sealed to a lower portion of said bag for drawing liquid from the lower portion of said chamber, said draw-off tube looping upwardly from said lower portion of said bag into an end portion of said stabilizing tube.

2. A bag according to claim 1, the end portion of said draw-off tube being removably but snugly received within said end portion of said stabilizing tube, the other end of said stabilizing tube being open to the atmosphere, said stabilizing tube having filter means located therein for filtering out micro-organisms,

3. A bag according to claim 2, said pocket extending the width of said bag and being open at either end, said draw-off tube being provided with means for closing and opening it to flow of fluid therethrough, said last-mentioned means being normally open, said means dividing said bag interior into said pocket and chamber comprising an elongated seal area at which said panels are sealed together, said drainage tube being hermetically sealed to an upper portion of said bag for flow of drainage fluid into an upper portion of said chamber.

3A. A bag according to claim 3, said means for closing and opening flow through said draw-off tube comprising a clamp.

4. A bag according to claim 1, said drainage tube extending through an upper side edge of said bag a substantial distance laterally into said chamber and said draw-off tube extending through the lower opposite side edge of said bag.

5. A bag according to claim 1, said drainage tube having a drip chamber therein.

6. A bag according to claim 1, one of said panels being transparent or translucent and the other panel being opaque, the transparent face of said bag being imprinted with vertically disposed volume graduations and numerals for indicating the level and quantity of drainage fluid in the bag.

7. A bag according to claim 6, said opaque sheet being white.

8. A bag according to claim 2, the end of said drainage tube having an adapter for connection with a catheter, said adapter having a removable cap applied thereto in a substantially air-tight manner, the fit between said draw-off tube and stabilizer tube being substantially airtight, whereby said fluid chamber is sealed from the atmosphere except through said stabilizer tube, filter means and draw-off tube.

9. A bag according to claim 2, said bag being packaged in a highly flexible plastic film package which is sealed except for at least one slit therein, whereby, when said packaged drainage bag is placed in gas sterilization apparatus, the sterilizing gas may pass through said slits into said container bag, thence through said stabilizing tube, including the filter, and said draw-off tube into said fluid chamber.

10. A bag according to claim 1, the horizontal dimension thereof being greater than its vertical dimension.

11. A bag according to claim 1, the lower edge thereof being bowed downwardly with the lowest portion thereof being located at a point intermediate the side edges thereof.

12. A bag according to claim 11, said bag having at least one slit above the fluid chamber and directly under said stabilizing tube for receiving a flexible strap for hanging said bag, said slit being located substantially directly above said lowest portion of said lower edge.

13. A bag according to claim 1, said drainage tube being provided with a fitting having a plurality of branches, one branch of which is sealed to said drainage tube, a second branch of which is connected to a catheter adapter in an air-tight manner and a third branch of which is sealed to an end of a flexible irrigating tube, said irrigating tube being adapted to be connected at its other end with a source of irrigating fluid for irrigating the bladder, whereby the bladder may be alternately irrigated from said irrigating source and drained into said drainage bag.

14. A bag according to claim 13, said irrigation tube having a drip chamber therein.

15. A bag according to claim 13, said second branch being sealed to an end of a flexible, plastic tube, the other end of which is sealed to a catheter adapter, said other end of said irrigating tube having sealed thereto an adapter for connection with said source of irrigating fluid, both of said adapters being capped in an air-tight manner.

16. A bag according to claim 1, said drainage tube being provided with a fitting having a plurality of tubular

branches, one branch of said fitting being sealed to an end of said drainage tube, a second branch of said fitting being connected with a catheter adapter in an air-tight manner, a third branch of said fitting being provided with a closure member normally closed to seal said third branch against flow of fluid therethrough, said closure member being adapted to be opened by insertion into said third branch of the tip of an irrigating syringe or of a rigid tubular adapter of an irrigation tube to thereby provide communication for flow of fluid between said syringe tip or tubular adapter and said catheter adapter, whereby alternating irrigation and drainage can be achieved.

16A. A bag according to claim 16, said closure member comprising a valve member normally biased to closed position to seal said third branch against flow of fluid therethrough, said valve member being adapted to be moved from closed seal position to open position by insertion into said third branch of said syringe tip or said original adapter for flow of fluid therethrough.

17. A bag according to claim 16A, said valve member comprising a hollow cylindrical member having an external shoulder comprising a valve surface and being slidably received within the internal passage of said third branch, said internal passage having an internal shoulder comprising a valve seat, resilient means in said third branch biased between said third branch and said slidable valve member to normally urge said valve member outwardly to close position in which said valve surface is yieldably held by said resilient means into engagement with said valve seat, said valve member being movable inwardly to open position by insertion of said syringe tip or said rigid tubular adapter into said third branch and into engagement with said valve member, in which open position said valve surface is moved inwardly out of engagement with said valve seat.

18. A bag according to claim 17, said valve member having an outer reduced hollow cylindrical portion, which has a radial hole in the wall thereof, and an inner enlarged hollow cylindrical portion, the interiors of said reduced and enlarged valve portions being separated by a cross wall, the juncture of said reduced and enlarged portions forming said external valve surface shoulder, the outer and inner end portions of said internal passage in said third branch being of reduced diameter with an enlarged diameter portion therebetween, the intersection of said reduced outer passage portion and said intermediate enlarged passage portion forming said internal valve seat shoulder, and the intersection of said inner reduced passage portion with said intermediate enlarged passage portion forming a second internal shoulder, said reduced valve portion being slidably received in said outer reduced passage portion and said enlarged valve portion being slidably received in but spaced radially inwardly of said intermediate enlarged passage portion, said resilient means comprising a spring, an end portion of which is received within said enlarged valve portion, said spring being biased between said second internal shoulder and said cross wall of said valve member, said hole in said reduced valve portion lying in said reduced outer passage portion when the valve member is in closed position but being movable inwardly into said intermediate enlarged passage portion when said valve member is in open position.

19. A bag according to claim 18, said syringe tip or rigid adapter being externally tapered, the end of said syringe tip or rigid adapter being of a size which adapts it to be inserted into the outer end of said passage in said third branch into engagement with the outer edge of said reduced valve portion to move said valve member to open position, the taper of said syringe tip or rigid adapter being such that it engages the outer end of said third branch to limit inward movement of said valve member and to close said end of said third branch against the flow of irrigating fluid therefrom.

20. A bag according to claim 1, also comprising a

plastic fitting for hermetically connecting at least one of said draw-off tube and drainage tube to said bag, said fitting comprising a flat base sealed to the surface of a bag panel, said base extending outwardly into a hollow elbow portion having an elbow passage therethrough to which is sealed said one of said draw-off tube and said drainage tube.

21. A bag according to claim 1, said means dividing said bag interior into said pocket and chamber comprising an elongated seal area at which said panels are sealed together.

22. A closed drainage system comprising a drainage receptacle, said receptacle having a flexible plastic inlet drainage tube connected therewith, said drainage tube having a multi-branched fitting, one branch of which is connected to an end of said drainage tube, another branch of which is connected to a catheter adapter, and a third branch of which is provided with a closure member normally closed to seal said third branch against flow of fluid therethrough but adapted to be opened to open said third branch to flow of fluid therethrough by insertion into said third branch of the tip of an irrigating syringe or a rigid, tubular adapter at the end of an irrigation tube, the other end of which is adapted to be connected with a source of irrigating fluid, whereby said bag may be used either for drainage without irrigation or for irrigation with an irrigating syringe or from said source of irrigating fluid, and alternating drainage.

22A. A system according to claim 22, said closure member comprising a valve member normally biased to closed seal position to seal said third branch against flow of fluid therethrough, said valve member being adapted to be forced out of closed position to open position to open said third branch to flow of fluid therethrough by insertion of said syringe tip or rigid adapter into said third branch.

23. A system according to claim 22A, including resilient means for urging said valve member to closed position, said valve member comprising a hollow cylindrical member which is open at its outer end, which is slidably received with the passage in said third branch and which has a radial hole in the wall thereof and a cross wall located axially inwardly of said hole to close said hollow member to flow of fluid therethrough, said hollow member having an external annular valve surface located axially inwardly of said hole, said passage of said third branch having an internal annular valve seat against which said valve surface is urged by said resilient means to close said branch against the flow of fluid therethrough, said valve surface being moved inwardly with said valve member and away from said valve seat when said valve member is moved to open position.

24. A system according to claim 23, said passage having an outer reduced diameter portion extending axially inwardly into an enlarged diameter portion, the juncture thereof forming an internal shoulder comprising said valve seat, said hole being located in said reduced passage portion when said valve member is in closed position and being moved into said enlarged passage portion when said valve member is moved to open position.

25. A system according to claim 24, said hollow member comprising an outer reduced diameter portion of said valve member slidably received in said reduced diameter passage portion, said reduced diameter valve portion extending axially inwardly into an inner enlarged diameter hollow cylindrical portion of said valve member slidably received in, but spaced radially inwardly from, said enlarged passage portion, the juncture between said reduced and enlarged portions of said valve member forming an external shoulder comprising said valve surface, said cross wall being located intermediate the ends of said valve member.

26. A system according to claim 25, said enlarged passage portion extending inwardly into a second reduced diameter passage portion to form a second internal

19

shoulder, said enlarged inner hollow valve member portion being enlarged both internally and externally and being open at its inner end, said resilient means comprising a spring, the outer end of which is received in said enlarged diameter valve portion and engages said cross wall and the inner end of which engages said second shoulder to urge said valve member to closed position.

27. A system according to claim 22A, said syringe comprising a tooth-paste tube-shaped, compressible, flexible, transparent or translucent, heat sealable, plastic package having a low rate of moisture transmission and being resistant to autoclaving conditions and containing irrigating fluid and having a reduced, threaded neck at one end thereof, said threaded neck extending axially into an externally tapered syringe tip dimensioned so as to be insertable into said third branch to bring the edge thereof into engagement with said valve member and thereby move it to open position, and so that engagement of the tapered periphery thereof with the end of said third branch limits movement thereof into said third branch

20

and closes said end of said third branch against flow of irrigating fluid therefrom.

28. A system according to claim 27, said syringe tip being provided with an elongated cap threaded to said neck at the base of said syringe tip.

29. A system according to claim 28, further comprising a band of flexible, heat shrinkable plastic shrunk tightly around the periphery of the base end of said cap and around the adjacent periphery of said neck to provide a removable, tamper-proof seal.

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