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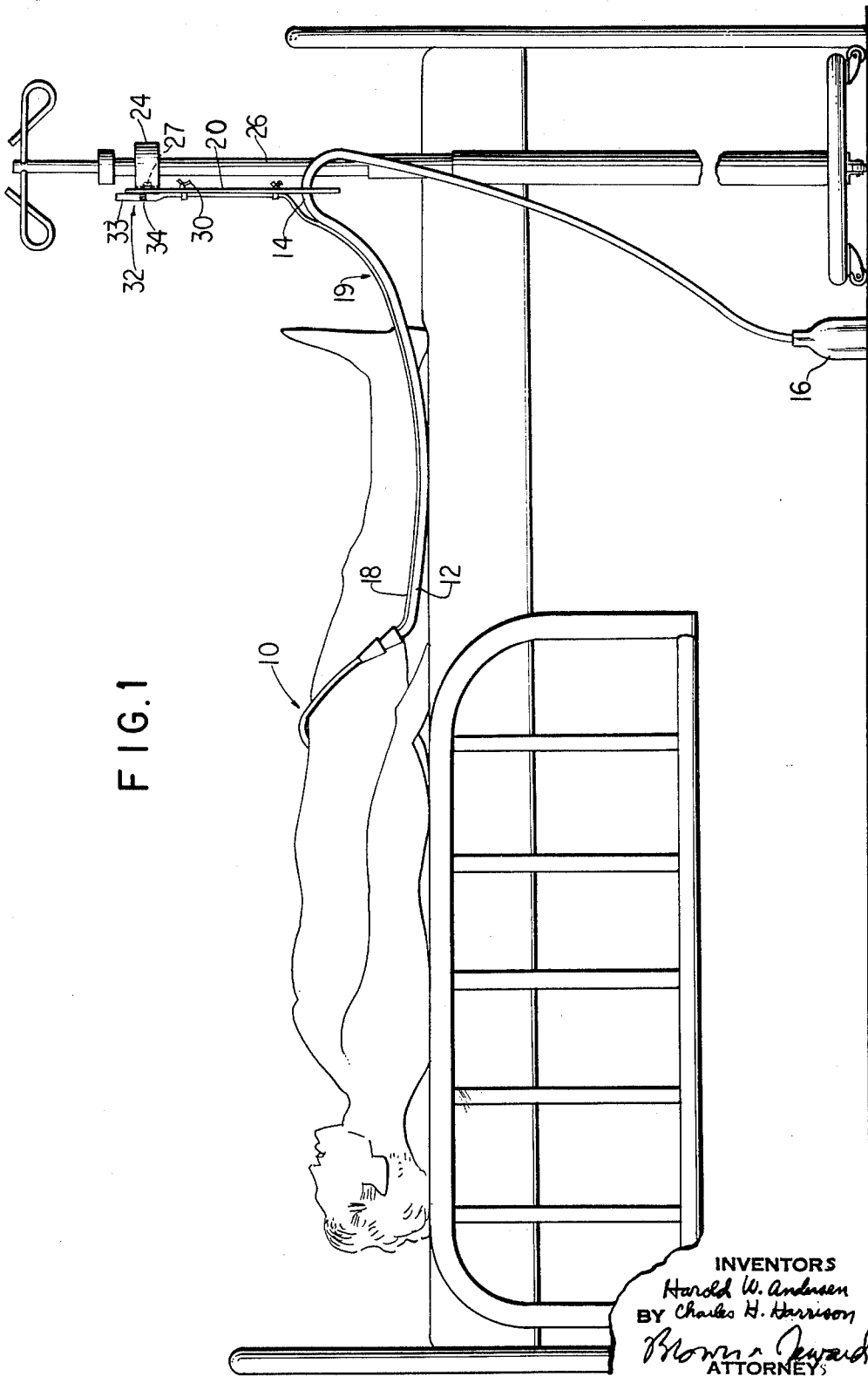
3,503,401

DRAINAGE CONTROL SYSTEM

Original Filed July 22, 1965

2 Sheets-Sheet 1

FIG. 1



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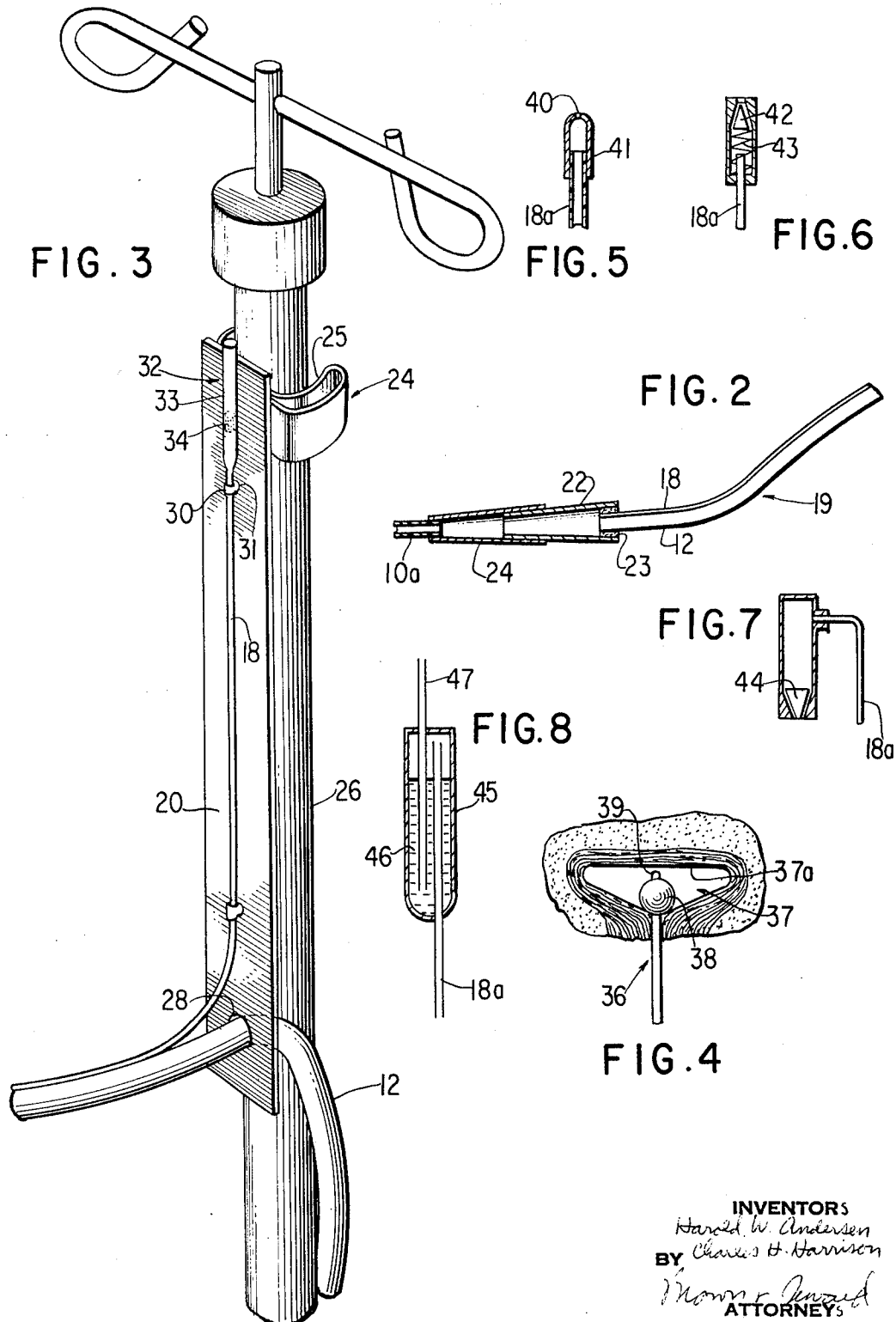
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DRAINAGE CONTROL SYSTEM

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Continuation of application Ser. No. 473,917, July 22, 1965. This application Aug. 27, 1968, Ser. No. 764,007

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4 Claims

ABSTRACT OF THE DISCLOSURE

A method and apparatus for urinary drainage in which the normally closed system includes an adjustably upward course between the bladder and the downward course leading to a drainage receptacle, with the provision of venting means in the upper portion of the system designed to admit atmospheric air cyclicly when the flow of liquid in the downward course causes negative pressure in the upward course, whereby the system is periodically emptied and permitted to refill in a simulation of normal physiological filling and emptying of the bladder.

This application is a continuation of application Ser. No. 473,917 filed July 22, 1965 and now abandoned.

This invention relates to drainage of fluids from the body and more particularly to a method and apparatus in which the condition of the fluid in the body is utilized to control periodic drainage thereof. The invention is particularly adaptable for use in draining the urinary bladder as will be described in detail in connection with the illustrated embodiment. However, it will be understood the invention has other applications, for example, in irrigating the bladder with antibiotic fluid and in draining the stomach with a Levin tube.

Heretofore, it has been a common hospital procedure to obtain continuous drainage of urine from the urinary bladder by means of a catheter passed transurethraly and retained in the bladder by a number of standard and conventional devices. It is usual practice to attach a relatively large bore, plastic drainage tube to the proximal end of the urinary catheter and lead this drainage tubing along a downhill path over the side of the bed into a collection bottle or bag which is placed below the level of the urinary bladder. Such an apparatus when functioning properly creates a syphon effect in the catheter only to the level of the connection between the catheter and the drainage tube. However, a syphon effect is not obtained in the drainage tube as the bore of the latter is large enough so that air bubbles pass up the drainage tube preventing a syphon action therein. With this arrangement generally continuous drainage is obtained in that the bladder is always kept empty, there being no provision for automatic and periodic filling and emptying of the bladder.

There are two basic objections to this system. First, the urinary bladder is a hollow distensible organ which depends upon alternate filling and emptying to maintain the tone of its muscular walls. Also periodic filling and emptying of the bladder is one of the major methods or mechanisms by which the concentration of bacteria in the bladder is kept at low levels. This mechanism depends on dilution of the bacteria existing in the bladder with sterile urine from the ureters followed by periodic and complete emptying of the bladder. It has been demonstrated that if bacteria are injected into a normal bladder in large concentrations, the bladder is capable of clearing these organisms by this mechanism within approximately 24 to 48 hours. If the bladder is kept from emptying completely, though still allowed to expel portions of its contents periodically or continually, the growth of bacteria in the bladder may be of such magnitude that infection will ensue.

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The second objection to the aforementioned conventional method is that most of the catheters used as indwelling bladder catheters do not conform to the contracted shape of the bladder so that "Foley tip necrosis" of the dome of the bladder, a syndrome well known to urologists and pathologists, may result. It is felt by some that this pressure ischemic ulcer of the dome of the bladder is the portal by which bacteria enter to infect the bladder wall. Such infections, common in patients with indwelling catheters, are caused when the dome of the bladder collapses and falls, or is drawn, down over the indwelling catheters, particularly over the tip of the catheter.

There are several pitfalls in the use of the aforementioned conventional drainage system which are very commonly encountered in hospitals and which accentuate this situation. For example, the drainage tube may be placed below the surface level of urine in the collection bottle or bag. Under these circumstances, the drainage tubing may fill with urine and exert a strong and continuous syphon action in the bladder. This draws the dome of the bladder down over the indwelling catheter and over the tip thereof very much enhancing the formation of pressure ulcers in the dome of the bladder. Also it has been demonstrated many times that submerging the end of the drainage tube in the urine will allow bacteria to swim up the slowly draining fluid in the drainage or connecting tubing and infect the bladder by that route.

Another pitfall of the aforesaid conventional drainage system is that if the drainage tubing is not led straight from the indwelling catheter to the collection bottle, urine will collect to form pockets in any loops which may be in the tubing, thereby causing a back pressure in the bladder with a resulting residual stagnant pool of urine therein. Such residual pooling is well known to hasten the onset of infection.

It is an object of the present invention to avoid the aforesaid difficulties of known prior art practices by providing a method and apparatus for drainage of fluids from the body with an indwelling bladder catheter or the like which automatically and periodically collapses and drains the cavity by syphon action, insuring its complete emptying, and which then allows the cavity to distend and collect the fluid once again to a predetermined pressure before recycling, the syphoning action essentially emptying and clearing the drainage tubing of fluid at the end of each syphoning cycle.

A further object is to provide a drainage system which reduces the chances of introducing bacteria into the body, which simulates physiological drainage of the cavity, and which functions in such a way as to maintain the muscular tone of the walls of the cavity.

Another object is to provide a drainage system which is relatively inexpensive and which utilizes a simple and uncomplicated arrangement readily adapting it for use by personnel already having training with conventional apparatus.

A further object is to provide certain improvements in the form, construction, arrangement and material of the several elements wherein the above named and other objects may effectively be attained.

A practical embodiment of the invention is shown in the accompanying drawings wherein:

FIG. 1 is an elevational view showing the overall arrangement of one embodiment of the invention.

FIG. 2 is a partial sectional view showing the connection between the catheter and the drainage tubing.

FIG. 3 is a perspective view of the plaque and the conduits which it supports.

FIG. 4 is a partial schematic view of a bladder with a Foley catheter in situ.

FIGS. 5 to 8 are partial views of alternate arrangements of the air vent conduit.

Referring to the drawings, FIG. 1 shows a patient lying in a standard hospital bed with a conventional indwelling catheter 10 (partly shown) in situ. The catheter 10 is connected to a drainage conduit or tube 12, the latter in turn extending to a position 14 elevated with respect to the bladder and then leading to a collection container 16 located below the level of the bladder. The container 16 may be a bottle as shown, or a collection bag supported on the bed or on a stand on the floor. Connected for communication with the drainage tube 12 at the juncture between the latter and the catheter 10 is an air vent conduit or tube 18 which leads to an elevated position where it is open to atmosphere.

The air vent tube 18 and a portion of the drainage tube 12 may be formed as biluminal tube 19 which leads from the catheter 10 to a support in the form of a plaque 20 where the biluminal tube 19 is separated in order that the air vent tube 18 may be extended to a higher elevation while the drainage tube 12 continues down to the collection bottle 16.

Turning to more specific details of construction of the illustrated embodiment, the biluminal tube 19 is connected to the catheter 10 as shown in FIG. 2 wherein a tapered connector 22 has its larger end suitably affixed to the end of the biluminal tube 19 as by adhesive 23 so that both axial passages of the biluminal tube 19 communicate with the interior of the connector 22. The connector 22 is joined to the catheter 10 by the interfering tapered fit with the catheter connector 24, the latter being shown as a tapered body having its smaller end affixed to the end of the catheter tube 10a. It will be understood that the connection between the catheter 10 and biluminal tubing 19 may vary from that shown, depending, for example, on the shape and form of the connector provided on the end of the catheter by each manufacturer. For example, where a tapered enlargement is provided at the end of the flexible catheter tubing, the tapered connector 22 may be fitted therein.

As previously mentioned, the drainage tube 12 and the air vent tube 18 lead to a position elevated with respect to the bladder where they are supported by the plaque 20. The plaque 20 has a clamp 24 with resilient arms 25 which holds the plaque on a support stand such as an I.V. pole 26 commonly found in hospitals. The clamp 25 is suitably fixed to the plaque 20 as by the fastener 27 and is readily adaptable to be raised or lowered on the stand 26 as desired. The plaque 20 has an opening 28 at its lower end to accommodate and support the drainage tube 12. The air vent tube 18, on the other hand, is separated from the drainage tube 12 at the plaque 20 and is extended upwardly along side the plaque where it terminates adjacent the upper end thereof. Suitable means such as plastic covered twist wires 30 may be used to support the air vent tube 18 on the plaque 20. Openings 31 are provided in the plaque to hold the twist wires in place as shown. The terminal end of the air vent tube is provided with a filter 32 for the air entering therein. The filter 32 may be a section of tubing 33 of larger diameter than the air vent tube 18 attached to the end of the latter, the larger diameter tubing 33 containing a filtering material such as a wad of cotton 34.

In operation, the plaque 20 is supported on the stand 26 initially at an elevation (not shown) so that its lower end is lower than the bladder while the upper end is preferably higher than the bladder. The drainage tube 12 is then arranged to provide a downhill path from the catheter 10 to the collection container 16 located at or near the floor line. The connection is made between the indwelling urinary catheter 10 and the biluminal tubing 19 as previously described. Urine is then allowed to flow into the drainage tube 12, and as it passes downwardly therethrough, it creates a negative pressure in the drainage tube 12 converting the system to a syphon to empty

the bladder. After the bladder is empty, air is automatically drawn in through the air vent tube 18 to the connection between the catheter 10 and biluminal tube 19 to break the syphon action and refill the drainage tube 12 with air which has been filtered through the cotton 34 before entering the system.

It will be understood that syphon action is established in spite of the air vent tube 18 because air flow to the latter is restricted as it passes through the interstices of the cotton filter 34 and also because the air vent tube has a smaller internal diameter than that of the drainage tube thereby offering greater resistance to the drainage of urine therefrom due to greater frictional resistance and the effects of capillary action and surface tension. Thus, during initial drainage before syphoning is started, some urine may flow into the air vent tube 18. After syphoning commences, the air vent tube is drained of this urine at a retarded rate, for the reasons just mentioned so as not to break the syphon in the drainage tube until the bladder is empty. Any urine flowing into the air vent tube 18 at the outset will not reach the level of the filter 32 because, as previously mentioned, the latter is located at a higher elevation than the apex of drainage tube 14.

After the bladder is initially drained and air has entered the drainage tube 12 through the air vent tube 18, the plaque 20 is moved up the stand to the position shown in FIG. 1 wherein the elevated section 14 of the drainage tube 12 is above that of the bladder, e.g. approximately six inches thereabove. As urine re-collects in the bladder, the pressure of this urine slowly causes the upstream side of the drainage tube 12 to refill until it reaches the elevated section 14 of the drainage tube at the plaque 20. At the same time, urine also flows into the air vent tube 18 to the same level as that in the drainage tube. Once the urine reaches the elevated section 14 it begins its downward course in the downstream side of the drainage tube to the collection bottle 16 and reconverts to a syphon emptying the bladder and the air vent tube 18. As previously described, the bladder is emptied before sufficient air can enter the system through the air vent tube 18 to break the syphon action. However, once the bladder is emptied, air is slowly admitted through the air vent tube 18 to the connection between the catheter 10 and drainage tube 12 to break the syphon and refill the drainage tube 12 with air. The system is then ready to recycle as the urine again begins to flow and gradually fill the drainage tube up to the elevated section 14, the recycling occurring as long as desired to periodically empty the bladder. The system operates automatically and requires no special tasks from an attendant other than to empty the collection bottle 16 and to periodically check to see that it is operating satisfactorily.

The system is readily adjusted for the starting pressure of the syphon merely by sliding the plaque 20 up or down on the stand 26 with the resilient clamp 24. The higher the elevated section of the drainage tube 12 above the level of the bladder, the greater the pressure of urine in the bladder required to start the syphon.

The above described arrangement allows the bladder to fill and periodically empty in a physiological manner in that the bladder drainage is controlled by intrabladder pressure which is, of course, related to the rate of urine input. The higher the rate of input to the bladder, the more quickly the pressure will rise and hence the more frequently the system will recycle. Thus the intracystic pressure initiates drainage in the same way it initiates urination.

With the arrangement described above, it makes little difference, in terms of harmful consequence, whether the end of the drainage tube 12 lies above or below the level of the urine in the collection bottle 16, nor does it make much difference whether the drainage tube 12 is looped on its way to the collection bottle 16. The only time the entire drainage tube 12 is filled with urine is when the syphon is actually functioning and the flow then is rapid

and forceful enough to prevent bacteria from swimming upstream thereagainst. At the end of the syphoning cycle, air is bled into the drainage tube 12 automatically, preventing bacteria from traversing the drainage tube from the collection bottle to the bladder during the time the bladder is refilling. This is contrasted to conventional drainage systems where there is a generally continuous flow from the catheter to the collection bottle, such flow being less rapid than that under a syphoning condition so as to provide what is frequently referred to as a "wet path," along which bacteria can find its way back into the bladder to cause infection. Thus in the conventional arrangement, if the end of the drainage tube is below the level of the urine in the collection bottle, or if urine is allowed to collect in a loop, bacteria therefrom can find its way along the "wet path" to the bladder. This is precluded in the present invention for the reasons mentioned above.

Because the invention provides for intermittent, automatic, complete emptying of the bladder followed by redistention thereof, it will tend to prevent the tip of the indwelling catheter from causing a pressure sore on the dome of the bladder. This is so because the bladder will be in contact with the tip of the indwelling catheter for only a short time out of the whole drainage-refilling cycle. Referring to the schematic view in FIG. 4, a conventional Foley catheter 36 is shown within the bladder 37. The catheter 36 has a retention balloon 38 and a tip 39 having openings (not shown) therein through which urine is admitted to the catheter 36 for drainage. When the bladder is full, it is distended to its more or less inverted pear shape (not shown) and there is no contact between the bladder and the tip 39 of the catheter. However, when the bladder is empty, it collapses so that the dome 37a thereof falls down over the tip 39 of the catheter 36 to irritate the bladder whereby "Foley tip necrosis" may result, particularly when the bladder is kept substantially empty over long periods of time as when the aforementioned conventional continuous drainage method is used. As previously stated, this problem is alleviated in the invention by allowing the bladder to start refilling immediately after it is emptied, thereby distending the bladder and keeping the dome away from the tip of the catheter as much as possible. The periodic distention and refilling of the bladder also maintains the tone of the muscular walls of the bladder.

The operation of the invention has been described as being initiated by locating the plaque so as to provide a downhill path for the fluid through the drainage tube to the collection bottle. This is to initially drain the bladder and relieve the patient before putting the system into automatic recycling operation. If desired, however, the plaque may be initially located at its elevated position (FIG. 1) for automatic operation at the outset.

The drainage tube 12 and the air vent tube 18 may be made of flexible and transparent plastic while the connector 22 may be made of a rigid plastic. The biluminal section 19 of the drainage tube and air vent tube may be made by joining two tubes along their axial lengths.

It will be apparent that the air vent tube 18 controls the air to the drainage tube 12 to break the syphon. In order to restrict the rate of entry of air into the air vent tube for the reasons previously mentioned, the cotton or other filtering material in the filter 32 may be packed tightly as desired. Also, as shown in FIG. 5, the air flow may be restricted by a pinhole orifice 40 included in a cap 41 on the end of the air flow tube 18a. As further alternate embodiments a check valve having a closure

member 42 biased by a spring 43 (FIG. 5) or a gravity operated closure member 44 (FIG. 7) may be used on the end of the air vent tube 18a. Also a fluid loaded check valve (FIG. 8) in which the end of the air vent tube 18a extends into a larger tube 45 continuing a fluid 46 and in which another conduit 47 leads from the larger tube 45 to atmosphere may be employed.

It will be apparent that other means besides the plaque 20 may be used for supporting the drainage tube 12 and air vent tube 18 in their elevated positions. For example, they may be supported on a bed post or on a wall in a room by suitable clips or clamps as desired. Also, the air vent tube may be connected to the drainage tube other than at the connection between the catheter and the drainage tube.

As previously mentioned, the invention is particularly adaptable for draining the urinary bladder and has been so described in connection with the illustrated embodiment. It will be understood, however, that the invention has other applications, for example, in irrigating the bladder with antibiotic fluid and in draining the stomach with a Levin tube.

What is claimed is:

1. Apparatus for draining a fluid from a body cavity, comprising a continuous tubular drainage conduit constituted by a catheter leading from said cavity and a drainage tube connected to said catheter, means supporting a section of said drainage tube at an elevated position above said cavity to define upstream and downstream sections leading up to and down from, respectively, said elevated section, the aforesaid disposition of said conduit providing for partial drainage of the cavity into said upstream section up to said elevated section and subsequent substantially complete drainage by syphoning action as the fluid flows past said elevated section to said downstream section, and air vent means comprising an air inlet in communication with the drainage conduit at a point adjacent the catheter and below the level of said elevated section and means associated with said inlet for preventing the escape of fluid from the system through said inlet whereby said syphoning action is broken after the cavity and conduit have been drained by the syphoning action.

2. Apparatus for draining a fluid from a body cavity according to claim 1 wherein said drainage conduit and air vent means comprise a biluminal tube.

3. Apparatus for draining a fluid from a body cavity according to claim 1 wherein said air vent means further comprises an air tube leading to an elevation higher than the elevated section of said drainage conduit and being adapted for entry of fluid into the portion of the tube which is lower than said elevated section.

4. Apparatus for draining a fluid from a body cavity according to claim 3 wherein said air tube has a bore smaller than that of the drainage conduit such that during syphoning of the drainage conduit, fluid which entered the air tube during the said partial drainage into the upstream section of the drainage conduit, is emptied at a slower rate to preclude emptying thereof until syphoning is completed.

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