SELF-VENTING DRAINAGE SYSTEM FOR BODY FLUIDS

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13 Claims

ABSTRACT OF THE DISCLOSURE

A body-fluid gravitational drainage system, such as a urinary catheter, for draining fluids from a body cavity by gravitational means, wherein the drainage channel is vented to the atmosphere during use so as to prevent development of a negative pressure within the body cavity and thus avoid damage to body tissue within the cavity. A bacterial filter unit which allows passage of air but not passage of body fluids, is positioned in the vent to filter the air entering the vent and to prevent leakage of body fluid through the vent, whether the filter be above or below the body cavity fluid level.

This invention is concerned with animal body-fluid drainage systems in which a tubing portion for positioning within the body is an essential part and in which a bacterial filter normally operative both above and below the body-fluid level permits bacteria-free air to break the negative pressure created by the body-fluid column in the system. It has been discovered pathologically that when tubing, as for instance an indwelling catheter, is utilized for body fluid drainage by gravitational means, a column of body fluid is formed in the drainage system which persists after the fluid source is drained. This column of fluid creates a suction, drawing the adjacent tissue such as, for instance, bladder mucosa into the drainage eyes of the indwelling catheter. The amount of suction is dependent upon the height of the fluid (such as urinary column). A column of fluid having a vertical drop of as little as six inches causes pseudo polyph to form in the adjacent tissue, such as bladder mucosa, at times causing denudation of the epithelium tissue and at times a hemorrhagic condition. Obviously, where denudation of the normal protective tissue, such as mucosa of the bladder, occurs, bacterial penetration and invasion is very much more probable.

In U.S. Patent No. 3,114,373 which relates to a gastrointestinal sump tube assembly, the possibility that mucosal surfaces may be drawn into the tube lumen and thus damage by suction from a high volume, low vacuum aspirator is recognized. An open tube is provided to draw in ambient air.

It is also generally recognized that ambient air contains bacteria. Thus, in the administration of parenteral fluids it has been the practice to vent the bottles containing these fluids through a bacterial filter so that the fluids will flow. At times very simple filters such as a wad of cotton in a tube above the fluid level have been used.

The most recent practice has been concerned with providing bottom filters which bubble filtered air up through the parenteral fluids. A filter of this latter type is illustrated in Canadian Patent No. 712,075, issued July 6, 1965 to Abbott Laboratories, North Chicago, Ill., upon an invention by Albert F. Bujan.

But worthwhile as these inventions are, they have not been concerned with the drainage of body fluids by gravitational means and until this invention no one had provided an adequate solution of how to drain such fluids without tissue damage in all of the various attitudes of patients whether prone, supine, sedent or ambulatory.

It is an object of this invention to provide a body fluid drainage system in which an effective bacterial air filter breaks the negative pressure created by the body fluid column whether the filter be above or below the body cavity fluid level.

It is a further object of this invention to provide a body fluid drainage system in which the bacterial air filter may be readily exchanged if it becomes inoperative without removal of the drainage tubing.

Other objects of the invention will be apparent from an examination of the drawings in which:

FIGURE 1 represents a typical fluid drainage system in which a bacterial filter forming a portion of a urinary catheter connects with a separate channel terminating in use within the bladder.

FIGURE 2 is a longitudinal section of the tip of the catheter of FIGURE 1.

FIGURE 3 is a modification of FIGURES 1 and 2 in which the channel connecting with the bacterial filter connects with the drainage channel of the catheter at a point longitudinally outward of the catheter drainage eye.

FIGURE 4 is a further modification of FIGURES 1 and 2 in that the channel connecting with the bacterial filter joins the drainage channel of the catheter externally of the patient's body and the filter is a screw-on type.

FIGURE 5 is a modification of FIGURE 4 in that the bacterial filter unit is attached by forcing the connecting tube into the open filter end.

FIGURE 6 is a further modification of FIGURES 4 and 5 in that the filter covers a hole opening directly into the catheter drainage channel exteriorly of the body.

FIGURE 7 is a longitudinal partial section of FIGURE 6 showing the filter seated in position.

FIGURE 8 illustrates, in partial longitudinal section, a filter assembly not integral with the catheter but which connects with the drainage channel of a normal retention catheter such as the Foley urinary catheter.

FIGURE 9 illustrates in longitudinal section a drainage channel with a combination needle-penetrating plug and end plug showing the filter in place with its needle penetrating the plug.

FIGURE 10 illustrates a bacterial maze in which the bacteria are trapped in the breather tube convolutions.

FIGURE 11 illustrates a typical filter unit of the invention in which a wad type bacterial filter whose functionality is limited or destroyed by urine or other body fluid is contained in a fluid impervious but air pervious cup.

For purposes of this invention "fluid impervious" is intended to describe that characteristic of a porous material which under a head of up to 10 inches of body fluid will not leak nor wet out sufficiently to prevent passage of air therethrough.

FIGURE 12 illustrates a filter unit similar to that of FIGURE 10 but with a sheet filter substituted for the wad type filter.

FIGURE 13 illustrates an impervious cylinder into which a plug of material, such as open cell foam, is forced which with a filter provides a filter unit which will pass air but not urine or other body fluids.

In FIGURE 14 is shown a filter unit in which the urine or other body fluid is in contact with the filter on one side with ambient air on the other side.

FIGURE 15 illustrates a fail-safe filter unit in which a second filter comes into action if the first becomes inoperative.

FIGURE 16 illustrates a simple apparatus for determining whether a filter may be used in direct contact with urine or other body fluids.

FIGURE 17 shows the typical filter holder illustrated in FIGURE 16 in cross section.

I have discovered that while some bacterial filters are operative only when they are relatively dry, others are
effective as well with liquids but not all liquids. Specifically, problems may arise when attempting to filter air through a filter when urine is in contact with the other side of the filter. Whether urine possesses natural wetting agents and sediments which prevent functioning of the filter or whether the lack of function is due to some other characteristic of urine is not known. I have found, however, that some filters which function well and filter the air in allowing it to pass through and into water on the opposite side do not function when urine is the fluid on the opposite side. Moreover, I have found that all such bacterial filters even cotton plugs are effective if there is interposed a porous material which is fluid impervious. Moreover, I have designed simple apparatus which will permit me to determine whether a filter needs to be protected from contact with urine or other body fluids. My invention, therefore, includes all bacterial filter means as is illustrated by typical examples shown in the drawings and described herein.

Referring once more to the drawings:

In FIGURE 1, a typical drainage system of the invention is shown including a retentive catheter of the self-inflating type 10 but modified by the inclusion of a bacterial filter 21 which terminates in a side arm 20, containing a filter unit 23. The drainage system catheter illustrated in FIGURE 1 has a flexible insertion main arm 11 which terminates in a tip 11a containing a drainage eye 13. The eye extends through the tip and intersects the main drainage channel 12. This channel extends from the intersection with the eye through the length of the catheter including the connection bell 11b. Two side arms 14 and 20 contain the infilblion reservoir 14a and the filter bell 20a respectively. Side arm 14 is terminated by a plug 15 and when the reservoir 14a is inflated as shown, a clamp 16 prevents release of the fluid from the reservoir. The side arm 14 contains a channel 17 which connects with an opening 18 in the main arm wall within a sealed bag 19. Upon release of the clamp 16, bag 19 is inflated by the fluid forced out by contraction of the reservoir 14a to become the retention means. Side arm 20 contains a channel 21 which leads to an eye 22 in the tip of the catheter. Side arm 20 also contains a filter unit 23 of the type illustrated in FIGURE 12 which is retained by the stretched bell 20b. The sectional diagram depicted in FIGURE 2 shows the connections between the channels 12, 17 and 21 and their respective eyes 13, 18 and 22.

In the drainage system as shown in FIGURE 1, the air enters the filter unit 23 and the latter extracts the bacteria-free air then passes down the channel 21 and into the bladder itself overcoming the negative pressure as the urine is pulled into the main drainage channel 12.

In FIGURE 3 is illustrated what is perhaps the preferred catheter tip for those urine or other fluid drainage systems in which the filter unit is arranged to be a part of the catheter itself as opposed to a system such as that shown in FIGURE 8. In FIGURE 3, the channel 21a connects with the filter unit at the exterior end of the catheter and with the main drainage channel 12b by an opening 24 below the eye 23a. Preferably, the opening 24 is positioned in the direction of urine flow. As the air enters due to suction as the urine or other fluid moves past, the negative pressure is broken.

The retention bag or balloon 29a, its eye 28a and its channel 27a are similar to those of FIGURE 1.

In FIGURE 4 is illustrated a further modification of the invention wherein the aeration channel 16b in side arm 20b opens into the main drainage channel 12b near the bell of the catheter. In this modification, the reservoir arm 14b and its channel 17b are unchanged and the catheter intersection of the channel 16a is similar to that of FIGURE 3 but with Foley inflatable retention catheter. The filter unit 29 contains a tubular adapter 29a having a female end for receiving side arm 20b and a male threaded end to which is screwed a perforated filter cap 29b containing the bacterial filter 29c. This arrangement permits ready replacement of the filter and retention means.

In FIGURE 5, a modification of the drainage system of FIGURE 4 illustrates a filter unit 23e into which the side arm 20c is inserted like a stopper thus connecting the filter unit to the main drainage channel 12c by means of the side arm aeraulating channel 21c. Again the reservoir side arm 14c and its channel 17c are unchanged. Again inwardly of channel 21c the catheter resembles a regular Foley inflatable retention catheter.

FIGURE 6 and its longitudinal enlarged section FIGURE 7 show a modification of FIGURE 4 in which there is no filter but with an opening 25 through the main arm into the main drainage channel 12d. The patch 26 containing the filter 27 which covers the hole 25 may be cemented, vulcanized or otherwise adhered or sealed in place, to the catheter wall by the seals 28. Inwardly of the filter the catheter is a typical Foley inflatable retention catheter with the usual side arm 14d containing an inflating channel 17d.

FIGURE 8 illustrates a typical drainage system of the invention utilizing a regular Foley inflatable retention catheter 30 including a reservoir side arm 31 and a connecting bell 32. A "Y" fitting 33 having tapered ends is fitted into the drainage tubing 34 at one end and into the catheter bell 32 at the other end. The channel on the filter arm 35 opens into the main channel 36. Preferably, the arm 35 points with the urine flow. Its open end is also slightly tapered and has a good seal with the filter holder 37 which contains the sealed-in filter 38. FIGURE 9 illustrates a portion of a main drainage channel of a urine or other body fluid drainage system 40 including a side arm 41 containing an end plug 42, a filter unit including a hollow needle 43, a filter holder 44 and a sealed-in filter 45 shown inserted into the plug to permit aeration with bacteria-free air. Obviously, the filter units of FIGURES 4, 5, 8, 9 and 15 may be replaced very readily. The other filters, with the exception of that shown in FIGURES 6, 7 and 10, may be replaced if they become clogged but with more difficulty.

In FIGURE 10 a filter unit operating under the maze principle first demonstrated by Pasteur is shown attached to aerate the main drainage channel 52 of the drainage system 50. The filter unit consists of a small hollow tube 51 which is adhered to a main drainage tube 54 and makes a number of spiral convolutions. The entrance 43 is shown inserted into the tube to permit aeration with bacteria-free air. Obviously, the filter units of FIGURES 4, 5, 8, 9 and 15 may be replaced very readily. The other filters, with the exception of that shown in FIGURES 6, 7 and 10, may be replaced if they become clogged but with more difficulty.
primary filter unit 103, secondary filter unit 103a. Unit 103a includes a ball check valve 104 with ball 105 shown seated in its hemispherical seat. When the primary unit fails to reduce the negative pressure for some reason, the ball 105 is lifted off its seat and air is pulled in around the ball to relieve the negative pressure. A grid 106 prevents excessive movement of the ball. Obviously, when the ball is displaced from its seat for any reason, the filter is open. The secondary unit should be so placed, therefore, as to be closed by gravity when the patient is in his predominant attitude and the primary unit is operative.

In FIGURE 16 is shown a testing unit by which bacterial filter elements may be tested. The unit consists of a Foley type catheter 80 in which the main channel 76 terminates in drainage eyes 74 and 74a. Side arm 81 includes channel 73 which latter terminates at the openings 73a within the retention bulb 78. A toy balloon 77, which prior to the test is filled with 200 to 400 cubic centimeters of fresh body fluid such as urine to assume the dotted inflated position is retained in the filled condition when the bulb 78 is inflated so tight as to occlude channel 76. The Foley catheter used may be one in which there is no reservoir 79 as indicated but rather the retaining bulb 78 is inflated by a syringe without inflation of the reservoir 79. With automatically inflatable catheters, however, the reservoir 79 is inflated and the bulb 78, after being inflated, is left in the partially inflated condition bulb 78. Inserted into the bulb the catheter 80 is a hollow fitting 82 which leads from the main drainage channel 76 into three separate channels, one leading through tubing 85 to a U tube manometer 86 with open end 75 and containing mercury, one leading through tubing 83 to a drainage receptacle 84 and the other leading through tubing 87 to filter holder unit 90 shown in enlarged section in FIGURE 17. The unit 90 consists of an open female threaded ring 89 and a male threaded filter platform 88. The testing unit may be utilized to test not only sheathed and wadlike filters but also the porosity of the ends of porous-ended filter cups. The material 91, therefore, may be any porous material which may be sufficiently compressible to make a seal. In practice, the filled balloon 77 is elevated so that about 8–10 inches of vertical distance from catheter eye 74 to tubing 87 exists.

The material to be tested is inserted into the female ring 89, and the male fitting is then driven down to form a seal with the sealing ring 92 on the filter platform.

The clamp 94 which is shown open in FIGURE 16 is closed for this test and the clamp 93 is then opened exposing the material to be tested to the vertical head of 8 to 10 inches of body fluid. If no fluid has penetrated the material being tested within a minimum of 30 minutes, the material is satisfactory so far as leakage of fluid is concerned. The next test is for porosity. Before opening clamp 94, note that the manometer indicates a positive pressure in millimeters of mercury. If the material being tested is not porous, as soon as clamp 94 is opened, the manometer will indicate a negative pressure depending on the vertical height of the fluid. If the material being tested is porous, air bubbles will be drawn into the pipe 82 and the negative pressure will be broken at that point. The manometer will indicate a reduction of negative pressure in millimeters of mercury to a point equivalent to the 8–10 inches of vertical head from the filter used in this test. By lowering the balloon 77 to about 3 inches a negative pressure is achieved similar to that one might expect with the filter working during a urinary catheterization with the patient in supine position. Where the patient is ambulatory and a vertical head of 8–10 inches of urine might exist above a filter unit placed near the bladder neck, fluid pockets may be formed in the bladder. Catheters of the type illustrated in FIGURES 1, 2 and 3, especially the latter would be very much preferred because these catheters break the negative pressure regardless of patients' attitude at a point which would prevent formation of such pseudo-polyps.

Those bacterial filters which cease to function to admit air when body fluids are directly in contact with their inner surfaces and those which cease to be bacterial filters because of wetting are suitable when they are used with a porous-ended filter cup, the end of which is material which does not show body fluid on the outer surface during the test. Obviously, the seal between the filter unit and its side arm channel must be fluid tight. This can be accomplished by friction fitting of elastic side arm material by solvent sealing, by heat sealing and other well-known methods. Likewise the filter may be retained hermetically by proofing in its holder or porous-ended cup or in position on the main drainage system by these and other well-known methods.

Of the materials demonstrated by the apparatus of FIGURE 16 to be suitable as a shield to prevent body fluid from contacting the bacterial filter, polyolefins are generally superior when they are used in proper pore size and open area. A preferred shield material is porous polyethylene obtainable from Forex Materials Corporation of Fairburn, Ga. The material which has been used with excellent success is about 3/64 inch thick and has an open area of about 50% composed of relatively straight channels each about 30–40 microns in diameter. This material will hold a head of 8 the retentive bulb 78. Inserted into the bulb the catheter 80 is a hollow fitting 82 which leads from the main drainage channel 76 into three separate channels, one leading through tubing 85 to a U tube manometer 86 and open end 75 containing mercury, one leading through tubing 83 to a drainage receptacle 84 and the other leading through tubing 87 to filter holder unit 90 shown in enlarged section of FIGURE 17. The unit 90 consists of an open female threaded ring 89 and a male threaded filter platform 88. The testing unit may be utilized to test not only sheathed and wadlike filters but also the porosity of the ends of porous-ended filter cups. The material 91, therefore, may be any porous material which may be sufficiently compressible to make a seal. In practice, the filled balloon 77 is elevated so that about 8–10 inches of vertical distance from catheter eye 74 to tubing 87 exists. The material to be tested is inserted into the female ring 89, and the male fitting is then driven down to form a seal with the sealing ring 92 on the filter platform.

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3. A catheter in accordance with claim 1 wherein the vent is positioned in the annular tubular wall along the proximal end thereof and the filter is positioned to filter air entering said vent.

4. A catheter in accordance with claim 1 wherein the annular tubular wall member includes a separate aeration channel extending the length thereof and terminating in a side arm projection at the proximal end thereof and a separate orifice at the distal end thereof, and having a bacterial filter positioned to filter air as it passes through the side arm channel.

5. A catheter in accordance with claim 1 wherein the vent comprises a side arm projection positioned at the proximal end of the annular tubular wall member defining an aeration channel communicating with the drainage channel and having the bacterial filter positioned to filter the air as it passes through the side arm channel.

6. A catheter in accordance with claim 2 wherein said static shield means comprises a material which is pervious to air and impervious to body fluids interposed between the bacterial filter and the vent.

7. A catheter in accordance with claim 2 wherein said static shield means comprises a hollow rigid retainer for carrying the filter and having a wall member interposed between the bacterial filter and the vent, said wall member being pervious to air and impervious to body fluids.

8. A catheter in accordance with claim 4 wherein the bacterial filter is carried by a relatively rigid retainer having an air pervious-body fluid impervious wall member interposed between the filter and the vent, said retainer disengageably fitted to the side arm projection.

9. A catheter in accordance with claim 4 wherein the side arm terminates in a relatively rigid retainer portion having a wall member separating the aeration channel from the retainer portion, said wall member being pervious to air and impervious to body fluids, and a bacterial filter disengageably fitted within the retainer portion said filter being separated from the vent by the air pervious-body fluid impervious wall member.

10. A catheter in accordance with claim 1 wherein the drainage channel includes a secondary vent opening having a bacterial filter connected to said vent, said filter being pervious to air and impervious to body fluids and positioned to filter air entering said vent, said secondary vent being designed to introduce filtered air into the drainage channel of the primary vent and filter fails to function.

11. In a catheter, for use in conjunction with a urinary collection system, having a distal end for inserting into an animal body cavity to be drained of fluids and an outward proximal end terminating in bell portion at said end and having an annular tubular wall defining a drainage channel, the improvement comprising in combination there-with a length of tubing having a main channel there-through engageable at its one end within the catheter bell such that the channel communicates with the drainage channel of the catheter and at its other end with the urinary collection system, said tubing having a vent opening therethrough at a point intermediate the ends thereof and a bacterial filter connected to said vent being pervious to air but impervious to body fluids and positioned to filter air entering said vent.

12. A catheter in accordance with claim 11 wherein the vent comprises a side arm projection positioned between the ends of the length of tubing, said side arm projection defining an aeration channel communication with the main channel thereof and having a bacterial filter positioned to filter air as it passes through the side arm aeration channel.

13. In a catheter having a distal end for inserting into an animal body cavity to be drained of fluids and an outward proximal end, and having an annular tubular wall defining a drainage channel, the improvement comprising in combination therewith a vent and bacterial filter unit consisting of a relatively smaller open tube-like conduit wound in spiraloid convolutions about a portion of the annular tubular wall proximate the proximal end thereof, said conduit having an end opening through said tubular wall so as to point in the direction of drainage flow through the drainage channel.

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DALTON L. TRULUCK, Primary Examiner.

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55—417; 128—295
UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,429,314

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February 25, 1969

It is certified that error appears in the above identified patent and that said Letters Patent are hereby corrected as shown below:

Column 2, line 49, "or" should read -- of --. Column 4, line 40, after "may" insert -- also --. Column 5, line 23, "my" should read -- may --. Column 7, line 38, "previ-" should read -- pervi- --.

Signed and sealed this 14th day of April 1970.

(SEAL)
Attest:
Edward M. Fletcher, Jr.
Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents