A non-clogging body fluid drainage apparatus (10) useful, for example, in a peritoneo-venous shunt (14) for draining ascites fluid which utilizes a conventional pressure sensitive, normally closed valve (20) in the shunt and which is further provided with a manually manipulatable flushing chamber (40) and with a normally open flow sensitive valve (50) on the inlet side (31) of the pressure-sensitive valve (20).
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Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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NON-CLOGGING VALVED DRAINAGE SYSTEM FOR BODY FLUIDS

This invention relates to the surgical management of body fluid accumulation, as in ascites and hydrocephalus, and in particular provides a non-clogging, valved drainage system useful in draining accumulated body fluids, for example, as a peritoneo-venous shunt for draining ascites fluids into the venous system.

Both ascites and hydrocephalus are serious maladies which are characterized by the accumulation of fluid, in one case in the peritoneal cavity, and in the other in a ventricle of the brain. It is known that both of these conditions can be managed surgically by implanting a pressure-sensitive valve in the body which is arranged to drain the accumulated fluid from the peritoneal cavity into a vein, such as the jugular vein, in the case of ascites and from the brain into the peritoneum in the case of hydrocephalus. One useful valve for accomplishing this purpose is described in LeVeen patent 3,910,283. This valve, which is normally closed, opens on the existence of a pressure differential of 3 to 5 centimeters of H₂O.

In the case of a peritoneo-venous shunt patients occasionally undergo occlusion of the valve system. This occurs with about 12% of such patients. Sometimes such occlusion is caused by small flecks of inflammatory exudate formed within the peritoneal cavity which are transported upwardly and lodge in the valve itself cementing the surface of the valve. In other situations fibrinoid material or a small fat globule can prevent the valve from rising above its seat by mechanical interference with such action. In such cases it may be desirable to flush the valve.
system with peritoneal fluid to dislodge small particles which may be blocking the valve. Also a clot can form at the very tip of the tubing entering the venous system which prevents egress of ascites fluid through the venous (distal) end of the system which lies in the superior vena cava.

Newkirk in U.S. patent 4,240,434 describes incorporating a pump in the system which can be manipulated rapidly to force fluid through the discharge side of the system thereby to dislodge any such accumulations. In this arrangement the valve is a slit valve offering resistance to flow and a flexible pumping chamber is incorporated in the system on the outlet side of the valve so that compression of the pumping chamber forces the fluid into the venous system. Such an arrangement is ineffective to clear a clogged valve. Moreover, if the valve itself is occluded or the compression of the pumping chamber is released too suddenly, blood can be drawn into the venous tubing and pumping chamber. In such event the blood clots can render the entire system functionless.

Placing two such valves in series with the pumping chamber between would increase the resistance of the system such that it would become insensitive and thus useless for its intended purpose.

In accordance with this invention problems of clogging of a body fluid drainage system which occur both in the valve parts and in the discharge tubing are avoided by including a flushing chamber, that is a variable volume chamber on the intake side of the conventional, normally closed pressure-sensitive valve used to control drainage. This variable volume chamber has at least a flexible wall which can be
located at a position where it can be manipulated by external pressure. A second valve which is flow-sensitive, as distinguished from pressure-sensitive, and which is normally open is located on the intake side of the system such that the variable volume flushing chamber is located between the two valves. Thus, occasional pressure on the flexible wall of the flushing chamber will operate to close the flow-sensitive valve on the intake system forcing the contents of the flushing chamber out through the normally closed pressure-sensitive valve thus clearing any particles which may have lodged in the valve itself through the discharge line. When the external pressure is removed flow ceases, and the pressure-sensitive valve closes preventing drawing blood or the like into the discharge side of the system.

Preferably, the variable volume flushing chamber is physically part of the valve housing for the pressure-sensitive valve. The valve housing is preferably located in the peritoneum, has its intake side, including the normally open, flow-sensitive valve, located inside the peritoneal cavity and has its discharge side placed external to the peritoneum and transversus and transversalis fascia. External manual pressure can thus be applied to the valve housing to flex the wall of the flushing chamber to decrease the volume of the chamber. This action closes the flow-sensitive valve, opens the pressure-sensitive valve and forces fluid through the discharge system. When pressure is released the pressure sensitive valve immediately closes thus preventing blood from being drawn into the system.

The resultant combination of a normally open flow-sensitive valve with no resistance to flow and a normally closed pressure-sensitive valve forms the ideal system for use in clinical surgery to drain both
the peritoneal cavity and other body cavities requiring transport of fluid into the venous system.

For a more complete understanding of this invention reference is made to the appended drawings

FIG. 1 is a perspective view of a valved drainage system in accordance with this invention;
FIG. 2 is a transverse section through the system of FIG. 1 taken at line 2-2 in FIG. 1;
FIG. 3 is a schematic drawing illustrating the placement of a valved drainage system in accordance with this invention in the treatment of ascites and
FIG. 4 is a fragmentary view similar to FIG. 2 illustrating a modification in the location of the flushing chamber.

Referring more particularly to FIGS. 1 and 2, there is illustrated a non-clogging valved drainage system 10 for use in a peritoneo-venous shunt in accordance with this invention. System 10 includes a first valve housing 20 having a valve element 21, a flexible flushing chamber 40 and a second valve housing 50 having a valve element 51.

Valve housing 20 is formed of injection molded polypropylene. Housing 20 is generally in the form of a flat cylinder 23 which is closed at its upper end, as is seen in FIGS. 1 and 2, by a concave portion 22. Its cylindrical sidewall 23 has a single castellated nipple 24 providing external communication to the interior chamber 25 of housing 20 through a bore 26 in nipple 24.

The underside of valve housing 20, as seen in FIG. 2, is closed with an annular member 27 which interconnects sidewall 23 and the upper portion of a depending cup-shaped base member 28. The bottom of
cup-shaped member 28 carries a depending hollow tube 29 which is tapered to a closed lower end from which extends a castellated nipple 30.

Nipple 30 has a bore 31 communicating with the hollow interior of tube 29 and thence through cup 28 to the interior 25 of valve housing 20. Nipple 30 is set at a downward angle of approximately 60° from the vertical, as seen in FIG. 2. The upper end of tube 29 projects upwardly in cup 28 forming a valve seat 32.

The inner face of annular portion 27 of valve housing 20 is provided with a pair of annular bosses 33 and 34 which form an annular channel 35 on the inner face of annular portion 27. Valve element 21 is formed of silicone rubber and includes as an integral unit a conical closure element 36 for seating on valve seat 32. Four arms 37 extending outwardly from the upper end of conical element 36 and terminating in a circumferential ring 38 form a resilient spider arrangement supporting valve element 21 with ring 38 firmly received in channel 35. The resiliency of arms 37 is such that only a small positive pressure differential on the underside of element 21 is required to lift conical closure element 36 off seat 32. This pressure is desirably on the order of 3 to 5 centimeters of H₂O.

Flushing chamber 40 is preferably made of silicone rubber and is formed as a cap which fits over the upper side 22 of valve housing 20 grasping side wall 23 with a depending cylindrical skirt 41 which is apertured at 42 to receive nipple 24. The top of flushing chamber 40 is in the form of a flat, closed chamber 45 having a lower sidewall 43 lying
against top 22 of valve housing 20 and an upper sidewall 44. The volume of chamber 45 is variable by flexing top wall 44.

To one side of chamber 45 a bore 46 is provided in flushing chamber 40 for external communication with chamber 45. A small tube 47 of silicone rubber is affixed in bore 46 and extends around sidewall 41 of pumping chamber 40 through an opening 39 in tubular portion 29 of the bottom of valve housing 20. Tube 47 is affixed in opening 39 and thus provides a permanent connection communicating the interior 45 of flushing chamber 40 with the interior of tube 29.

A collar 12 of foamed silicone rubber having a notched rim 13 is secured over tube 29 firmly against the underside of cup 28 and is appertured at 15 to receive tube 11.

Second valve housing 50 is made of injection molded polypropylene and has a central bell-like portion 52 enclosing a valve chamber 53. The wider end of portion 52, the lower end as seen in FIGS. 1 and 2, carries a castellated nipple 54, and the narrower, upper, end of bell portion 52 carries a castellated nipple 55. Nipples 54 and 55 are generally coaxial with each other and with the axis of bell-like portion 52. Nipple 54 has an internal bore 56 communicating with chamber 53, and nipple 55 similarly has a bore 57 communicating with chamber 53.

Valve element 51 is formed of silicone rubber tapering from a flanged circular base 58 to a pair of flat lips 59 which are slightly parted under normal conditions and which close together upon any reverse flow. The interior of valve housing 50 at the wide
end of bell portion 52 is provided with a coaxial, internal, annular groove 60 adjacent bore 56 which is designed to receive flanged base 58 of element 51 such that the open base faces bore 56 and lips 59 extend into chamber 53 facing bore 57. Obviously, base 58 fits snuggly into groove 60 in order to provide a fluid tight seal between them.

The apparatus is assembled together with a tube of silicone rubber 14 fitting over castellated nipples 30 and 55 holding the discharge side of valve 51 in communication with the interior of tube 29 and hence with the interior of flushing chamber 40 and the intake side of valve 21.

Drainage device 10 can be used, for example, in the control of ascites, as seen more clearly with reference to FIG. 3, by connecting a section of fenestrated tubing 16 to nipple 54. Device 10 is then partly introduced through an opening made in the peritoneum with collection tubing 16 located within the peritoneal cavity, with collar 12 affixed in the opening in the peritoneum and with the membrane itself being closed about notch 13 such that the bulk of valve housing 20 and flushing chamber 40 are located on the exterior of the peritoneum and transversus and transversalis fascia.

A section of silicone rubber tubing 17 is affixed over nipple 24 and carried up to the jugular vein, indicated by the reference letter J, through which it is introduced and carried down toward the superior vena cava, V.C. where it terminates.

Care should be taken during implantation of device 10 that all air has been expelled and the entire interior filled with fluid from the peritoneal cavity before the final connection is made to the
jugular vein.

Since valve element 51 is normally open, valve 21 functions in the arrangement depicted in FIG. 3 in the same manner as described in the above noted LeVeen patent No. 3,910,283. The pressure of fluid in the peritoneal cavity is of course transmitted through normally open valve element 51 and tube 11 into interior 45 of flushing chamber 40 such that interior 45 is normally filled with ascites fluid. When external pressure is applied to wall 44, for example, by the patient placing his fingers on his skin overlying device 10 this pressure causes wall 44 to flex inwardly thereby displacing ascites fluid from interior 45 of flushing chamber 40 into the interior of tube 29 and hence causes flow to start in the reverse direction through valve 51 which immediately closes such that the external pressure applied to wall 44 causes a pressure build up in the tube 29 sufficient to unseat valve element 21 lifting closure element 36 off valve seat 32. This action occurs even in the presence of particles which may have jammed valve element 21 because the pressure is sufficiently great to overcome the mechanical blockage and ascites fluid from chamber 45 thus flows through valve 21 causing a flow downstream through tubing 17. When the external pressure is withdrawn from wall 44 the pressure differential across valve element 21 suddenly falls causing valve element 36 to seat on valve seat 32 preventing any reverse flow in tubing 17. At the same time fluid will flow through valve 51 opening it and refilling chamber interior 45. When chamber interior 45 is refilled functioning of valve 21 resumes in its normal manner.

FIG. 4 illustrates a modified construction of more simplified design producing essentially the same
functions as described with respect to device 10.

In FIG. 4, the reference numeral 70 designates a valved drainage system in accordance with this invention. System 70 includes a valve housing 80 formed of injection molded polypropylene of generally flat cylindrical shape having a flat closed upper end 81 and a cylindrical side wall 82 from which a castellated nipple 83 projects. Housing 80 also has a bottom end closure in the form of an outer annular flat portion 84 which retains a shallow cup-shaped bottom portion 85 having a central opening 86 formed by a short tubular upwardly projecting portion 87 functioning as a valve seat. Annular bottom portion 84 also is interiorly provided with a pair of annular bosses 88 and 89 which form a groove 90. Tubular portion 87 also functions to provide fluid communication through opening 86 into the interior 92 of valve housing 80. A bore 91 in nipple 83 provides external fluid communication to interior 92 of housing 80. Valve housing 80 is further provided with a short depending skirt 93 aligned with cylindrical side wall 82 which is provided with an external annular groove 94.

A valve element 95, identical with valve element 21 has a conical closure element 96 on its lower end and carries four arms 97 radiating from its upper end and terminating in a peripheral rim 98. Valve element 95 is positioned in interior 92 of housing 80 such that rim 98 is firmly secured in groove 90 with closure element 96 seated against valve seat 87. The resiliency of arms 97 and the location of the various components is such that, as in the case of valve element 21, valve element 95 is lifted off its seat 87 by a small positive differential pressure on the
underside of closure element 86 of the order of 3 to 5 centimeters of $H_2O$.

Valve 95 in valve housing 80 functions in the same manner as the valve 21 described with reference to FIGS. 1 and 2. The flow-sensitive valve, however, is formed in a unitary silicone rubber bottom cap 100 which also functions in cooperation with bottom closure on valve housing 80 to define a flushing chamber 110.

Cap 100, which is inverted in the normal sense of a cap, as shown in FIG. 4 has a generally annular flat bottom 101 with an upstanding peripheral sidewall 102 having an internal annular bead 103 positioned such that cap 100 can be snapped onto the bottom of valve housing 80 with bead 103 received in groove 94. Bottom 101 of cap 100 is also provided with a depending tubular leg 104 which is offset at approximately 45° from a vertical axis through housing 80, as seen in FIG. 4.

Integrally moulded with leg 104 and bottom 101 is a normally open valve element 105 having a configuration similar to that of valve element 51. Thus, the lower end of valve element 105 is of generally circular cross-section and tapers inwardly up to a pair of opposing flat lips 106 which are normally slightly parted. Thus fluid flow is permitted in a direction upwardly through valve element 105, as seen in FIG. 4. Reverse flow will, however, immediately cause lips 106 to close together sealing valve element 105.

As can be seen by reference to FIG. 4 lips 106 in the normal undistorted position of cap 100 are positioned approximatley in opening 86 leading into valve seat 87 such that free fluid communication between the interior 110 of cap 100 forming the flushing chamber is permitted around valve element 105 into valve seat tube 87.
The employment of valved drainage device 70 is essentially the same as that of device 10 except that the collection tubing system is positioned inside tube 104. The discharge tubing 17 is, of course, fitted over castellated nipple 83. Also, the membrane of the peritoneum is located about tubing 104 such that valve 105 is actually located outside the peritoneal cavity, as distinguished from valve 51 which is located inside the peritoneal cavity.

After implanting the device pressure is applied on the end surface 81 of valve housing 80 which causes annular bottom 101 of cap 100 to flex, decreasing the volume of flushing chamber 110 with the same result in the operation of valves 95 and 105 as occurred in the operation of valves 21 and 51 described above.

In describing the above constructions the valve housings 20, 50 and 80 have been described as though they were single piece constructions. Obviously, this is not the case, and such constructions must be made of several parts fitted together with fluid-tight joints. Similarly, joints and connections, such as the fitting of rim 98 in groove 90 and other joints between separate parts must be mechanically secure and in most cases obviously must also be fluid-tight.

Where desired chemically inert sealants, such as silicone adhesives, can be employed. Where parts are indicated to be polypropylene, other rigid, chemically inert materials can be used. Similarly, where parts are indicated to be silicone rubber, other flexible, chemically inert elastomers can be used.
The Claims:

1. Body fluid drainage apparatus including:
   means defining a variable volume chamber,
said means including a wall portion movable by fluid
pressure within said chamber to a filled position and
movable upon application of external pressure to a
retracted position in which the volume of said chamber
is less than the volume of said chamber in said
filled position of said wall portion;
   a flow-sensitive valve having an inlet
and an outlet, said flow-sensitive valve being
normally open and operable to closed position by
fluid flow in a direction from said outlet to said
inlet thereof; and
   a pressure-sensitive valve having an
inlet and an outlet, said pressure-sensitive valve
being normally closed and operable to open position
to permit fluid flow in the presence of a positive
fluid pressure differential between the fluid on the
inlet side thereof and the fluid on the outlet side
thereof;
   the outlet of said flow-sensitive valve,
the interior of said variable volume chamber and the
inlet of said pressure-sensitive valve being connected
in open fluid communication.

2. Apparatus according to claim 1 which
further includes rigid housing enclosing said pressure-
sensitive valve with the inlet to said valve on one
end of said housing.
3. Apparatus according to claim 2 in which said means defining a variable volume chamber is positioned against the said housing on the end thereof opposite said inlet.

4. Apparatus according to claim 3 in which said housing is cylindrical and said means defining a chamber is a cap fitting over said end of said housing opposite said inlet.

5. Apparatus according to claim 2 in which said means defining a variable volume chamber includes said end of said housing including said inlet to said valve.

6. Apparatus according to claim 5 in which said wall portion of said chamber is a cap fitting over said end of said housing including said inlet to said valve.

7. Apparatus according to claim 6 in which said flow-sensitive valve is mounted through said cap.
AMENDED CLAIMS
(accepted by the International Bureau on 21 March 1983 (21.03.83))

(a) Body fluid drainage apparatus including:
means defining a variable volume chamber,
said means including a wall portion movable by fluid
pressure within said chamber to a filled position and
movable upon application of external pressure to a
retracted position in which the volume of said chamber
is less than the volume of said chamber in said
filled position of said wall portion;

a flow-sensitive valve having an inlet
and an outlet, said flow-sensitive valve being
normally open and operable to closed position by
fluid flow in a direction from said outlet to said
inlet thereof; and

a pressure-sensitive valve having an
inlet and an outlet, said pressure-sensitive valve
being normally closed and operable to open position
to permit fluid flow in the presence of a positive
fluid pressure differential on the order of 2 to 5 centimeters
of H₂O between the fluid on the inlet side thereof and the
fluid on the outlet side thereof;

the outlet of said flow-sensitive valve,
the interior of said variable volume chamber and the
inlet of said pressure-sensitive valve being connected
in open fluid communication.

(b) Apparatus according to claim (a) which
further includes rigid housing enclosing said pressure-
sensitive valve with the inlet to said valve on one
end of said housing.
3. Apparatus according to claim 2 in which said means defining a variable volume chamber is positioned against the said housing on the end thereof opposite said inlet.

4. Apparatus according to claim 3 in which said housing is cylindrical and said means defining a chamber is a cap fitting over said end of said housing opposite said inlet.

5. Apparatus according to claim 2 in which said means defining a variable volume chamber includes said end of said housing including said inlet to said valve.

6. Apparatus according to claim 5 in which said wall portion of said chamber is a cap fitting over said end of said housing including said inlet to said valve.

7. Apparatus according to claim 6 in which said flow-sensitive valve is mounted through said cap.
INTERNATIONAL SEARCH REPORT

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 3

According to International Patent Classification (IPC) or to both National Classification and IPC

INT. CL 3 A61M 27/00

II. FIELDS SEARCHED

Minimum Documentation Searched 4

Classification System Classification Symbols

US 604/8-10, 604/247

Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched 4

III. DOCUMENTS CONSIDERED TO BE RELEVANT 14

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* Special categories of cited documents: 14

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"F" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search 3

10 February 1983

Isa/US

Date of Mailing of this International Search Report 3

18 FEB 1983

Signature of Authorizing Officer 30

D.L. Truluck

Form PCT/ISA/210 (second sheet) (October 1981)