United States Patent [19]

Schulte

[11] **3,769,982**

[45] **Nov. 6, 1973**

[54] **PHYSIOLOGICAL DRAINAGE SYSTEM WITH CLOSURE MEANS RESPONSIVE TO DOWNSTREAM SUCTION**

[76] Inventor: **Rudolf R. Schulte,** 5377 Overpass Rd., Santa Barbara, Calif. 93105

[22] Filed: **Sept. 24, 1971**

[21] Appl. No.: **183,463**

[52] **U.S. Cl.** **128/350**

[51] **Int. Cl.** **A61m 27/00**

[58] **Field of Search** ..... 128/350 V, 350 R

[56] **References Cited**

UNITED STATES PATENTS

3,111,125	11/1963	Schulte	128/350 V
3,601,128	8/1971	Hakim	128/350 R
3,503,402	3/1970	Schulte	128/350 V
3,492,996	2/1970	Fountain	128/350 V

Primary Examiner—Lucie H. Laudenslager

Attorney—D. Gordon Angus et al.

[57] **ABSTRACT**

A physiological drainage system for draining liquids from a source of the human body to a region where it is disposed of. The latter region is at a different elevation from the source region. The system is provided with a control which is responsive to downstream suction. When the suction is excessive, the control closes the system to flow so as to prevent over-drainage of the source region. The control comprises a valve which remains open to flow at normal rates and downstream suction levels, and which closes when the downstream suction level is above some predetermined level.

30 Claims, 28 Drawing Figures

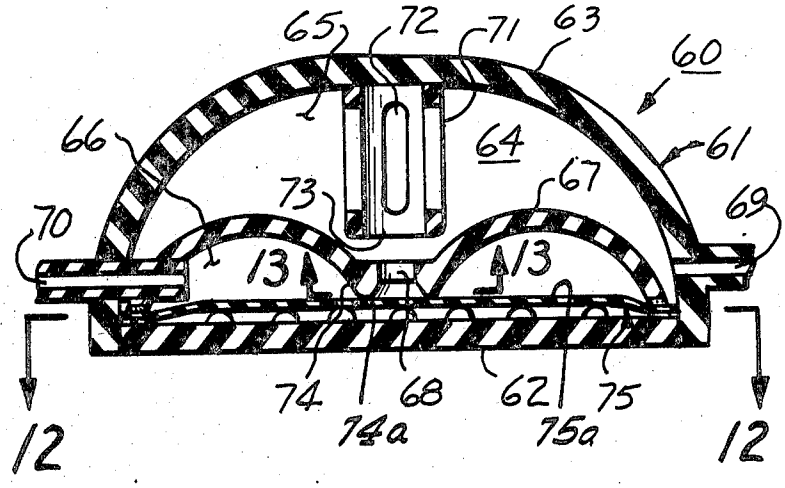


FIG. 1

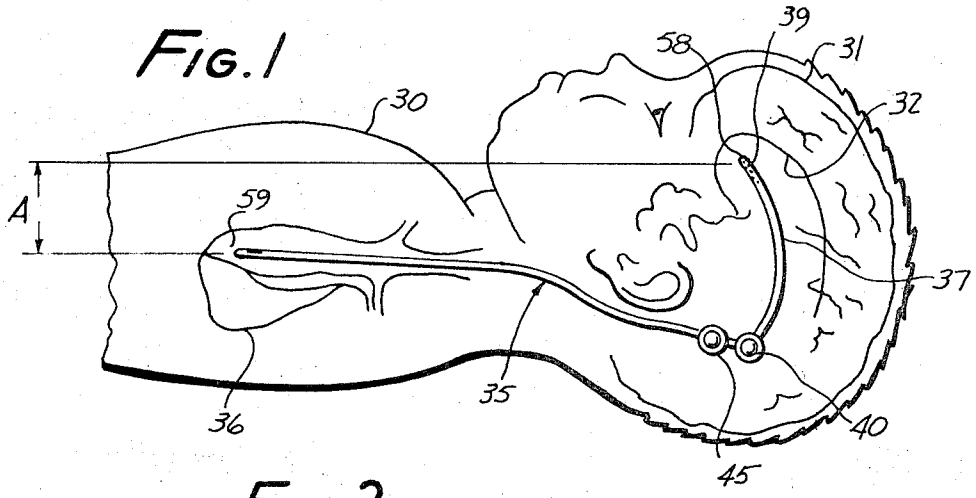


FIG. 2

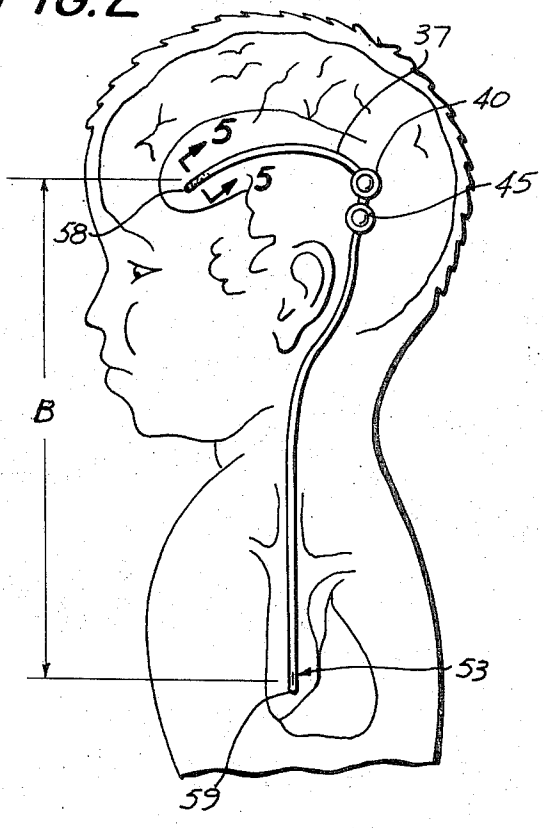


FIG. 3

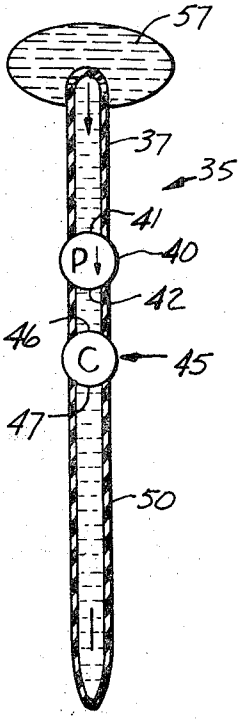
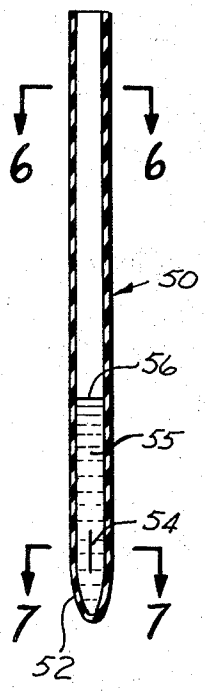


FIG. 4



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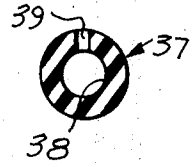

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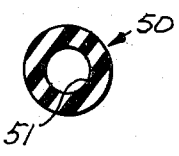

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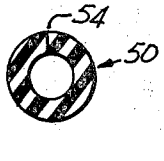

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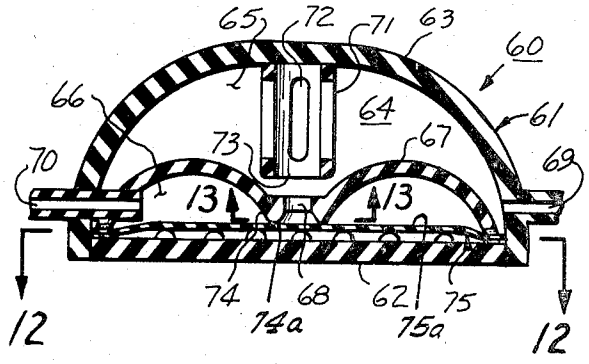
FIG. 8



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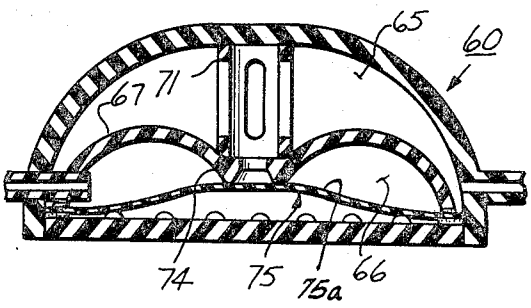

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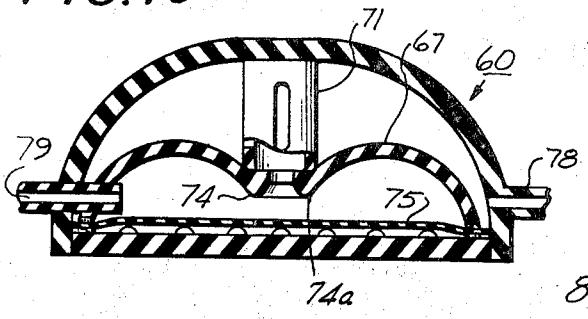

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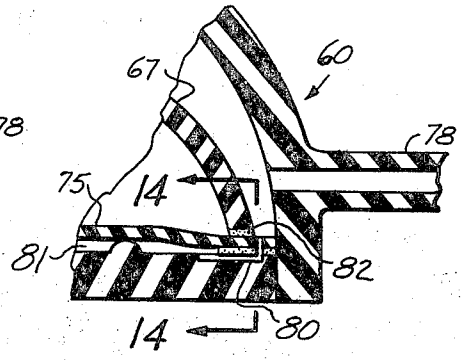

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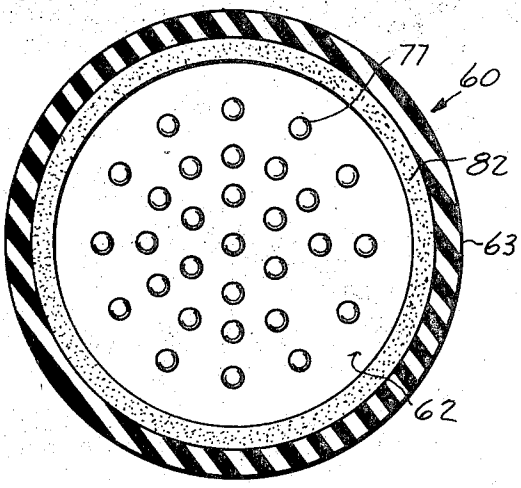

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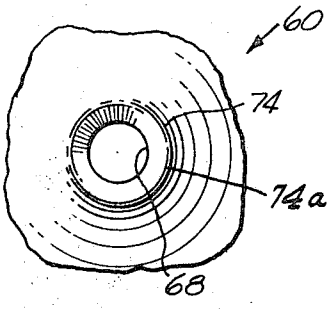

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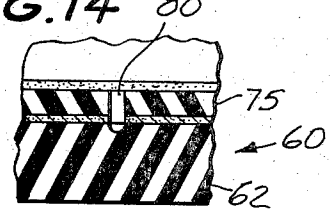

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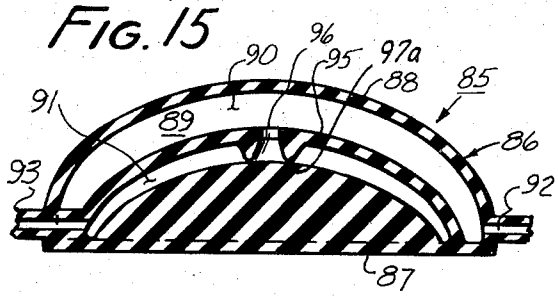
FIG. 15



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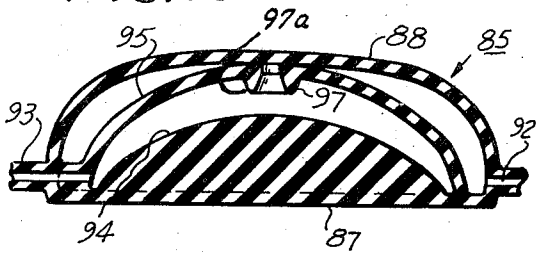

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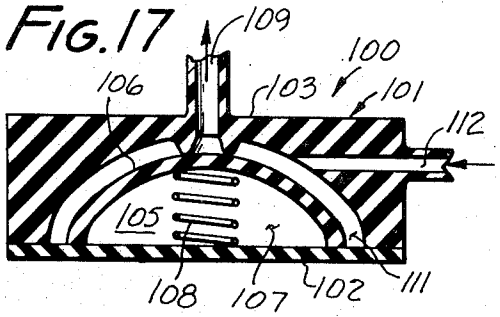

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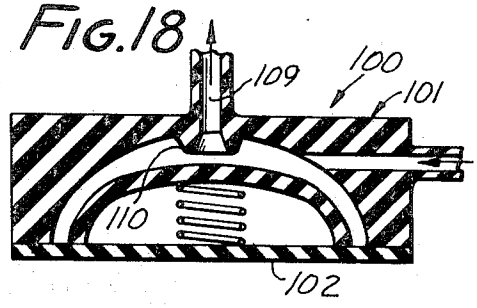
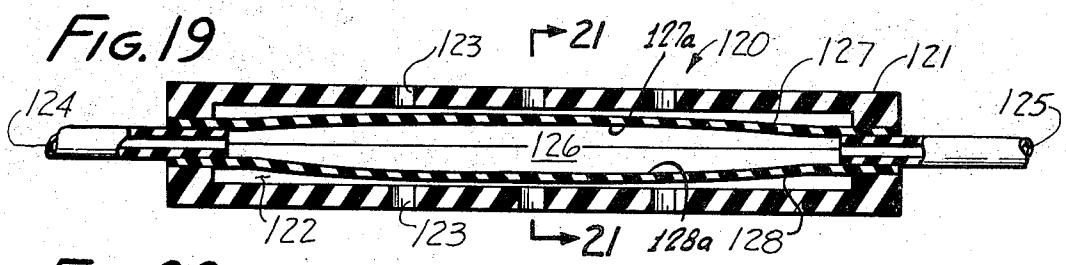


FIG. 19



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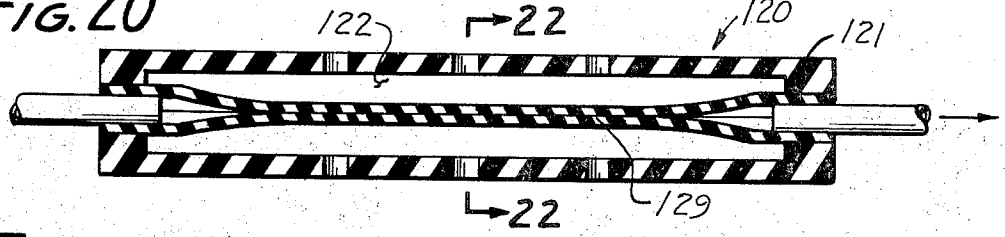

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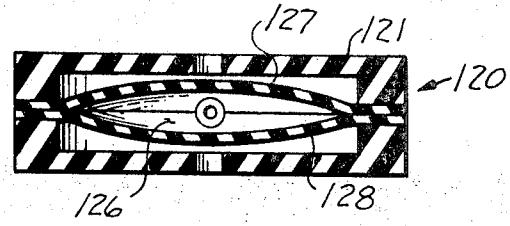

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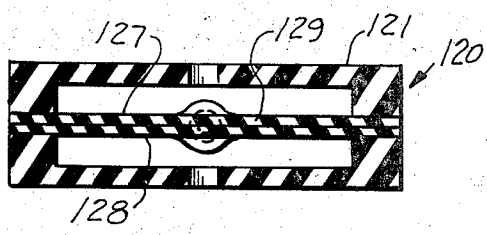

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FIG. 23

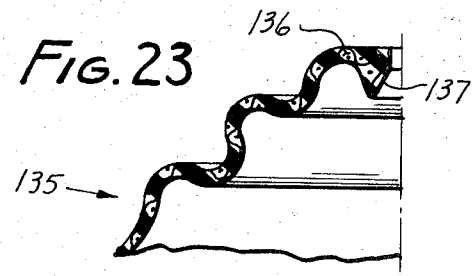
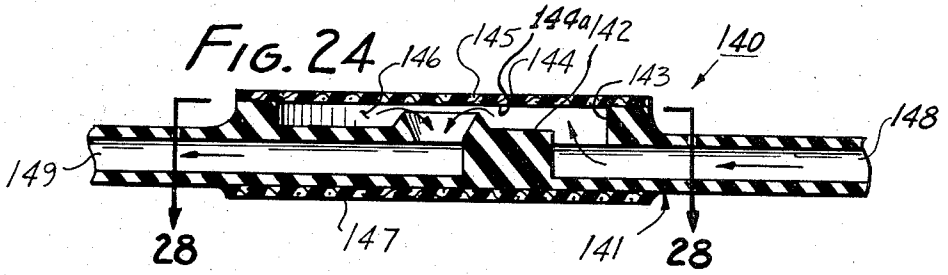


FIG. 24



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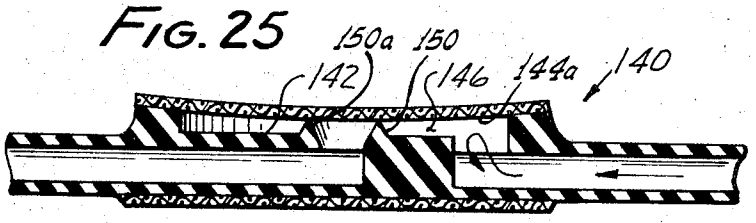


FIG. 26

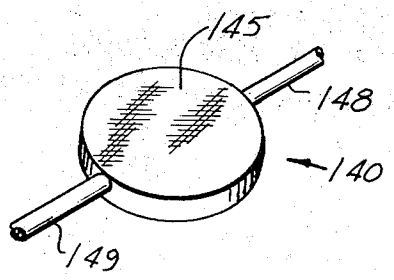


FIG. 27

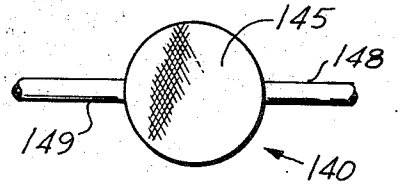
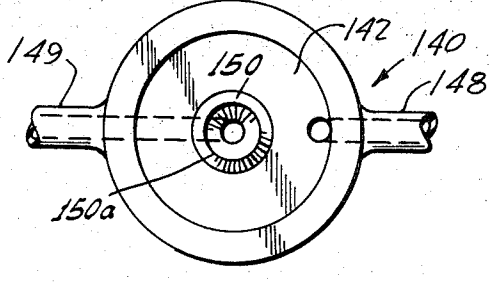


FIG. 28



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PHYSIOLOGICAL DRAINAGE SYSTEM WITH CLOSURE MEANS RESPONSIVE TO DOWNSTREAM SUCTION

This invention relates to physiological drainage systems of the type used for draining excess liquid from a source region of the human body to a drainage region. An example is found in the alleviation of the symptoms of hydrocephalus, in which ailment the natural drainage systems from the cranium fail to provide sufficient drainage. It is necessary to drain excess fluid from the cranium in order to prevent brain damage and death.

Drainage systems for alleviation of the symptoms of hydrocephalus and of other ailments of the body in which unwanted quantities of fluid remain in some source region of the human body are well known. A classical example of one such system is shown in U.S. Pat. No. 3,111,125, issued to Rudolf R. Schulte on Nov. 19, 1963. In thus shunt system, a drainage catheter is inserted in a source region to be drained, the ventricles of the brain, for example. The catheter is connected to a shunt tube which extends along a selected route to another region of the human body, such as to the heart, where the excess fluid is disposed of. It is common practice to provide a check valve at the free end of the shunt tube in order to prevent fluids from backing up into the system. it is also common practice to provide a pump in the system to assist the system's functioning. The pump means ordinarily remains open to forward flow, may act as a reverse flow check valve, and can also impel fluid in one or both directions depending on how the valve is manipulated.

Systems according to the foregoing arrangement are in widespread use throughout the world, and have provided dramatically successful results in alleviating the distress of hydrocephalus. In this ailment, before such shunt systems were devised, brain damage and death were frequent consequences. Because such systems have been used, thousands of persons today are alive and leading normal lives.

Of course, over the years during which systems of the above type have been in use, a number of problems have developed which, while not serious enough to contra-indicate the usage of the system, still indicate that there is room for improvement of the system. One such problem is a tendency to over-drain the source region, even though the shunt system may be set to open only at a relatively high positive pressure within the cavity. It is undesirable to remove too much fluid from the ventricles of the brain, because then fever and listlessness are apt to result, and the possibility that the body may develop its own drainage system as a consequence of the maintenance of some positive pressure level in the brain is frustrated.

It is an object of the system of this invention, instead of over-draining the source region, to leave the proper amount of fluid therein, and as a consequence, a proper pressure level.

Analysis indicates that one cause of the over-draining effect is that, because the shunt system ordinarily remains full of liquid, and because the person in whom it is implanted moves to various angular positions relative to the vertical, the "hanging" fluid column which develops in the shunt tube will vary from position to position, and a siphoning-pumping action results. Therefore, even though the system, when in static equilibrium at one body attitude may drain the source region to exactly the right degree, still this equilibrium can

suddenly be upset merely by a change in body position, and a different drainage condition could result. This variability cannot be controlled, because it results from the normal body movements of the user. Accordingly, it is an object of this invention to provide a means which will close down the system to fluid flow so as to protect the source region against excessive drainage due to downstream suction so that, no matter what the position of the user, the suction effect will not tend to over-drain the source region. Instead, the system will drain only when suction below a given level exists (i.e. when excessive suction does not exist), accompanied by sufficient positive pressure to cause expulsion of fluid from the source region and through the system.

This device is, in one sense a "siphon breaker," but is not to be confused with ordinary siphon breakers which are widely known. The classical type of siphon breaker, which seeks to avoid siphoning from a region as the consequence of an upstream break in a line, ordinarily functions to admit gas into a fluid stream so as to break the suction. Of course, it is impossible to introduce gases into a system in the human body, where the system connects to the brain and to the bloodstream. Accordingly, while this device acts to break a suction force, it is not to be confused with classical suction or siphon breakers, because it does not relieve the suction force. Instead, it blocks it.

Another classical device utilized in controlling unwanted movement of fluids is a common check valve which operates on a differential pressure concept, usually being spring-loaded to a closed position, and opened in the direction of forward flow by a differential force which overcomes the spring bias. The device of this invention needs carefully to be distinguished from the classical check valve. In the check valve, there is an impediment to flow in one direction and free flow in the opposite direction under a suitable or sufficient differential pressure. It is to be noted that, in this device, however in some respects it may physically resemble a check valve, it closes to stop the flow of fluid in the intended direction of forward flow when excessive downstream suction is exerted. Such suction would open the classical check valve because it would contribute all the more to the differential pressure needed to open the same. Accordingly, the usual considerations of stopping flow with check valves and with siphon breakers are not pertinent to this invention.

This invention provides a control which permits the free flow of fluid from a source region to be drained to a receiving region to receive the same which will close to the forward direction of flow when an excessive downstream suction exists. In some embodiments of this invention, the control will remain closed regardless of the upstream pressure, and will not open again until the downstream suction is relieved, such as by the person's assuming a position in which a lesser suction exists.

In the use of this device it may, at first blush, appear that this closure means might tend to keep the system closed for an unwarranted length of time. As will later be apparent, the ordinary motions of turning over in bed, of sitting up, standing up, sitting down, and leaning over will of themselves cause changes of suction level which are likely to permit the control to open and again permit drainage. Accordingly, it is another object of this invention to provide a control responsive to downstream suction which will permit drainage to occur

under predetermined suction and differential pressure conditions, stop the drainage when an excessive downstream suction is exerted on the system which might over-drain the region to be drained, and still be open in a number of normal positions of the human body such that proper drainage will in fact occur with sufficient frequency to meet the needs of the user.

A device according to the present invention includes a body having a pair of flow ports entering a cavity, and between them flexible means which is adapted to move to close the outlet which is downstream as to direction of flow when excessive suction exists downstream.

According to an optional feature of the invention, the flexible means is so disposed and arranged that, when once it closes the control, the control remains closed until the suction is sufficiently relieved, regardless of the upstream pressure, assuming it to be greater than the suction level, of course.

The above and other features of this invention will be fully understood from the following detailed description and the accompanying drawings in which:

FIG. 1 shows a reclining person with a system according to the invention implanted in him;

FIG. 2 shows the same person in an erect position;

FIG. 3 is a schematic view of a system according to the invention;

FIG. 4 is an enlarged fragmentary view of a portion of the system of FIG. 3;

FIG. 5 is a cross-section taken at line 5—5 in FIG. 2;

FIGS. 6 and 7 are cross-sections taken at lines 6—6 and 7—7, respectively, in FIG. 4;

FIG. 8 is an axial section of an embodiment of a control according to the invention in one operating position;

FIGS. 9 and 10 are views similar to FIG. 8 showing the device of FIG. 8 in other operating conditions;

FIG. 11 shows an optional feature which may be embodied in the device of FIG. 8;

FIG. 12 is a cross-section taken at line 12—12 in FIG. 8;

FIG. 13 is a fragmentary cross-section taken at line 13—13 in FIG. 8;

FIG. 14 is a fragmentary cross-section taken at line 14—14 in FIG. 11;

FIGS. 15 and 16 are axial cross-sections of another embodiment of the invention, shown in two operating positions;

FIGS. 17 and 18 are axial cross-sections of another embodiment of the invention in two different operating positions;

FIGS. 19 and 20 are axial cross-sections of still another embodiment of the invention in two different operating conditions;

FIGS. 21 and 22 are cross-sections taken at lines 21—21 and 22—22 in FIGS. 19 and 20, respectively;

FIG. 23 shows an optional type of diaphragm useful in this invention;

FIGS. 24 and 25 are axial cross-sections of the presently preferred embodiment of the invention in two operating positions;

FIG. 26 is a perspective view of the device of FIG. 24;

FIG. 27 is a top plan view of the device of FIG. 24; and

FIG. 28 is a cross-section taken at line 28—28 of FIG. 24.

FIG. 1 illustrates a person 30 afflicted with hydrocephalus having a cranium 31 enclosing a brain 32, the ventricles of which are surfeited with fluid because the normal drainage passages of the body are not draining the same. As a consequence, development of this brain would be retarded unless the resulting fluid pressure were relieved. The person's skull would be distended, and in general, he would be subjected to intense pain, mental retardation, and possibly death.

It is for the purpose of draining the excess fluid that the system 35, according to the invention, is provided. The system shown drains fluid from the ventricles of the brain to the heart 36, from which it is carried in the bloodstream to be disposed of by normal physiological functions of the purification of the blood. This system includes a drainage catheter 37 which has, as best shown in FIGS. 2 and 5, a tubular cylindrical wall 38 with a plurality of drainage ports 39 therethrough near one end. The catheter is inserted so that these ports are placed in the source region. The other end passes through the burr hole in the skull through which the drainage end of the catheter was inserted.

A pump 40 according to the aforesaid Schulte U.S. Pat. No. 3,111,125 is connected to the drainage catheter. This pump is optional. It exists to flush either the upstream or the downstream portions of the system, and to create pumping surges should such be desired. This is a very useful additional feature for use with this invention, but it is not essential to the practice of this invention.

The pump has an inlet 41 connected to the drainage catheter and an outlet 42 connected to the control 45 according to this invention. Both the pump and the control may be formed with flat bottoms and low profiles so they can be laid against the skull and fit beneath the scalp. The control has a first and second flow port 46, 47, respectively, the first upstream flow port (46) being connected to the outlet of the pump and the second downstream flow port (47) being connected to a shunt 50 of the type shown in the aforesaid Schulte patent and also shown in FIG. 4. If the pump is not used, the control is connected directly to the catheter. The term "upstream" is used to mean the direction from which flow originates. In some embodiments of this system, both ends are regarded as potentially upstream. However, speaking generally, "upstream" means toward the source region from the control, and "downstream" means toward the disposal region.

The shunt may be a simple open-ended tube, but it is usually best for it to include check valve means at its free end so that reverse flow of fluids will not occur into the shunt from the disposal region. The shunt is tubular and has a cylindrical wall 51 extending to a closed end 52 adjacent to which there is a check valve 53 in the form of a slit 54. Slit 54 is cut through the wall of the tube without removal of material so that a differential pressure derived from a greater pressure on the outside than on the inside will tend to press the edges of the slit together and close the valve, while a reverse differential pressure will tend to bow the wall outward, opening the slit and permitting drainage.

Were shunt 54 to be held freely in the air, hanging vertically as shown in FIG. 4, liquid 55 would fall to a given level 56 which indicates the differential pressure required to open the slit valve. Liquid above that level would open the slit and drain out. In the system as schematically shown in FIG. 3, it would be the more usual thing for the system to remain substantially full of liquid, there being few if any breaks in the column; how-

ever, such might be in the form of a vacuum break downstream of the control, whose length depends on the length of column supported above the level 56. It is this additional column of liquid hanging from the control which exerts the suction that it is the function of this control to resist.

As schematically shown in FIG. 3, the system taps a region 57 to be drained by the drainage catheter 37. Pump 40, if used, passes fluid from the catheter to control 45 and shunt 50, and then into a disposal region where the fluid is disposed of. In order to illustrate the different suction conditions in the system which are derived from changes in posture of the person, reference should now be made to FIG. 1 wherein the person is shown reclining. It will be seen that the maximum pressure in the system is derived from a column of fluid whose height is shown by dimension A. This is the height of a vertical column measured from the inlet end of the drainage catheter to the discharge end of the shunt. It will be noted that there is substantially no suction exerted below the pump or the control. In fact, but for the check valve 53, there would actually be a reverse pressure at the control from the outlet end. It will also be recognized that the dimension A would "disappear" were the person to lie on his side with tip 58 of the drainage catheter at the same elevation as the tip 59 of shunt 50.

An extreme but common situation, and one which it is the function of this invention to control, is shown in FIG. 2 with the person in the erect position. A dimension B represents the column between the two tips. In this case, the hanging column of fluid in shunt 50 is very long, perhaps 12–18 inches in length, and its effect would be to siphon liquid out of the brain, perhaps excessively. The means whereby this has been resisted in the past has been to make the slit valve 53 open at a relatively high pressure, thereby lessening the effective sunction column above level 56 as heretofore discussed. However, this makes the system less sensitive, and is something of a "brute force" means of approaching the problem. Furthermore, close selection of the level 56 is quite difficult, and adjustment is impossible in the implanted tube. A better technique would be to enable the region to be drained at any desired outlet pressure, but to prevent it from being drained excessively because of excessive suction forces. That is the purpose of the control of the instant invention. Incidentally, the pulsing variations of suction derived from frequent changes of position cause strong pumping pulses, which could overcome a slit valve, but which are stopped by the control.

FIG. 8 shows one embodiment of a control 60 according to the invention which may be utilized at the location shown schematically by control 45 in the system, as may the other embodiments hereafter disclosed. Control 60 has a body 61 with a flat base 62 and a dome 63 forming a cavity 64 therein which is divided into two chambers 65, 66 by a flexible diaphragm 67 with a central flow port 68 (sometimes called a "third flow port") therethrough. The intended downstream flow through this control is from first flow port 69 to second flow port 70, port 69 being upstream and port 70 being downstream.

A support 71 projects into the cavity from the dome, to which it is attached. It has a plurality of passages 72 in its wall and a central opening 73 in communication with the passages and in alignment with flow port 68. A seat 74 is formed on the diaphragm surrounding the flow port and facing into chamber 66. A complementary diaphragm 75 extends across the cavity adjacent to the base. It is prevented from adhering to the base by a plurality of raised buttons 77 which are molded integrally with the base. Ports 69 and 70 form connectors 78, 79 by means of which the control may be coupled into the system.

Control 60 is shown in three different positions in FIGS. 8, 9, and 10. The positions of FIGS. 8 and 9 are closed positions and that of FIG. 10 is its normal open position.

FIG. 11 shows an optional feature which may be incorporated in the control of FIG. 8, when it is desired to resist suction only if exerted from the downstream end. In this case a vent passage 80 is formed interconnecting the first chamber 65 to a relief chamber 81 formed between the base and the complementary diaphragm. The function of this vent passage will further be discussed below.

The device is shown assembled by layers of cement 82, which are shown in dotted notation. This control and all other embodiments of the invention are preferably made out of the same material of construction, a convenient example of which is medical grade silicone rubber. The parts may individually be molded and then cemented together. In some embodiments variuus of the portions may be vulcanized together without cement. It is to be understood that, in all of the drawings herein, the parts where joined together to form continuous structure are fluid-tight at their joints except as otherwise indicated. The required flexibility of certain parts is generally secured by selection of their respective thicknesses.

FIGS. 15 and 16 show another embodiment of the invention. A control 85 has a body 86 constructed of a flat base 87 and a dome 88. These form a cavity 89 between them. The cavity is divided into chambers 90, 91 which are respectively connected to first and second flow ports 92, 93. Port 93 will ordinarily be the downstream port, although in this embodiment the selection is immaterial, because the control functions bidirectionally. The base includes a dome-shaped inner surface 94, which faces convex upwardly toward a flexible diaphragm 95. This diaphragm divides the cavity into the aforesaid two chambers 90 and 91. A flow port 96 (sometimes called a "third flow port") passes through the diaphragm and a seat 97 extending around this port, facing into the chamber 91.

The device of FIGS. 15 and 16 is shown in these two figures in its actuated position with the diaphragm flexed. In its unflexed condition, the diaphragm will assume a position midway between the two positions, and so there will be free flow between ports 92 and 93 through flow port 96. Exertion of sufficient suction at either of the two flow ports will cause the diaphragm to assume a respective one of the illustrated positions.

FIGS. 17 and 18 show another embodiment of the invention wherein a control 100 has a body 101 with a base 102 and a cover 103. A cavity 105 is formed in the body. A flexible diaphragm 106 bows upwardly in the diaphragm with a chamber 107 beneath it. A bias spring 108 is placed in chamber 107 which tends to force the central portion of the diaphragm upwardly toward a first flow port 109, which is surrounded by a seat 110 that projects into chamber 111 of cavity 105. A second flow port 112 also enters chamber 111. This

embodiment differs from the previous embodiments in that flow does not occur through the diaphragm, but instead is always on the same side thereof. The normal relaxed position of the diaphragm is that shown in FIG. 17, and its actuated position, when suction does not occur and sufficient positive pressure exists to open the control, is shown in FIG. 18, both of which will be more fully described below.

FIG. 19 shows still another embodiment of the invention wherein a control 120 includes a body 121 having a cavity 122 therein. The cavity is vented by vent ports 123 through its wall, although if desired these may be closed and the cavity filled with a spongy or springy means for exerting a reference pressure as will later be discussed. The device is a generally flat lozenge having first and second ports 124, 125 entering at its ends. Within the body the ports connect to a flow chamber 126 of variable volume which is formed between a pair of diaphragms 127, 128 that are generally flat sheets of elastic resilient material which, under proper conditions of pressure and flow rates, will bow apart as shown in FIG. 1 to enlarge the flow chamber 126, or under suction conditions where closure occurs, draw together to form a closure line 129 as shown in FIG. 22.

FIG. 23 illustrates a portion of a diaphragm which is flexible, but not necessarily resilient in the "elastic" sense of the term. Except for diaphragms such as complementary diaphragm 75, which is best made elastic, the diaphragms merely need to be movable to accomplish their purpose. Even in diaphragm 75, a spring could be substituted for the elasticity as a source of restorative force. This illustrative diaphragm 135 has a fabric reinforcement 136 which will prevent stretching. However, a number of bellows-convolutions enable the seat 137 to move axially relative to the rim edge of the diaphragm. Such a construction can generally be substituted for the other diaphragms shown in the drawings.

Furthermore, a certain amount of freedom to move is provided by the rim supports for the various diaphragms. These controls usually do not measure more than between about 9 to 15 mm. across, and some resilient yielding of structure will be expected to occur, which frees up the diaphragm for movement.

The presently preferred embodiment of the invention is shown in FIGS. 24–28. It is a variation of the device of FIGS. 17 and 18, and illustrates that the diaphragm need not be movable freely and separately within a body cavity, but can instead be used to form a body wall for the cavity. An advantage of such an arrangement is that a biasing force or pressure can be derived from the body region surrounding the control, such as from pressure-contact with fatty tissue in various regions, or even from exposure to fluids in this region.

Control 140 includes a body 141 having a flat, relatively rigid base 142 with a peripheral rim 143 around the top of it. A flexible diaphragm 144, preferably having a fabric reinforcement 145 to reduce or eliminate stretch, is peripherally attached to the rim and sealed thereto in order to form a cavity 146 in the body. Thus the diaphragm is both a cover and a diaphragm, and its operative part for flow control is its surface which is exposed in the cavity.

Another fabric reinforcement 147 is cemented to the base to reduce or eliminate stretching of the base. A first and a second flow port 148, 149, respectively, pass through the body. Flow port 148 will be connected to the region to be drained, and flow port 149 to the receiving region.

Flow port 149 rises in the cavity at the center of the cavity, and is surrounded by a seat 150 which projects into the cavity (this cavity will sometimes be called a "flow chamber" in the same sense as chamber 111 in FIGS. 17 and 18).

Flow port 148 rises into the cavity at a point laterally spaced from the seat. The diaphragm, when it contacts the seat as in FIG. 25, closes the control to flow. It is open in FIG. 24. FIG. 24 illustrates the relaxed condition of the control in the absence of distortive forces.

The terms "first sealing surface" and "second sealing surface" are sometimes used herein. The first sealing surface is a portion of a diaphragm which faces toward another sealing surface, which surfaces can make contact with one another to close the control to flow. The diaphragm is imperforate outside of the area occluded when the sealing surfaces abut one another.

As an example of the usage of this terminology, in FIG. 8, diaphragm 67 has a sealing surface 74*a* formed as the crown of seat 74. Surface 74*a* is on the diaphragm and in the cavity 64. Complementary diaphragm 75 has a "second" sealing surface 75*a* which faces first sealing surface 74*a*. In FIG. 9, the area bounded by surface 74*a* is occluded as a consequence of abutment of the two sealing surfaces.

In FIG. 15, a first sealing surface 97*a* is formed as the crown of seat 97, and second sealing surface 94 (the dome-shaped inner surface) is formed on the base. Both are in the cavity, and they face one another. Also, the upper surface of diaphragm 95 faces the bottom surface of dome 88, for the same purpose. In both cases, the area occluded is defined by the outer boundary of the area of abutting contact, and the area of the diaphragm which is not occluded is imperforate. Like considerations apply to the construction of FIG. 17.

In FIG. 19, the first and second sealing surfaces are surfaces 127*a* and 128*a*.

In FIG. 24, the first sealing surface is surface 144*a* which is on the diaphragm and in the cavity. It faces a second sealing surface 150*a* formed as the crown of seat 150. The diaphragm is imperforate outside of the area occluded when the sealing surfaces abut one another, that is, outside of the crown.

The operation of the system and of the controls according to the invention will now be described. The system will have been implanted in the patient as shown by the use of conventional surgical techniques. A burr hole is formed in the skull after peeling the scalp back to expose the skull. Then, using a stylette, the drainage end of the catheter is thrust into the ventricles of the brain so that the drainage ports stand in the source region. The pump, if one is used, is connected to the catheter, and the control is connected to the pump. The shunt tube is passed through the channels in the body to the heart, is trimmed to the proper length and connected to the control. Then, the connections are sutured as required, and the scalp is closed over the system. The pump itself usually forms a closure for the burr hole. The system is now installed and ready for operation, and any of the controls of FIGS. 8 through 28 may be utilized at the location illustrated generically by control 45 in FIG. 3, with its respective flow ports connected in that system instead of flow ports 46 and 47.

The function of the system is to drain the ventricles of the brain, or whatever source region is being

drained, while resisting excessive suction forces. The control behaves as though the pump is not present, because the control acts to shut down the system in response to downstream suction. The upstream pressure produced by the pump does not upset the operation of the control.

The configuration of FIGS. 8–10, without the modification of FIG. 11, will first be discussed in detail. When the system is in steady flow condition, with gradual drainage in progress, diaphragms 67 and 75 will assume the positions shown in FIG. 10, and there will be free flow from flow port 69 to flow port 70. This is the preferred direction of downstream flow to be controlled, wherein flow port 69 occupies the position shown by flow port 46 in FIG. 3.

Should a downstream suction surge be exerted at flow port 70, the pressure in flow chamber 66 will drop, and it will not instantaneously be relieved by pressure from flow chamber 65. In fact, the size of flow port 68 is selected so as to comprise a flow restriction so as to delay equalization of pressure between the two chambers. Diaphragm 67 will therefore deflect to the position shown in FIG. 8 and, depending on the resilience and fluid content of the region beneath complementary diaphragm 75, diaphragm 75 may also rise. The result will be an adherence between the seat 74 and the complementary diaphragm, thereby sealingly separating flow chambers 65 and 66 from each other. The force tending to hold these diaphragms together is, in this and all embodiments except that of FIGS. 19–22, distributed over the annular area, these controls being circular in plan. The only unbalanced force will be that exerted over the area of the complementary diaphragm within the perimeter of seat 74 which, however, has some pressure behind it, too. The effect in a practical system is that the seat, while adherent to the complementary diaphragm, can shift axially (up and down in FIG. 8), but will remain in firm sealing contact with the complementary diaphragm so as to close the flow port as long as a sufficient degree of suction is exerted downstream to make this closure. It will be noted that this closure will not be broken by upstream pressure because this upstream pressure also exerts a compressive effect over the entire diaphragm in opposition to the suction, thereby tending to hold the two diaphragms together, and within practical limits, any differential force on the complementary diaphragm inside seat 74 will be insufficient to cause opening. Accordingly, this control is locked shut to flow until the suction is relieved.

It is also shown in FIG. 9 that control 60 can be used with its connections reversed from those described, or can protect against suction surges in either direction of flow. If suction is exerted at flow port 69, both of the diaphragms 67 and 75 will have been brought up until they are stopped by support 71, at which time the sealing contact is made at seat 74. Again, the negative suction pressure is exerted over the full area of the diaphragm, including that within seat 74, and initial suction in the entire cavity will have caused both diaphragms to move before flow through port 70 appreciably raises the pressure in chamber 66. Pressure within flow chamber 66 is opposed by the support, and upstream pressure exerted at flow port 70 will not separate the diaphragms within a wide range of relationships between pressure and suction. The device as shown in FIGS. 8–10 is, therefore, bi-directional in effect should such be desired. Because of the dimensional relationships, it is preferably connected to the likelier source of suction at flow port 70.

Should only a uni-directional suction control be desired, then the function of the device may be made even more positive by the improvement shown in FIG. 11, wherein a vent passage 80 interconnects flow chamber 65 to relief chamber 81 beneath complementary diaphragm 75. Now, consider FIG. 8 with this modification, and with suction exerted at flow port 70. In such event, pressure is exerted on the outside of both diaphragms, and suction is exerted in the region between them. Accordingly, there is no differential pressure effect between the diaphragms within seat 74, and there is a strong, compressive force locking both diaphragms together over their full annular areas outside of seat 74 so long as there is suction downstream, and there is no way that positive pressure in flow chamber 65 can break this firm lock. It is necessary for the suction to be relieved before this valve can open again.

Re-opening of the valve is assured by making the diaphragm 67 somewhat springily flexible so that it tends to return to the position shown in FIG. 10, and initially laying diaphragm 75 flat so that it tends to return to the position shown in FIG. 10. Both diaphragms are also so flexible, and in the case of diaphragm 75, so elastic, that the differential pressures involved will readily bring them toward each other so as to close and lock the control. Accordingly, the vent passage 80 is optional, but does provide a significant improvement in the function of the device when only uni-directional suction control is desired. It will be noted that the use of this modification would be unsuitable were suction to be exerted at flow port 69 because then the differential pressure on diaphragm 75 within seat 74 would be nullified, and the diaphragms would be drawn apart by suction and forced apart by pressure.

FIG. 15 shows a flow control 85. Its diaphragm 95 is made of flexible material which tends to occupy a position intermediate between those shown in FIGS. 15 and 16. When fluid flows at gradual rates and low suction (which is the normal situation), it flows through the control without impediment. The dome, in this case, is also flexible and forms, in effect, a complementary diaphragm and is shown deflected somewhat in FIG. 16.

FIG. 15 shows closure of the control when excessive suction is exerted at flow port 93. In such event, pressure will have dropped in flow chamber 91 and, because of the fluid flow restriction through flow port 96 and past the outer edge of seat 97, pressure will have dropped in flow chamber 91 enough that diaphragm 95 will be drawn down so that seal 97 seals on dome-shaped inner surface 94. Now it will be seen that the control is locked and remains locked. This effect is also helped by any upstream pressure which continues to exert a locking downward pressure on the diaphragm, and the pressure cannot by-pass the seat to relieve the suction. This differential pressure (which must, of course, be sufficient to overcome any springiness in the diaphragm) will prevent the control from opening until the suction is relieved.

FIG. 16 illustrates locking of the device should sufficient suction be exerted at flow port 92. In this event, pressure in flow chamber 90 will have dropped so as to draw down the dome and draw up diaphragm 94 to make a seal between them, thereby separating the two flow chambers and preventing flow until the suction is

again relieved. The closure remains, as in FIG. **15**, except that in the condition of FIG. **16** there is a small additional differential pressure to be considered on the surface bounded by the seat.

FIGS. **17** and **18** show still another flow control which is intended for operation at somewhat higher pressures than the other embodiments. FIG. **17** shows the device in its normally closed condition. It is also the condition which would occur when sufficient suction is exerted at flow port **109**. In the event that strong suction exists in flow port **109**, its negative force on the diaphragm caused by an abrupt drop in cavity pressure, combined with the mechanical force of the spring, will close the valve unless and until unusually high pressures are exerted in flow port **112**. Should, however, there be no excessive suction, and there be normal drainage pressure at flow port **112**, the effect is to build up sufficient force over the diaphragm outside the seat **110** to move the diaphragm to the position shown in FIG. **18**, thereby opening the valve to flow as shown. This opening will not be particularly large because of the effect of the spring. Therefore, should sudden negative surges of suction be exerted in flow port **109**, there will be a quick lowering of pressure over the diaphragm below and at a region surrounding the region just beneath seat **110** which will be adequate to unbalance the situation and close the valve. While this device is more responsive to upstream pressure than the other embodiments of the invention, still it has significant utility for the purposes described.

The device of FIG. **19** comprises a pair of housing parts that enclose a pair of contiguous flat, resilient sheets. These sheets in repose act as diaphragms that tend to lay against one another, and which will be bowed apart by sufficient pressure exerted between them. Should there be enough pressure at the upstream end and an absence of excessive suction at the downstream end, then a flow chamber **126** will open up, as shown in FIGS. **19** and **21**, and a continuous channel will be formed between the two flow ports. If, however, a sufficient suction is exerted at the downstream port, then the lesser pressure will cause the diaphragms to move together and seal to form a closure plane between them, along which fluid will not flow. This closure can be overcome only by a very substantial upstream pressure which must overcome not only the ambient surrounding pressure that tends to force the diaphragms together, but also to peel them apart where they are pressed together by the differential between suction and ambient pressure. The practical effect in a shunt installed in a human body is that the device remains closed so long as suction is exerted downstream and is not opened by practical levels of upstream pressure. The effectiveness of this device may also be improved by providing means to vary the force which tends to bias the diaphragms together. Vents **123** admit body fluids under ambient pressures, and the device could also be packed with springy sponge-like material, or even with springs, which would exert a restorative force tending to keep the device closed against incoming pressures and to amplify the effect of downstream suction.

The device of FIGS. **24–28** operates like that of FIGS. **17** and **18**. Instead of a bias spring, it utilizes force derived from the surrounding region such as body tissue to resist movement of the diaphragm away from the seat. Normally, it leaves a small-area flow channel above the seat, and the outside force and inside fluid forces about balance in order to permit slow flow. In the event excessive suction is applied downstream, the lowered pressure at the center of the diaphragm will pull it down to close the control as shown in FIG. **25**, and the control tends to remain closed because the outer annular region retains about the same pressure relationship between inside and outside as it had before, but the central portion is under a strong closing force. Of course, this can be overcome by a sufficient upstream pressure, but it must be substantial, and by the time it is exerted, the user will probably have changed his position and relieved the suction.

Incidentally, it should be noted that in FIG. **25** some yielding of the rim has been shown to illustrate means whereby the flexible diaphragm, although drawn fairly tightly across the rim, can move down to close the seat even though there may be little, if any, stretch in the diaphragm itself.

While at first glance it might appear that the devices of this invention, when once closed could not be reopened, a consideration of the practical use of the system will show otherwise. A reasonably active person will, within the course of a few hours, roll over, stand up, sit down, or assume other positions which will create widely varying dimensions A and B (FIG. **1** and **2**), with both positive and negative differential pressures, and without any at all. Accordingly, even though the control might interrupt flow through the system for brief periods of time, such an interruption in a slow-draining device is not critical, and it does overcome a still more critical problem, namely that of over-drainage.

In addition to the line-seal made at the respective seats by the diaphragms, it can also be expected for there to be some area contact between diaphragms which are brought into contiguity, which makes a more positive seal. In order to simplify the drawings, this area seal has not specifically been illustrated. Where it occurs, it tends to make the closure more certain.

In the devices of FIGS. **8–16**, the control should be built so that its normal tendency, absent any differential pressure through it, is to be open.

Furthermore, in all of the embodiments, relative flow port sizes may be selected to provide restrictions which delay change of pressure in respective flow chambers so as to make the operation of the valve even more reliable. This is an optional consideration for the designer's use.

This is a practical control and system. It must have a long life, and be simple in construction and operation. All parts (except the spring in FIGS. **17** and **18**) can be made of medical grade silicone rubber, which the body will accept. The relative stiffness of the various parts is determined as a function of their thickness.

In controls of this type, a certain amount of cut-and-try is necessary. However, after making a few of any type, the values of the design parameters can readily be determined. Accordingly, this device provides a means for preventing over-drainage of source regions in the human body, thereby providing a system which drains to a datum level and no farther, and providing the individual with a constant livable condition rather than one which varies from time to time in a manner which might upset him.

This invention is not to be limited by the embodiments shown in the drawings and described in the de-

scription, which are given by way of example, and not of limitation, but only in accordance with the scope of the appended claims.

I claim:

1. A suction control for a physiological drain wherein the control closes in response to excessive downstream suction, said control comprising: a body having an internal cavity, a first and a second flow port through the body into the cavity, a flexible diaphragm extending across the cavity; a first sealing surface in said cavity on said diaphragm; and a second sealing surface in the cavity adapted to make a closure with the first sealing surface between the flow ports as a consequence of the exertion of sufficient suction at one of said ports to cause at least one of said sealing surfaces to move toward and against the other, the diaphragm being imperforate throughout its entire area which lies outside of that portion of the second sealing surface which is occluded when the said sealing surfaces abut one another.

2. A suction control according to claim 1 in which the diaphragm 41 across the cavity to divide it into two chambers, there being a third flow port through said diaphragm interconnecting the chambers, and in which the first sealing surface surrounds the third flow port, and the second sealing surface comprises a wall of one of the chambers, each of the first and second flow ports entering a different respective flow chamber outside the area bounded by a sealing surface.

3. A suction control according to claim 2 in which a third sealing surface is provided which comprises a wall of the other of said chambers.

4. A suction control according to claim 3 in which at least one of said walls is flexible.

5. A suction control according to claim 1 in which the diaphragm extends across the cavity to divide it into two chambers, there being a third flow port through said diaphragm interconnecting the chambers, in which the first sealing surface surrounds the third flow port, each of the first and second flow ports entering a different respective flow chamber outside the area bounded by a sealing surface, in which a flexible complementary diaphragm extends across the cavity in one of said flow chambers, with one of the first and second flow ports entering the flow chamber between the two diaphragms, a surface of said complementary diaphragm forming a sealing surface, and a support member in the other flow chamber supporting the diaphragm away from the wall of the cavity.

6. A suction control according to claim 5 in which the support is tubular, axially aligned with the third flow port, and perforated to permit flow inside the support and through its wall.

7. A suction control according to claim 5 in which a vent passage interconnects the flow chamber entered by the other of said first and second flow ports to a relief chamber located between the complementary diaphragm and the wall of the cavity.

8. A suction control according to claim 7 in which the support is tubular, axially aligned with the third flow port, and perforated to permit flow inside the support and through its wall.

9. A suction control according to claim 8 in which spacer means prevent adherence of the complementary diaphragm to the wall of the cavity.

10. A suction control according to claim 1 in which the diaphragm extends across the cavity to divide it into two chambers, its sealing surface facing one of said flow ports and adapted to close the same, the other of said flow ports entering the same chamber as the said one of said flow ports.

11. A suction control according to claim 10 in which bias spring means is mounted in the chamber which does not receive the flow ports, and biases the sealing surface toward the first-named flow port.

12. A suction control according to claim 1 in which a pair of said diaphragms is provided, said diaphragms being substantially flat sheets laid against one another and sealed to each other to form an internal flow chamber when fluid pressure is exerted between the diaphragms, the flow ports opening into said flow chamber at linearly spaced-apart locations, each of said diaphragms carrying one of said sealing surfaces.

13. A suction control according to claim 12 in which a body surrounds said diaphragms to form a cavity receiving the same and permitting their distention by insertion of fluid under pressure.

14. A physiological drainage system provided with a control for resisting over-drainage as a consequence of downstream suction comprising: a drainage catheter adapted to drain fluid from a source region; a shunt tube to dispose of fluid collected by said catheter; and a suction control comprising: a body having an internal cavity, a first and a second flow port through the body into the cavity, a flexible diaphragm extending across the cavity; a first sealing surface in said cavity on said diaphragm; and a second sealing surface in the cavity adapted to make a closure with the first sealing surface between the flow ports as a consequence of the exertion of sufficient suction at one of said ports to cause at least one of said sealing surfaces to move toward and against the other, the catheter being connected to one flow port and the shunt tube to the other; the diaphragm being imperforate throughout its entire area which lies outside of that portion of the second sealing surface which is occluded when the said sealing surfaces abut one another.

15. A physiological drainage system according to claim 14 in which the shunt tube is provided with a check valve at a location removed from its connection to the control.

16. A physiological drainage system according to claim 14 in which a pump is connected into the system between the catheter and the control.

17. A physiological drainage system according to claim 16 in which the shunt tube is provided with a check valve at a location removed from its connection to the control.

18. A physiological drainage system according to claim 14 in which the diaphragm extends across the cavity to divide it into two chambers, there being a third flow port through said diaphragm interconnecting the chambers, and in which the first sealing surface surrounds the third flow port, and the second sealing surface comprises a wall of one of the chambers, each of the first and second flow ports entering a different respective flow chamber outside the area bounded by a sealing surface.

19. A physiological drainage system according to claim 14 in which the diaphragm extends across the cavity to divide it into two chambers, there being a third flow port through said diaphragm interconnecting the chambers, in which the first sealing surface surrounds the third flow port, each of the first and second flow ports entering a different respective flow chamber

outside the area bounded by a sealing surface, in which a flexible complementary diaphragm extends across the cavity in one of said flow chambers, with one of the said first and second flow ports entering the flow chamber between the two diaphragms, a surface of said complementary diaphragm forming a sealing surface, and a support in the other flow chamber supporting the diaphragm away from the wall of the cavity.

20. A physiological drainage system according to claim **19** in which a vent passage interconnects the flow chamber entered by the other of said first and second flow ports to a relief chamber located between the complementary diaphragm and the wall of the cavity.

21. A physiological drainage system according to claim **14** in which the diaphragm extends across the cavity to divide it into two chambers, its sealing surface facing one of said flow ports and adapted to close the same, the other of said flow ports entering the same chamber as the other of the said flow ports.

22. A physiological drainage system according to claim **14** in which a pair of said diaphragms is provided, said diaphragms being substantially flat sheets laid against one another and sealed to each other to form an internal flow chamber when fluid pressure is exerted between the diaphragms, the flow ports opening into said flow chamber at linearly spaced-apart locations, each of said diaphragms carrying one of said sealing surfaces.

23. A suction control according to claim **1** in which the diaphragm forms a bounding wall of said cavity, and is so disposed and arranged as to shut off flow between the flow ports as a consequence of exertion of sufficient suction on the control.

24. A suction control according to claim **23** in which the said diaphragm forms an outer wall of the control.

25. A suction control according to claim **24** in which the control is generally circular in plan view, and in which a seat surrounds the second flow port at the center of the control, the diaphragm overlaying the said seat and the entry of the first flow port into the cavity.

26. A suction control according to claim **25** in which the diaphragm is fabric-reinforced.

27. A suction control according to claim **14** in which the diaphragm forms a bounding wall of said cavity, and is so disposed and arranged as to shut off flow between the flow ports as a consequence of exertion of sufficient suction on the control.

28. A physiological drainage system according to claim **27** in which the said diaphragm forms an outer wall of the control.

29. A physiological drainage system according to claim **28** in which the control is generally circular in plan view, and in which a seat surrounds the second flow port at the center of the control, the diaphragm overlaying the said seat and the entry of the first flow port into the cavity.

30. A physiological drainage system according to claim **29** in which the diaphragm is fabric-reinforced.

* * * * *

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,769,982 Dated November 6, 1973

Inventor(s) RUDOLF R. SCHULTE

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

Col. 1, line 26	"it" should read --It--
Col. 2, line 12	"not" should read --not--
Col. 5, line 38	"sunction" should read --suction--
Col. 6, line 27	"variuss" should read --various--
Col. 12, line 20	"Fig." should read --Figs.--
Col. 13, line 21 (Cl. 2, line 2)	"41" should read --extends--
Col. 14, line 20 - Col. 15, line 28	cancel these claims (Patent claims 14-22, inclusive)
Col. 16, lines 13-29	cancel these claims (Patent claims 27-30, inclusive)

On the cover sheet, after the abstract, "30 Claims" should read -- 17 Claims --.

Signed and sealed this 15th day of October 1974.

(SEAL)
Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents

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