

[54] **SURGICAL DRAIN FOR SHUNTING FLUID**

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[58] Field of Search..... **128/350, 350 V, 274; 251/342**

[56] **References Cited**

UNITED STATES PATENTS

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2,969,066	1/1961	Holter et al.	128/350 V

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3,452,757	7/1969	Ames.....	128/350 V
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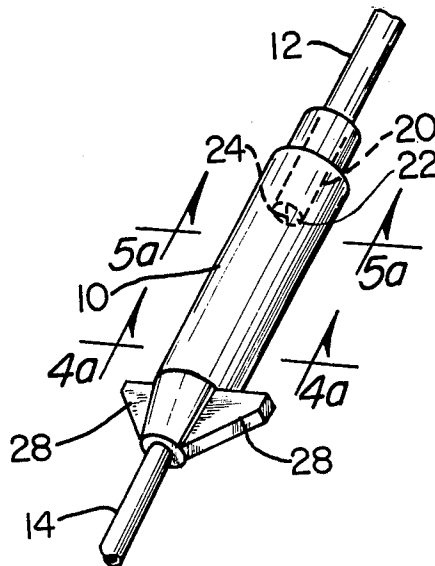
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[57] **ABSTRACT**

Hydrocephalus shunt which includes a subcutaneous pump, devoid of rigid or metallic parts, characterized by a one-way slit valve which may be distorted and opened by digital pressure in the plane of the slit to break up and dislodge any particulate matter which may be clogging the valve. The body of the pump includes means for positioning said pump, following subcutaneously implanting thereof, within the body tissue such that the slit is maintained in a position generally normal to the surface of the cranium. Said means of said pump may include projections which may be sewed to soft tissue beneath the scalp or may include a pump of predetermined cross section such as of oval cross-sectional configuration.

4 Claims, 8 Drawing Figures



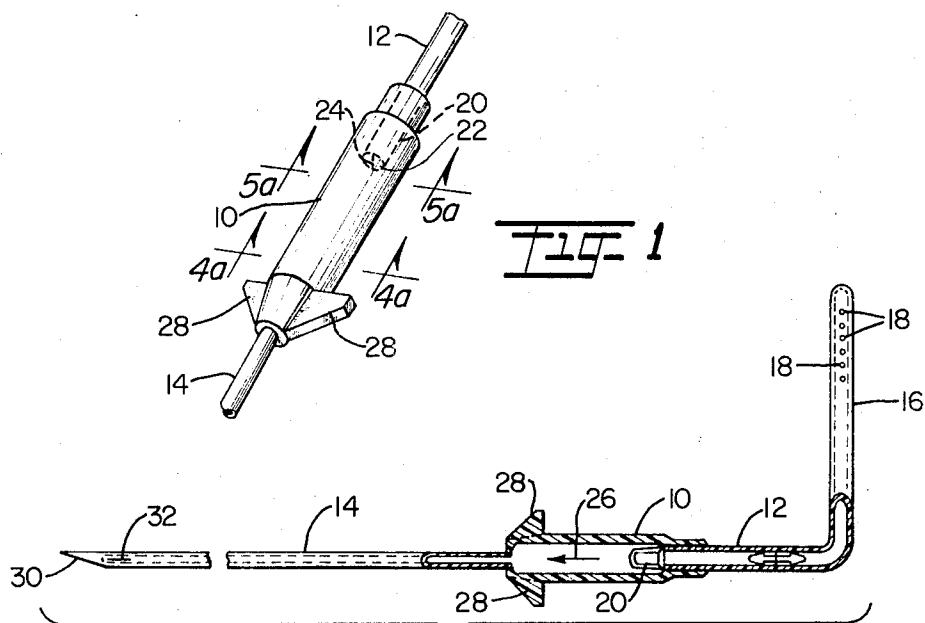
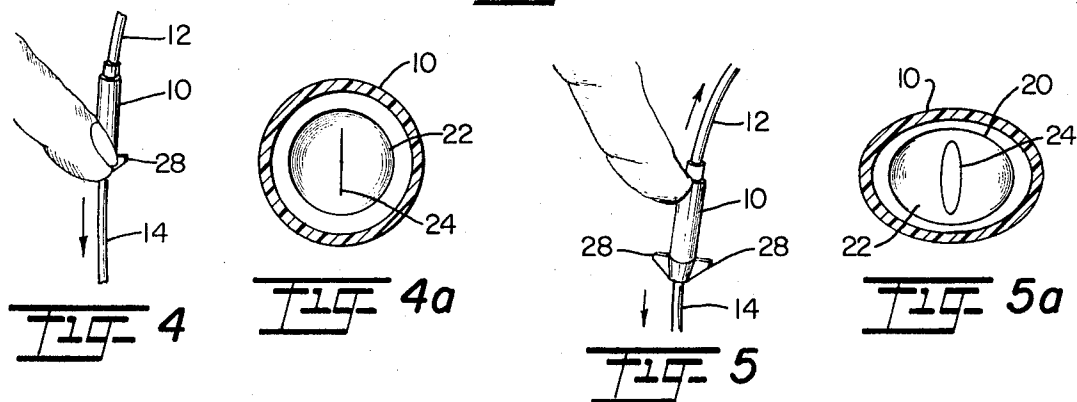
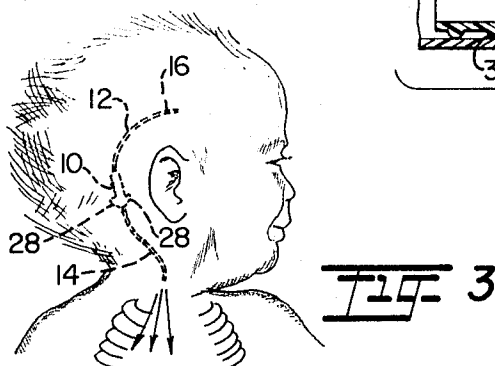
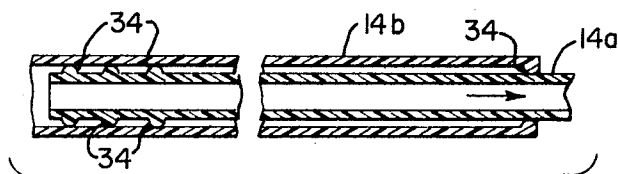


FIG. 6

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SURGICAL DRAIN FOR SHUNTING FLUID

BACKGROUND OF THE INVENTION

In the treatment of hydrocephalus it is common practice to provide a drain tube, containing one or more valves, also known as a shunt, between the source of cerebrospinal fluid within a ventricular cavity of the patient and the vascular system, such as the jugular vein. It is generally recognized that the shunt should be provided with at least one check or one-way valve which may open due to the slight differential pressure between the inlet or proximal end of the shunt and its outlet or distal end, and close in event the pressure differential reverses, which may occur by coughing or straining of the patient, thereby to prevent a reverse flow of blood or other fluid through same. The patent to Heyer U.S. Pat. No. 3,020,913 is exemplary of a single valve shunt of the type referred to. Since this type of shunt is implanted in the patient it will be apparent that there is no external control over the valve in the event it becomes clogged with particulate matter. The patent to Holter et al., U.S. Pat. No. 2,969,066, is exemplary of another type of shunt which includes a pump, also implanted beneath the skin, which may be manually operated by digital pressure, the pump comprising a resilient compressible rubber tube. With this type of pump two check valves are required, these being normally closed valves but adapted to open in normal operation by the higher pressure which exists in the ventricular cavity. If it is desired to pump fluid through the Holter-type shunt by digital manipulation the pump tube is compressed which increases the pressure within same and opens the outlet or distal valve. Upon release of pressure on the pump tube the distal valve closes and the resilient recovery of the tube to its normal volume creates a reduced pressure in same which normally opens the inlet or proximal valve and permits fluid to enter through same. However, in the event the proximal valve is clogged by particulate matter and does not open by the differential pumping pressure, the shunt then becomes inoperative and surgical replacement may become necessary.

The patent to Schwartz U.S. Pat. No. 3,109,429 is similar to the Holter device, employing a compressible pump tube but differs principally in that the check valves are normally open rather than normally closed. This patent discusses disadvantages of the Holter shunt and also briefly outlines the history of such devices, the problems involved, and certain desiderata which should be met.

SUMMARY OF THE INVENTION

The present invention is probably most closely related to the Holter device in that it employs a subcutaneous pump tube with a normally closed inlet slit valve which, in one mode of operation, may open by pump pressure in the same manner as in the Holter device. The inlet valve, however, differs in that it may also be manually opened by digital pressure in the event that it is clogged and will not open by fluid pumping pressure. Manual manipulative control over the inlet valve thus renders it possible to flush the ventricular apertures in the shunt, the proximal slit valve, and a distal slit valve, thus removing any clogging matter disposed in any part of the shunt. Since the inlet slit valve can be effectively opened only by pressure in the plane of the slit, suitable means such as projections are formed on the valve body to permit it to be sewn to soft tissue beneath the scalp in a position such that the slit is disposed normal to the cranium and remains in such position against any tendency to rotate or migrate from the desired position. More specifically, the projections are in the form of a pair of flat extending wings, the plane of which lies parallel with the skull and normal to the proximal slit direction. A further feature is that the valve body and its slit valve are integrally molded from silicone rubber and no metal or rigid parts are employed in the shunt. The principal objectives of the invention are thus to provide a shunt pump having a slit check valve which may be manually distorted and opened by digital pressure in contradistinction to only fluid differential pressure, and suitable means on the pump for implanting it in a position

such that the slit valve is disposed normal to the skull. Another objective is to provide a shunt pump which reduces the possibility of patient injury in the event of a blow to the head. Another objective is to eliminate all metallic parts which might induce tissue reaction or blood coagulation. A further objective is to provide a shunt which is extremely simple in construction and so economical to manufacture that it may be made available to those of limited means. Still further objectives, advantages, and salient features will become more apparent from the description to follow, the appended claims, and the accompanying drawing.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is an isometric view of a pump showing the proximal valve;

FIG. 2 is a longitudinal central section through the pump of FIG. 1, illustrating its intermediate position between inlet and outlet drain tubes;

FIG. 3 illustrates a position of implantation of the invention; FIG. 4 illustrates one mode of operation of the pump;

FIG. 4a is a section taken on line 4a—4a, FIG. 1, illustrating the slit valve when the pump is operated in the mode of FIG. 4; FIG. 5 illustrates another mode of operation of the pump;

FIG. 5a is a section taken on line 5a—5a, FIG. 1, illustrating the slit valve when the pump is operated in the mode of FIG. 5; and

FIG. 6 is a longitudinal section through an alternative form of pump outlet drain tube.

DESCRIPTION OF PREFERRED EMBODIMENT

Referring now to the drawing, and first to FIGS. 1 to 3, the subject of the invention comprises, in general, a resilient pump tube 10 interposed between an inlet tube 12 and an outlet tube 14, a suitable catheter 16, having apertures 18 near its end, being connected directly or with intermediate devices, to tube 12, the construction as so far described being conventional and surgically implanted in a patient as in the Holter device previously referred to and also as illustrated in FIG. 3.

Pump tube 10 is provided with a tubular projection 20 extending into one end of same and spaced from the inner wall of tube 10 which is provided with a conical or dome shaped end wall 22 having a slit 24 in same which is closed except when fluid is draining in the direction of arrow 26, FIG. 2. A pair of flat diametrically opposed and radially extending wings 28 are disposed adjacent the other end of tube 10 which may be sewed to soft tissue with the wings lying parallel with the skull and the slit perpendicular to the skull. Tube 14 is provided with a tapered closed end 30 to aid in implanting into a blood vessel and a pair of diametrically opposed longitudinally extending slit valves 32 are provided adjacent its closed end which are also normally closed but may open when fluid is flowing into the blood vessel or other position of discharge of the fluid. While these slits in part determine the flow rate of fluid through the entire shunt, they may be lengthened by a scalpel to increase their calibrated flow rate at the discretion of the surgeon prior to implantation.

During normal operation subsequent to implantation, fluid flows through apertures 18 in catheter 16, thence through tube 12, slit valve 20, pump tube 10, outlet tube 14 and slit valves 32. Since the pressure in the ventricular cavity slightly exceeds the pressure at the position of discharge, fluid will readily and naturally flow from the ventricular cavity to the position of discharge. In the event that the pump tube slit valve 24 or the discharge slit valves 32 should become clogged with particulate matter at some future time, it then becomes necessary to open same by manual application of digital pressure on the skin to compress the pump tube which is, in effect, a variable chamber device, the volume of which may be reduced by flattening from a normally circular section to a somewhat elliptical section. FIG. 4 illustrates application of digital pressure at a point remote from slit valve 24 in which the pumping action would be like that in the Holter device,

that is, if slit valve 24 is clogged it could be made to open by the differential pressure, upon release of digital pressure, when the tube resiliently returns to its normal circular cross section. This mode of operation, however, is intended principally for opening clogged slit valves 32 to produce flow in the direction of the arrow, FIG. 4. In the other mode of operation the pump tube is compressed at a point adjacent slit valve 24 as illustrated in FIG. 5. This distorts projection 20, flattening it in the plane of the slit and opening it as shown in FIG. 5a. In this mode of operation flow may take place in the directions of the two arrows, FIG. 5, also back flushing any matter clogging apertures 18, which flow conditions, so far as known, were not possible to attain in pump-type shunts of the prior art by manipulation of the shunt through application of pressure through the skin. As will now become apparent, the invention provides means for (a) forward flushing of a normally closed and clogged one-way discharge valve (b) for manually opening a normally closed and clogged one-way inlet valve, and (c) for back flushing clogged inlet apertures in the catheter communicating with fluid in the ventricular cavity, thus enabling the opening of the various apertures and valves without resort to surgical replacement of the shunt in event of malfunction. Pump tube 10, wings 12 and projection 20 are integrally molded from flexible material such as Silastic, a trade name of Dow Corning Corporation of Midland, Mich. for a silicone rubber, after which slit 24 is cut. Tubes 12 and 14 are then attached within apertures in the ends of the pump tube by suitable medical grade Silastic rubber adhesive.

FIG. 6 illustrates an alternative form of outlet tube comprising telescopic portions 14a, 14b, sealed by annular projections 34. With this construction the outlet tube may be lengthened with body growth, since the tubes can be extended by sliding one with respect to the other under the skin by careful manipulation of the tubes. This operation can be performed externally without the need for surgery.

The means 28 for affixing the pump tube in a predetermined position to prevent rotation or other migration of same may be of a form other than radially extending wings, such as any non-circular form which will serve the same function.

In view of all the foregoing, it will now be readily appreciated that an improved hydrocephalus shunt has been described. This shunt, which is installed beneath the surface of the skin, may be suitably manipulated through the skin to remove any clogging matter which may become disposed in any part of the shunt even though there is no direct access to the shunt itself without surgery. Further, the shunt includes means for resisting any tendency of the shunt to rotate or migrate from a desired position. Finally, the shunt is formed without incorporating therein any metal or rigid parts.

It is to be understood that this invention is not limited to the exact embodiment shown and described, which is merely by way of illustration and not limitation, as various other methods will be apparent to those skilled in the art. For example, the pump tube 10 may be formed to have a predetermined cross-sectional configuration, such as an oval-shaped cross-sectional configuration, which, following subcutaneously implanting thereof, cooperates with the body tissue to maintain the slit in a position normal to the surface of the cranium. An oval-shaped configuration similar to that of the tube 10 as shown in FIG. 5a is contemplated although the ratio of the minor axis to the major axis would be less than that shown.

What is claimed is:

1. A surgical drain for shunting fluid from a body cavity, said drain being adapted to be subcutaneously implanted, said drain comprising:
 - a. an inlet conduit adapted to have a first end thereof disposed within a body cavity;
 - b. an outlet conduit adapted to have a first end thereof positioned outside of said body cavity for discharge of fluid, said first end having a normally closed, one-way slit valve formed therein and adapted to be opened by a differential pressure between the body cavity and the position of discharge of the fluid; and

- c. an elongate, generally cylindrically shaped, pump tube constructed from a resilient, nonmetallic material, such as silicone rubber, and interconnecting said inlet and outlet conduits, said pump tube including means for determining the clogging up of said surgical drain at any one of three separate points, said means including:

1. an inlet into said pump tube, said inlet comprising an end wall integrally formed with said pump tube, said end wall having a slit formed therein to form a one-way slit valve, said slit adapted to be opened by digital pressure applied thereto in a direction substantially in the plane of a slit and radially outwardly from the slit without creating undesirable back pressure in the inlet conduit, thereby enabling the determination whether said slit valve has become clogged up,
2. a single pump chamber disposed downstream from the slit valve of said pump tube, taken with respect to the direction of fluid flow from the inlet of the pump tube to the outlet conduit, (i) said pump chamber being of sufficient length that, upon actuation thereof by application of digital pressure thereto, fluid is caused to flow only through the outlet conduit and the slit valve formed in the outlet conduit without opening of otherwise affecting the operation of the slit valve or the pump tube thereby enabling the determination whether clogging up of said outlet conduit or its slit valve exists, (ii) said pump chamber, upon actuation thereof by application of digital pressure thereto and simultaneous opening of the pump tube slit valve by application of digital pressure thereto in the plane of the slit thereof, causing fluid to flow in opposite directions, thereby enabling the determination whether clogging up of said inlet conduit exists where it has previously been determined that neither the pump tube inlet slit valve nor the outlet conduit and its slit valve is clogged up, and
3. means for affixing and maintaining said pump tube, following subcutaneously implanting thereof, within body tissue such that the slit in the pump tube slit valve is disposed in a predetermined position substantially normal to the skin whereby digital pressure applied to said slit valve will distort said end wall and open the slit without rotating said slit out of its said predetermined position normal to the skin, whereby said means enables the opening of said pump tube slit valve with the application of minimum digital pressure.
2. A drain in accordance with claim 1 wherein the means for affixing the pump tube to body tissue comprises a pair of opposed projecting flat wings integrally formed thereon.
3. A drain in accordance with claim 2 wherein the drain tube is provided with a closed end and the outlet valve comprises a pair of diametrically disposed longitudinally extended slits through its wall.
4. In a surgical drain for shunting fluid from a body cavity, such as ventricle cavity, and of the type adapted to be subcutaneously implanted and including a flexible pump tube which may be compressed by digital pressure applied to the skin, the pump having a one-way slit valve, the drain also having a one-way outlet valve, the valves being normally closed and adapted to be opened by the differential pressure between the cavity and the position of discharge of the fluid, the improvements in combination comprising:
 - a. said slit valve being disposed within the pump tube adjacent one end thereof and having an end wall with a transversely extending normally closed slit therein,
 - b. the pump tube and end wall being integrally formed of resilient non-metallic material, such as silicone rubber,
 - c. the slit adapted to be opened by digital pressure applied to the pump tube in a direction substantially in the plane of the slit and at a position on the pump tube adjacent and radially outward from the slit,
 - d. said pump tube including means for positioning said tube, following subcutaneously implanting thereof, within body tissue such that the slit is disposed substantially normal to

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the skin, whereby digital pressure applied to same may distort said end wall and open the slit, and
e. the drain tube is formed of at least two telescoping sealed portions having different diameters for permitting it to be lengthened to accomodate body growth, the portion having the larger diameter including an annular, radially inwardly extending rib formed on the inner surface thereof, the portion having the smaller diameter including one or

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more annular radially outwardly extending ribs formed on the outer surface thereof, each rib of one of said portions being disposed in sealing engagement with the adjacent surface of the other said portion, and the rib of one portion cooperating with an adjacent rib of the other portion to resist longitudinal separation of one portion from the other.

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