

[54] **DEVICE FOR DRAINING
CEREBROSPINAL FLUID IN CASES OF
HYDROCEPHALUS**

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[22] Filed: **Dec. 28, 1970**

[21] Appl. No.: **101,906**

[52] **U.S. Cl.**.....128/350 V, 128/231

[51] **Int. Cl.**.....A61m 01/00, A61m 27/00

[58] **Field of Search**.....128/350 R, 350 V, 247, 231

[56] **References Cited**

UNITED STATES PATENTS

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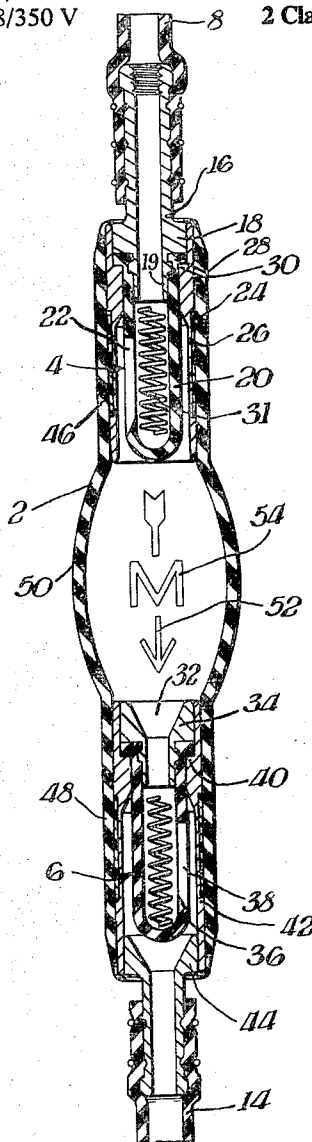
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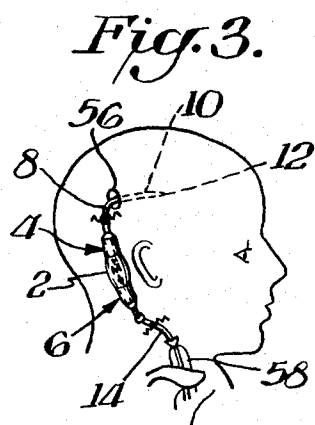
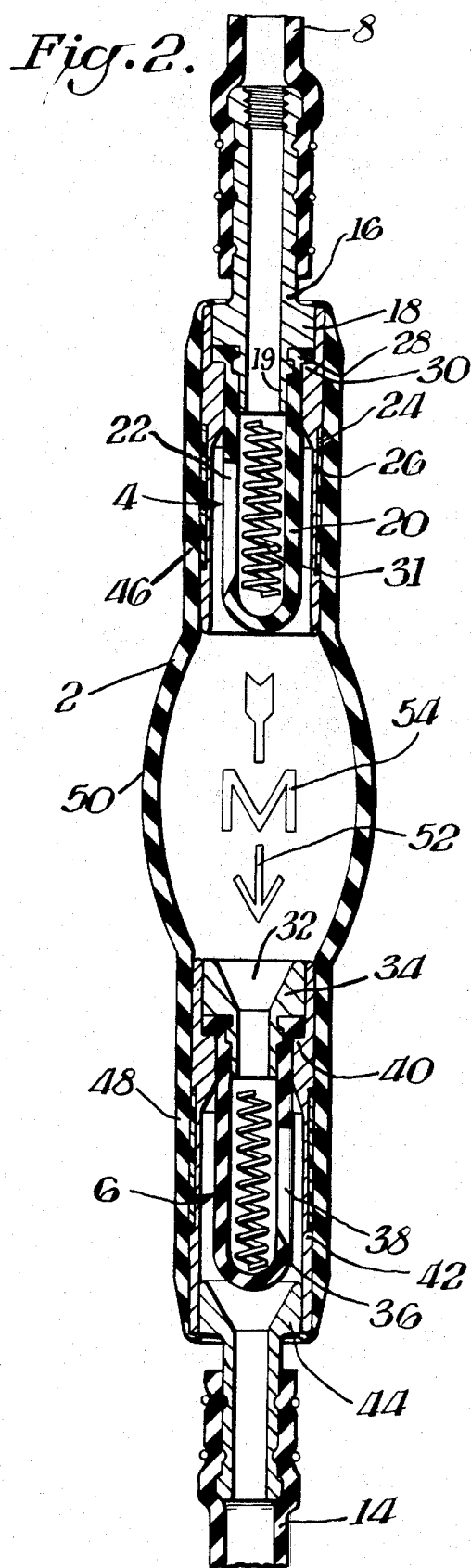
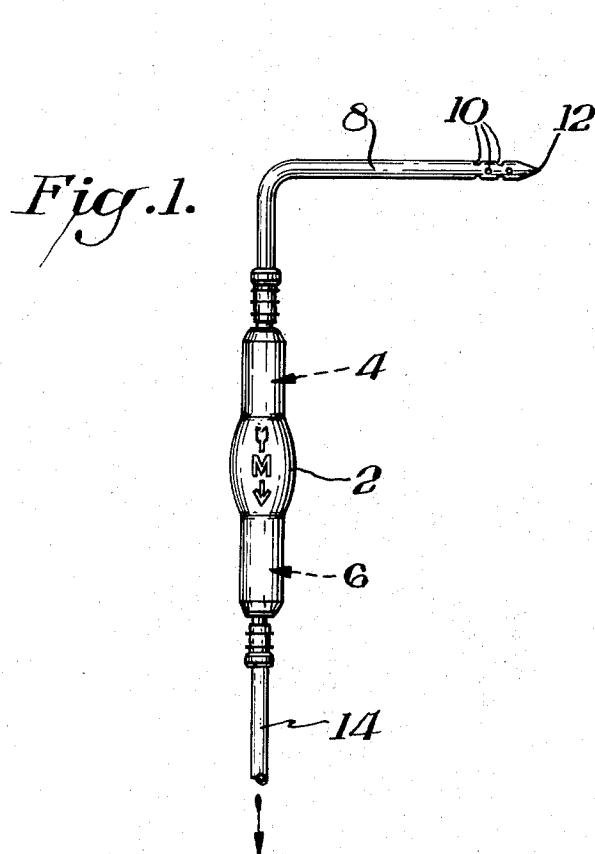
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[57] **ABSTRACT**

A device for the draining of cerebrospinal fluid (CSF) in cases of hydrocephalus, of the type having upstream and downstream normally closed check valves which are designed to pass CSF in one direction only in response to predetermined values of fluid pressure, and having a pumping chamber between the valves for manipulation to insure that the device is functioning properly, the pumping chamber having an enlarged bulbous portion with a lateral dimension substantially greater than the diameter of the remainder of the device, the enlarged bulbous portion being molded to shape from medical grade silicone rubber, and having flow direction or other indicia molded thereon.

2 Claims, 3 Drawing Figures





DEVICE FOR DRAINING CEREBROSPINAL FLUID IN CASES OF HYDROCEPHALUS

BACKGROUND OF THE INVENTION

This invention relates to the field of surgical devices designed for the draining or shunting of cerebrospinal fluid principally to the jugular vein in cases of hydrocephalus, and more particularly to an improvement in a valve device of the type disclosed in Holter and Spitz Pat. No. 2,969,066 granted Jan. 24, 1961.

The valve device disclosed in the aforesaid Holter et al patent has been widely accepted by the medical and surgical profession, and has prompted further research and development by others resulting in several commercially available devices of the same general character. This development has saved numerous lives and relieved considerable human suffering, but the valve devices presently on the market, including that of the Holter et al patent, still have certain deficiencies.

First, the pumping chamber on most of such valve devices is fabricated from a length of standard extruded tubing, and is thus never larger in diameter than the check valve portions of the valve device. This presents a troublesome problem because there is a substantial danger that the valve assembly may be extruded through a rongeuired slot in the skull, especially with the delicate skull of infants. Another problem is that such tubing does not provide the desired positive digital pressure "feel" in determining if and where a blockage of the system should occur. Furthermore, the tubing presently employed for the pumping chamber presents an unfortunately narrow "target" for the needle injection of medicines, contrast medium or other substances that may be desired by the attendant physician. In addition, an unhappy compromise must be struck with respect to the diameter of the tubing, because if it is sufficiently small to make a fluid-tight stretch fit with the valve portions at either end, then the central pumping chamber portion is too narrow to be of optimal use, and utilization of larger diameter tubing requires additional closure means at the ends to insure fluid-tight fittings. Finally, with extruded tubing there is no adequate means of including permanently visible indicia to indicate the direction of flow or identify other flow characteristics of the valve device; labels for this purpose have proved impractical because of the difficulty of insuring that they remain in place during sterilization and the like. Finally, with valves of this nature it has become apparent that some means of increasing the pumping volume should be provided to improve the "flushing" characteristics for freeing the sensitive slit valves of tissue fragments and occasional foreign matter by accelerating contained fluid to flush or circulate fresh CSF into static areas of the assembly.

Thus, there is a recognized need for a valve device for draining CSF in cases of hydrocephalus which solves the foregoing problems.

SUMMARY OF THE INVENTION

This invention provides a device for the draining of CSF in cases of hydrocephalus which comprises first and second check valves which are normally closed and which are designed to open and permit flow of fluid in response to a predetermined value of fluid pressure on the upstream side thereof, and a flexible pumping chamber between the first and second valves which is

directly formed to final shape from a flexible, tissue compatible material such as medical grade silicone rubber and which includes upper and lower tubular portions adapted to connect with adjacent tubular members and, by virtue of the inherent elastic characteristics of the material, to provide a fluid-tight connection without need of auxiliary clamping devices, and having a mid-section with an enlarged bulbous portion with a lateral dimension substantially greater than the diameter of the upper and lower tubular portions. The enlarged bulbous portion of the flexible pumping chamber may have indicia indicating the direction of fluid flow and/or other valve flow characteristics molded or otherwise included directly thereon. The enlarged bulbous portion in the presently preferred embodiment is generally circular in lateral cross-section, and the upper and lower tubular portions thereof are positioned co-axially with respect to the enlarged bulbous portion.

BRIEF DESCRIPTION OF THE DRAWINGS

Numerous advantages of the present invention will become apparent to one skilled in the art from a reading of the detailed description in conjunction with the accompanying drawings, wherein similar reference characters refer to similar parts, and in which:

FIG. 1 is an elevational view showing the valve device of this invention;

FIG. 2 is an enlarged longitudinal sectional view showing the pumping and drainage portions of the device; and

FIG. 3 is a diagram showing the application of the device to a patient.

DETAILED DESCRIPTION

Referring in more particularity to the drawings, the device comprises a flexible pumping chamber 2, which may be of the order of three inches in length, which is closed at its upper end by a first check valve indicated generally at 4 and at its lower end by a second check valve indicated generally at 6. To the upper check valve assembly 4 there is affixed a tube 8 which may be of silicone rubber and which is provided with openings 10 for the reception of the cerebrospinal fluid, the end of the tube being desirably closed as indicated at 12.

Associated with the lower valve assembly 6 is a tubular member 14 which is desirably of silicone rubber and which is arranged to enter and be secured within the jugular vein, as in the principal use.

Reference may now be made to FIG. 2 which shows the details of the valves 4 and 6. A member 16 preferably of stainless steel or other metal which will not be corroded by body fluids is provided with a flange 18 and with an extension 19 having a locking ridge on its outer wall tightly embraced by the open end of a thimble 20 desirably of silicone rubber which is provided with a slit 22 such as may be made by a sharp blade and which functions as the actual valve. An identification band 24 surrounds an upstream tubular member in the form of a stainless steel sleeve 26 which is secured to the flange 18 of the member 16. The thimble 20 is desirably molded directly to shape, and it has a flange 28 extending radially outward around its upstream end to secure a good seal between the flange 18 and an internal shoulder 30 on the tubular member 26.

A small coil spring 31 may be included within the upstream thimble 20 to prevent inadvertent collapse thereof. The stem of the member 16 is corrugated to secure well the tube 8 which may be bound thereon by tying with silk thread. The sleeve 26 may also be corrugated to form a connection with the flexible pumping chamber 2 without use of silk thread or other clamping arrangements, as explained in more detail below.

The outlet valve 6 shown in the lower portion of FIG. 2 is generally similar to the inlet valve, comprising a member 32 provided with a flange 34 and carrying on an extension with a locking ridge a thimble 36 which is slitted as at 38 in the same fashion as the thimble 20, and optionally may contain a coil spring in similar fashion. A shoulder 40 secures the flange of this thimble on the member 32 and the interposed flange provides a good gasket closure. A downstream tubular member in the form of a sleeve 42, which carries the shoulder 40, encloses the entire assembly just described, and the sleeve 42 is connected to a reduction member 44 to receive the tubular member 14, the member 44 being corrugated so that the tube 14 may be secured thereon by suitable clamping means such as tying with silk thread.

The flexible pumping chamber 2 shown in the mid-portion of FIG. 2 is located between the first 4 and second 6 check valves. It is formed to final shape by a process such as molding from a tissue compatible material such as medical grade silicone rubber. The chamber includes an upper tubular portion 46 and a lower tubular portion 48 which are adapted to connect with the upstream tubular sleeve member 26 and the downstream tubular sleeve member 42, respectively. The tubular portions 46 and 48 are initially molded or otherwise formed with a diameter which is sufficiently small that these portions may be stretched around the sleeve members 26, 42 to provide a permanent, fluid-tight connection without the necessity of silk thread or other closure devices.

The mid-section of the flexible pumping chamber has an enlarged bulbous portion 50 with a normal lateral dimension substantially greater than the diameter of the upper and lower tubular portions 46, 48 when they are stretched over the upstream and downstream tubular members 26, 42, respectively. The enlarged portion 50 is generally circular in lateral cross-section, although other shapes are contemplated, and the upper and lower tubular portions 46, 48 are positioned substantially co-axially with respect to the enlarged bulbous portion.

An important aspect of the present invention is the provision of indicia indicating the direction of fluid flow 52 and/or other valve flow characteristics 54 molded directly into the outer surface of the silicone rubber. This provides positive identification and insures that the attendant physician does not erroneously apply the device to the patient in the reverse direction. It has been found that the direct molding of such indicia overcomes the difficulty of insuring that labels and the like remain in place during sterilization.

The entire assembly is of quite small lateral dimension, and the directly molded pumping chamber according to this invention provides a noticeably enlarged and easy to identify portion thereof. The average external diameter of the tubular portions 46 and 48 is about

three-sixteenth inch, and the device is customarily recessed in a similarly dimensioned rongeur slot in the skull. The enlarged bulbous portion 50 of the valve according to this invention prevents accidental extrusion of the device through the skull, especially the delicate skull of infants, after repeated manipulation of the pumping portion of the device.

The thimbles 20, 36 in one exemplary embodiment have external diameters of the order of one-eighth inch and wall thickness of approximately 0.020 inch, the slits 22 and 38 being about three-sixteenth inch in length. Under these conditions both valves open to permit forward flow under a pressure gradient between the tubes 8 and 14 of the order of thirty millimeters of water, opening occurring by the dilation of the thimbles 20 and 36 to open the slits 22 and 38. On the other hand, reverse flow is completely stopped against any pressure gradient which may be expected during use, closing taking place due to the resiliency of the thimbles when there is no pressure gradient and remaining closed until the forward pressure gradient occurs. In the forward direction, the valve will pass small particles of tissue which may occur in the ventricular fluid, and the enlarged bulbous portion 50 of the pumping chamber according to this invention provides a significantly larger pumping volume which produces a higher fluid velocity to improve the cleaning and flushing characteristics of the slit valves.

The use of the device is illustrated in FIG. 3. The device is inserted beneath the skin with the tube 8 extending through an opening 56 in the skull. The device below the tube 8 is threaded under the skin and by means of a lower incision the tube 14 is generally inserted into and secured in the jugular vein 58. Proper function may be determined by pressing upon the skin covering the enlarged bulbous portion 50. If unusual resistance to pressure is noted indicating that the outlet side of the shunt system may have become closed, the situation may generally be rectified by producing a pumping action by pressure and release on the enlarged bulbous portion 50. In the event that the inlet side of the shunt system should be clogged, that fact will be evident since the bulb will not expand to original size upon release of pressure. The enlarged bulbous portion 50 provides a much more positive digital pressure "feel" in determining if and where a blockage should occur, a notable deficiency with previous valves of this character. Moreover, the enlarged portion provides a more readily accessible "target" in which to needle inject medicines, contrast medium or other substances that may be desired by the attendant physician.

While the above described embodiment constitutes the presently preferred mode of practicing this invention, other embodiments and equivalents are included within the scope of the actual invention, which is claimed as:

1. A device for the draining of cerebrospinal fluid in cases of hydrocephalus comprising a non-flexible upstream tubular member adapted to be positioned along a rongeur slot in the patient's skull, a non-flexible downstream tubular member, a normally closed one-way check valve supported within each tubular member, the check valves each including a thin walled flexible member in the form of a thimble provided with slit means expandable between open and closed posi-

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tions and being arranged to open and permit flow of fluid therethrough in response to a predetermined value of fluid pressure on the upstream side thereof, a flexible pumping chamber directly molded to shape from flexible tissue compatible material, the pumping chamber including an upper tubular portion stretched around the upstream tubular member and a lower tubular portion stretched around the downstream tubular member to provide fluid-tight connections thereto and to position the upstream and downstream tubular members generally co-axially with respect to each other, the pumping chamber further including a mid-section having an enlarged bulbous portion with a lateral dimension substantially greater than the diameter of the upper and lower tubular portions when they are stretched around the upstream and downstream tubu-

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lar members, the lateral dimension of the bulbous portion being sufficiently great to prevent the device from being inadvertently depressed through the patient's skull in the area of the rongeur slot.

5 2. A device for the draining of cerebrospinal fluid as in claim 1 wherein the flexible pumping chamber is directly molded to shape from medical grade silicone rubber, the lateral dimension of the bulbous portion is sufficiently great to be readily distinguished by finger-
10 tip feel from the upper and lower tubular portions despite an overlying layer of the patient's skin, and at least one of the non-flexible tubular members includes identification indicia thereon which is visible through the silicone rubber tubular portion stretched
15 therearound.

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