United States Patent

[11] 3,583,387

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[73] Assignee **said Garner, by said Bullara**

[54] **PRESSURE ABSORBING APPLIANCE FOR TREATING HYDROCEPHALUS**
9 Claims, 3 Drawing Figs.

[52] **U.S. Cl.** **128/1,** 128/275
[51] **Int. Cl.** **A61b 19/00,** A61f 5/00
[50] **Field of Search** ..... 128/2, 350, 350 V, 1, 76, 275; 138/26, 30

[56] **References Cited**
UNITED STATES PATENTS

3,111,125	11/1963	Schulte	128/350V
3,162,213	12/1964	Peters	138/30
3,503,402	3/1970	Schulte	128/350V

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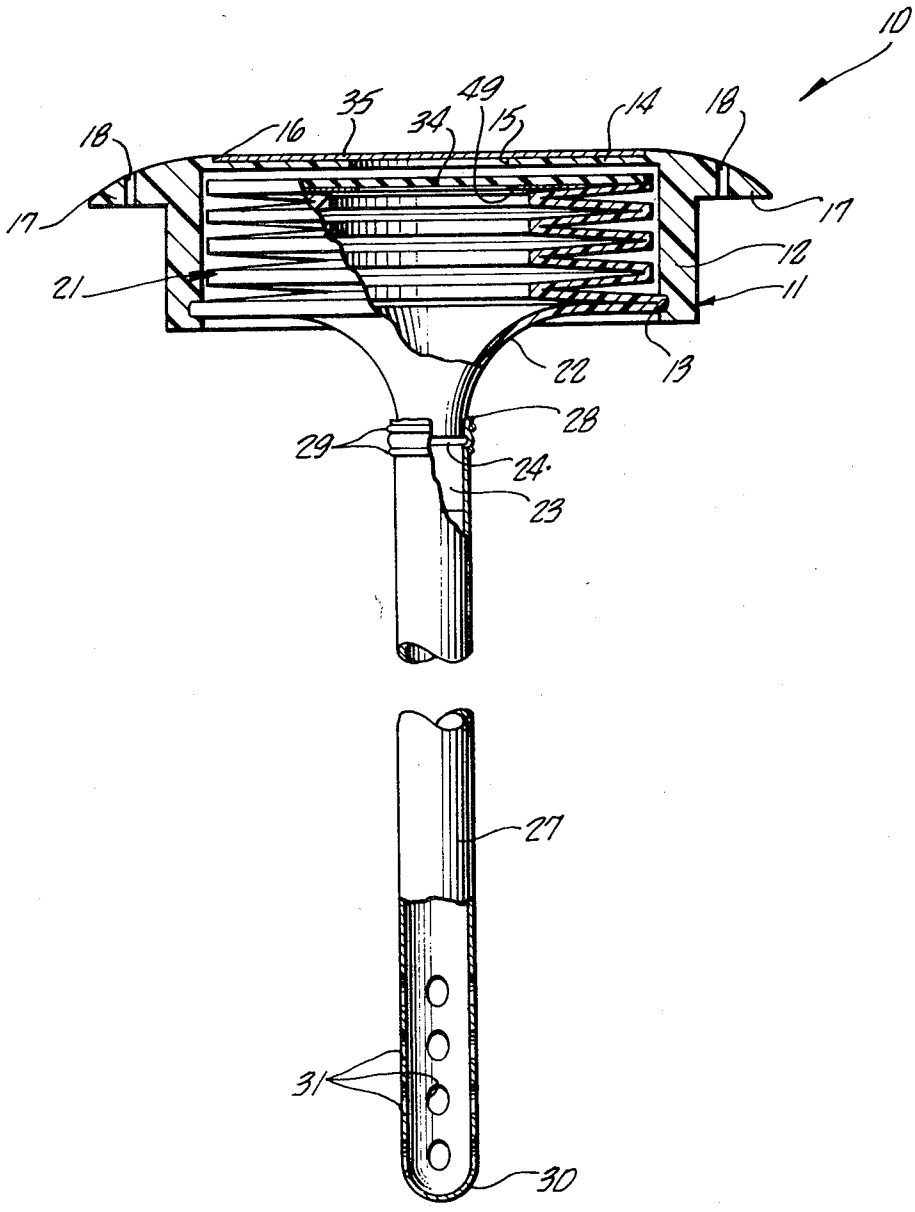
ABSTRACT: An expansible bellows having a variable internal volume is mounted in a housing adapted for implantation in the skull of a patient suffering from hydrocephalus. A tube extends from the bellows for insertion into a ventricle of the brain. When so installed, the bellows is filled with ventricular fluid at an average or static pressure. Pulsation of choroid plexus blood vessels in the brain tends to cause a periodic increase in fluid pressure, but bellows expansion in response to increased pressure minimizes the actual increase in fluid pressure. The resulting suppression of pulsatile pressure peaks and dissipation of energy by the bellows appears to be an effective technique for treating hydrocephalus.



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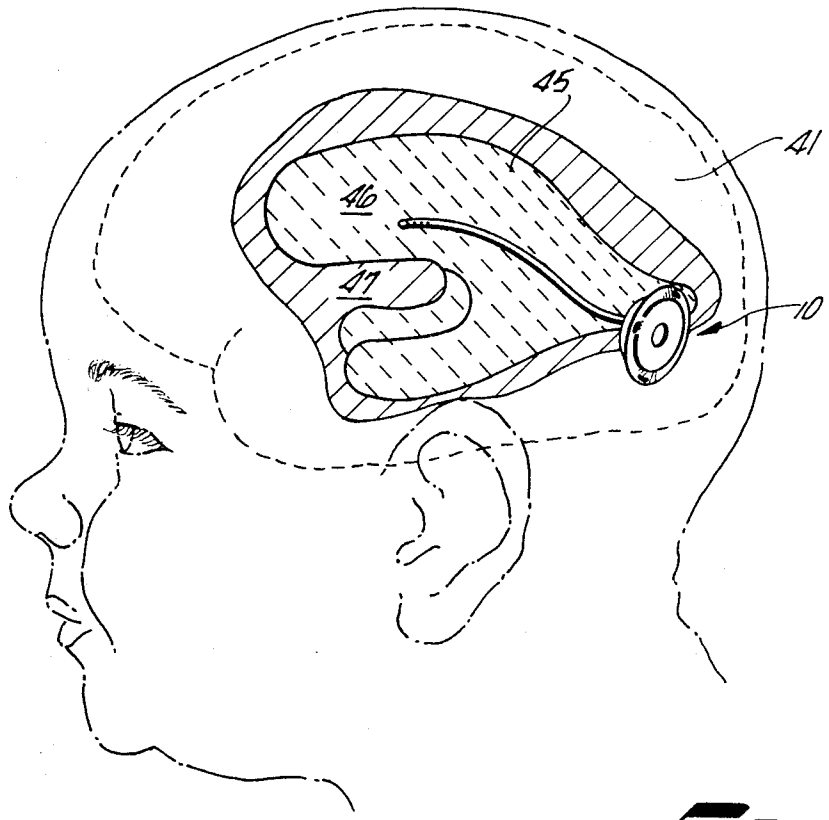

FIG 1

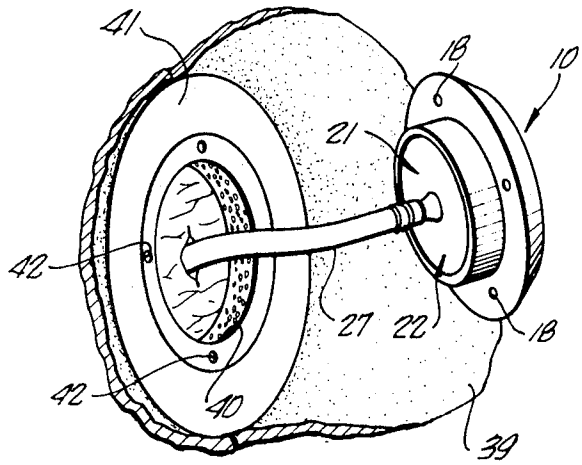

FIG 2

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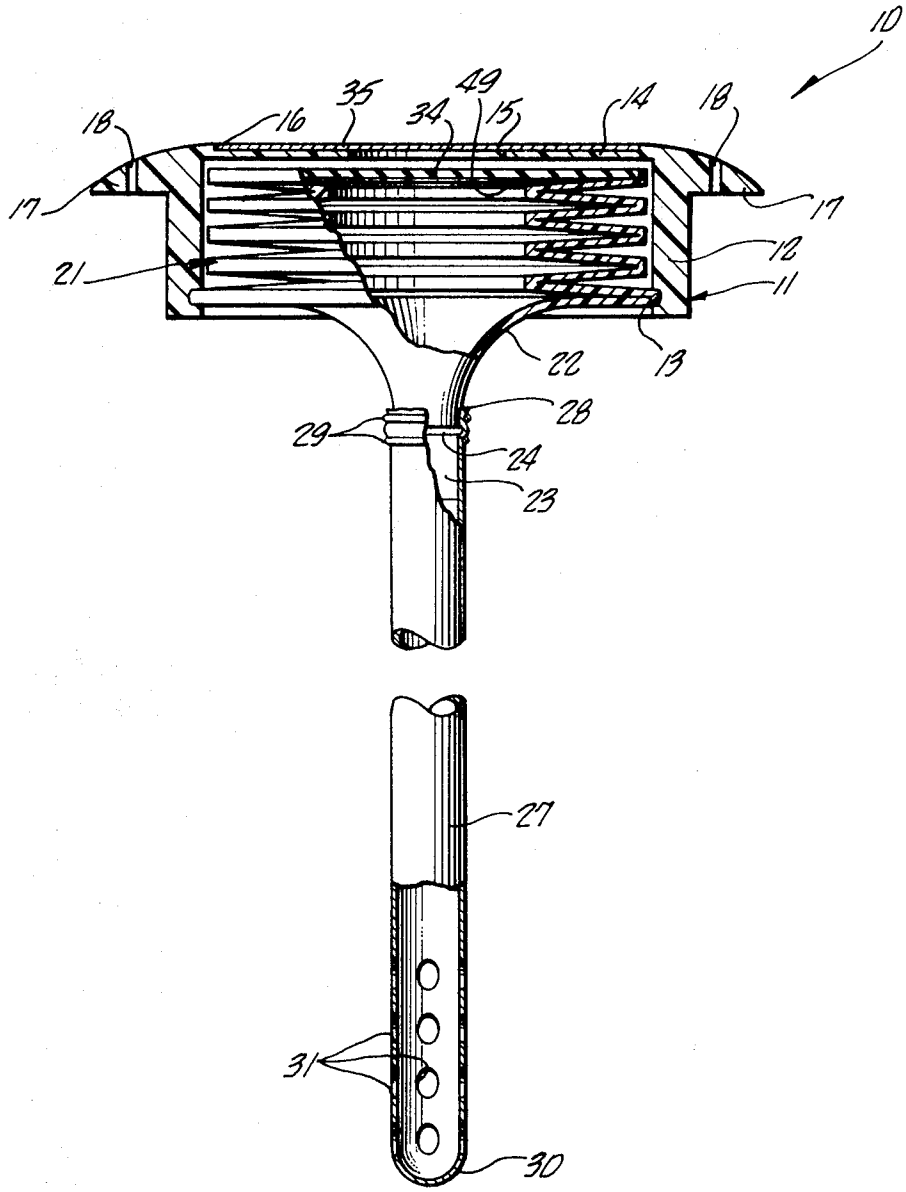

FIG 3

PRESSURE ABSORBING APPLIANCE FOR TREATING HYDROCEPHALUS

BACKGROUND OF THE INVENTION

Hydrocephalus is a brain condition in which cerebrospinal fluid accumulates at abnormally high pressure in ventricles or chambers within the brain. The ventricles expand in response to the pressure exerted by the fluid, and surrounding brain tissue is compressed between the ventricles and the skull. Hydrocephalus usually occurs in babies or young children, and, if unchecked, results in brain damage, enlargement and deformation of the head, and eventual death.

One technique for treating hydrocephalus involves surgical insertion of a drainage tube which couples the brain ventricles to the jugular vein so excess cerebrospinal fluid in the ventricles is drained into the venous system of the body. Several forms of appliances useful in this technique are shown in U.S. Pat. Nos. 2,969,066, 3,020,913, and 3,111,125. There remains, however, a need for improved treatment techniques and appliances which avoid long lengths of tubing susceptible to clogging, which are simpler to install and maintain, and which are directed to the root cause of excessive fluid pressure in the brain ventricles.

Recent research on hydrocephalus indicates that static pressure of ventricular fluid is influenced by periodic variation in fluid pressure arising from a pulsatile expansion of a bed of capillaries in the ventricles and known as the choroid plexus. It is thought that hydrocephalus stems from a malfunction of natural cerebral-circulation mechanisms which normally absorb energy arising from physical pulsation of the choroid plexus. Research results indicate that static pressure in the brain ventricles can be reduced and controlled if the pulsatile pressure peaks are absorbed or otherwise suppressed.

The appliance of this invention limits and absorbs the increase in ventricular-fluid pressure arising from choroid-plexus pulsation, and thereby provides indirect control and reduction of static pressure in the ventricle. The appliance is intracranial and does not require internal or external tubes leading to the jugular vein as in presently known devices described in the aforementioned patents. Installation is accomplished by relatively straightforward surgical techniques, and the appliance is left in place permanently or until the patient no longer exhibits symptoms of hydrocephalus.

SUMMARY OF THE INVENTION

Briefly stated, the invention relates to a pressure-absorbing and energy-dissipating appliance for relieving excess fluid pressure in a body cavity such as a brain ventricle. The appliance includes a housing adapted to be secured in the body as by implantation in the skull. A resilient chamber-defining means such as an expansible bellows is supported within the housing, and has an internal chamber of variable volume. The chamber is resiliently expansible and has a normal volume when filled with fluid at a static pressure, and an expanded volume when the fluid pressure tends to increase in pulsatile fashion. A tube is connected to the resilient means in fluid communication with the chamber, and the tube extends from the resilient means and housing for insertion in the body cavity.

Preferably, both the housing and the resilient means include aligned portions defining self-sealing diaphragms through which a hypodermic needle can be inserted to extend into the expansible chamber. The appliance is formed of materials which are compatible with the body so the appliance may be implanted on at least a semipermanent basis. An annular flange extends outwardly from an outer end of the housing to rest against the skull or other bone structure, and holes are provided in the flange to receive ligatures for securing the appliance in place.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in detail with reference to the attached drawings, in which:

FIG. 1 is a side view, partly in section, of a child's head and showing a skull implantation of an appliance according to the invention;

FIG. 2 is an enlarged view of the skull showing the appliance ready to be ligated in place; and

FIG. 3 is an elevation, partly broken away and in section, of the appliance. DESCRIPTION OF THE PREFERRED EMBODIMENT

A pressure-absorbing appliance **10** according to the invention is shown in detail in FIG. 3. The appliance includes a housing **11** having a cylindrical sidewall **12**. An annular groove **13** is formed in the inner surface of the inner or distal end of sidewall **12**, and an outer end of the sidewall is partially closed by a radially inwardly extending annular flange **14** having a central circular opening **15** therethrough. Flange **14** is stepped to define an annular shoulder **16**. An annular attachment flange **17** extends radially outwardly from the outer end of housing **11**, and has a plurality of ligature holes **18** therethrough.

An expansible chamber-defining means such as a bellows **21** is mounted within housing **11**. The bellows is of conventional accordian-pleat construction, and is closed at one end by an integral end wall **22** which tapers longitudinally away from the bellows to define a hollow inlet tube **23**. An annular retaining rib **24** extends from the surface of the tube adjacent its end. As seen in FIG. **3**, the folds or annuluses of bellows **21** have an outside diameter smaller than the inside diameter of sidewall **12** of the housing, and the bellows can therefore expand or contract freely in response to internal pressure variations without binding or dragging on the inner surface of the sidewall. End wall **22**, on the other hand, has an outside diameter slightly larger than the inside diameter of sidewall **12**, and is adapted to snap into groove **13** of the sidewall in detent fashion to retain the bellows within the housing.

A ventricular probe or tube **27** has a first end **28** which makes a snug slip fit over inlet tube **23** and retaining rib **24**. First end **28** is secured to the inlet tube by a pair of ligatures **29** which are tied tightly around the assembled tubes during surgical installation of the appliance. A distal second end **30** of tube **27** is closed, but a plurality of lateral openings **31** (typically about 1 millimeter diameter) extend through the wall of the tube adjacent the second end. Openings **31** are in communication through the hollow interior of tube **27** with the expansible chamber defined by the hollow interior of bellows **21**.

The outer end of bellows **21** is closed by a circular sheet or diaphragm **34** of a self-sealing material such as silicon rubber sold under the trademark "Silastic." A housing diaphragm **35**, formed of the same material as diaphragm **34**, is seated on flange **14** within annular shoulder **16**, and extends across central opening **15** of the housing. The purpose of diaphragms **34** and **35** is to permit a physician to insert a hypodermic needle therethrough into the interior chamber of bellows **21** when the appliance is installed. Medication may thereby be introduced into the cerebral spinal fluid within the bellows, or fluid can be withdrawn for analysis. The patency of the system can also be evaluated by this technique, and any obstructions in tube **27** can be flushed clear. A clearance of 0.05 inch or more exists between diaphragm **34** and inwardly extending flange **14** such that the bellows can expand longitudinally when subjected to pulsatile pressure.

The entire appliance, which is intended for a long term implantation, is of course constructed from materials which are compatible with the human body. Plastic material as sold under the trademark "Teflon" is satisfactory for forming housing **11** and bellows **21**. The bellows and housing may also be made of stainless steel or gold-plated nickel if metal construction is preferred. Ventricular tube **27** is preferably formed from tubing of plastic material sold under the trademark "Silastic."

In a typical appliance, sidewall **12** of housing **11** has a diameter of about three-eighths to one-half inch, and attachment flange **17** has a diameter about three-sixteenths inch larger than the diameter of the sidewall. The sidewall is ap-

proximately one-fourth inch long, and ventricular tube 27 is typically 1 to 2 inches long. A tube with an outside diameter of 3 millimeters and a bore of 2 millimeters has been found satisfactory for the appliance. Diaphragms 34 and 35 should be relatively thick for proper self-sealing action after being punctured by a hypodermic needle, and a thickness of about 3 millimeters provides satisfactory results.

Bellows 21, in a typical appliance, has an internal volume of about 0.25 cubic centimeters when filled with cerebrospinal fluid at a normal static pressure of about 15 to 25 millimeters of water. The ventricular volume change during pulsation of the choroid plexus is relatively small, and it is adequate in most cases if the bellows has approximately a 50 percent internal volume expansion when subjected to fluid pressure of say 15 to 20 times the normal static pressure.

Referring to FIGS. 1 and 2, the pressure-absorbing appliance is installed using conventional surgical techniques. A posterior parietal-occipital inverted-horseshoe-shaped scalp flap 39 is turned, and a standard trephine opening 40 is made in skull 41 of the patient, the opening having a diameter slightly larger than the outside diameter of sidewall 12 of the appliance. Small holes 42 are drilled at the edge of the trephine opening to receive retention ligatures, and 3–0 silk sutures (not shown) are passed through the holes. The dura mater of the brain is then incised, and the cortex is lightly coagulated.

A ventricular cannula (not shown) is next passed into the lateral ventricle of the brain, and is then withdrawn. Ventricular tube 27 is next passed along the cannula-formed tract into a lateral ventricle 45 of the brain. The outer end of the tube is then cut to length and secured over inlet tube 23 by ligatures 29 which are typically 3–1 silk ligatures. The previously placed silk retention ligatures are then passed through ligature holes 18 in the attachment flange of the housing, and the housing is tied into place on the skull. The appliance is then checked for proper function by ascertaining patency of the tube by passing a 026 hypodermic needle through the diaphragms.

When so installed, the bellows of the appliance is immediately filled with cerebrospinal fluid 46 which flows from the ventricle through openings 31 and the bore of tube 27 into the internal chamber defined by the bellows. The bellows then expands slightly to define a normal internal volume in response to the static pressure exerted by the cerebrospinal fluid. Upon pulsation of the choroid plexus the pressure of the fluid tends to rise due to the slight reduction in ventricular volume, but an excessive pressure increase is prevented by the resulting expansion of the bellows which compensates for the reduced volume of the ventricle.

The bellows is more resilient than brain tissue 47 surrounding the ventricle, and the bellows chamber therefore expands to compensate for reduced ventricular volume. The high fluid-pressure pulsatile peaks which characterize hydrocephalus are thus suppressed, and it has been found that this produces a beneficial effect which tends to lower an excessively high static pressure within the ventricle. Energy is also dissipated from the overall system by the work done in flexing of the bellows, resulting in damping of the excessive energy created by the choroid plexus.

Bellows motion and displacement can be sensed electrically if the bellows includes a metal component or element usable as one plate of a capacitor. For example, a metal-foil disc 49 can be secured to bellows diaphragm 34 as shown in FIG. 3. The disc is centrally apertured to provide clearance for a hypodermic needle introduced through diaphragms 34 and 35. An external electrode (not shown) is secured over diaphragm 35, and the capacitance of the resulting parallel-plate capacitor is measured using conventional techniques. Bellows movement is manifested by a variation in capacitance arising from a change in spacing of the disc and electrode.

Although the invention has been described in a presently preferred form, it will be clear that the inventive concept can be incorporated in other specific types of apparatus. For example, an expansible balloonlike reservoir can be substituted for bellows 21, or other types of expansible chamber-defining means can be used. As another example, a spring-loaded piston in a cylinder is useful to define an expansible chamber, and further damping of the system can be obtained by bypassing part of the fluid past the piston and returning the bypassed fluid to the ventricle in a return line. Similarly, different types of skull-attachment plates can be used to implant the appliance in the skull. It is intended that all such variations and modifications be encompassed within the scope of the following claims which define the invention in detail.

We claim:

1. A pressure absorbing appliance for relieving excessive fluid pressure in a human-body cavity, comprising:
   - a housing adapted to be secured in the body;
   - an expansible bellows supported in the housing and having an internal chamber of variable volume, the chamber having an inlet opening; and
   - a tube connected to the bellows in fluid communication with the chamber inlet opening, and extending from the bellows and housing for insertion in the cavity;
   - the bellows being movable within the housing to vary the chamber volume in response to fluid pressure variations, and the chamber being closed other than at the inlet opening so fluid therein is isolated from the housing, the appliance being made of body-compatible materials suitable for implantation.

2. The appliance defined in claim 1 in which a portion of the bellows is formed of a self-sealing member through which a hypodermic needle can be inserted.

3. The appliance defined in claim 2 in which the housing has an outer end defining an opening in alignment with the self-sealing bellows portion, and further comprising a second self-sealing member secured to the outer end of the housing across the opening.

4. The appliance defined in claim 3 in which the housing is generally cylindrical and in which the outer end of the housing includes an attachment flange extending radially outwardly therefrom, the attachment flange having ligature holes formed therethrough.

5. The appliance defined in claim 4 in which the bellows has an end wall remote from the outer end of the housing, the end wall having a portion which tapers to define an inlet adapted for connection to said tube.

6. The appliance defined in claim 5 in which said end wall inlet portion defines an outwardly extending, annular retaining rib.

7. The appliance defined in claim 6 in which said tube defines a plurality of inlet openings extending laterally therethrough.

8. A pressure-absorbing appliance for treatment of hydrocephalus by relieving excessive pulsatile pressure of cerebrospinal fluid in a brain ventricle, comprising:
   - a housing adapted for skull implantation;
   - resilient means supported in the housing and having an internal expansible chamber with a normal volume when filled with cerebrospinal fluid at static pressure, and an expanded volume when the fluid pressure tends to increase due to ventricular pulsation, the chamber having a single inlet opening; and
   - a tube connected to the resilient means in fluid communication with the chamber inlet opening, and extending from the resilient means and housing for insertion in the ventricle;
   - the chamber being closed except for the inlet opening so fluid in the appliance is isolated from the housing, and the housing, resilient means and tube being made of body-compatible materials suitable for implantation.

9. The appliance defined in claim 8 in which the resilient means includes a metal element usable as a portion of a capacitor whereby motion of the resilient means arising from ventricular pulsation can be monitored electrically.