United States Patent

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[54] **VENTRICULAR CATHETER WITH VALVE AND PUMP FLUSHING MEANS**
5 Claims, 3 Drawing Figs.

[52] **U.S. Cl.** **128/350,** 128/232
[51] **Int. Cl.** **A61/m 27/00**
[50] **Field of Search** ..... 128/350, 214, 231, 232, 278, 273, 274; 103/148, 152, 204; 137/(Inquired), 103/148, 152

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ABSTRACT: The invention is a drainage catheter system, particularly adapted for ventricular drainage, comprising a system in which a drainage catheter is connected to an elastically compressible antechamber, the outlet of which is connected to a one-way passage valve means. The outlet of the latter feeds via a catheter into the blood stream. The antechamber is upstream in respect to the valve means, and because of its resiliently collapsible nature, as well as the fact that the valve means may also be resiliently collapsed, the system is adapted for testing to make sure the drainage is proper, and also to clear out any obstructions in the system.

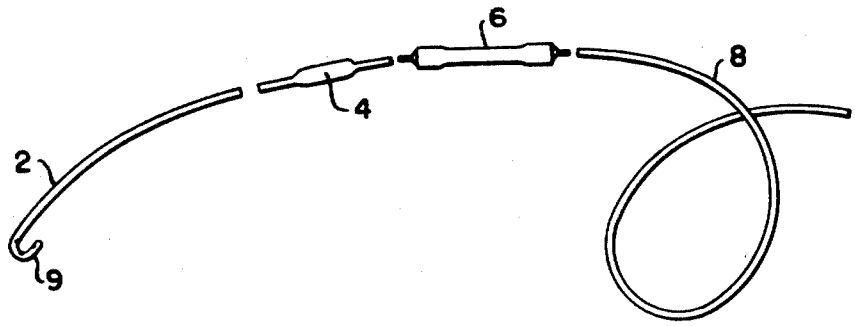


FIG. 1

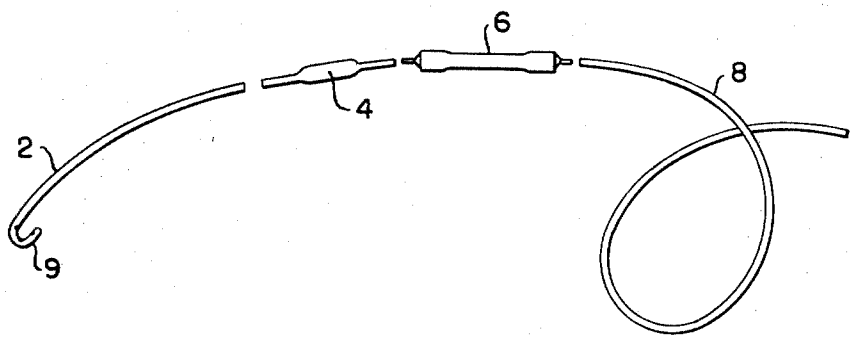
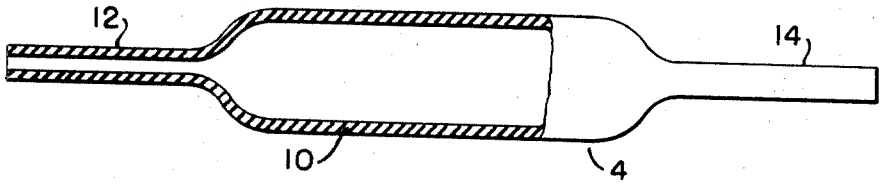


FIG. 2



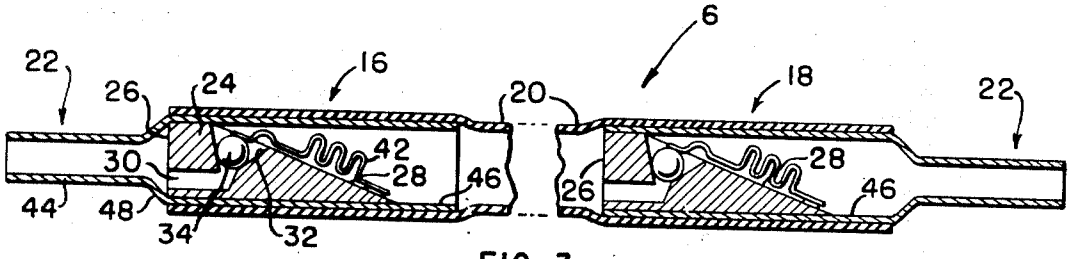


FIG. 3

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VENTRICULAR CATHETER WITH VALVE AND PUMP FLUSHING MEANS

This invention relates to a ventricular catheter system, and in particular to such a system for the continuous controlled drainage of cerebrospinal fluid from the cerebral ventricles into the bloodstream in cases of hydrocephalus and similar conditions, where there is difficulty in the free circulation and absorption of the cerebrospinal fluid.

In the drainage of cerebral ventricles, particularly where there needs to be a continuous controlled drainage, certain problems arise. Among these are particularly the problems of being able to take fluid samples from the system readily and with minimum likelihood of contamination; the problem of facilitating sterilization of the system components prior to implantation; the problem of being able to determine the position of, and clear, obstructions, if any occur, in a connected system without having to open the system; and the facilitating of making pressure readings in the system. It is the general purpose of this invention to provide a system of the above class which overcomes these problems.

Therefore, an object of this invention is to provide a system of the class described in which it is possible to tell where an obstruction lies in the system without having to open the system; the provision of a system of the above class in which it is possible in most cases to clear an obstruction if such should occur; the provision of a system in which it is possible to obtain pressure readings within the drainage system; and the provision of a system in which it is relatively easy under sterile conditions to obtain fluid samples. Other objects and advantages of this invention will be in part obvious and in part pointed out hereinafter.

The invention accordingly comprises the elements and combinations of elements, features of construction, and arrangements of parts which will be exemplified in the structures hereinafter described, and the scope of the application of which will be indicated in the appended claims.

In the drawings, which illustrate one embodiment of the invention:

FIG. 1 is a view showing the system of this invention;

FIG. 2 is a view, partly in section, showing an exemplary antechamber used in this invention; and

FIG. 3 is a sectional view of an exemplary valve unit used in this invention.

Throughout the drawings, similar reference characters indicate like parts. Also, in some of the drawings, certain parts may have been relatively enlarged for the purposes of clarity and illustration.

Referring now to FIG. 1, the drainage system of this invention is shown as comprising the four items illustrated which may be assembled into a single unit for use. The four items are a ventricular catheter **2**, an antechamber **4**, a valve-unit **6**, and a cardiac catheter **8**. In the system as shown, the means of connecting the several units of the system are conventional means. For example, a separate connector (not shown) may be used, if desired, between the proximal end of the ventricular catheter and the inlet end of the antechamber; similarly, if desired, a separate connector may be used between the outlet end of the antechamber and the inlet end of the valve unit; and like means may be used to connect the outlet end of the valve unit to the cardiac catheter. Since such connectors are not a part of this invention, no further description thereof will be given.

The ventricular catheter is preferably one described and claimed in co-pending U.S. Pat. application Ser. No. 521,209, filed January 17, 1966, now U.S. Pat. No. 3,419,010 issued December 31, 1968, and briefly consists of a cerebrospinal catheter of resilient material having a tip **9** which is hook-shaped with its entrance orifices on the inner curve of the hook. For further details of its construction and method of implantation, attention is called to said patent application, the details of which are incorporated herein by reference.

Referring to FIG. 2, there is shown in cross section the construction of the antechamber **4**. Chamber **4** is a tubular enclosure made of an elastically deformable material such as silicon rubber. That is, the wall **10** of the chamber, if pressed inwardly, will move inwardly elastically to restrict or stop the flow of fluid through the chamber, and when the pressure is removed, the wall **10** will return elastically to its original position. Chamber **4** has an inlet **12** and an outlet **14**. The ventricular catheter is connected (See FIG. 1) to the inlet **12** of the chamber **4**.

Valve-unit **6** is a one-way passage valve, that is, it permits fluid to flow therethrough in one direction but not in the other. As drawn in FIG. 1, fluid will flow through valve unit **6** from left to right. Such a valve may be that shown, for example, in co-pending U.S. Pat. application, Ser. No. 363,110 (now U.S. Pat. No. 3,288,142, issued November 29, 1966), the construction of which is shown in FIG. **3** herein and of which a brief description is as follows, attention being called to said last specified application for complete details which are incorporated herein by reference: the valve unit **6** comprises a pair of spring operated ball-type check valve assemblies made of metal or other relatively inert and non-toxic material not affected by temperature in the surgical sterilization range. The twin valve assemblies are arranged in series to face in the same direction, that is, the outlet of one valve assembly is adjacent the inlet of the other, and the individual valve assemblies are connected by a flexible conduit.

The valve assemblies are for the most part identical and are illustrated generally by numerals **16** and **18**. As indicated, they are connected together by a length of flexible hollow tubing or conduit **20**. Each check valve assembly comprises a check valve fitted within an outer hollow, cylindrical capsule **22** which is open at both ends. Each check valve has the body portion **24** which is formed from an elongated solid cylinder preferably of stainless steel, which is cut obliquely to its longitudinal axis from a point spaced from but near the inlet end face **26** of the body portion to form a downwardly sloping outlet face **28** which forms the outlet end portion of the valve body. An inlet passage **30** extends inwardly into the body **24** parallel to its longitudinal axis, but below the center line thereof, from the inlet end face **26**. At the upper end of the obliquely slanting outlet end face **28**, a funnel-shaped bore **32** extends downwardly into the body **24** to meet the inlet passage **30**, the funnel-shaped bore **32** symetrically decreasing in diameter from the outside of the body and having an inverted frusto-conical shape. The interior of the bore **32** is polished to a mirror-like finish and holds a ball **34** which is loosely contained herein. The ball **34** is a highly polished sphere of either the identical material as the valve body **24** or a hard material which will not establish an electro-potential with the valve body, synthetic sapphire being the preferred material. The diameter of the ball **34** is intermediate that of the top and bottom portions of the conical bore **32** so as circumferentially to contact the wall of the conical bore **32** intermediate its length and hermetically seal the passage from the inlet of the valve to the outlet, this passage comprising the inlet passage **30** and the connecting tapered bore **32**. A flat spring **36** preferably of stainless steel, overlies the obliquely slanting outlet face **28** with the lower end of the spring suitably fastened to the outlet face, and the upper end contacting the top of the valve ball **34** to force it resiliently downwardly into a seating engagement with the bore **32**. (In the particular embodiment shown, the spring illustrated has three loops to provide extra length and suitable resilience.) Obviously, the spring constant can be varied by varying the width of the spring, and thus valves with different operating pressures can be provided.

Each capsule **22** is preferably made of stainless steel, and has two cylindrical end portions **44** and **46** of different diameters joined by a tapered intermediate section **48**. The large end portion **46** of each valve fits within one end of the aforementioned flexible tubular conduit **20** which connects the two valve assemblies **22**.

As illustrated in FIG. **3**, in one valve assembly **16**, the check valve is installed with the inlet end face **26** of the valve body adjacent the tapered intermediate section **48**, so that the inlet

passage **30** is directly connected with the small diameter end portion **44** of the capsule. In the other valve assembly, the check valve **18** is installed in the capsule in the reverse direction, that is, the inlet end face **26** thereof is adjacent the open end of the large diameter end portion **46** of the capsule so that the slanting outlet end face **28** of the valve is adjacent the small end portion of the capsule.

As in the case of the antechamber, the conduit **20** is made of a flexible resilient material having normally a shape as shown, and which is capable of returning elastically to the said shape if the wall of the conduit is first collapsed and then released. Also, as has been indicated, the valve unit comprising the two valves **16** and **18** together with the flexible conduit **20** is installed in the system of this invention so that cerebrospinal fluid will flow from left to right as drawn, that is, from valve **16** to valve **18**.

The cardiac catheter is connected to the outlet of valve-unit, that is, to the outlet end of valve **18**.

While a specific kind of check valve is shown, nevertheless other check valves may be used, provided they are connected as a valve-unit by means of a flexible conduit. The reason for this will be understood in the following description which explains the use of the system and its advantages.

In view of the fact that the four principle elements of the system may be disconnected, each of these elements may be sterilized using proper sterilization procedures, or, the four units as assembled may be sterilized as a complete system, and after sterilization the system may be placed in the sterile field and disassembled to facilitate manipulation.

In use, the ventricular catheter is suitably implanted, and is then trimmed to the desired length. The antechamber, valve unit, and cardiac catheter are then connected and implanted, following accepted surgical techniques.

The purpose of the antechamber is four fold: first of all, pressure readings may be taken by the introduction thereinto of a small hypodermic-needle probe. Secondly, fluid samples of the cerebrospinal fluid may be obtained by the same means. Third, clogging, if it occurs, can be readily located by the proper manipulation of the antechamber; and fourth, by proper manipulation, clogged areas may be cleared, all as explained below.

The system may be tested by placing the end of the ventricular catheter in a beaker of clean water, and then by squeezing and releasing the flexible conduit of the valve-unit several times, the system may be filled with water and thus forced out of the end of the cardiac catheter. If the antechamber is compressed and returns to its original shape after release of the pressure, the system is functional up to this point. If the valve-unit is squeezed and released, and both readily compresses and then returns to its original shape after release of the pressure, the system is functional throughout. This two step procedure is the one that should be employed for periodic inspection of the system function after implantation.

A clogged system may be simulated, prior to implantation, as follows: the symptom will be a clogging of the ventricular catheter, and this may be simulated by pinching this catheter. With the ventricular catheter thus closed, the antechamber is squeezed and released. It will compress readily, because any fluid contained therein will be forced out of the valve-unit. However, as long as the ventricular catheter is clogged, the antechamber walls will remain compressed together, since the action of the closed ventricular catheter combined with the action of the one-way check valves in the valve-unit **6** prevents any reverse flow of fluid which would permit the antechamber to return to its normal shape. The remedy for this condition, in vivo, is to occlude firmly the connection between the outlet side of the antechamber and the inlet side of the valve-unit, and then by squeezing the antechamber, it will act as a pump, forcing fluid backward through the ventricular catheter and freeing the clogged area.

The next situation that may be tested for is clogging between the antechamber and the valve-unit. The symptom may be simulated by pinching the connecting tube between the antechamber and the valve-unit. If, now, the antechamber is squeezed and released, it will react normally (assuming the ventricular catheter is not blocked). On the other hand, if while maintaining the connection pinched as thus described, the valve-unit is squeezed and released, the flexible conduit **20** will compress readily, but will remain flat because of the one-way action of the valves in the valve-unit. The latter is, then, the symptom of a system clogged between the antechamber and the valve unit. The remedy, in vivo, is firmly to occlude the ventricular catheter just prior to the inlet end of the antechamber, and then the latter is squeezed. It will force its contained fluid toward and through the valve-unit, and thus free any blockage in the connection between the antechamber and the valve-unit.

Thirdly, a symptom is clogging in the valve-unit output, that is, in the cardiac catheter. This symptom may be simulated by pinching the cardiac catheter. With this catheter pinched, if the antechamber is squeezed and released, it will react normally. On the other hand, if the valve-unit is squeezed, it will resist compression because valve **17** will not permit the flow of fluid backward, but the pressure will be transmitted through valve **18** to the point of compression of the cardiac catheter. This resistance to compression is the indication of a system clogged in the valve-unit output or in the cardiac catheter. The remedy, in vivo, is firmly to squeeze the valve-unit. This action will force fluid through the clogged area in the cardiac catheter and dislodge any debris therein.

After implantation, if the system is clogged in the areas causing the antechamber or valve-unit to remain compressed, the clogging is rarely complete, and enough fluid will seep by the obstruction to allow those components to return slowly to their original shape. Testing can therefore be readily done. After implantation, the force required to occlude the sections or to squeeze closed the conduit of the valve-unit or the walls of the antechamber, may be provided by pressing the respective component against the patient's skull with a finger.

It is to be noted that one of the main advantages of the system is the ability to detect the location of clogged areas. This function and advantage is obtainable by the cooperation between the antechamber and the one-way valve unit.

Another advantage of the system is that the units may be made small in size, and thus implantation of the antechamber and the valve-unit by means of subcutaneous tunnel is facilitated.

A further advantage is that the system may be periodically tested after implantation by two basic steps: first, the antechamber is pressed and released. If it readily compresses and returns to its original shape, the system is functional to that point. Secondly, the valve-unit is pressed and released. If it readily compresses and returns to its original shape, the entire system is functional. If either the antechamber or the valve-unit fails to return to its shape, or if resistance to compression is felt, then, as explained above, the location of the clogged area will be known and the proper steps to remove the obstruction may be followed.

For clearance of an obstructed ventricular catheter in normal situations, the system is occluded between the antechamber and the valve-unit, and then the antechamber is firmly pressed. This should be sufficient to clear the obstruction. However, if the obstruction cannot be dislodged with this method, a syringe of sterile saline solution may be used by penetrating subcutaneously the antechamber under aseptic conditions. Forcing the fluid of the syringe into the antechamber, with the connection between the antechamber and the valve unit occluded, will generally provide sufficient pressure to dislodge any obstructions in the ventricular catheter. A small diameter needle should be used, and one should avoid injecting large amounts of fluid.

In the event that the clogging is between the antechamber and the valve unit, the ventricular catheter is to be occluded, and then the antechamber is to be pressed. This should be sufficient to clear the obstruction, but if not, the syringe method

described may be followed, with the ventricular catheter manually occluded. This same technique may be used to clear abnormal clogging in the valve-unit output or the cardiac catheter.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

It is to be understood that the invention is not limited in its application to the details of construction and arrangement of parts illustrated in the accompanying drawings, since the invention is capable of other embodiments and of being practiced or carried out in various ways. Also, it is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

As many changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings, shall be interpreted as illustrative and not in a limiting sense, and it is also intended that the appended claims shall cover all such equivalent variations as come within the true spirit and scope of the invention.

I claim:

1. A ventricular drainage device surgically implantable beside the skull for relieving excess pressure within the brain comprising, in combination, a catheter for ventricular drainage, an ante-chamber, a valve unit, and a conduit for draining fluid toward the heart, all connected in series for the passage of fluid from the catheter through the ante-chamber through the valve unit and to the conduit, said ante-chamber being a resiliently collapsible walled enclosure having spaced apart tubular inlet and outlet portions at separate ends of said enclosure extending from said enclosure, said tubular portions being in substantial planar alignment to permit said portions to be positioned alongside the skull, said walled enclosure being of larger cross-sectional area than said tubular portions to render the ante-chamber pumpable by digital pressure against the skull while flow through the ante-chamber may be controlled by selectively occluding the drainage device by digital pressure against the skull.

2. A ventricular drainage device as defined by claim 1 wherein the said ante-chamber is composed entirely of flexible resilient material.

3. The device defined by claim 1 wherein said valve unit includes a resilient wall portion and a second one-way valve means downstream therefrom, rendering said valve unit pumpable such that pressure on said wall portion forces fluid toward the heart and said second valve means prevents fluid flow into the valve unit in the reverse direction.

4. The device defined by claim 1 wherein said ante-chamber connects to said valve unit through a collapsible resilient conduit occludable by pressure against the skull.

5. The device defined by claim 2 wherein said valve unit includes a resilient wall portion and a second one-way valve means downstream therefrom, rendering said valve unit pumpable such that pressure on said wall portion forces fluid toward the heart and said second valve means prevents fluid flow into the valve unit in the reverse direction.