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[54] CHECK VALVE FOR DRAINAGE OF FLUID INTO THE VASCULAR SYSTEM OR INTO A BODY CAVITY FOR THE TREATMENT OF HYDROCEPHALUS INTERNUS AND EXTERNUS

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

[58] **Field of Search** ..... 128/350 V; 137/536

[56] **References Cited**

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[57] **ABSTRACT**

The check valve for drainage of fluid into the vascular system or into a body cavity for the treatment of hydrocephalus internus and externus is fabricated of synthetic material and has a body with screw thread on each side. On the proximal side of the valve is screwed a connector, which has a cone and a cylindrical part to receive a proximal catheter, in addition to a screw thread for the fixing of a screw cap. On the connector is a shoulder serving as a stop for the screw cap and preventing shearing of the proximal catheter. The connector has a longitudinal bore which drains the fluid into the catheter, the bore widens to a cone and this cone is obturated by a piston, which possesses four longitudinal slots. A spring lays in the bore and can be adjusted by a regulating screw for the purpose of pressure calibration of the fluid.

3 Claims, 2 Drawing Figures

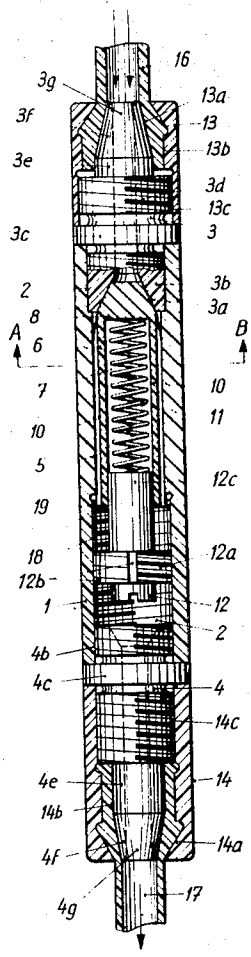
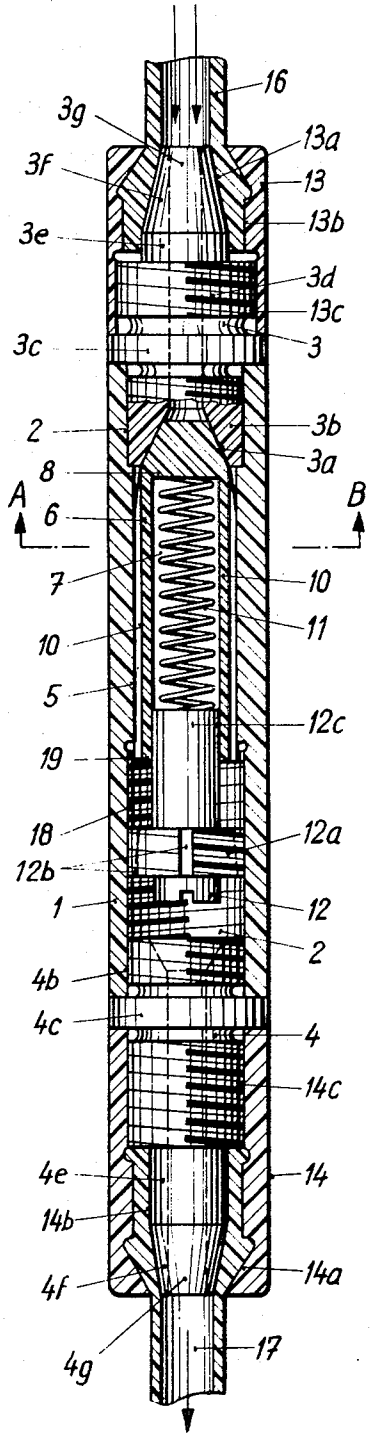


Fig.1


16
3g
13a
3f
13
3e
13b
3d
13c
3c
3
2
3b
8
3a
A
B
6
7
10
10
11
5
12c
19
18
12a
12b
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12
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4b
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14c
4e
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14b
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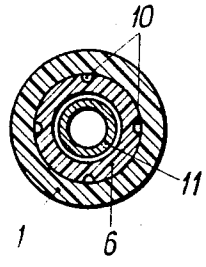
4g
17

Fig.2


10
11
1
6

CHECK VALVE FOR DRAINAGE OF FLUID INTO THE VASCULAR SYSTEM OR INTO A BODY CAVITY FOR THE TREATMENT OF HYDROCEPHALUS INTERNUS AND EXTERNUS

The present invention relates to a check valve for drainage of fluid into the vascular system or into a body cavity for the treatment of hydrocephalus internus and externus.

In the various treatment principles of hydrocephalus internus and externus the draining of the fluid into the vascular system or into a body cavity is effected by the insertion of a valve. For this purpose three types of valves have been developed. Two of them present some now well-known disadvantages. The third valve has been developed on the basis of the disadvantageous experienced with the first two valves and has only recently been on the market; experiences with this valve type are not yet available and only few scientific publications have yet appeared on this matter in the literature. The well-known disadvantage of the above first two mentioned valves can be summarized as follows:

a. Insufficient and unconstant calibration of pressure.

b. Dead spaces in the system relative to the flow of fluid and resulting there from, stasis of the fluid.

c. Slipping off and shearing off of the catheter from the valve connectors following the increase, respectively of softening and tensile stress at the points of ligature.

d. Electrostatic charging of the material; slit valve and pumping device are made of silicone so that in the case of infection the bacteria adhere to the valve and make this a source of infection.

e. Insufficient sterilizability in the autoclave of the material employed.

f. Inadequate performance of the valve, resulting in the necessity of valve replacement.

g. Internal gumming up of the valve device if the protein content of the fluid is too high.

h. Pressure necrosis as a consequence of the valve diameter size.

The first two mentioned valves are slit valves of silicone rubber, which allow an excess pressure in the valve an out flow and inhibit a back flow on an excess pressure outside the valve. The principle and the materials used do not allow an exact calibration. On storage and later after application of the valves, changes occur and in the course of time the elasticity and thereby the calibrated pressure of the silicone rubber change.

The inlet and outlet catheters are, in all the valves described till now, fixed by means of ligatures on metal connectors of the valve. There is the danger of these connections being severed by the ligatures cutting into the catheter, by slipping off of the end of the catheter and by shearing off the catheter and may lead in this manner sooner or later to serious complications.

The above-mentioned valves are constructed with materials which take up electrostatic charges and therefore, in the event of infection, bacteria adhere to the valve and cleaning can only be effected in rare cases by self-rinsing or active antibiotic rinsing by puncture.

The three valves previously mentioned, are valves for a single use and if they are to be removed for renewal they can never be replaced, because they cannot be sterilized or are not dismountable.

In the case of new-born infants and especially for premature births some of said valves are large and lead frequently to pressure necrosis.

A complication to be feared and caused by the valves known until now is the above-mentioned pressure-necrosis above the valve or in the region of the wound on the neck and by the sepsis which occurs. This danger is particularly great in the case of nursing infants whose scalps have bad blood circulations, because some of the valves are rigid and relatively large.

The object of the invention is to effect draining of cerebrospinal fluid by means of a check valve, with which it is sought to overcome the above mentioned inadequacies.

The valve according to the invention is characterized by the fact, that it is made of synthetic material and consists of a body which has a threaded end part, on each side, that on the proximal side of the valve is screwed a connector, which has a cone and a cylindrical part to receive a proximal catheter, and has also a threaded part, for the fixing of a cap, which has a cone different from the connector and clamps in this manner the proximal catheter on the connector, that on the connector is formed a shoulder which serves as a stop for the cap and prevents shearing of the proximal catheter, that the connector has a longitudinal bore which conducts the fluid from the catheter, that the bore enlarges to a cone and that this cone is obturated by a piston which possesses on its circumference four longitudinal slots for the flow of the fluid, that inside the piston a spring is disposed, which is situated outside the stream of fluid, that the spring can be adjusted with a regulating screw for calibrating the pressure of the fluid, which screw possesses a cylindrical part that serves as a stop for the spring on the one hand and as a slideway for the piston on the other hand, that in the threaded part of the regulating screw four longitudinal slots are to be found, which enable the flow of fluid, that on the distal end of the valve a connector is screwed in, the diameter of which is slightly smaller that the diameter of the proximal connector, in order to take into consideration the dimensions of the distal catheter.

For a better understanding of the invention the annexed drawing in conjunction with the following description, shows, by way of illustrative but non-limiting example, one embodiment of the invention.

In the drawing:

FIG. **1** shows a longitudinal section through the embodiment of the invention;

FIG. **2** shows a cross section along the line A–B of FIG. **1**.

In the embodiment shown in FIGS. **1** and **2**, the valve consists of a body **1** of a cylindrical shape and which has in both end portions a screw thread **2**, each of which receives a connector **3** and **4** which, preferably, are made of polyphenylenoxide, since this material is physiologically neutral, possesses good mechanical qualities, is stable to changes in temperature, is easily sterilized, has very good dimensional stability, is insensitive to electrostatic charges, has good chemical resistance to most of acids, bases, alcohols and water, and guarantees a constant flow of the cerebrospinal fluid. The proximal connector **3** consists of an internal conical part **3***b*, a shoulder **3***c*, that serves as a stop to a screw cap **13**, a threaded part **3***d*, on which, the cap **13** is screwed, a cylindrical part **3***e*, a conical part **3***f* and a bore **3***g*. The catheter **16** is disposed on the cylindrical piece **3***e* and the conical part **3***f*. The distal connector **4** is constituted by the same elements and parts **4***b–f*.

In the cylindrical bore **5** of the valve **1** is situated the valve-piston **6**. This piston consists of a conical part **8** and a bore **7**, which receives a steel spring **11**. The valve piston **6** has four longitudinal slots **10** through which flow the fluid to be drained. The conical part **8** enters the conical part of the connector **3***a* and closes the latter. The spring **11** is positioned in the bore **7** away from the fluid being drained and presses the valve piston **6** into the inner cone **3***a*. The pressure regulation is effected by means of the regulating screw **12**. This consists of a threaded part **12***a*, four longitudinal slots **12***b* and a cylindrical part **12***c* which extends into the bore **7** and regulates the spring **11**. By this means the pressure can be regulated to within 2 cm of water.

On the proximal connector **3** the catheter is fixed with the screw cap **13** and no ligature is disposed there. This screw cap consists of a conical part **13***a* the slope of which is different from that of the conical part **3***f*, a cylindrical part **13***b*, which clamps the catheter **16** and a threaded part **13***c*, which is screwed on the threaded part **3***d*. On the distal connector **4** the catheter **17** is fixed with the screw cap **14** which is constituted by the parts **14***a* –**14***c* in an analogous manner. The fluid to be drained is led by means of the bore **4***g* in the connector **4** to the distal catheter **17**. If the fluid is now flowing through the catheter **16** in the direction of the arrow through the bore **3***g*,

to the piston **6**, the latter is pushed back and the fluid can continue to flow through the four longitudinal slots **10** and **12***b* and also through the bore **4***g* into the catheter **17**. The piston remains open until the pressure falls to the value regulated by the regulating screw **12**. A back flow is impossible, because the fluid will accumulate in the chamber **18**, charges the ring area **19** and will in this manner move the piston again into its initial position, that is to say fully into the cone **3***a*.

The above-described novel valve is so constructed, that by means of regulation of a spring, the pressure may be regulated individually for each valve. The spring is situated outside the stream of fluid. The stream itself is wide and has no dead spaces. No parts are intercalated in the fluid path on which fragments of tissue, fibrin and coagula may adhere and could introduce occlusions. Even storage for many years or multiple sterilizations do not alter the pressure calibration.

The novel valve is provided with conical connectors by which the catheter is fixed by a conical screwed cap; ligatures are no longer utilized. Slipping off of the catheters is impossible. In order that the fixing may be optimal and that shearing by a too severe tightening may be avoided, the connection is constructed so that the screwed cap is drawn on to a shoulder. In this manner it is ensured that the surgeon's connection is made correctly. This means of connection is rapid and positive and also offers great advantages at the time of subsequent recatherizations.

The above-described novel valve, which, except for the spring **11**, is constructed entirely of synthetic materials, is in length and in diameter smaller than the known valves. This is mainly based on the fact, that with this valve a pumping device can be dispensed with; if it is taken in consideration that the possibility of pumping was at first developed for control purposes, it is superfluous with a well-installed and well calibrated drainage system. A pumping-system does not ensure freedom of flow and the final diagnosis of a valve connection will always be determined clinicaly or by ventrical puncture by pressure measurement and isotope methods. In other words: the pumping device introduces more disadvantages (size of the valve, dead spaces in the flow path, electrostasis of the silicone) than advantages.

We claim:

1. A check valve for draining fluid into the vascular system or into a body cavity for the treatment of hydrocephalus internus and externus, comprising a cylindrical body having a longitudinal bore and which has inlet and outlet ends thereof with screw threads in said ends; a proximal connector having first screw threads in threaded engagement with the screw threads in the inlet end of said body and closing said inlet end, said connector having a cone shaped part insertable in an end of a proximal catheter, a cylindrical part with an external screw threads and a shoulder between said cylindrical part and said first screw threads, a screw cap which has a bore with an internal cone shaped portion on a different slant from that of said connector cone shaped part and a cylindrical portion being in threaded engagement with said connector cylindrical part external screw threads whereby said cap can retain said proximal catheter end on said proximal connector, said screw cap being seated on said shoulder which serves as a stop for said screw cap, said connector having a longitudinal bore for the passage of the fluid which bore widens to a cone, a piston slideably mounted in said body bore, having a closed end bore, a conical end slideably in said bore cone for closing the same and four longitudinal slots on its periphery for ensuring the flow of fluid, a spring inside said piston bore away from the fluid, a regulating screw having a cylindrical part providing a stop for said spring and having said piston slideable thereon, said regulating screw having a screw threaded peripheral part in which are situated four longitudinal slots for the flow of fluid and which is in threaded engagement with the screw threads in the outlet end of said body, a distal connector, is threadably mounted in the outlet end of said body, has a end portion insertable in an end of a distal catheter and a longitudinal bore and a second cap detachably connected to said distal connector and capable of retaining said distal catheter end on said distal connector.

2. A check valve according to the claim **1** wherein said body and connectors are of polyphenylenoxide.

3. A check valve according to the claim **1**, wherein said body bore has a chamber between said piston and said regulating screw in which the fluid can accumulate and load the piston to avoid a back flow of blood and fluid and thus to urge the piston into its connector closing position.

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