SELF-CLOSING VALVE DEVICE FOR IMPLANTATION IN THE HUMAN BODY

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This invention relates to a self-closing valve device for implantation in the human body. More particularly, the invention relates to a valve which may be implanted in the human body without deleterious effects and which may be left therein for a relatively long period of time without undue discomfort to the patient and which will be self-sealing and will permit ready insertion there-through of a catheter or other medical instrument through which suitable medicaments may be introduced into the human body.

By way of illustration, the valve herein disclosed is especially adapted for implantation in the abdomen for use in the treatment of peritoneal dialysis, which is a treatment administered to a patient whose kidneys are either malfunctioning or not functioning at all. It is a procedure whereby a fluid called dialysate is introduced into the peritoneal cavity, the fluid then passes through the peritoneum by osmosis or actions similar thereto. After a preselected time the fluid, after having passed back through the peritoneum carrying the waste material normally rejected by the kidneys is drained. This roughly is a description of the transfer process. The introduction of dialysate into the peritoneal cavity has heretofore been accomplished by making an incision in the body wall each time a catheter insertion is required. It is apparent that after a number of such dialyzing procedures have been performed the abdominal wall is a mass of scar tissue.

An object of the invention is to provide a valve adapted to satisfy the following requirements:

(1) Permanently implantable.
(2) Body compatible.
(3) Functionally reliable to provide a snug fit between the catheter or other suitable medical instrument and the valve to prevent leakage of the dialysate during the filling or draining phases of the procedure and to provide a positive and automatic closure of the valve after the catheter or the like has been removed.
(4) A device adapted to be readily autoclaved or sterilized in a hot air oven without damage and which presents a unitary structure having a smooth outer surface free of cracks or crevices. Since the device may be implanted in the human body for a relatively long period of time, it is important that the device be as small as possible in order to minimize discomfort to the patient.

In general, the device embodies a housing or body portion within which is secured a valve member in the nature of a sphincter ring, which in the preferred embodiment takes the form of an elastomeric torus which is restricted radially so as to completely close its central orifice. This permits a lubricated probe such as a catheter or other suitable instrument to be readily passed through its central orifice so as to provide a snug fit between the catheter and the sphincter ring. The housing or body provides suitable rigidity as to hold the sphincter ring radially compressed and to provide means for securing the valve, such as by sutures, in implanted position.

Further objects, features and advantages of the invention will appear from the following specification and claims taken in connection with the accompanying drawings, in which:

FIG. 1 is a top plan view of the device showing the present embodiment of the device in approximately full scale;
FIG. 2 is a cross sectional view taken at 2—2 of FIG. 1 on a substantially enlarged scale;
FIG. 3 is a top plan view of the valve element of the device shown in FIGS. 1 and 2 on a somewhat larger scale than shown in FIG. 1 and in its normal condition before assembly;
FIG. 4 is a sectional view taken at 4—4 of FIG. 3;
FIG. 5 is a sectional view similar to FIG. 2 showing a modification; and
FIG. 6 is a cross sectional view similar to FIG. 2 showing a further modification of the device.

Referring to the drawings, and more particularly to FIGS. 1 and 2, the device is designated in general as 10 and comprises a valve element 11 secured within an axial bore 12 of a housing having a laterally extending peripheral flange 13. The housing consists of a rigid member 14 and a flexible encapsulating cover 15 which is preferably molded on and adhered to the rigid member 14 and is formed of medical grade elastomeric material tolerant to and compatible with the human body. A material which has been found highly satisfactory for this purpose is a medical grade silicone rubber having a durometer hardness of about 40 on the Shore scale. The specific material is known in the trade as "Medical Grade SILASTIC® Elastomer" obtained from Dow Corning Corporation of Midland, Mich.

The valve element 11, which I call a sphincter ring, is the most important part of the device. It is made of medical grade elastomeric material tolerant to and compatible with the human body. This element is presently made by molding a soft paste which, after curing, has substantially the same chemical composition as that of the molded coating 15 but is preferably much more resilient. The specific material which has been found entirely satisfactory for the molding of the valve element 11 is known in the trade as "Medical Adhesive Type A," which is a ready-to-use silicone material of medical grade developed for adhering silicone rubber to itself and to many other materials and is made by Dow Corning Corporation of Midland, Mich. The element 11 should be highly resilient; such as a durometer hardness of about 25 on the Shore scale. As molded, and before insertion in the bore 12, this element is in the shape of a torus ring as shown in FIGS. 3 and 4 and has an outer diameter D greater than the diameter of the bore 12 whereby, when assembled in bore 12, the ring 11 is laterally constricted; and the inner diameter d of the torus ring is of such a diameter that it is completely closed when said ring is constricted within the bore 12. The relationship of the diameters D and d and the resilient characteristics of the material are such as to permit ready insertion into the valve member 11 of a catheter or other medical instrument without exertion or undue pressure and to auto-
matically close and effect a reliable seal when such instrument is removed. In the present embodiment of the invention, a torus ring having a durometer hardness of about 80 Shore A, with a diameter D of 0.500" and a diameter d of 0.011" has proven entirely satisfactory when constricted in a bore 12 having a diameter about 3/4" smaller than the diameter D (i.e. about 0.438"").

The torus ring 11 is secured in position within the bore 12 of the member 14 as by means of medical adhesive designated as 16 of the type from which the valve member 11 is molded. It will thus be seen that the sphincter ring valve member 11 and the encapsulating housing or body 14-15 are unitarily interconnected to provide a unit which presents a smooth outer surface free of cracks or crevices, which will be well tolerated in the body, causes no irritation to tissues and which is highly resistant to the effects of body fluids, aging and oxidation and is water repellent. Also, the unit as a whole can be repeatedly autoclaved or sterilized in a hot air oven without damage and remains rubbery and elastic for as long as six months at 300° F. or up to two weeks at 500° F. At normal body temperature said material remains rubbery and elastic substantially indefinitely for all practical purposes.

The stiffening member 14, in the present embodiment made of nickel steel, serves to stiffen the elastomeric material 15 to adequately hold the valve member 11 in constricted condition and also to stiffen the peripheral flange by which the device is held in position in the human body, as for example, by suitable suturing through holes such as 17 (FIGS. 1 and 2) passing through the stiffening flange of the element 14. It will be understood that the stiffening element 14 may be made of any suitable material having the desired stiffness and be compatible for the desired use. One such other material which may be mentioned is acrylic butyl styrene. The sutures may be readily sewn through the elastomer comprising the coating 15 without providing holes therein corresponding to the holes 17. The sutures are somewhat diagrammatically shown as 18 (FIG. 2) which serve to firmly secure the valve device 10 to the abdominal wall 19. It is contemplated that since the thickness of the abdominal wall 19 will vary from patient to patient, the device will preferably be made in different sizes so that the axial length of the housing 14-15 will extend below the flange 13 a suitable distance to accommodate the thickness of the abdominal wall 19.

According to one method of utilizing the device; under local anesthesia, an incision is made in the lower mid-abdominal wall and the device is sutured to the subcutaneous fascia of the abdominal wall 19 and the skin is disposed over the device and is permitted to heal. When it is necessary to dialyze a patient, procaine is inserted into the skin and a small incision is made in the skin and the usual type of catheter used for dialysis is then put through the incision and through the valve member 11 into the peritoneal cavity. As above pointed out, the construction of the valve 11 is such that the catheter easily slips through the valve. When dialysis is discontinued, the catheter is then removed and the valve automatically seals itself. When repeated dialyses are necessary, incisions may be made in the skin in different areas merely by moving them to one side or the other. In use there has been no evidence of infection or leakage and the patients have tolerated the procedure extremely well. It is contemplated that further use of the device may indicate that the precaution of placing the skin over the device may be unnecessary and that the skin together with the subcutaneous fascia may be sutured beneath the flange 13 and the sphincter ring 11 may be relied upon to form a sufficiently dependable seal.

Modification (FIG. 5)

FIG. 5 shows a modification in which the entire unit as well as the parts are identical except that the stiffening element 14 is provided with an annular rib 14a disposed within the bore designated 12a and this rib is engaged within the cooperating groove 11a formed in the valve member 11a. The interlocking internal rib 14 and the cooperating groove 11a serve as additional means for securing the valve member and body together.

Modification (FIG. 6)

FIG. 6 shows a modification in which the entire unit as well as the parts are identical except that in the embodiment of FIG. 6, in addition to the upper flange 13a, a substantially identical flange 13b is provided and encapsulating material 15b extends inwardly under the lower flange of the stiffening member 14b and thence upwardly within the bore 12a to adjacent the valve member 11a. In the use of the device shown in this embodiment, the upper flange 13a may be sutured to the subcutaneous fascia in the manner above described in connection with FIG. 2 and the lower flange 13a may be sutured to the peritoneum designated as P. In the use of the device of this embodiment, the peritoneum is provided with an opening designated PO, so that when the catheter or other suitable instrument is inserted through the valve member 6, the dialyzing fluid may be introduced into the peritoneal cavity.

Having thus described my invention with particularity with reference to the preferred form, it will be obvious to those skilled in the art, after understanding my invention, that other changes and modifications may be made thereinto without departing from the spirit and scope of the invention and I aim in the appended claims to cover such changes and modifications as are within the scope of the invention.

What I claim is:

1. A self-closing valve device for implantation in the human body comprising a housing having an axially extending bore and a laterally extending peripheral flange, a sphincter ring formed of medical grade elastomeric material tolerant to and compatible with the human body and adapted to be autoclaved or sterilized in a hot air oven without damage, said ring being secured within said bore to provide therewith a unitary device, said ring having a normal outer diameter greater than the diameter of said bore, whereby said ring is laterally constricted, and a relatively small inner diameter which is completely closed when said ring is constricted within said bore, said unitary device presenting a smooth outer surface free of cracks or crevices and which will be well tolerated in the human body free of irritation to tissues and highly resistant to the effects of body fluids.

2. A self-closing valve device for implantation in the human body comprising a housing having an axially extending bore and a laterally extending peripheral flange, a sphincter ring formed of medical grade elastomeric material tolerant to and compatible with the human body and adapted to be autoclaved or sterilized in a hot air oven without damage, said ring being secured within said bore, said ring having a normal outer diameter greater than the diameter of said bore, whereby said ring is laterally constricted, and a relatively small inner diameter which is completely closed when said ring is constricted within said bore, said body portion comprising a relatively rigid reinforcing member provided with a sleeve portion and a flange portion adjacent one end thereof, said reinforcing member being encapsulated by medical grade elastomeric material tolerant to and compatible with the human body.

3. A self-closing valve device for implantation in the human body comprising a housing having an axially extending bore and a laterally extending peripheral flange, a valve member in the shape of a torus consisting of medical grade silicone rubber or the like material having a durometer number of the order of about 25 on the Shore scale, said torus valve member being secured within said bore, said torus valve member having a normal outer diameter greater than the diameter of said bore, whereby
said torus valve member is laterally constricted, and a relatively small inner diameter which is completely closed when said torus valve member is constricted within said bore, said body portion comprising a relatively rigid reinforcing member provided with a sleeve portion and a flange portion adjacent one end thereof, said reinforcing member being encapsulated by medical grade elastomeric material tolerant to and compatible with the human body.

4. A device as set forth in claim 3 wherein the diameter $D$ of said torus is about 0.50", the bore of the housing is about 0.438" and the diameter $d$ of said torus is about 0.01".

5. A self-closing valve device for implantation in the human body comprising a housing having an axially extending bore and a laterally extending peripheral flange, a sphincter ring formed of medical grade elastomeric material tolerant to and compatible with the human body and adapted to be autoclaved or sterilized in a hot air oven without damage, said ring being secured within said bore, said ring having a normal outer diameter greater than the diameter of said bore, whereby said ring is laterally constricted, and a relatively small inner diameter which is completely closed when said ring is constricted within said bore, said body portion comprising a relatively rigid reinforcing member provided with a sleeve portion and flange portions adjacent respectively opposite ends thereof, said reinforcing member being encapsulated by medical grade elastomeric material tolerant to and compatible with the human body.

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