3.378,011
SELF-INFLATING CATHETER WITH MEANS TO PREVENT LEAKAGE OF INFLATION FLUID

John P. Vitello, 198 Robin Hill Road, Williamsville, N.Y. 14221
Filed Jan. 23, 1965, Ser. No. 466,383
5 Claims. (Cl. 128—349)

This invention relates to self-inflating balloon catheters and pertains more particularly to means for prolonging the useful storage life thereof.

Self-inflating bag catheters may conventionally employ water or other liquid contained within an inflated, elastic reservoir tube which fluid, when released, is adapted to inflate the retention sleeve or bag of the catheter device and so retain the same in proper position within the bladder of the patient after insertion of the catheter. The elastic reservoir tube is normally constructed of rubber or other suitable elastic material and although such materials are not normally propense to leak fluid, there is a definite tendency for inflating fluid leakage to occur while the reservoir tube is in inflated condition. As a result, it may occur that during the normal storage time prior to use of such catheter devices that sufficient fluid leakage will occur as to render the device useless. This is a serious problem particularly in view of the fact that the precise amount of fluid contained within the inflated reservoir tube is such that when released for inflating the retention bag, a rather precise amount of fluid must be transferred to the bag area for effecting distention thereof to the desired size. Obviously, then, no substantial degree of inflating fluid volume diminution can be tolerated.

Attempts have been made to coat the inflated reservoir tube with a suitable material forming a sealant therefor but this solution is not entirely satisfactory owing to the fact that flaking and peeling away of the coating material or sealant occurs in response to the release of the inflating fluid to perform its bag or sleeve distending function. As a consequence, flakes and strips of the coating sealant form debris which are contaminants for an otherwise sterile field.

The present invention is directed to a catheter device which overcomes the above disadvantages and, more particularly, it is of primary concern in connection with this invention to provide an improved catheter device of the type generally specified hereinafore wherein the inflated reservoir tube is enclosed in a flexible but substantially inelastic bag or sac which forms a barrier at the outer surface of the inflated portion of the reservoir tube.

More particularly, it is an object of this invention to provide a barrier or seal for the inflated reservoir tube of a self-inflating bag catheter in which the sealing means is in the form of an enclosure against the inner surface of which the inflated reservoir tube is engaged to form, theret, and substantially throughout the area of the inflated reservoir tube, a seal or barrier preventing the loss of fluid from the inflated reservoir tube and thus prolonging the storage life of the catheter device.

A further object of this invention resides in the provision of a bulbous encasing sleeve or sac which is anchored in place by the plug normally closing the open end of the reservoir tube and through which the inflating fluid is administered so that the bulbous sleeve is retained firmly in place and in proper sealing relationship to the inflated reservoir tube portion disposed therewithin.

A further object of this invention is to provide an assembly as described in which the conventional plug for the reservoir tube is clamped and more securely held in place by the sealing means for the reservoir tube.

Other objects and advantages of this invention will appear from the specification hereinafter and the accompanying drawing, wherein:

FIG. 1 is a plan view of a catheter constructed in accordance with the present invention and illustrating a portion of the sealing device and inflated reservoir tube broken away to show details of construction;

FIG. 2 is a longitudinal section taken through the assembly shown in FIGURE 1 but illustrating the reservoir tube in relaxed condition after having expelled the inflating fluid therefrom to the anchor sleeve device of the catheter;

FIG. 3 is a transverse section taken substantially along the plane of section line 3—3 and illustrating the sealing relationship between the inflated reservoir tube and the pouch or sac enclosing the same;

FIG. 4 is a transverse section taken substantially along the plane of section line 4—4 in FIGURE 2 showing the same assembly as in FIGURE 3 but with the reservoir tube relaxed; and

FIGS. 5, 6 and 7 are views illustrating sequential operations in the formation of the sealing device.

With reference now more particularly to FIGURES 1 and 2, the catheter device therein is indicated generally by the reference character 10 and will be seen to include a main shaft portion 12 provided, at its distal end, with a bluntly tipped or nose 14 having side drainage openings 16 therein, the nose or tip 14 being rounded or otherwise smoothly configured so as to provide ease in insertion through the urethra of the patient. As can be best seen in FIGURE 2, the main shaft 12 is provided with a drainage passage 18 extending to the tip 14 and communicating with the drainage openings 16 and, at the proximal end of the device, a drainagetube portion 20 is provided which is adapted to be connected to any suitable drainage mechanism 22. The main shaft 12 is also provided with an inflating lumen 24 which has an opening 26 rearwardly of the tip 14. A sleeve or bag 28 is joined or otherwise sealed or fused with the shaft body 12 at opposite ends 30 and 32 of the sleeve to permit fluid under pressure in the distention lumen 24 to inflate the sleeve or bag 28 in the manner illustrated in FIGURE 2. It will be understood, of course, that the shaft 12 is inserted through the urethra sufficiently to place the tip 14 and the sleeve 28 within the patient's bladder so that when the bag 28 is inflated as shown in FIGURE 2, the catheter is firmly anchored within the bladder so as to prevent accidental removal or retraction of the device.

The distention fluid lumen 24 communicates with a branched reservoir tube portion 34 which is provided, at its proximal end, with a plug member 36 thereby closing the open end of the tube 34. Initially, the tube portion 34 is pinched off or closed by a suitable clamp device 38 to allow inflation of the reservoir tube 34 between the member 38 and the plug 36 by the insertion of a hypodermic needle through the plug 36 and the injection of a prescribed amount of fluid into the tube 34. This, of course, is entirely conventional and by reason of the fact that the catheter device is formed of elastic material, the elastic tube 34 will swell and form a reservoir of pressurized fluid which, when released by removal of a clamp 38, will inflate the bag 28 substantially as is shown in FIGURE 2.

As has been stated, the problem encountered with catheter devices of this nature concerns the leakage of
the fluid from the inflated reservoir tube 34 which, although relatively slow, nevertheless prohibits any lengthy storage time of the catheter device prior to its use. According to the present invention, a seal or barrier is provided at the outer surface of the distended portion of the tube 34 so as to preclude the gradual leakage of pressurizing fluid therefrom. The manner in which this is accomplished specifically may be best seen by reference to FIGURES 5-7 inclusive. As shown in FIGURE 5, the proximal end of the reservoir tube 34 is sandwiched between a pair of sheets 40 and 42 constructed of substantially inelastic material such as polyvinyl chloride, polyethylene or the like.

These sheets are then heat-sealed together as indicated by the cross-hatched areas 44 in FIGURE 6 so as to form collars 46 and 48 more or less firmly engaging the reservoir tube 34 at spaced points thereof, the former collar 46 preferably embracing the large region of the proximal end of the reservoir tube 34 within which the plug 36 is received. Ultimately, the sheets 40 and 42 may be trimmed away just outside the heat-bonded regions thereof substantial as is shown in FIGURE 7. At this point, the relaxed reservoir tube, as is shown in FIGURE 4 is loosely housed within the barrier sac or bag 50 formed by the process illustrated in FIGURES 5-7 and the clamp device 38 is applied at or near the collar portion 48 substantially as is shown in FIGURE 1 wherein the pressurizing fluid is injected into the tube so as to cause the reservoir tube 34 to swell between the collar portions 46 and 48 to the extent that the outer surface of the reservoir tube between such collar portions engages against the inner surface of the sac or bag 50. This effect is illustrated in FIGURES 1 and 3, the pressurizing fluid being indicated therein by the reference character 52. A good, tight sealing barrier is formed by virtue of the fact that the material or bag 50 is substantially inelastic as compared to the reservoir tube 34 so that the bag 50 is merely tightly inflated but not significantly distended. This effect also causes the reservoir tube 34 to swell and very tightly engage with the collar portions 46 and 48 of the bag, in effect, to be wedged therewithin so that throughout the distended area of the tube 34, a sealing barrier is provided which will prevent the leakage of pressurizing fluid therefrom.

It will be noted that it is not essential that the clamp device 38 be engaged exactly on the collar 48 since it is only necessary that it be close thereto. If the clamp device 38 is spaced from the collar 48 by only a slight amount, the region of the reservoir tube between the collar 48 and the device 38 will not swell and distend under the influence of the pressurizing fluid so that no problem of leakage will occur therewith.

I claim:

1. In an inflatable bag catheter device of the type having an elongate main shaft portion provided with a tip at its distal end and a drainage tube portion, an inflatable reservoir tube branching from said main shaft portion, an elastic reservoir tube surrounding said main shaft portion adjacent its distal end, and a distention fluid lumens communicating said reservoir tube with said sleeve, the improvement comprising:

means for closing the proximal end of said reservoir tube,
releasable clamp means closing said reservoir tube at a point spaced from said means for closing the proximal end of the reservoir tube to form a fluid chamber therebetween,

a sealing bag enclosing a portion of said reservoir tube between said releasable clamp means and said means for closing said reservoir tube, and enclosing a volume substantially greater than the enclosed portion of the reservoir tube when relaxed, said bag being constructed of fluid impervious and flexible but substantially inelastic material,

and a quantity of fluid in said chamber of an amount to expand the enclosed portion of said reservoir tube into contact throughout with the inner surface of said sealing bag.

2. In the inflatable bag catheter of the type having an elongate main shaft portion provided with a tip at its distal end and a drainage tube portion at its proximal end and a drainage passage communicating said tip and said drainage tube portion, an elastic reservoir tube branching from said main shaft portion, an inflatable sleeve surrounding said main shaft portion adjacent its distal end, and a distention fluid lumen communicating said reservoir tube with said sleeve, the improvement comprising:

means blocking said reservoir tube at spaced points thereon to define an inflating fluid chamber therebetween,

a quantity of fluid within said chamber of such amount as to inflate said tube,

and a sealing bag enclosing the inflated portion of said tube and contacting the inflated portion of said tube throughout the outer surface thereof to form a sealing barrier at and throughout the outer surface of said inflated portion of said tube, said sealing bag being constructed of fluid impervious material.

3. In an inflatable bag catheter of the type having an elongate main shaft portion provided with a tip at its distal end and a drainage tube portion at its proximal end and a drainage passage communicating said tip and said drainage tube portion, an elastic reservoir tube branching from said main shaft portion, an inflatable sleeve surrounding said main shaft portion adjacent its distal end, and a distention fluid lumen communicating said reservoir tube with said sleeve, the improvement comprising:

means blocking said reservoir tube at spaced points thereon to define an inflating fluid chamber therebetween,

a quantity of fluid within said chamber of such amount as to inflate said tube,

and a substantially inelastic bag enclosing the inflated portion of said tube and contacting the inflated portion of said tube throughout the outer surface thereof to form a sealing barrier at and throughout the outer surface of said inflated portion of the tube, said sealing bag being constructed of fluid impervious material.

4. In an inflatable bag catheter device of the type having an elongate main shaft portion provided with a tip at its distal end and a drainage tube portion at its proximal end and a drainage passage communicating said tip and said drainage tube portion, an elastic reservoir tube branching from said main shaft portion, an inflatable sleeve surrounding said main shaft portion adjacent its distal end, and a distention fluid lumen communicating said reservoir tube with said sleeve, the improvement comprising:

a pair of sheets of fluid impervious and substantially inelastic material sandwiching a portion of said reservoir tube therebetweeen, said sheets being joined together to present necked portions snugly engaging said reservoir tube at spaced points thereon and intervening portions between said necked portions which allow inflation of the reservoir tube between the necked portions,

means blocking said reservoir tube substantially at said spaced points to define an inflating fluid chamber, and a quantity of fluid in said chamber of an amount to expand said reservoir tube into contact throughout with the inner surfaces of said sheets.

5. In an inflatable bag catheter device of the type having an elongate main shaft portion provided with a tip at its distal end and a drainage tube portion at its proximal end and a drainage passage communicating said tip and said drainage tube portion, an elastic reservoir tube branching from said main shaft portion, an inflatable
sleeve surrounding said main shaft portion adjacent its distal end, and a distention fluid lumen communicating said reservoir tube with said sleeve, the improvement comprising:

5 a substantially inelastic sac enclosing a portion of said reservoir tube, said sac having a necked down portion at its opposite ends engaging spaced points along the reservoir tube and being bulbous therebetween, said sac being constructed of fluid impervious material,

6 means for blocking said reservoir tube adjacent said necked down portions of the sac to define an inflating fluid chamber therebetween, and a quantity of fluid in said chamber in an amount to expand the enclosed portion of said reservoir tube into sealing contact throughout with the bulbous inner surfaces of said sac.

References Cited

UNITED STATES PATENTS

<table>
<thead>
<tr>
<th>Patent Number</th>
<th>Date</th>
<th>Inventor</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,050,066</td>
<td>8/1962</td>
<td>Koehn</td>
<td>128—349</td>
</tr>
<tr>
<td>3,190,291</td>
<td>6/1965</td>
<td>Foley</td>
<td>128—349</td>
</tr>
<tr>
<td>3,275,001</td>
<td>9/1966</td>
<td>Rosecrans</td>
<td>128—349</td>
</tr>
<tr>
<td>3,235,069</td>
<td>2/1966</td>
<td>Bennett et al.</td>
<td>206—632</td>
</tr>
</tbody>
</table>

OTHER REFERENCES


DALTON L. TRULUCK, Primary Examiner.
Disclaimer


Hereby enter this disclaimer to claim 2 of said patent.