

[54] **SELF-INFLATING CATHETER WITH
DEFLATING MEANS AND RESERVOIR**

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[51] **Int. Cl.**..... **A61m 25/02**

[58] **Field of Search**..... **128/349 B, 349 BV**

[56] **References Cited**

UNITED STATES PATENTS

3,275,001	9/1973	Rosecrans	128/349 BV
3,378,011	4/1968	Vitello	128/349 B
3,379,197	4/1968	Hayes	128/349 B

3,482,576	12/1969	Ericson et al.	128/349 BV
3,599,620	8/1971	Balin	128/349 B
3,602,226	8/1971	Ericson	128/349 B

Primary Examiner—Channing L. Pace

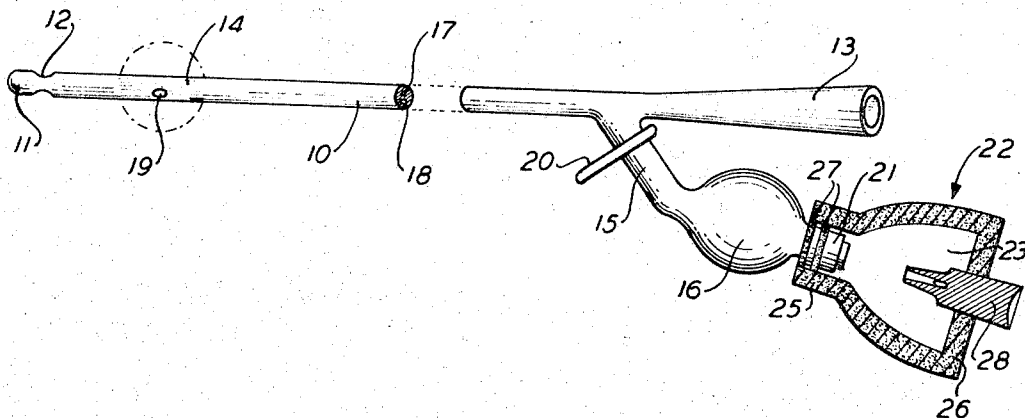
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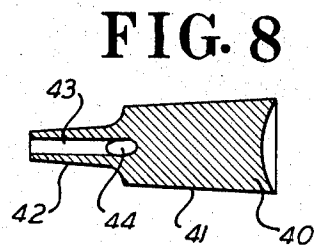
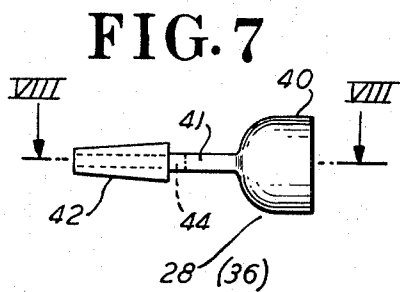
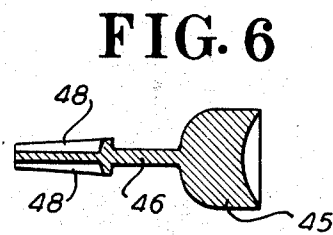
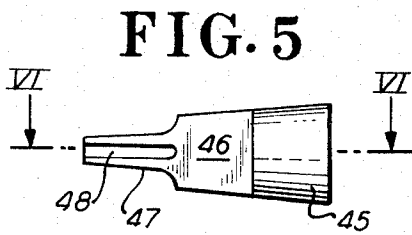
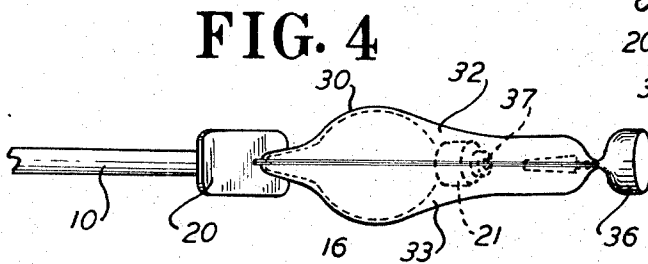
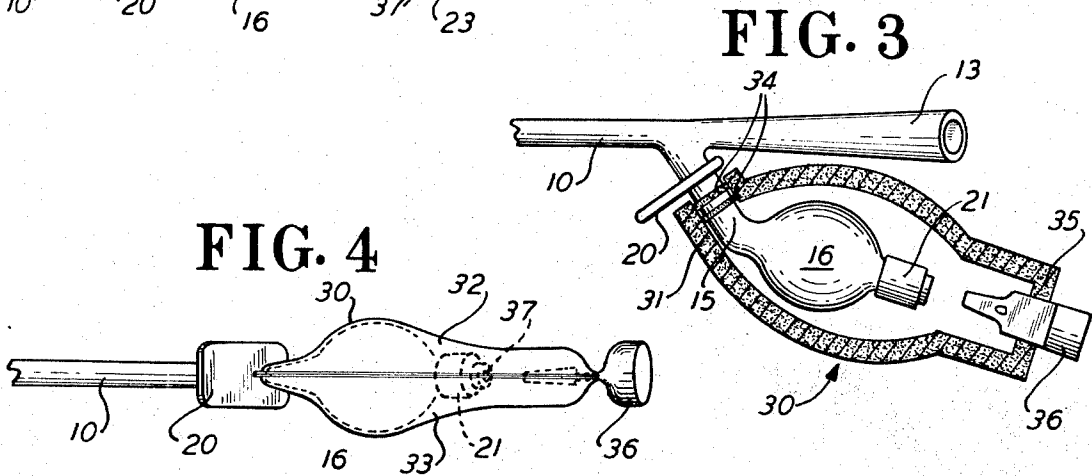
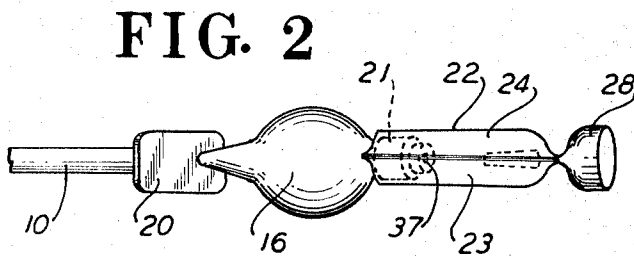
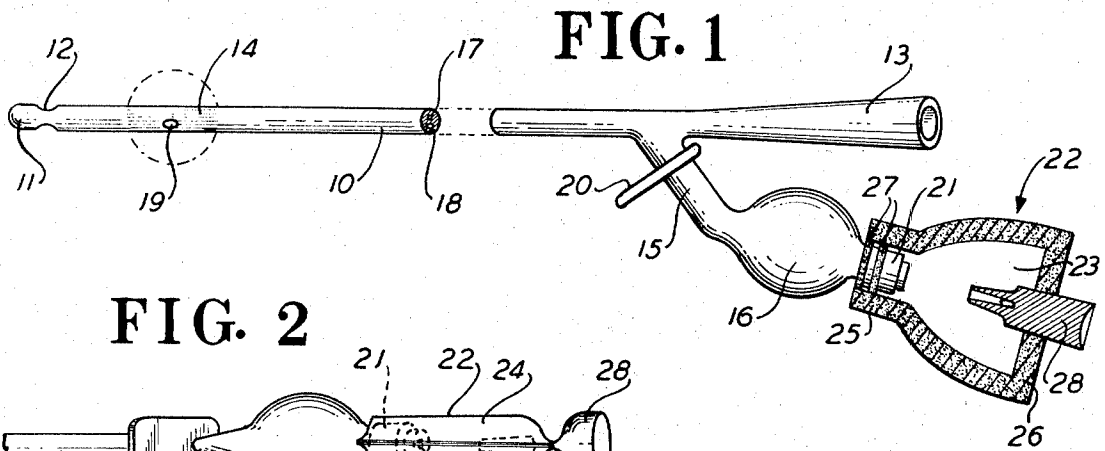
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ABSTRACT

An inflatable retention catheter having a resilient, valved, reservoir retaining a fluid under pressure, for automatic inflation of a retention balloon, is provided with an auxiliary reservoir enclosing or attached to the resilient reservoir and having in its wall a valve release device adapted to be manipulated to open the reservoir valve and permit emptying of the balloon, the fluid being received in the auxiliary reservoir.

9 Claims, 8 Drawing Figures





SELF-INFLATING CATHETER WITH DEFLATING MEANS AND RESERVOIR

This invention relates to Foley (balloon) catheters of the self-inflating type, i.e. provided with a resilient, valved, reservoir which is initially loaded with a fluid, such as sterile water, under pressure such that when released into the inflation lumen of the catheter, it will flow into and inflate the balloon for retention of the distal end of the catheter in a body cavity such as the bladder. A catheter of this type is shown in Rosecrans U.S. Pat. No. 3,275,001. The reservoir is normally provided with a valve through which the fluid may be passed, under pressure, from a syringe. When the catheterization is to be terminated the balloon must be allowed to deflate, and this is effected most neatly by using a syringe to withdraw the fluid through the valve. On the other hand it is quite a common practice to merely cut off the reservoir and let the fluid spill out, hopefully but not necessarily into a suitable receptacle.

It is an object of this invention to provide an auxiliary reservoir which surrounds at least the valve, which has sufficient capacity to hold the fluid expelled from the balloon (when deflation is desired) and which has conveniently located in its wall a device which can be manipulated (externally) to open the valve and enable the fluid to escape from the balloon and first reservoir into the auxiliary reservoir, where it is retained without spilling and can be discarded with the used catheter.

A further object of the invention, in one of its aspects, is to enclose the inflation reservoir within the auxiliary reservoir to minimize loss of the inflation fluid through the inflation reservoir wall during storage, thus greatly increasing the shelf life of the catheter. This function is disclosed (without provision of deflation means) in the patents to Vitello, U.S. Pat. No. 3,378,011; Hayes, U.S. Pat. No. 3,379,197; Balin, U.S. Pat. No. 3,599,620, and Ericson, U.S. Pat. No. 3,602,226.

Practical embodiments of the invention are shown in the accompanying drawing, wherein:

FIG. 1 represents an elevation of a complete self-inflating catheter, the auxiliary reservoir being in longitudinal section, the inflated shape of the balloon being in broken lines, and part of the catheter shaft being broken away;

FIG. 2 represents a detail view of the reservoir end of the catheter shown in FIG. 1 looking upward from the bottom of that figure;

FIG. 3 represents a detail view, corresponding to the reservoir end of FIG. 1, showing in section a modified form of auxiliary reservoir.

FIG. 4 represents a view of the parts shown in FIG. 3, looking upward from the bottom of that figure;

FIG. 5 represents an elevation of one form of valve opening device;

FIG. 6 represents a longitudinal section on the line VI—VI of FIG. 5;

FIG. 7 represents an elevation of an alternative form of valve opening device; and

FIG. 8 represents a longitudinal section on the line VIII—VIII of FIG. 7.

Referring to the drawing, a typical self-inflating Foley catheter has a shaft 10, a distal tip 11, drainage eyes 12, drainage funnel 13, inflatable retention balloon 14, side arm 15 and inflation reservoir 16. The drainage lumen 17 extends from the eyes 12 to the funnel 13 and a

small inflation lumen 18 extends from one or more holes 19, within the balloon, through the side arm 15 to the reservoir 16. The reservoir is designed to be closed by a clamp 20, at a point between the reservoir and the shaft 10, and is filled with an inflation fluid, such as sterile water, through a one-way valve 21 (which may be of the type shown in Garth U.S. Pat. No. 3,087,492). The elasticity of the reservoir 16 is such that, upon removal of the clamp, a substantial part of the inflation fluid will be forced into the balloon 14, inflating it to perform its intended function of retaining the catheter tip within the body cavity (e.g., bladder).

According to the present invention, as exemplified in FIGS. 1 and 2, the auxiliary reservoir 22 is formed of two flat sheets 23, 24 of flexible heatsealable plastic film having narrow ends 25 and wider ends 26. The narrow ends are sealed into fluid-tight engagement around the valve 21, the seal being perfected, if necessary, by one or more bands of adhesive 27, and the wider ends 26 are similarly sealed into fluid-tight engagement with a valve opening device 28, the side edges of the sheets being sealed together flatwise to form a somewhat flattened bag, as shown in FIG. 2.

In the modified form, shown in FIGS. 3 and 4, the auxiliary reservoir 30 encloses the inflation reservoir, the narrow ends 31 of the flat sheets 32, 33 being sealed into fluid-tight engagement around the side arm 15 between the reservoir 16 and the clamp 20, the tightness of the seal being assured by bands of adhesive 34, if necessary. The wider ends 35 of the sheets 32, 33 are similarly sealed around a valve opening device 36 (which may be the same as the device 28) and the side edges of the sheets are sealed together flatwise to form an elongated flattened bag, as shown in FIG. 4.

Each of the auxiliary reservoirs 22 or 30 must, initially, have sufficient free capacity to enable it to receive, without back pressure, a quantity of fluid corresponding to the capacity of the retention balloon. This is normally either 5 cc. or 30 cc. and the invention is particularly applicable to the 5 cc. type, although larger auxiliary reservoirs could be provided, if desired.

The valve opening device 28 (or 36) comprises handle 40, a flat web 41 and a prod portion 42, said portion having an axial bore 43 extending from the distal end of the prod to a transverse passage 44 adjacent to the proximal inlet 37 thereof. The prod may be tapered and must be small enough to be received easily in the end of the valve 21 and to push in the valve stem in order to open the valve.

The alternative form of valve opening device, shown in FIGS. 5 and 6, has a handle 45, a flat web 46 and a prod portion 47, said portion being tapered and provided with longitudinal grooves 48, extending from the distal tip to points adjacent the proximal end of the prod.

In the manufacture of a self-inflating catheter having an auxiliary reservoir, the inflation reservoir must be loaded with fluid before the auxiliary reservoir is closed. One suitable sequence of steps comprises, preparing the loaded catheter, providing an auxiliary reservoir with the valve opening device sealed in its wider end, placing the narrower end of said reservoir in position to be sealed, and sealing it, e.g., to the valve as shown in FIGS. 1 and 2. Otherwise the auxiliary reservoir, with both ends open, can have its narrower end sealed to the valve (FIGS. 1 and 2) or to the side arm

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(FIGS. 3 and 4) before the fluid is placed in the inflation reservoir, the wider end of the auxiliary reservoir being sealed around the valve opening device thereafter.

A self-inflating catheter provided with the auxiliary reservoir is inserted into and retained in a patient in the normal manner. When it is desired to remove the catheter, the valve opening device is manipulated to insert the prod into the end of the valve, against the end of the valve stem (which is usually grooved or ridged) to open the valve and permit fluid to escape. As the balloon deflates to an extent permitting removal of the catheter, the fluid is collected in the auxiliary reservoir with no possibility of spillage.

Since the function of the prod is merely to open the valve and permit escape of the fluid, its cross-sectional form may be varied widely so long as it retains sufficient strength and cannot occlude the valve opening.

It will be understood that various changes may be made in the form, construction and arrangement of the several parts without departing from the spirit and scope of the invention and hence I do not intend to be limited to the details shown or described herein except as the same are included in the claims or may be required by disclosures of the prior art.

What I claim is:

1. A self-inflatable retention balloon catheter comprising a main shaft having a drainage lumen extending from the proximal end of said shaft to a first lateral opening adjacent the distal end thereof and an inflation lumen extending from a first point spaced from said proximal end to a second point proximal of said first lateral opening, an inflatable balloon surrounding said shaft at said second point, a second lateral opening connecting the distal end of the inflation lumen with the interior of said balloon, a tubular inflation arm communicating with the proximal end of the inflation

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lumen at said first point, valve means having an inlet communicating with the interior of said inflation arm, means for selectively closing said inflation arm at a point spaced from said valve to form an inflation reservoir in said arm adapted to contain inflation fluid, an auxiliary reservoir loosely enclosing said valve means inlet, and a valve opening device in said auxiliary reservoir and manually movable to a valve opening position, the capacity of the auxiliary reservoir being at least substantially equal to the inflated volume of the balloon.

2. A catheter according to claim 1 wherein the auxiliary reservoir is constituted by two sheets of plastic film edge sealed together, and wherein the valve opening device is held between said sealed edges.

3. A catheter according to claim 1 wherein the auxiliary reservoir loosely encloses the inflation reservoir.

4. A catheter according to claim 2 wherein the valve means is held between said sealed edges.

5. A catheter according to claim 2 wherein the inflation arm is held between said sealed edges and the auxiliary reservoir loosely encloses the inflation reservoir.

6. A catheter according to claim 1 wherein the valve opening device includes a handle and a prod, the prod being adapted for insertion into the valve means inlet to open the valve.

7. A catheter according to claim 6 wherein the prod is longitudinally grooved.

8. A catheter according to claim 6 wherein the prod is traversed by a longitudinal bore.

9. A catheter according to claim 6 wherein the auxiliary reservoir is constituted by two sheets of plastic film edge sealed together and wherein the handle and the prod are connected by a web, the web being held between the sealed edges of the auxiliary reservoir.

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