June 22, 1965 F. E. B. FOLEY 3,190,291

SELF-INFLATING BAG CATHETER

Filed Oct. 8, 1962

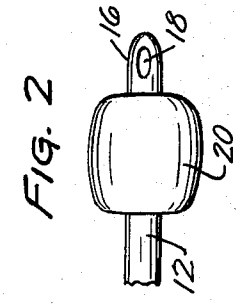

FIG. 2

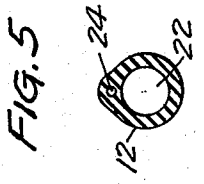

FIG. 5

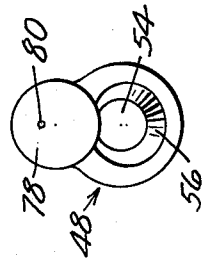

FIG. 8

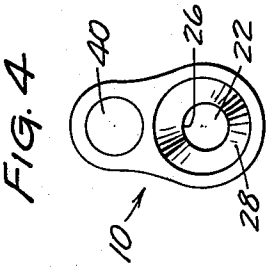

FIG. 4

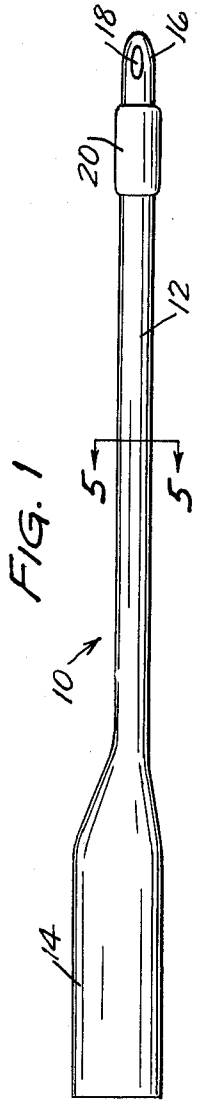

FIG. 1

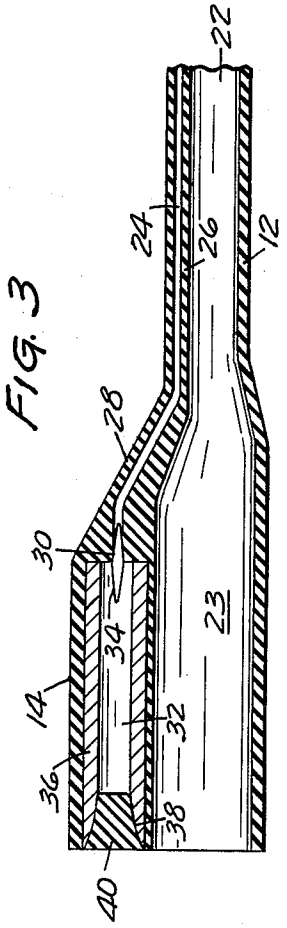

FIG. 3

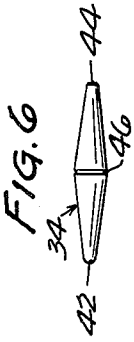

FIG. 6

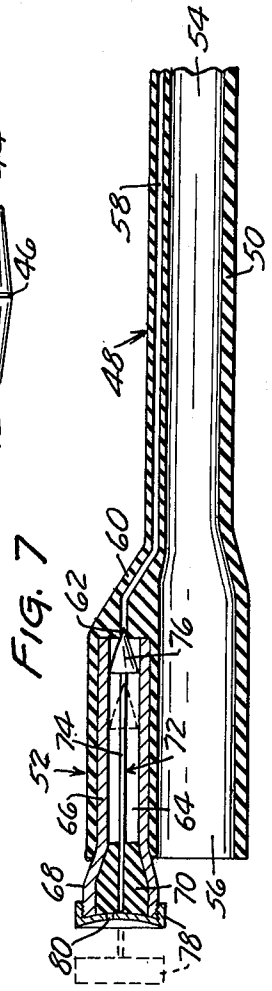

FIG. 7

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SELF-INFLATING BAG CATHETER

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This invention relates to a bag catheter and more particularly relates to a self-inflating bag catheter.

Inflatable bag catheters have been well known in the catheter art and have been in common use for at least the last twenty-five years. Such a catheter comprises essentially an elongated flexible shaft of soft rubber or the like with an inflatable sleeve or bag surrounding the shaft adjacent the distal end thereof. Ordinarily at the proximal end portion of the shaft there is provided a flexible divergent tube which communicates with an inflating lumen or passage through the wall of the shaft into the inflatable bag. The purpose of this divergent tube is to facilitate injection of fluid into the sleeve for inflating same without disturbing the positioning of the proximal end of the main shaft. At the distal end of the catheter body forwardly, and if desired, rearwardly, of the inflatable sleeve are one or more drainage inlet ports which open into the drainage passage or lumen provided by the tubular bore of the shaft. This drainage passage drains through the proximal end of the shaft body which is generally enlarged for interfitting with a glass tube or the like for conducting drainage fluid to a suitable container from the catheter.

These inflatable bag catheters are conventionally used to drain urine from the human bladder. In use the catheter is introduced into the bladder through the urethra and positioned so that the drainage inlets and the inflatable bag are within the bladder. The proximal end portion of the shaft and the divergent tube remain outside of the body of the patient and the catheter is positioned in place by the injection of fluid through the divergent tube and the inflating lumen into the bag whereby the bag forms a balloon retaining the catheter distal end portion within the bladder and preventing inadvertent displacement therefrom.

To inflate the bag, water is generally measured into a hypodermic syringe to a predetermined volume. The divergent tube has a closed end, usually in the form of a soft rubber plug. The hypodermic needle of the syringe is pushed through the plug into the bore of the tube, which bore of course constitutes a continuation of the inflating passage. The water from the syringe is then injected into the tube and the bag inflated. Upon withdrawal of the needle, the soft rubber plug is self-sealing so that no water escapes from the tube and the bag remains inflated.

Because of the retention of the catheter in living tissue the inflating water must be maintained in aseptic condition. Thus, the water, syringe, needle, and such auxiliary equipment as funnel, pipette, water container, etc., as may be needed for inflation must be sterilized and maintained in a sterile state during inflation. The resulting inflating procedure is a cumbersome operation at best and usually requires in addition to the physician an assistant to the physician.

In accordance with this invention a bag catheter is provided which not only contains its own inflating fluid but which is also self-inflating and which needs no external agency either to facilitate or maintain the inflation of the bag. The catheter of this invention is a self-inflating bag catheter which is so constructed as to maintain the inflating fluid in a compressed, but readily expansible state, until bag inflation is required. This new catheter is so constructed that the divergent tube is eliminated and the catheter is in effect a single, unitary shaft construction with the proximal end portion of the

catheter being slightly larger than the proximal end portions of the main shafts of the now used bag catheters.

The present invention, which enables catheters to be formed as a unitary shaft with no divergent appendages facilitates both packaging and handling as well as eliminating the processing and molding steps heretofore necessary to form the divergent end tube. Thus, while with my invention a self-inflatable bag catheter can be constructed utilizing either divergent tube constructions or unitary shaft constructions, a significant advantage of my invention is the production of a self-inflating bag catheter free from any divergent appendages without sacrificing any convenience in use of the catheter.

The self-inflating bag catheter of this invention comprises an elongated flexible tubular shaft or soft feeling rubbery material, usually natural rubber latex. The shaft has proximal and distal ends and the main bore of the shaft constitutes a drainage passage or lumen through the length of the shaft for drainage of fluid through the shaft from the distal to the proximal ends. An inflatable bag or sleeve surrounds and has its edges peripherally sealed to the shaft adjacent the shaft distal end so that the bag is free to expand to an inflated balloon surrounding the catheter shaft. An inflating passage or lumen is provided through the shaft wall, parallel to the drainage passage, and opening at one end into the inflatable bag and at its other end into an enlarged chamber formed in the proximal end portion of the catheter. The wall of this chamber is suitably rigidified so that expansible inflating fluid is maintained therein in a compressed state without distortion of the catheter shape. Openable means is provided between the chamber and the inflating passage normally sealing off communication therebetween which means is readily disruptable from a position externally of the catheter, allowing the compressed fluid to expand and inflate the thin bag at the distal end of the catheter.

The invention will be further described with reference to the embodiments shown in the accompanying drawing wherein:

FIGURE 1 illustrates the self-inflating bag catheter in an uninflated state;

FIGURE 2 is a view of the distal end portion of the catheter disclosing the catheter bag in its inflated condition;

FIGURE 3 is an enlarged cross-sectional view through the length of the proximal end portion of the shaft illustrating one construction whereby the expansible fluid is maintained in a compressed state prior to bag inflation;

FIGURE 4 is an end view of the proximal end of the catheter;

FIGURE 5 is a cross-sectional view through the shaft body taken substantially along the plane of section line 5—5 of FIGURE 1;

FIGURE 6 is a view of a closure means for sealing off the passage between the fluid supply chamber and the bag inflating passage;

FIGURE 7 is a view similar to that of FIGURE 3 of the modified catheter construction; and

FIGURE 8 is an end view of the proximal end of the catheter of FIGURE 7.

It is to be understood that the illustrations of the drawing are not drawn to scale and in some instances may in fact be considerably exaggerated for clarity of cross-sectional details.

Referring first to the modification illustrated in FIGURES 1–6, the inflating bag catheter of this invention is designated in its entirety by the numeral **10**. The catheter comprises an elongated generally cylindrical shaft **12** terminating in a soft, blunted distal end **16** and having a relatively enlarged proximal end portion **14**. In use, the catheter is inserted only to the juncture of the shoulder

28 between the main body of the shaft 12 and the enlarged proximal end portion 14.

At its distal end 16 the shaft is provided with drainage inlet ports 18. Rearwardly of the inlet ports 18 at the distal end portion of the shaft 12 the inflatable sleeve 20 of the catheter is attached. As is apparent from an examination of FIGURE 1, sleeve 20 in its normal state simply envelops the shaft like a shaft-conforming band whereas in its inflated state as shown in FIGURE 2, it provides an enlarged balloon surrounding the shaft end.

The drainage inlet ports 18 communicate, as illustrated in FIGURES 3–5, with the tubular bore 22 of the shaft 12 which bore serves as the drainage lumen of the catheter. The drainage lumen 22 is enlarged as at 23 at the proximal end portion of the catheter for the coupling therewith of any drainage attachments. The passage 24 extending parallel to the drainage passage 22 opens at its distal end into the space between the sleeve 20 and the shaft 12 and it is through this passage that the inflating fluid for the bag passes. This inflating passage 24 follows the shoulder 28 to termination point 30 in the proximal end portion 14 of the shaft wherein it opens into a tubular chamber 32. A frangible closed end tube 34 normally closes communication between passage 24 and chamber 32.

In the modification illustrated in FIGURES 3 and 4, the tubular wall of the chamber 32 is lined with a suitable rigidifying liner 36 which may be in the form of a simple aluminum tube or the like over which the rubber latex forming the shaft may be formed. The proximal end portion of the inside wall of the rigid liner 36 is bevelled outwardly as at 38 for the sealing reception therein of a soft rubber plug 40, which closes off the entrance thereto.

The frangible tube 34 may be in the nature of a simple glass tube, one end of which is closed as at 42, which closed end projects into the chamber 32. The open end portiion of tube 34 frictionally seats within the inflating passage 24. Intermediate its ends the tube may be scored as at 46.

Once the catheter is made and the plugs 34 and 40 in place, a controlled amount of an expansible inflating fluid can be injected through a hypodermic needle or the like through the plug 40 into the chamber 32 and retained therein in a compressed state. When the catheter is to be used the physician need simply flex the proximal end portion 14 of the catheter whereupon the frangible tube 34 is broken and the compressed fluid expands through the inflating passage 24 into the sleeve 20 and inflates the sleeve.

A modified form of catheter is illustrated in FIGURE 7 and designated in its entirety by the numeral 48. This catheter also comprises an elongated shaft body 50 through which a drainage passage 54 extends having an enlarged proximal end 56 accommodated by the enlarged proximal end portion 52 of the shaft. The wall of the shaft is provided a bag inflating passage 58 which follows the jog of the shoulder 60 of the catheter shaft to its proximal end 62 where it opens into a tubular chamber 64.

The tubular chamber 64 has the wall thereof rigidfied with a rigid liner 66 which may be in the form of a small aluminum tube or the like as in the previous modification. The proximal end of the tube 66 projects beyond the end of the catheter and is flared outwardly to form a bell-shaped end. A soft rubber plug 70 normally closes this bell-shaped end.

An elongated shank 72 projects through the plug 70 into the chamber 64 and at the end thereof terminating in the chamber provided with a cone-shaped tip 76 which normally seals off communication between chamber 64 and inflating passage 58. At the end thereof projecting through the soft rubber plug 70 the shaft is attached to a cap 78 which may be screwed into place over the bell-shaped end 68 or otherwise releasably fixed thereto. The

cap is provided with an opening 80 therein which opens against the soft rubber plug 70.

In the use of the catheter modifications of FIGURE 7, the inflating fluid may be injected through the opening 80 and through the plug 70 into the chamber 64 where it is retained until the cap 78 is unscrewed and pulled away from the proximal end of the shaft whereupon the closure tip 76 opens communication between the chamber 64 and the inflating passage 58.

Of course, other closure means and closure disrupting means other than those just illustrated can be used in the practice of this invention as can differing chamber wall rigidifying means. With respect to the latter it is contemplated that the chamber wall can be rigidified simply by embedding a plastic or metal spirally wound coil therein.

The inflating fluid to be used must be one which is not toxic to the human body, which does not unduly permeate the walls of the inflated sleeve when the sleeve is immersed in body fluids and preferably one which is readily handleable for compression. Certain inert fluorocarbon fluids such as those of the "Freon" or "Kel-F" family are suitable. A preferred fluid has been found to be perfluorocyclobutane C_4F_8, marketed under the trade name "Freon-C318" by E. I. du Pont de Nemours & Company. This fluid is extremely inert and has been found to provide an ideal expansible fluid for use with natural rubber bodied catheters; it has a boiling point of about 21° F. which enables encapsulation in liquid form with safety and dispatch at relatively low pressures. This fluid does not unduly swell natural latex rubber and has been found to have long retention in thin latex rubber balloons over long periods of time when the inflated balloon is immersed in urine, the normal environment for the inflated balloon.

From the foregoing it will be seen that the present invention provides a greatly improved urethal bag catheter.

I claim:

1. A self-inflating bag catheter comprising an elongated flexible rubbery shaft for draining body fluids therethrough, said shaft having proximal and distal ends and having an inflatable sleeve mounted thereon adjacent said distal end, the proximal end portion of said shaft having a chamber therein, said shaft having an inflating passage therethrough intercommunicating said chamber and said inflatable sleeve, readily openable sealing means normally sealing off communication between said chamber and said inflating passage, an expansible fluid sufficiently impermeable to the wall of said chamber for storage therein maintained within said chamber in a compressed state for inflation of said sleeve upon opening of said sealing means, and means rigidifying the shaft wall forming said chamber to prevent distortion thereof by said inflating fluid.

2. A self-inflating bag catheter comprising an elongated flexible rubbery shaft for draining body fluids therethrough, said shaft having proximal and distal ends and having an inflatable sleeve mounted thereon adjacent said distal end, the proximal end portion of said shaft having a chamber therein, said shaft having an inflating passage therethrough intercommunicating said chamber and said inflatable sleeve, readily openable sealing means normally sealing off communication between said chamber and said inflating passage, an expansible fluid sufficiently impermeable to the wall of said chamber for storage therein maintained within said chamber in a compressed state for inflation of said sleeve upon opening of said sealing means, and means rigidifying the shaft wall forming said chamber to prevent distortion thereof by said inflating fluid, said readily openable sealing means comprising a frangible tube having a closed end projecting into said chamber and an open end frictionally seated within said inflating passage and openable by fracture upon flexing said shaft in the vicinity of the juncture of said inflating passage and said chamber.

3. A self-inflating bag catheter comprising an elon-

gated flexible rubbery shaft for draining body fluids therethrough, said shaft having proximal and distal ends and having an inflatable sleeve mounted thereon adjacent said distal end, the proximal end portion of said shaft having a chamber therein, said shaft having an inflating passage therethrough intercommunicating said chamber and said inflatable sleeve, readily openable sealing means normally sealing off communication between said chamber and said inflating passage, an expansible fluid sufficiently impermeable to the wall of said chamber for storage therein maintained within said chamber in a compressed state for inflation of said sleeve upon opening of said sealing means, and means rigidifying the shaft wall forming said chamber to prevent distortion thereof by said inflating fluid, said readily openable sealing means comprising an elongated shank having a passage closing means at one end seating in said inflating passage, the other end of said shank projecting exteriorly of said catheter for unseating said closing means upon movement thereof away from said inflating passage.

4. A self-inflating bag catheter comprising an elongated flexible rubbery shaft for draining body fluids there-

through, said shaft having proximal and distal ends and having an inflatable sleeve mounted thereon adjacent said distal end, the proximal end portion of said shaft having a chamber therein, said shaft having an inflating passage therethrough intercommunicating said chamber and said inflatable sleeve, readily openable sealing means normally sealing off communication between said chamber and said inflating passage, an inert fluorocarbon fluid maintained within said chamber in a compressed state for inflation of said sleeve upon opening of said sealing means, and means rigidifying the shaft wall forming said chamber to prevent distortion thereof by said inflating fluid.

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