

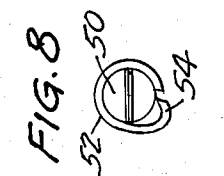
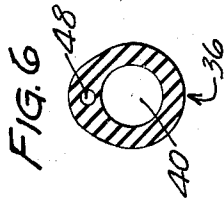
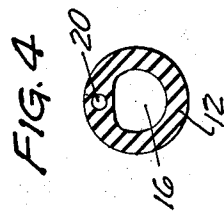
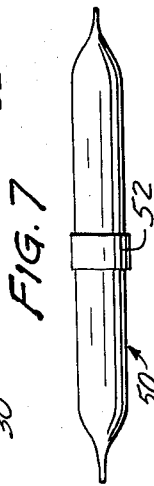
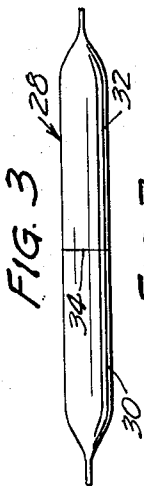
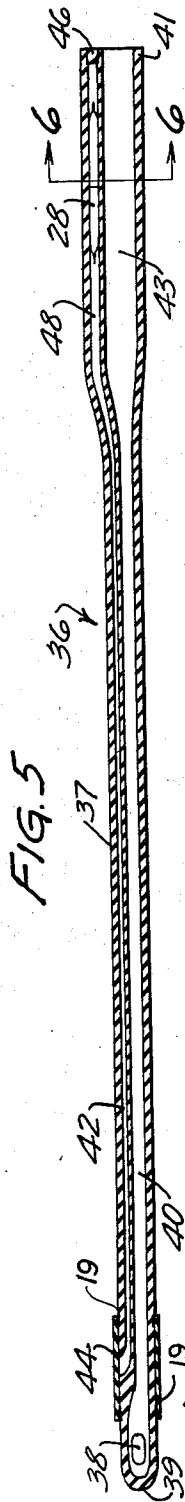
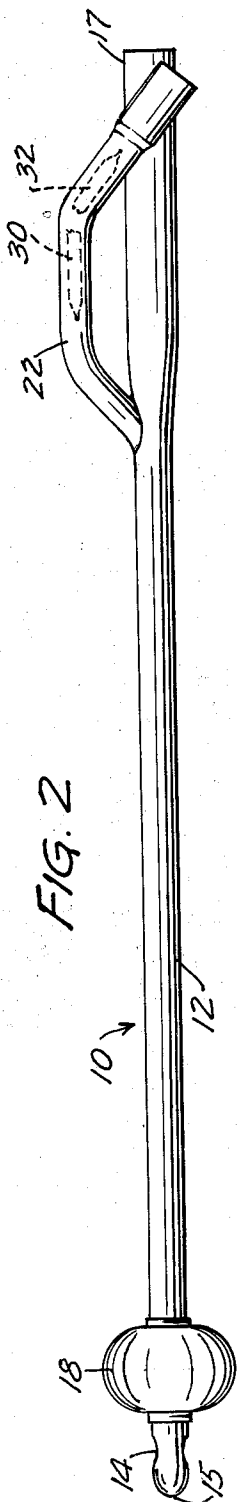
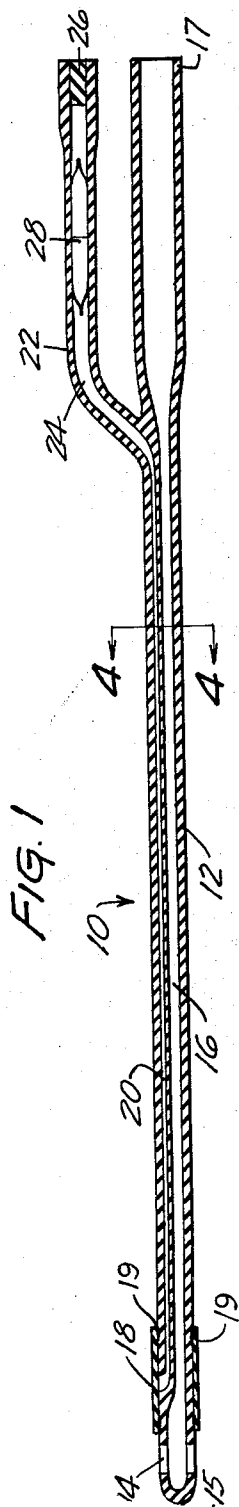
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3,152,592

SELF-INFLATING BAG CATHETER

Filed Sept. 13, 1961



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3,152,592
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 are well known in the catheter art and have been in common use for at least the last 25 years. Such a catheter comprises essentially an elongated flexible soft rubber tubular shaft having an inflatable sleeve or bag surrounding the shaft adjacent the distal end, and a flexible divergent tube to facilitate bag inflation projecting from the wall of the shaft adjacent the proximal end. At the distal end of the catheter body forwardly of the inflatable sleeve are one or more drainage inlets which open into the drainage channel provided by the tubular bore of the shaft. This channel drains through the proximal end of the shaft body. Running parallel to the drainage channel within the wall of the shaft is a distention duct which opens at its distal end into the inflatable sleeve of the catheter and at its proximal end into a continuation duct which forms the bore of the divergent tube.

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 and the divergent tube remain outside the body of the patient and the bag is then inflated by injecting fluid into the distention duct through the divergent tube to retain the catheter in position and prevent inadvertent dislodgement.

To inflate the bag, water is 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 forms a continuation of the distention duct. The water from the syringe is then injected into this tube and the bag inflated. Upon withdrawal of the needle, the plug closes the needle formed opening so no water escapes and the bag or balloon remains inflated.

Water, rather than a gaseous fluid such as air is used to inflate the catheter bag because an exact amount can be readily measured and thus the volume displacement of the inflated bag predetermined. Also, water does not permeate rubbery walls as do many gases and the inflation remains relatively permanent until the water is drained by opening the closed end (by cutting usually) of the divergent tube.

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

I have invented a self-inflating bag or balloon catheter which contains its own inflating fluid and requires no extraneous paraphernalia for its inflation thereby greatly extending the versatility and ease of application of bag catheters. With my invention the urethral bag catheter becomes a self contained entity which contains its own inflating means and fluid. Further, with my invention, a bag catheter may be made as a simple, single shaft device without impairing the convenience of its use, and no divergent distention tube as is presently found in inflatable

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bag catheter construction need be provided. Also, with my invention it is safe to use gaseous fluids for bag inflation.

The present invention, which enables a catheter to be formed as a single shaft construction without impairing the convenience of its use, facilitates packaging and handling of the catheters as well as eliminating the processing and molding steps heretofore necessary to form the divergent end found on the previously used inflatable bag catheter. Thus, while my invention of a self-inflatable bag catheter may utilize either divergent tube constructions or unitary shaft constructions, a significant advantage of my invention is the production of a self-inflating bag catheter having a unitary shaft free from a divergent tube appendage but without any corresponding loss of convenience in use.

In accordance with a preferred form of my invention a self-inflating bag catheter is provided having housed completely therewithin adjacent the proximal end thereof a readily rupturable capsule or container. The capsule contains therewithin a measured amount of fluid compressed to a predetermined degree and is constructed in such a manner that by simple deformation of the proximal end portion of the catheter as by squeezing pressure or flexing of the portion of the catheter wall within which the capsule is contained the capsule will readily rupture and release the fluid therein. The released fluid expands and inflates the bag whereby the catheter is maintained in place until the bag is deflated by permitting the expanded fluid to escape through the proximal end of the catheter.

The invention will be described in somewhat more detail with reference to the accompanying drawing wherein:

FIGURE 1 is a side elevational view in cross section of one form of self-inflating bag catheter made in accordance of this invention;

FIGURE 2 is a side elevational view of the bag catheter of FIGURE 1 with the catheter bag shown in its inflated state;

FIGURE 3 is a side elevational view of one form of fluid containing capsule forming a part of the catheter;

FIGURE 4 is a cross-sectional view through the catheter shaft taken substantially along the plane of section line 4—4 of FIGURE 1;

FIGURE 5 is a side elevational view in cross section of a preferred form of self-inflating catheter made in accordance with this invention;

FIGURE 6 is a cross sectional view of the catheter of FIGURE 5 taken substantially along the plane of section line 6—6 of FIGURE 5;

FIGURE 7 is a side elevational view of a modified form of rupturable fluid containing capsule; and

FIGURE 8 is an end view of the modified capsule of FIGURE 7.

Referring now to the drawing in detail, it is to be understood that the figures thereof are illustrative only. These figures are not drawn to scale but are representative of the principles of the invention rather than precisely scaled structures.

In FIGURES 1 and 2 there is disclosed one embodiment, designated in its entirety by the numeral 10, of a self-inflating bag catheter made in accordance with the teachings of this invention. As is apparent, the catheter 10 comprises an elongated rubbery flexible hollow shaft 12 having one or more drainage inlets 14 adjacent the closed smoothly blunted (for ease of insertion) distal end 15 thereof which inlets open into the tubular passage of the shaft which passage forms an elongated drainage channel 16 extending substantially throughout the length of the catheter shaft and opening into the enlarged proximal end portion 17 of the shaft.

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Surrounding the distal end portion of the shaft 12 and disposed immediately rearwardly of the drainage inlets 14 of the catheter shaft is an elastic sleeve or bag 18, the edges of which are circumferentially sealingly and permanently adhered to the outer wall of the catheter shaft by suitable means such as adhesives or vulcanization, this sealing adherence being illustrated by the thickened lines 19, with the remainder of the sleeve remaining unattached so that the sleeve upon inflation forms a bag surrounding the distal end portion of the shaft as shown in FIGURE 2.

Extending longitudinally along the shaft 12 and formed within the wall of the shaft is a distention duct 20 which opens at its distal end through the shaft wall into the space under the sleeve 18 and at its proximal end into a divergent tube 22 joined at an angle to the portion of the catheter shaft wall at the juncture of the enlarged proximal end portion of the shaft to the main length of the shaft. The tubular passage of this divergent tube 22 forms an extension 24 of the distention duct 20, being somewhat enlarged therefrom. The end of the divergent extension is closed by any suitable means such as a plug 26, which seals the tube after insertion into the passage 24 thereof of a small rupturable container or capsule such as 28 or the like. The size of the capsule is such that it fits snugly within the enlarged extension 24 of the distention duct 20 and is held frictionally therewithin.

The capsule or container 28 contains an expansible fluid. With reference to FIGURE 3 it will be seen that the container 28 is composed of a small closed end tube with a weakening center groove or the like 34 extending circumferentially therearound so that the capsule can be readily split into two halves to release the contents. Upon bending the divergent tube extension 22 as shown in FIGURE 2, the capsule 28 separates into its two halves 30 and 32 and the fluid released therefrom expands to distend the sleeve 18 into an inflated bag surrounding the distal end portion of the catheter shaft 12.

With my self-inflating catheter construction no extraneous aids are necessary for inflation of the catheter bag. Thus, the present invention eliminates the necessity for what has heretofore been standard practice in bag catheter inflation, namely the preparation of sterile water in measured amounts and the utilization of sterile syringe and hypodermic equipment to inject the water into the distention duct for expansion of the bag 18. With my invention, gaseous fluids, or liquids which expand under atmospheric conditions to gaseous fluids, can be readily used as the inflating means, rather than water from a syringe, as the amounts may be pre-measured under controlled conditions and supplied as a part of the catheter itself. Thus, control of the final inflated bag volume may be predetermined by the manufacturers using industrial precision measuring equipment thereby providing a controlled inflation not subject to the human errors possible with physician controlled inflation.

With the conventional inflatable bag catheter, since the bag is within the body of the patient upon expansion, water is used so that the precise expansion of the bag within the body of the patient is known; this presents over-inflation with resultant discomfort and possibly damage to the patient; air or other gases could not readily be used because of the uncertainty raised by the inability to readily measure the volume of air going into the system with conventional equipment used for injecting fluids. My invention eliminates these problems heretofore encountered with gaseous fluids.

A self-inflating bag catheter possessing no divergent appendage made in accordance with the present invention is disclosed in FIGURE 5. This presently preferred form of catheter is designated in its entirety by the numeral 36 and is seen to consist of a single, elongated flexible shaft 37 having adjacent the closed, smoothly blunted distal end 39 thereof one or more drainage inlet openings 38 opening into shaft drainage channel 40.

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Sleeve 44 surrounding the shaft end portion immediately rearwardly of the drainage inlet openings 38 is attached thereto in the same manner as described with respect to sleeve 18 in the embodiment shown in FIGURES 1 and 2.

However, the distention duct 42 formed within the wall of the catheter shaft 37 continues within the shaft wall throughout the length of the proximal end portion 41 of the shaft, opening into the proximal end of the shaft. The distention duct 42 is enlarged in the portion thereof within the proximal end portion 41 of the shaft as at 48 and within this enlarged duct portion 48 is disposed a suitable expansible fluid filled capsule or container such as 28. The proximal end of the distention duct is sealingly closed off by a suitable plug 46 or the like which is emplaced or formed after insertion of the capsule into the enlarged end portion 48 of the distention duct. The catheter is then ready for use.

The proximal end portion 43 of the drainage channel 49 of the catheter 36 is larger than the remainder of the channel and has a generally circular cross section for slipping over glass tubing or the like to conduct the drainage to a suitable container. Thus, as shown in FIGURE 6 the cross sectional shape of the catheter shaft at this end is generally ovoid or oval with a greatly thickened wall portion to accommodate the enlarged passage 48 of the distention duct 42, within which the expansible fluid containing capsule 28 is frictionally housed, while still providing a circular cross-section for the end portion 43 of the drainage channel. For inflation of the sleeve 44 in the manner of the sleeve 18 of FIGURE 2, it is simply necessary, when a capsule of the type designated as 28 is used, to flex the proximal end of the catheter shaft to separate the capsule into its component parts and release the fluid to inflate the sleeve or bag 44.

Of course, other forms of fluid containers than that of 28 can be used and an example of one such other form is shown in FIGURES 7 and 8 wherein a readily puncturable tubular shell 50, which may be of a suitable plastic such as heat-sealable polyethylene or the like, is provided with a stiff ring 52 therearound. The ring 52 is somewhat ovoid in shape and has a pointed probe 54 bearing against the wall of the capsule 50 so that upon squeezing pressure applied through the catheter wall to the ring 52, the probe 54 penetrates the wall and releases the fluid held therewithin. Other rupturing arrangements for capsules can also be used.

Since catheters are usually introduced into the bladder through the urethra of the patient to draw off urine or other accumulated fluids, bag catheters are conventionally made of soft pliable elastic stretchable rubbery materials such as rubber latex, silicone rubber, or similar inert rubbery substance. Consequently, in selecting an expansible fluid for use as the inflating means for the bags of these catheters, it is necessary that the fluid selected be chemically inert to the particular rubber-like material used in the formation of the catheter shaft and sleeve under conditions of use and that inflating fluid be retained by the catheter material against leakage in a urine environment.

A typical self-inflating bag catheter is composed of a soft latex rubber shaft about 17 inches long with an outer shaft diameter through the major shaft length of about $\frac{1}{4}$ inch, the enlarged proximal end portion of the shaft in a catheter of the preferred type having a major diameter of about $\frac{1}{2}$ inch and a minor diameter of about $\frac{3}{8}$ inch; the enlarged proximal end portion of the distention duct of either catheter type hereinbefore described, when using a capsule such as 28, has about a $\frac{1}{8}$ inch diameter.

Capsules such as 28 have been made from glass tubing and stainless steel (12 gauge stainless steel $\frac{3}{16}$ inch O.D. tubing) such capsules being about $1\frac{1}{2}$ inches long and filled with about $\frac{1}{40}$ cc. of a gaseous fluid (gaseous at normal room temperatures and atmospheric pressure). Nitrogen has been encapsulated as a highly compressed gas and CO₂ has been encapsulated in liquid form in

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stainless steel tubing; however, perfluorocyclobutane (C_4F_8), manufactured under the trade name "Freon-C318" by E. I. du Pont de Nemours & Company is a preferred fluid and it may be packaged readily in less rigid puncturable capsules. This latter chemical (perfluorocyclobutane) has been found to provide an ideal expandable fluid for use with natural rubber 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 chemical does not swell natural latex rubber and does not leak out through the thin latex rubber bag over long periods of time when the inflated bag is submerged in urine, the normal environment for this inflated bag. Further, this chemical is extremely inert and safe for use.

Self-inflating latex-rubber bag catheters containing these C_4F_8 loaded glass capsules of the kind illustrated by numeral 28 have been readily inflated by simple flexing the catheter to separate the capsule halves. The catheter bags so inflated have evidenced no observable loss of fluid when submerged in urine after several weeks inflation.

With this and other rubbers, other expandable liquid and/or compressible gases can be used which are inert to the particular rubber used and which do not escape through the walls of such rubbers. The particular fluid selected will, of course, be determined in accordance with the encapsulating medium or container used to hold the fluid as well as the compatibility of the fluid with the catheter rubber.

To prepare filled glass capsules 28, one end of a short length of glass tubing was closed by heat and the tubing cooled below the boiling point of liquid C_4F_8 (cyclic); about $\frac{1}{10}$ cc. of C_4F_8 was then fed into the tube after which the open end of the tube was fused closed. Then, intermediate its length the tube was grooved for ready separation into halves.

A similar technique has been to fill stainless steel tubes with expensible fluids, except that the stainless steel tubing ends were spot welded closed rather than fused.

From the foregoing it will be seen that the present invention provides a greatly improved urethral bag catheter. Of course, variations in techniques for measuring, filling and enabling capsule rupture, from the simplified hand techniques herein described will readily occur to those skilled in the capsule making and filling arts; also, different gaseous fluid-catheter rubber combinations than those disclosed herein may be utilized. However, the principles of my invention and the mode of practicing the same are believed set forth in sufficient detail to enable those reasonably skilled in the art to understand and make use of my invention.

I claim:

1. A self-inflating bag catheter comprising an elongated flexible tubular shaft, the tubular shaft passage forming a drainage channel therethrough opening into the proximal end of the shaft, said shaft having at least one drainage inlet opening adjacent the distal end thereof communicating with said drainage channel, an inflatable sleeve surrounding and sealingly attached to said shaft adjacent the distal end thereof in such a manner that it is free to expand to form an inflated bag about said catheter shaft, said shaft having a distention duct extending longitudinally therealong and separated from said drainage channel, said distention duct opening at one end into the inflatable bag portion of said sleeve and extending longitudinally along said shaft for the major portion of the shaft length, means sealingly closing the other end of said distention duct and a rupturable container carried within said duct and positioned adjacent the proximal end of said shaft, said container containing in a compressed state a fluid which expands upon release therefrom to inflate said bag, said container having means associated therewith causing said container to rupture upon the application of duct deforming pressure to said distention duct in the area of said container.

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2. The catheter of claim 1 wherein said catheter has a divergent tube branching from said shaft adjacent the proximal end portion of said shaft, the tubular passage of said divergent tube constituting the proximal end portion of said distention duct, said container being housed within said divergent tube.

3. The catheter of claim 1 wherein said distention duct is contained in its entirety within said shaft, and has an enlarged closed end at the proximal end of said shaft.

4. A self-inflating bag catheter comprising an elongated flexible hollow shaft of a soft elastic rubber having a drainage channel therethrough opening into the proximal end thereof and having at least one drainage inlet opening adjacent the distal end thereof communicating with said drainage channel, an inflatable sleeve surrounding and sealingly attached to said shaft adjacent the distal end thereof in such a manner that it is free to expand to form an inflated bag about said catheter shaft, the wall of said shaft having a distention duct formed therein and extending longitudinally along the shaft for the major portion of the shaft length, said distention duct opening at one end into the inflatable bag portion of said sleeve and at its other end into the proximal end of said shaft, means sealingly closing said other end of said distention duct and a rupturable capsule being carried within said duct and positioned adjacent the proximal end of said shaft, said capsule containing therewithin in a compressed state an expandable fluid which upon release therefrom inflates said sleeve, said capsule being so constructed as to rupture upon the application of duct deforming pressure to said shaft in the area of said capsule.

5. A self-inflating bag catheter comprising an elongated flexible hollow shaft of a soft elastic rubber having a drainage channel therethrough opening into the proximal end thereof and having at least one drainage inlet opening adjacent the distal end thereof communicating with said drainage channel, an inflatable sleeve surrounding and sealingly attached to said shaft adjacent the distal end thereof in such a manner that it is free to expand to form an inflated bag about said catheter shaft, said shaft having a distention duct extending longitudinally along the shaft for the major portion of the shaft length and opening at one end into the proximal end of said shaft and at its other end into the inflatable portion of said sleeve, the portion of said duct adjacent said shaft proximal end housing therewithin a pressure rupturable container containing therein an expandable sleeve inflating fluid, means sealing the proximal end of said duct whereby upon rupture of said container said sleeve is inflated by said fluid as the fluid expands.

6. The catheter of claim 5 wherein said shaft is of natural-latex rubber and said fluid is perfluorocyclobutane.

7. A self-inflating bag catheter comprising an elongated, flexible, tubular shaft having proximal and distal ends, the tubular bore of said shaft constituting a drainage channel through the length of said shaft, an inflatable bag attached to and surrounding said shaft adjacent the distal end thereof and which upon inflation retain said catheter in position, said shaft having a bag inflating passage therein extending along the length thereof, said bag inflating passage opening at one end into said bag and at its other end into the proximal end of said shaft, means within said bag inflating passage containing an expandable fluid in a compressed state adjacent the proximal end of said shaft, said containing means including fluid releasing means operable exteriorly of said shaft adjacent the shaft proximal end to release said fluid whereupon the fluid will expand to inflate said bag.

8. A self-inflating bag catheter comprising an elongated, flexible, tubular shaft having proximal and distal ends, the tubular bore of said shaft constituting a drainage channel through the length of said shaft, an inflatable bag attached to and surrounding said shaft adjacent the

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distal end thereof, and which upon inflation retains said catheter in position, said shaft having a bag inflating passage therein extending along the length thereof, said bag inflating passage opening at one end into said bag and at its other end into the proximal end of said shaft, means within said bag inflating passage containing perfluorocyclobutane fluid in a compressed state adjacent the proximal end of said shaft, said containing means including fluid releasing means operable exteriorly of said shaft adjacent the shaft proximal end to release said fluid whereupon the fluid will expand to inflate said bag.

9. A self-inflating bag catheter comprising an elongated flexible tubular shaft, the tubular shaft passage forming a drainage channel therethrough opening into the proximal end of the shaft, said shaft having at least one drainage inlet opening adjacent the distal end thereof communicating with said drainage channel, an inflatable sleeve surrounding and sealingly attached to said shaft adjacent the distal end thereof in such a manner that it is free to expand to form an inflated bag about said catheter shaft, said shaft having a distention duct extending longitudinally therealong and separated from said drainage channel, said distention duct opening at one end into the inflatable bag portion of said sleeve and extending longitudinally along said shaft for the major portion of the shaft length, means sealingly closing the other end of said distention duct, means retaining an expansible bag inflating fluid in a compressed condition in the proximal end portion of said distention duct, and fluid release means operable from the exterior of said catheter to release fluid into said distention duct and inflate said bag.

10. The catheter of claim 9 wherein said fluid is perfluorocyclobutane.

11. A self-inflating bag catheter comprising an elongated, flexible, tubular latex rubber shaft having proximal and distal ends, the tubular bore of said shaft constituting a drainage channel through the length of said shaft, an inflatable bag attached to and surrounding said shaft adjacent the distal end thereof, and which upon inflation retains said catheter in position, said shaft having a bag inflating passage therein extending along the length thereof, said bag inflating passage opening at one end into said bag and at its other end into the proximal

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end of said shaft, means within said bag inflating passage containing perfluorocyclobutane fluid in a compressed state adjacent the proximal end of said shaft, said containing means including fluid releasing means operable exteriorly of said shaft adjacent the shaft proximal end to release said fluid whereupon the fluid will expand to inflate said bag.

12. A self-inflating balloon catheter comprising an elongated, flexible, tubular shaft having proximal and distal ends, the tubular bore of said shaft comprising a drainage channel through the length of said shaft, an inflatable sleeve attached to and surrounding said shaft adjacent the distal end thereof, and which upon inflation retains said catheter in position by formation of an enlarged balloon surrounding said shaft, said shaft having a balloon inflating passage therein extending along the length thereof and separated from said tubular bore, said inflating passage opening at its distal end into said sleeve, means closing the proximal end of said balloon inflating passage, a balloon inflating fluid within said balloon inflating passage adjacent said proximal end thereof, means confining said fluid within the proximal end portion of said balloon inflating passage under compressive forces, said confining means including means closing said balloon inflating passage adjacent the proximal end thereof between said sleeve and said balloon inflating fluid, said closing means being releasable exteriorly of said catheter to release said inflating fluid from its confinement to inflate said balloon.

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