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DISPOSABLE CARTRIDGE FOR INFLATING BAG CATHETERS

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ABSTRACT OF THE DISCLOSURE

A disposable cartridge for inflating bag catheters comprising a flexible pouch having a tubular tip projecting from the open end of the pouch and communicating the interior of the pouch with the surrounding environment, the pouch having a rupturable cartridge therein containing a catheter bag inflating fluid under sufficient constrictive pressure to propel the inflating fluid from the pouch through the pouch tubular tip to cause inflation of a catheter bag.

The present invention relates to a device for inflating bag catheters.

For many years the inflatable bag urethral catheter has been an indispensable means of continuous drainage of the human bladder; it has been a useful and oft-used tool of the urologist. Essentially, an inflatable bag urethral catheter comprises an elongated tubular shaft having an expansible bag adjacent the distal end thereof capable of being expanded by an inflating fluid into a balloon around the distal end portion of the catheter shaft. After insertion of the catheter through the urethra and passage of its distal end portion into the bladder, the balloon is expanded and seats within the bladder, thus retaining the distal end portion of the catheter within the bladder and providing constant drainage of urine therefrom.

Conventionally these bag catheters are made with a drainage channel throughout the length thereof so that the fluid from the bladder drains through the tubular catheter shaft. The catheter shaft also has an inflation duct running parallel to but separated from the drainage channel, one end of this inflation duct opens into the expansible bag and the other end of the inflation duct opens into a distention tube which diverges from the proximal end portion of the tubular catheter shaft. The distention tube is a flexible branch off the main catheter shaft, readily manipulatable during introduction of fluid into the inflation duct to expand the bag and retain the catheter in place.

Conventional inflatable bag catheters may be equipped with different types of inflation duct end closures through which fluid is introduced into or evacuated from the inflation duct of the catheter. A common one is a self-sealing soft rubber plug in the end of the distention tube. The hypodermic of a syringe penetrates this self-sealing plug and a measured amount of water from the syringe is forced through the needle to expand the bag. Upon withdrawal of the needle through the self-sealing plug, the plug seals itself and the catheter bag remains inflated until the distention tube adjacent the self-sealing plug is cut away to permit the fluid to escape from the bag. Alternatively the fluid may be evacuated from the bag by inserting a hypodermic needle through the self-sealing plug. Another closure is a valve closure through which fluid is introduced or evacuated by a tubular penetrating probe.

Until recently, in all commercially useful inflatable bag urethral catheters in order to inflate the bag, it was necessary to sterilize water, a container for holding the sterile water, a hypodermic needle and syringe, then fill the sterile syringe with the sterile water, plunge the

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syringe needle, or other penetrating probe, into the proximal end of the distention tube of the bag catheter and then force the liquid contents from the syringe into the inflation duct and inflate the bag. Essentially this procedure was followed for the past 30 years.

I have invented in recent years a self-inflating bag catheter which dispenses with the cumbersome and costly procedures theretofore used to inflate bag catheters. A preferred embodiment of this kind of catheter is described in detail in my copending application Ser. No. 137,889 filed Sept. 13, 1961 now U.S. Patent No. 3,152,592 issued Oct. 13, 1964. In these self-inflating catheters two basic principles are found. First, means is provided which normally occludes passage through the inflating duct between the proximal end of the catheter and the inflatable bag. Second, within the portion of the catheter adjacent the proximal end thereof, an inflating fluid is retained in a confined condition under constrictive pressure such that upon release of the means occluding passage through the inflating duct, the inflating fluid is self-propelled into the bag to inflate the same.

While these self-inflating catheters permit the production of catheters complete with inflating fluid as self-contained units, there are situations where their use is not practical. Thus, because of variations in bag expansion requirements in special patient categories such as children, or those with afflictions which do not permit normal catheter bag expansion, there are many catheter applications which do not readily admit of the use of self-inflating catheters having relatively fixed expanded volume. Even though the number of such special situations may represent as much as 20% of the bag catheters used, the bag expansion requirements are too diverse to render economical the production of self-inflating catheters therefor.

For those special situations and for those who for one reason or another require conventional bag catheters, I have now invented a simple, disposable inflation cartridge for use with conventional catheters which shares many of the advantages of the self-inflating bag catheter and still avoids all of the disadvantages of the conventional inflating paraphernalia.

A disposable cartridge for inflating bag catheters made in accordance with this invention comprises a flexible pouch having a tubular tip of reduced size projecting from the open end thereof and communicating the interior of said pouch with the surrounding environment. The tip constitutes a penetrant for a bag catheter inflation duct end closure. Within the pouch a catheter bag inflating fluid is retained under sufficient constrictive pressure to propel the inflating fluid from the pouch through the pouch tip with sufficient force to cause inflation of a catheter bag. Fluid release means normally closes passage of the fluid from the pouch. The release means, while not susceptible to inadvertent release, is adapted to readily release fluid from the cartridge upon penetration of the cartridge tip through a catheter inflation duct end closure.

While the disposable bag catheter inflation cartridge of this invention is susceptible of many embodiments, a preferred embodiment of the invention is illustrated in the accompanying drawing wherein:

FIGURE 1 is a side elevational view, with parts in cross section for clarity of detail, of a disposable cartridge for inflating conventional bag catheters made in accordance with my invention;

FIGURE 2 is a side elevational view similar to FIGURE 1 of the cartridge of FIGURE 1 with a different kind of end closure penetrating tip;

FIGURE 3 is a perspective view of a conventional bag catheter with which the inflation cartridge may be used;

FIGURE 4 is a side elevational view disclosing the

manner of use of the cartridge in inflating a bag catheter having one form of inflation duct end closure; and

FIGURE 5 is a view similar to FIGURE 4 disclosing the inflation of a bag catheter having an end closure penetrated by the type of penetrating tip illustrated in FIGURE 2.

Referring now to the accompanying drawings in detail, the disposable cartridge of this invention is illustrated in its entirety by the numeral 10 in FIGURE 1 and will be seen to comprise a flexible tubular pouch 12 of considerably greater length than diameter and having a tubular tip 14 of reduced size projecting from the open end thereof. A protective sheath 15 normally protects this tip and keeps it sterile until use of the cartridge. The tubular tip 14 is in the form of a hollow needle communicating the interior of the pouch 12 with the surrounding atmosphere. A suitable gasket or hub 16, or other mounting member, on the penetrating tip 14 sealingly attaches the penetrating tip to the pouch wall at the open end of the pouch 12.

Preferably, the pouch 12 is a simple tubular sheath of flexible thermoplastic vinyl chloride polymer, or other suitable plastic or rubber, and the penetrating tip mounting hub 16 may also be of a suitable thermoplastic material whereby the pouch and sealing member can be heat-sealed to one another to provide a fluid tight seal. However, the mounting hub 16 may be metal or other material and adhesively joined or otherwise secured to the pouch. The pouch should desirably be sufficiently transparent that the contents of the pouch are visible to the unaided eye.

Carried within the pouch is an elongated tubular ampoule 18. In this preferred embodiment of the invention this ampoule may be a glass tube having both its ends sealed, and having a scoreline 20 therearound intermediate its ends to cause the ampoule to separate cleanly into two parts upon being subjected to bending stress.

Prior to sealing one of the ends of the glass ampoule, it is filled with a measured amount of a suitable catheter bag inflating fluid, which fluid is retained in the ampoule under much greater pressure than that of the surrounding atmosphere.

A particularly useful fluid has been found to be perfluorocyclobutane, a nontoxic, and normally gaseous fluid which is nevertheless liquid at a temperature of approximately 21.1° F. and which does not diffuse through thin rubber latex bags in a urine environment. By maintaining the temperature of the ampoule below the boiling temperature (21.1° F.) of this fluid, the ampoule is readily filled with the fluid while the fluid is in liquid phase. Then, the ampoule is sealed, as by melting the tip in a normal glass tube closing operation, and the ampoule allowed to return to normal temperature whereupon the fluid is maintained within the ampoule in a liquid phase under elevated pressure and at a much smaller volume than would be its normal gaseous volume under atmospheric conditions.

FIGURE 2 illustrates the cartridge of FIGURE 1 with a blunt ended tubular probe 22 as the penetrating tip. This hollow probe comprises a penetrant for opening a valve-type catheter inflating duct end closure.

In FIGURE 3 there is illustrated a conventional inflatable bag catheter 24 of natural latex rubber, consisting essentially of a flexible tubular catheter shaft 26 having an inflatable bag 28 adjacent the distal end 30 thereof and having a distention tube 32 diverging from the shaft 26 adjacent the proximal end 34 thereof.

As illustrated in FIGURE 4, the distention tube has within it a passageway which is in extension of the inflation duct 36 which travels the length of the catheter shaft and opens into the inflatable sleeve or bag 28. Self-sealing plug 38 normally closes the open end of this inflating duct 36 so that fluid cannot pass through it.

In order to inflate the catheter bag, using the cartridge 10 of FIGURE 1, the hypodermic needle tip 14 of the

cartridge 10 is pushed through the self-sealing plug 38 until it communicates with the inflating duct 36. By making the ampoule 18 of a rigid material such as glass the cartridge can be readily used as a handle to press the needle 14 through the self-sealing plug. Once the needle has penetrated the plug, fluid is released from the cartridge simply by flexing the pouch 12 as illustrated in FIGURE 4. Upon such flexing the ampoule breaks along the scoreline and the fluid contents thereof are released, whereupon the expanding fluid enters the inflation duct 36 and inflates the catheter bag to the desired volume, e.g., 5 cc., 7 cc., 10 cc., depending upon the predetermined amount of fluid that has been retained within the ampoule. Following bag inflation the needle is withdrawn through the self-sealing plug and the cartridge is discarded whereupon the catheter is self-retained in the bladder.

In FIGURE 5, the use of the cartridge 10 with the penetrating tip 22 of FIGURE 2 is illustrated. As will be noted in this figure, the distention tube 32 of the catheter has a valve closure 40 closing the end of the inflating duct 36. Penetration of the probe-like tip 22 into the valve passage 42 of the valve opens the valve and permits passage of fluid into the inflating duct. Removal of the penetrating tip 22 causes the valve to close again whereby no inflating fluid escapes from the inflation duct 36 of the catheter.

While there has been illustrated and described a preferred embodiment of my invention it will be apparent to those skilled in the art that various minor modifications are possible. Thus, for example, the penetrating tip of the pouch may itself be utilized as the means to release the fluid from the pouch, resistance to penetration of the penetrant, causing the penetrating tip to release the fluid from the pouch. Further, by stiffening of the pouch (as by thickening the wall) the fluid can be retained directly within the pouch without an ampoule and, if bulk is not a problem, the fluid need not even be an expansible one, but can be a fluid such as water retained within a constrictive envelope of rubber or the like.

However, in the preferred embodiment of the invention shown, several advantageous, and in themselves novel, structural characteristics are apparent. The combination of the flexible tubular pouch with the rigid ampoule provides a rigid handle for facilitating penetration of the penetrating tip of the cartridge while at the same time maintaining the inflating fluid in a very small volume so that the bulk of the cartridge is extremely small, a dozen or so of the cartridges being fitted into a box not much larger than a small match-box. The flexibility of the pouch combined with the strength of the rigid ampoule, guard against inadvertent breakage and fluid release. The advantages of shipping, storage, and handling with this combination is apparent to all. Further, by making the pouch and the ampoule both of transparent material, the physician is visually aware of the rupture of the cartridge ampoule upon flexing of the pouch. By using a fluid such as perfluorocyclobutane (which is liquid at relatively small pressure and thus extremely safe to handle) the physician is further aided in his evaluation of the successful use of the cartridge by the visual observation of the disappearance of all the liquid from the cartridge upon ampoule rupture.

It is believed this invention usefully fills a gap between the self-inflating bag catheters recently introduced and the conventional syringe inflatable bag catheters still required in many catheter applications.

I claim:

1. A disposable cartridge for inflating bag catheters comprising a flexible pouch having a rigid tubular tip of reduced size projecting from the open end thereof and communicating the interior of said pouch with the surrounding environment, said tip comprising a penetrant for a bag catheter inflation duct end closure, a catheter inflating fluid within said pouch, means within said pouch maintaining sufficient constrictive pressure on said in-

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flating fluid to propel said fluid from said pouch through said tip upon fluid release from said pouch with sufficient force to inflate a catheter bag, and fluid release means normally closing passage of said fluid through said pouch tip whereupon release of fluid may be prevented until penetration of said tip through a catheter inflation duct end closure, said constrictive pressure retaining means sufficiently rigidifying said pouch to enable said pouch to serve as a rigid cartridge body to enable positioning of said cartridge and penetration of said cartridge tip into a catheter end closure.

2. A disposable cartridge for inflating bag catheters comprising a flexible, tubular pouch of greater length than diameter, said pouch having a rigid tubular tip of reduced size projecting from the open end thereof and communicating the interior of the pouch with the surrounding environment, means sealingly mounting said tip in the open end of said pouch, said tip comprising a penetrant for a bag catheter inflation duct end closure, a rigid, tubular ampoule within said pouch, the length and diameter of said ampoule being only slightly smaller than those of said pouch and stiffening said pouch and forming a rigid cartridge body for facilitating positioning thereof for penetration of said tip into a catheter end closure, a bag catheter inflating fluid carried within said ampoule in a compressed state at a volume much less than the normal volume of the fluid in the surrounding atmosphere, the amount of compression being sufficient so that upon release of the fluid from the ampoule, the fluid will expand sufficiently to inflate a catheter bag to a predetermined volume upon passage of the fluid through said tip into a catheter bag inflation duct, said ampoule having a weakened portion for breakage thereof to release the fluid therefrom upon bending flexure of said pouch.

3. A disposable cartridge for inflating urethral bag catheters comprising a flexible, tubular pouch of greater length than diameter, said pouch having a tubular tip of reduced size projecting from the open end thereof and communicating the interior of the pouch with the surrounding environment, means sealingly mounting said tip in the open end of said pouch, said tip comprising a penetrant for a bag catheter inflation duct end closure, a rigid, tubular ampoule within said pouch, a bag catheter inflating fluid carried within said ampoule in a compressed state at a volume much less than the normal volume of the fluid in the surrounding atmosphere, the amount of compression being sufficient so that upon release of the fluid from the ampoule, the fluid will expand sufficiently

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to inflate a catheter bag to a predetermined volume upon passage of the fluid through said tip into a catheter inflation duct, said ampoule having a weakened portion for breakage thereof upon flexure of said pouch to release the fluid therefrom, said pouch and ampoule being of transparent material, the length and diameter of said ampoule being only slightly less than those of said pouch and forming said pouch into a rigid catheter body to facilitate positioning of said cartridge for penetration of said tip thereof into a catheter end closure and said fluid being perfluorocyclobutane.

4. The cartridge of claim 3 wherein said penetrating tip is a hollow needle.

5. The cartridge of claim 3 wherein said penetrating tip is a blunt ended probe.

6. A disposable cartridge for inflating bag catheters comprising a flexible, tubular pouch of greater length than diameter, said pouch having a tubular tip of reduced size projecting from the open end thereof and communicating the interior of the pouch with the surrounding environment, means sealingly mounting said tip in the open end of said pouch, said tip comprising a penetrant for a bag catheter inflation duct end closure, means having bag catheter inflating fluid therein carried within and rigidifying said pouch, said fluid being in a compressed state at a volume much less than the normal volume of the fluid in the surrounding atmosphere, the amount of compression being sufficient so that upon release of the fluid from the pouch, the fluid will expand sufficiently to inflate a catheter bag to a predetermined volume upon passage of the fluid through said tip into a catheter bag inflation duct, and fluid release means normally closing passage of said fluid through said pouch tip whereupon release of fluid may be prevented until penetration of said tip through a catheter inflation duct end closure.

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