United States Patent

[11] 3,599,620

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Continuation of application Ser. No. 508,673, Nov. 19, 1965, now abandoned.

[51] **Int. Cl.** **A61m 25/00**
[50] **Field of Search** 128/348, 351, 246, 325, 344

[56] **References Cited**

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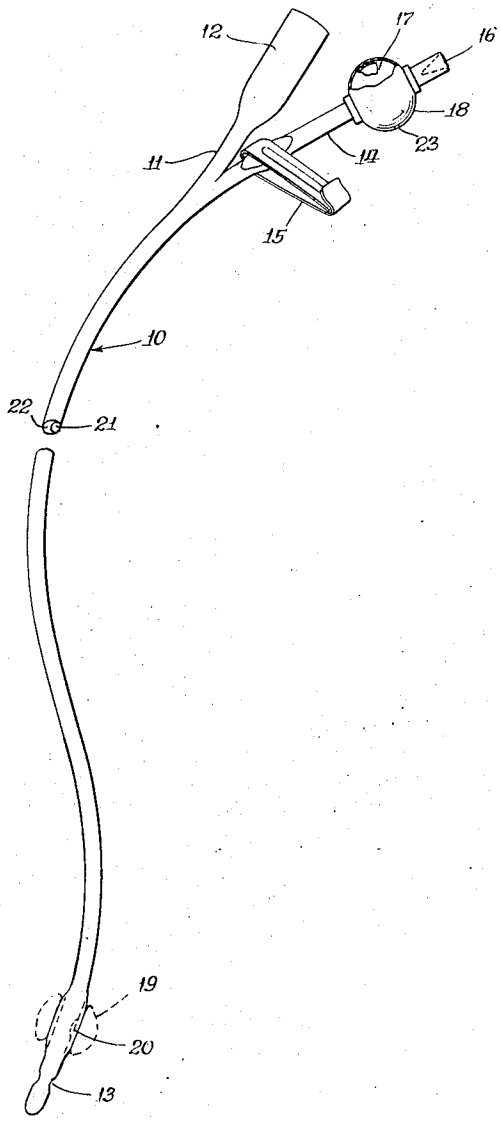
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[54] **RESILIENT RESERVOIR ASSEMBLY**
6 Claims, 5 Drawing Figs.

[52] **U.S. Cl.** ..... **128/349 B,** 128/246

ABSTRACT: An inflatable retention catheter's resilient inflated reservoir retaining a fluid under pressure is enclosed by a jacket which reduces fluid loss through the reservoir wall during storage and does not inhibit deflation of the reservoir.



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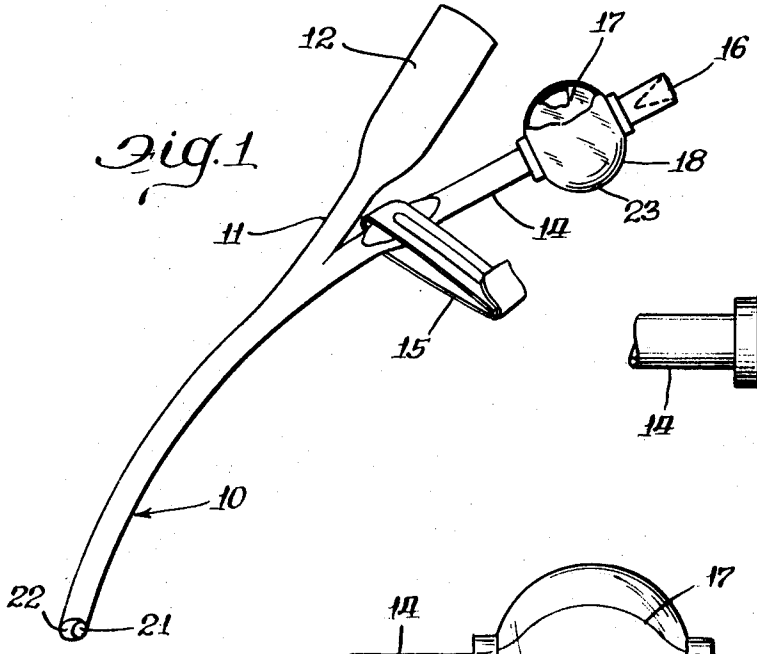


Fig. 1

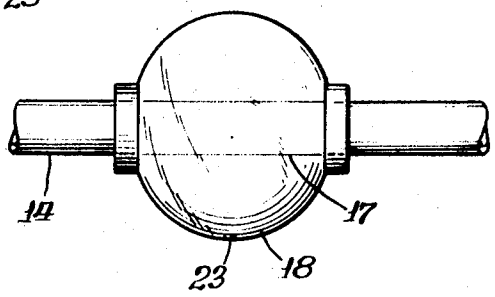


Fig. 2

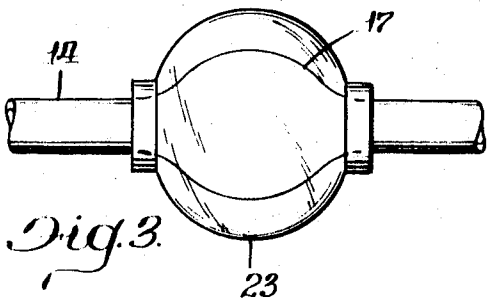


Fig. 3

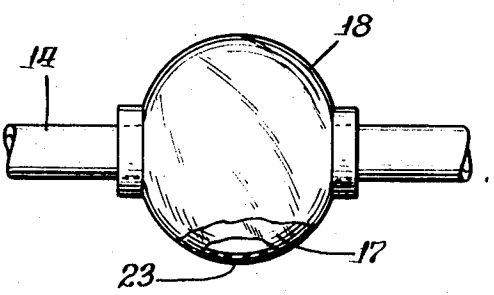


Fig. 4

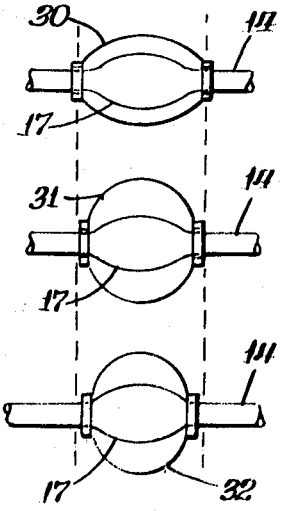


Fig. 5



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RESILIENT RESERVOIR ASSEMBLY

This application is a continuation of Ser. No. 508,673 filed Nov. 19, 1965 and now abandoned.

This invention relates to self-inflating catheters, that is, to catheters which have a fluid distended elastic reservoir which upon release of the contained fluid exerts sufficient pressure while deflating to inflate an inflatable retention bulb or balloon near the distal end of the catheter. More specifically, this invention relates to means for reducing fluid loss from the reservoir through its walls in storage and prior to use.

For purposes of this invention, the distal end of a catheter is considered to be that end which is inserted into an animal body whereas the proximal portion of the catheter is that portion which is intended to be outside the body.

The reservoir of a self-inflating catheter is preferably kept as small as possible to eliminate bulkiness but it is kept within size limitations for other reasons. The retention bulb of an inflatable bulb indwelling catheter has definite size limitations. On the one hand, it has to be large enough to retain the distal end of the catheter in the bladder when the bulb is inflated after insertion. On the other hand, it should not be so large as to interfere with the efficiency of the catheter as a drainage device or to cause undue irritation of the bladder.

These size limitations are important when it is considered that the elastic reservoirs in use today have fairly high fluid losses through their walls and the difference in volume between maximum and minimum desirable inflation of the retention bulb is not very great.

Attempts have been made in the past to provide self-inflating catheters with small reservoirs by coating the distended reservoir with various gas and vapor retentive coatings. Unfortunately, however, such coatings are comparatively inelastic (and some become more so on aging) when compared with the elastic rubber reservoir and, therefore, must be kept at a thickness considerably less than optimum in order to avoid restricting reservoir deflation. Furthermore, such coatings may present a very unattractive appearance when the reservoir is deflated and their thinness restricts the loss of fluid to the bare minimum necessary for practical usage. What has been unattainable until this invention has been a self-inflatable catheter whose shelf life has been substantially increased.

It is the primary object of this invention to provide a cover for the elastic reservoir of a self-inflating catheter which does not inhibit deflation of the reservoir and which significantly reduces fluid loss from the reservoir.

Other objects of the invention will be apparent from the drawings and from the specification.

It has been found that a reservoir covering jacket whose walls are of sufficient thickness to significantly reduce fluid loss is effective in this respect provided a fluid-retaining seal is maintained between the ends of the reservoir and the jacket.

Referring to the figures:

FIG. 1 illustrates a self-inflating catheter with the jacket of the invention in place over the inflated reservoir thereof.

FIG. 2 illustrates in detail the jacketed reservoir of FIG. 1 prior to inflation of the latter.

FIG. 3 is an illustration of the jacketed reservoir of FIG. 2 with the reservoir partially inflated.

FIG. 4 is an illustration of the jacketed reservoir of FIG. 2 with the reservoir fully inflated.

FIG. 5 illustrates the comparative values as fluid retentive jackets of prolate spheroidal, true spherical and oblate spheroidal jackets.

It has been found that when a tubular elastic reservoir is inflated, it tends to assume a prolate spheroidal form in the inflated portion. It would appear at first glance that a jacket closely following the contour of the inflated reservoir would be the most desirable form for a jacket. But as can be seen from the schematic illustrations in FIG. 5 when partial fluid loss occurs, the prolate jacket **30** begins to lose its fluid-retaining seal first, the true spherical jacket **31** loses its fluid-retaining seal next while the oblate jacket **32** is just at the point of losing its fluid retaining seals. Thus, while all of the spheroidal shapes are somewhat effective, the oblate jacket would prevent excessive loss of fluid for a longer period than either of the other shapes. However, while a spheroidal shape is the preferred shape, the end seals and the distance between them are more important than the jacket shape. For instance, one could utilize a cuboid shape so long as the fluid-retaining seal areas are present at both ends and the distance between them is less than the reservoir length when partially inflated. The jacket obviously should not be substantially greater in volume than the volume of the inflated reservoir.

Referring once more to the drawings:

In FIG. 1, the self-inflating catheter **10** consists of a tubular main drainage arm **11** with a connector end **12** and a discharge end **13** connected by a drainage channel **22**. An inflating side arm **14** normally has its inflating channel **21** closed by a clamp **15** and its proximal end closed by the plug **16**. The inflating channel **21** and the drainage channel **22** are contained within the main arm from the point where the side arm **14** meets the main arm until channel **21** terminates in orifice **20** within the inflatable sleeve **19**. On the side arm **14**, between the plugged proximal end and the point where the side arm joins the main arm, an inflated reservoir **17** is covered by and sealed against fluid loss by the spheroidal jacket **18** which compresses the reservoir longitudinally from its normally prolate spheroidal shape to a more nearly spheroidal shape or even to an oblate spheroidal shape. The compressed reservoir presses against the jacket at each end to form pressure seals which prevent, or at least very much restrict, fluid loss from the jacket interior at the seals. In practice, the jacket is slipped over the proximal side arm end in place over the reservoir and the latter is inflated by a syringe or other fluid discharge means. The end seals are so effective that to obtain maximum inflation of the reservoir, it is desirable to vent the jacket as with the vent **23**. Substantially self-closing vents may be made in jackets of flexible material by piercing them from the outside inwardly. This causes a hole with rather jagged edges to be produced and as the reservoir fills, the hole edges interfit to provide a substantial closure. It is to be understood, however, that the jacket is effective whether a vent is or is not provided, or whether the vent hole is closed.

In FIG. 2, the reservoir **17** on side arm **14** is uninflated and seals are not yet formed with the jacket **18**.

In FIG. 3, the reservoir **17** has been inflated sufficiently so that the reservoir ends are beginning to form seals against the jacket interior. As soon as the seal is effective, the vent **23** relieves the internal pressure between the reservoir and the jacket.

In FIG. 4, the reservoir **17** is fully inflated and the end seals which progressively increase in width as the reservoir is inflated meet near the equatorial circle of the jacket. The hole **23**, if not substantially closed is sealed around its edges by the inflated reservoir.

Vents made in jackets with a hot needle and whose bores take an hourglass configuration which measures at its widest point approximately 0.012 inches in diameter cause fluid losses only slightly greater than unvented jackets. With fully inflated 11 ½ cc. reservoirs at 70° F. maintained for 3 years, for instance, such a vent causes the jacket to lose only one-half cc. more fluid than an unvented jacket.

Preferably, the jackets of this invention are blow molded in one piece of thermoplastic materials including glass. But they could be made of metal. Plastic materials can be injection molded in two pieces which can be joined by any of several methods including solvent sealing, ultrasonic welding, heat sealing, cementing, etc. For the most part, the wall thickness should be upwards of 5 mils for most plastic jackets, somewhat less for glass jackets and at least 1 mil for metal jackets. The thickness obviously depends upon the strength and fluid transmission rate of the materials used.

Suitable thermoplastic materials include polyethylene, polypropylene, polycarbonate, phenoxy resins and styrene

blends such as styrene-acrylonitrile resins. The latter three materials like glass are very attractive because of their transparency. Obviously, materials with low fluid transmission rates are to be preferred since they may be made proportionately thinner.

While jackets with volumes in the range of 8 to 12 cc. are preferred, the size is optional and animal catheters and special hemostatic or pediatric catheters with larger or smaller retaining bulbs may require proportionately larger or smaller reservoirs and corresponding jackets.

It has been postulated [Journal of Polymer Science 18:201 (1955) Berry and Watson] that stress relaxation of sulfur vulcanizates is essentially the result of first order degradation of more than one type of cross-link. Our own tests with vulcanized latex tends to corroborate these postulations. But regardless of the explanation of the deterioration of the rubber latex, the pressure within inflated rubber latex reservoirs does deteriorate with time. If the known deterioration in pressure continues for a sufficient period of time, it eventually becomes insufficient to inflate the retention bulb. With an unprotected aged reservoir, therefore, it may be necessary to squeeze the reservoir to inflate the retention bulb. I have discovered, however, that when the reservoir is inflated but not permitted to assume its natural inflated contours, the distorted inflated reservoir exerts a higher pressure upon the same fluid contents than it does when it has its natural inflated contours. Not only is this initially true but it continues to be true as the pressures in the distorted and naturally contoured reservoirs deteriorate with time. The jackets of this invention, therefore, so long as they are effective in distorting the reservoir, not only retain the fluid with minimal loss but also retain the fluid at higher pressure than otherwise. This insures that there will be sufficient liquid at higher pressure for a longer period of time.

For example, when observed within the range of temperatures from 0° F. to 120° F., a coated catheter reservoir (¼ mil polyvinylidene chloride coating) loses water approximately 60 percent as fast as an uncoated catheter. A catheter of the invention (substantially spherical except at ends) loses water approximately 10 percent as fast as an uncoated catheter so long as the reservoir is effectively distorted.

Likewise, in the same observed temperature range, the jacketed reservoir of the invention, when inflated with the same amount of water as a similar but unjacketed reservoir, initially exerts a greater pressure on the contents which can be regulated by the relative size of the jacket but reasonably is in the range of 2 to 10 pounds per square inch greater. Until the jacket becomes ineffective due to loss of the end seals, the difference in pressure, while reduced, continues to be significant.

The jacketed reservoirs of this invention need not be integral with catheters. In some embodiments the reservoir assembly is detachable after inflation of the inflatable retention means. In other embodiments the reservoir assembly is attached only during inflation of the inflatable retention means. Connection may be accomplished by insertion of a hollow needle or by well known valvular means.

I claim:

1. In combination, a self-inflatable bag catheter comprising an elongated flexible thin-walled drainage tube open at its proximal end and having at least one lateral opening in its distal end, a thin-walled elastic sleeve adjacent the distal end of said drainage tube, said sleeve being bonded along its marginal zones to the exterior surface of said drainage tube to form a fluidtight seal along said marginal zones of said sleeve and being unattached to said drainage tube along its central region whereby the central region of said sleeve is free to expand laterally of said drainage tube upon the introduction of an inflating fluid into the space formed between the unattached central region of the sleeve and the exterior surface of the drainage tube adjacent thereto, a flexible inflation tube opening at its distal end into the space formed between the unattached central region of the said sleeve and the exterior surface of the drainage tube adjacent the central region of the said sleeve, the proximal end of said inflation tube terminating in an elastic inflation arm offset from the proximal end of said drainage tube including a resilient inflated reservoir retaining a fluid under pressure, the natural shape of said reservoir when unrestrained when inflated being prolate in which the axis thereof which is parallel with the length of the inflation arm is the major longitudinal axis, and a jacket enclosing the inflated reservoir, said jacket restricting said inflated reservoir to a shape other than a prolate shape with its longitudinal axis parallel with the inflation arm and restraining the inflated reservoir to a smaller longitudinal dimension than it would assume inflated with the same amount of fluid when unrestrained so that said axis of said reservoir which is parallel with the length of the inflation arm is no greater than a major axis thereof perpendicular thereto and the amount of fluid in the restrained and restricted shaped inflated reservoir being the same as the amount of fluid in the reservoir inflated when unrestrained and unrestricted.

2. The catheter of claim 1 wherein a portion of the jacket interior is spheroidally concave.

3. The catheter of claim 1 wherein the interior of the jacket is predominantly spherically concave in which all axes passing through the center thereof are substantially of equal length.

4. The catheter of claim 1 wherein the interior of the jacket is predominantly oblately spheroidally concave in which the axis thereof parallel to the length of the inflation arm is shorter than an intersecting axis perpendicular thereto.

5. The catheter of claim 1 wherein the interior of the jacket is predominantly prolately spheroidally concave in which its major axis intersects the longitudinal axis of the inflation arm and is perpendicular thereto.

6. The catheter of claim 1 wherein the interior surface of the jacket is in sealing contact with the exterior surface of the inflated reservoir throughout substantially its entire surface area, the restrained and restricted shape of said inflated reservoir being such that upon partial loss of fluid from the reservoir and consequent deflation of the reservoir the total surface contact between the jacket and reservoir is greater, for the same amount of fluid loss, than the total surface contact between a reservoir and enclosing jacket of a prolate shape corresponding to the prolate shape the reservoir would have if inflated when unrestrained.