



1

2

3,460,540

**PLASTIC CATHETER WITH RUBBER BALLOON**  
Joseph L. Gagne, Warwick, R.I., assignor to Davol Inc.,  
Providence, R.I., a corporation of Rhode Island  
Filed Apr. 18, 1966, Ser. No. 543,403  
Int. Cl. A61m 25/00

U.S. Cl. 128—349

3 Claims

### ABSTRACT OF THE DISCLOSURE

A plastic catheter having a rubber tip secured to its distal end, a thin layer of rubber latex fused to and covering the portion of the plastic catheter adjacent its distal end, including the aforesaid tip, and an inflatable rubber sac fused to said rubber latex layer, said plastic catheter further comprising a plastic funnel portion secured to the proximal end of the catheter, said funnel portion having a drainage passage in alignment with the catheter drainage lumen and an inflating passage in communication with the inflating lumen of the catheter.

The present invention relates generally to medical and surgical products and is more particularly concerned with catheters.

A primary object of the instant invention is the provision of a novel catheter of the so-called urethral or retention type, and the method of manufacture thereof.

Catheters of the urethral or retention type have been in use for many years and traditionally comprise a flexible and resilient tubular body portion having elongated drainage and inflating lumens extending longitudinally therethrough. An opening is provided in the catheter wall extending into communication with the inflating lumen, and an inflatable sac or balloon is secured to the catheter in overlying relation with respect to the inflating opening, whereupon introduction of fluid pressure through the inflating lumen will cause the sac or balloon to distend. The distal end of the catheter is normally rounded and closed off, with the exception of a drainage eye provided at said distal end in the catheter wall in communication with the drainage lumen, said drainage eye being located distally of the aforesaid balloon or sac. At the proximal end of the catheter, funnel portions are provided in communication with the inflating and drainage lumens, respectively, the tubular body normally being bifurcated adjacent its proximal end whereupon the proximal ends of the inflating and drainage lumen extend angularly from each other. Catheters of this general type are illustrated in United States Patents Nos. 2,248,934 and 2,308,484.

Catheters of the general type described supra have been conventionally made of rubber, the usual manufacturing technique involving a series of latex dips, much in the manner described in United States Patent No. 2,320,157, for example. Although rubber latex catheters of this type have proven to be quite satisfactory in operation and use, it has been found that certain advantages are achieved by making the body portion of the catheter of a clear plastic material. More specifically, in urethral catheters constructed of rubber latex, it has been found that after a certain degree of usage, there is a build-up of calcium salts in the drainage lumen of the catheter, which build-up serves to reduce the drainage capacity of the catheter, and in extreme cases might even occlude the catheter so as to completely block off drainage. By constructing the catheter body portion of a nontraumatic, flexible and nontoxic plastic, the catheter will function substantially as effectively as the conventional rubber latex catheter, but, at the same time, the plastic will resist the undesirable build-up of calcium salts mentioned above. In addition, where the catheter body portion is constructed of plastic, it is pos-

sible to provide a larger diameter drainage lumen for a given outer diameter; and hence, without increasing the outer diameter of the catheter, by using plastic it is possible to provide a catheter having greater drainage capacity in addition to being resistant to undesirable build-up of calcium salts such as would tend to decrease the drainage capacity of the catheter. Also, by making the body portion of the catheter of a clear, transparent plastic, added advantages are obtained in that the catheter can be visually inspected to insure that proper drainage is taking place, etc.

On the other hand, even though it has been found desirable to provide a urethral catheter having a plastic body portion, it has, at the same time, been found that plastic balloons or sacs do not function nearly as effectively as the conventional rubber latex balloons or sacs. Specifically, plastic balloons or sacs do not have the resilience or elastic memory of rubber latex, and hence it has been found in practice that in operation and use rubber latex balloons or sacs are much more efficient and durable than plastic balloons.

It is therefore a primary object of the instant invention to provide a urethral catheter having a plastic body portion in combination with a rubber latex balloon.

It has also been found that where a plastic tip is fused or otherwise applied to the distal end of the plastic catheter, a relatively hard and heavy mass exists at said tip. On occasion, this relatively hard distal tip has been found to be a source of internal irritation to the patient, sometimes causing bladder spasms.

It is therefore another object of this invention to provide a catheter having a plastic body, but having a distal tip on said body that is of a soft, resilient material, such as soft rubber, and that is of hollow configuration for added softness.

Another important object of this invention is the provision of a novel and improved method of manufacturing a combination plastic and rubber catheter.

Another object is the provision of a combination plastic and rubber catheter, and a method of making same, having novel and improved means for associating and assembling the inflating and drainage funnels with the catheter body.

Other objects, features and advantages of the invention will become apparent as the description thereof proceeds when considered in connection with the accompanying illustrative drawings.

In the drawings which illustrate the best mode presently contemplated for carrying out the instant invention:

FIG. 1 is a front elevational view of a catheter constructed in accordance with the instant invention;

FIG. 2 is an elevation section, on an enlarged scale, of the catheter shown in FIG. 1;

FIG. 3 is an elevational view, partly in section, showing the plastic tubing from which my catheter is made;

FIG. 4 is an elevational view of the tubing shown in FIG. 3 after certain steps have been performed during the manufacture of my catheter;

FIG. 5 is an elevational view of the tubing after further steps have been performed;

FIG. 6 is a sectional view of the funnel unit which forms a part of my invention;

FIG. 7 is a perspective view of the balloon or sac per se which forms a part of my invention;

FIG. 8 is a section taken on line 8—8 of FIG. 1; and FIG. 9 is a section taken on line 9—9 of FIG. 6.

Referring now to the drawings and more particularly to FIGS. 1 and 2 thereof, there is shown generally at 10 a catheter which is constructed in accordance with the instant invention. The catheter 10 comprises an elongated body portion 12 having a drainage lumen 14 and

an inflating lumen 16 extending longitudinally there-through. The body portion 12 is constructed of any suitable nontraumatic, flexible and nontoxic plastic, such as polyvinyl chloride, and may be formed by an suitable manufacturing technique, although extruding is preferred. As will be seen most clearly in FIG. 3, the body portion 12 is actually a length of tubing, cut to the desired length, and open at its opposite extremities. The distal end 18 of body portion 12 is provided with a rounded hollow tip 20 of soft rubber or the like that is secured to the adjacent extremity of body portion 12 by any suitable means such as cementing. As will be seen, the tip 20 closes off the distal extremity of body portion 12, although an opening 22 is provided in the wall of body portion 12 adjacent the distal extremity thereof. It will be understood that opening 22 is in communication with drainage lumen 14 so as to permit introduction thereto of fluids to be drained, all in a manner well known in the art.

Secured adjacent the distal end of body portion 12, by a technique hereinafter to be described in detail, is a rubber latex balloon or sac 24, it being noted that said balloon extends around body portion 12 and is in communication with inflating lumen 16 by means of opening 26 extending through the wall of the body portion. It will be understood that as fluid under pressure is forced through inflating lumen 16, it will be introduced into balloon 24 through opening 26, whereupon the balloon will be caused to distend to assume the broken-line position shown in FIG. 2. Thus, when a patient is catheterized inflation of balloon 24 will retain the catheter within the patient, all in a manner well known in the art.

As will be seen, and as will be understood, the opening 22 is necessarily located distally of balloon 24. It will be further understood that the provision of the soft hollow rubber tip 20 at the distal end of the catheter comprises an important feature of the instant invention since it has been found that such a tip is nontraumatic in use whereas a relatively hard plastic distal tip sometimes causes bladder spasms in the patient.

At its proximal end 28, body portion 12 receives a funnel unit generally indicated at 30 (FIG. 6). The funnel unit 30 is preferably molded of any suitable plastic, such as by injection molding, and comprises a main tubular portion 32 having a lower bore 34 adapted to snugly and slidably receive therein the upper end of body portion 12. The unit 30 further comprises an integral, angularly extending funnel portion 36 having an inflating bore 38 extending therethrough into communication with bore 34. As will be seen, the tubular portion 32 of funnel unit 30 is provided with an upper bore 40 in alignment and communication with lower bore 34.

In order that lumen 16 may properly function as an inflating lumen for distension of balloon 24, it is necessary that the upper extremity of lumen 16 be closed off, and this is done by any suitable means, such as by pressing therein a plug 42. Slightly below the plug 42 there is provided in the wall of body 12 an aperture 44 communicating with the upper end of lumen 16. Now, when the funnel unit 30 is slidably mounted on the upper or proximal end of body portion 12, it will be seen that bore 40 is in communication with drainage lumen 14, while at the same time the unit 30 is aligned so that inflating bore 38 is in alignment with the aperture 44 whereupon communication is provided between bore 38 and lumen 16. It will thus be seen that with the funnel unit 30 fixedly secured to the proximal end of body portion 12, which securement may be effected by any suitable means, such as solvent fusing or the like, introduction of fluid under pressure through bore 38 will function to distend the balloon or sac 24, all in a well-known fashion. At the same time, the desired drainage through catheter 10 is provided via opening 22, lumen 14, and bore 40.

Since the body portion 12 is constructed of a suitable plastic, such as polyvinyl chloride, and since the balloon or sac 24 is constructed of rubber latex, certain unusual

manufacturing techniques and procedures are employed during the manufacture of the catheter 10, and hence the overall method of making catheter 10 will now be described. The initial steps in to provide the body portion 12 having the drainage lumen 14 and inflating lumen 16 extending longitudinally therethrough, as shown in FIG. 3. As hereinbefore described, the body portion 12 is constructed of a suitable plastic, such as polyvinyl chloride, and is preferably made by an extrusion process. The next step is to close off the distal end 18 of body portion 12 by applying thereto a rounded hollow tip 20 of soft rubber or the like. This may be done by any suitable means, such as by cementing the tip 20 to the extremity of the body portion 12. Since it is desired that the tip 20 be hollow for added softness, the tip may be most easily made by molding.

A suitable dipping form, such as metal rod 46, is then inserted into drainage lumen 14, and the distal portion of body 12 is then dipped into a suitable adhesive, such as a neoprene adhesive. The depth to which the body portion 12 is dipped into this adhesive is not critical, although in practice approximately half the length of the body portion 12 is preferably dipped. The body portion 12 is then removed from the adhesive dip and allowed to thoroughly dry, after which it is again dipped to approximately the same depth, this time in a rubber latex bath. The body portion is then removed and the latex is allowed to coagulate or cure, after which the same latex dip is again repeated. This results in an inner latex layer 48 being formed around the bottom half of the outer surface of body portion 12, including rubber tip 20.

The eye 26 is now cut through the wall of body portion 12 into communication with inflating lumen 16, and then a separate rubber latex sleeve 24a is slid upwardly over the body portion 12 until the eye 26 is substantially centered with respect thereto. It will be understood that the sleeve 24a makes a relatively snug resilient engagement with body portion 12. At this point, the body portion 12, with the sleeve 24a mounted thereon, is again dipped into a latex bath, removed, allowed to cure or coagulate, and then this dipping and curing step is again repeated. This results in the outer latex layer 50 being formed, it being understood that above and below the sleeve 24a the layers 48 and 50 actually fuse to form one layer 52. After the last latex dip and curing, the outer surface of body portion 12, and particularly the part thereof that has been subjected to the aforesaid latex dips, is oxidized, such as by chlorination, to eliminate any surface tackiness. The body portion 12 is then slidably removed from form 46.

At this point, the opening 22 is provided through body portion 12 into communication with drainage lumen 14, it being important that the opening 22 be located below or distally of balloon 24.

The next step is to close off the upper or proximal end of inflating lumen 16, and this may be done by any suitable means, such as by forcing therein a rigid plug 42 of vinyl. The aperture or opening 44 is then provided in the wall of body portion 12 so as to provide an entrance to inflating lumen 16, it being noted that aperture 44 is located just below plug 42. The separately manufactured injection molded funnel unit 30 is now ready for assembly and securement to the proximal end of body portion 12, as hereinbefore described. The outer surface of the proximal end portion of body 12 may be coated with a suitable solvent, as shown at 54 in FIG. 5, whereupon when the unit 30 is slidably engaged thereover, it will be rigidly fused in place. As hereinbefore described, when the unit 30 is secured to body portion 12, bore 40 is in alignment and communication with drainage lumen 14, while inflating bore 38 communicates with inflating lumen 16 due to its alignment with aperture 44.

It will therefore be seen that there has been provided in accordance with the instant invention a catheter capable of accomplishing all of the foregoing objects. Specifically,

5

the structure of catheter 10, and the method of making same, enable the hereinbefore enumerated benefits and advantages of a plastic body portion to be achieved, while at the same time obtaining the benefits and advantages of a rubber latex balloon or sac.

While there is shown and described herein certain specific structure embodying the invention, it will be manifest to those skilled in the art that various modifications and rearrangements of the parts may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular form herein shown and described except insofar as indicated by the scope of the appended claims.

What is claimed is:

1. A catheter comprising an elongated, flexible body constructed of a non-rubber thermoplastic material having a drainage lumen and an inflating lumen extending longitudinally therethrough, a tip secured to the distal end of said body, a thin layer of rubber latex fused to and covering the outer surface of said body adjacent the distal end thereof and also covering said tip, a rubber sleeve surrounding said body adjacent the distal end thereof and overlying said rubber latex layer, a second rubber latex layer covering said sleeve and said first layer whereby to secure the opposite ends of said sleeve to said body while at the same time leaving the inner surface of said sleeve disconnected with respect to said body, a first eye located between the distal end of said sleeve and said tip in communication with said drainage lumen, and a second eye in the wall of said body providing communication between the interior of said sleeve and said inflating

6

lumen, whereby when fluid under pressure is introduced through said inflating lumen, said sleeve will distend to form an inflatable sac.

2. The catheter of claim 1 further characterized in that said inflating lumen is closed at its proximal end, an aperture in the wall of said body communicating with said inflating lumen adjacent its closed end, and a plastic funnel member telescopingly secured over the proximal end of said catheter, said funnel member having a drainage passage in communication with the aforesaid drainage lumen and an inflating passage aligned with said aperture so as to provide communication to said inflating lumen.

3. The catheter of claim 1 further characterized in that said tip comprises a soft hollow rubber member secured to said body at its distal end.

#### References Cited

##### UNITED STATES PATENTS

761,235	5/1904	Kepler	128—349
2,173,527	9/1939	Agayoff	128—349
2,896,629	7/1959	Warr	128—349
2,930,377	3/1960	Cowley	128—344
3,112,748	12/1963	Colburn	128—350
3,292,627	12/1966	Harautuneian	128—349

##### OTHER REFERENCES

Lancet, #7371, Dec. 5, 1964, p. 1218.

DALTON L. TRULUCK, Primary Examiner