

[54] **DISPOSABLE CATHETER APPARATUS**  
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 [22] Filed: **July 17, 1970**  
 [21] Appl. No.: **55,769**

[52] U.S. Cl. .... **128/349 R, 206/63.2 R**  
 [51] Int. Cl. .... **A61m 25/00**  
 [58] Field of Search..... **128/348, 349 R, 350 R, 260, 128/261, 239; 206/63.2 R**

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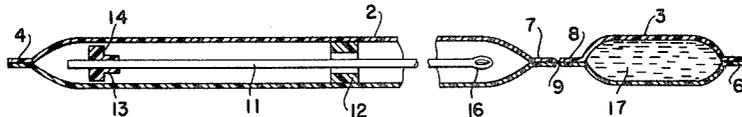
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[57] **ABSTRACT**

A urethral catheter tube formed of a flexible low-friction plastic is carried in a transparent plastic casing one end of which is flattened and severably joined to a plastic cap member. The other end of the casing is closed to form a reservoir. The cap member is a closed vessel containing a lubricant. When the cap is separated from the casing it can be opened to permit application of the lubricant and the casing also opened to permit insertion and implantation of the catheter. Both the lubricant and the catheter tube can be maintained in a sterilized condition and the catheter remains sterile during implantation since it can be worked out of the casing by aseptically contacting it through the casing walls, the net result being that the catheter need not be contacted by human hands.

**10 Claims, 4 Drawing Figures**



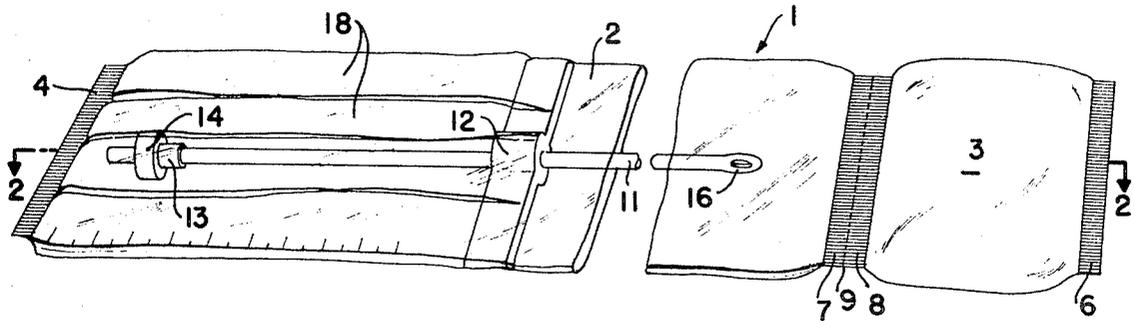


FIG. 1

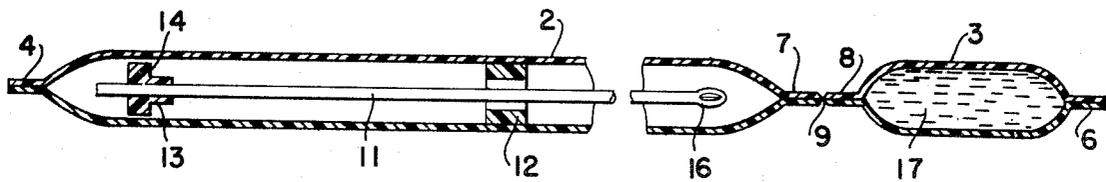


FIG. 2

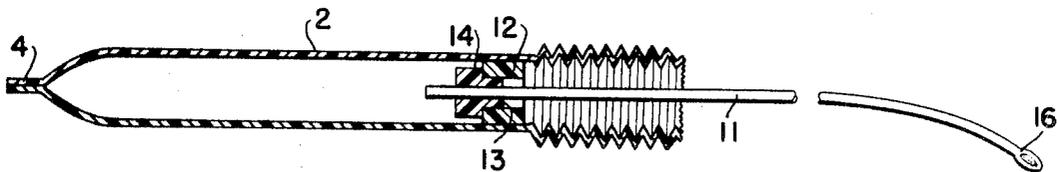


FIG. 3

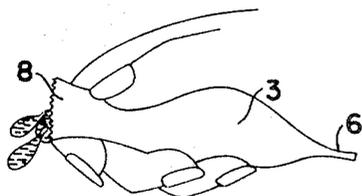


FIG. 4

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## DISPOSABLE CATHETER APPARATUS

The invention described herein may be manufactured and used by or for the Government of the United States of America for governmental purposes without the payment of any royalties thereon or therefor.

### BACKGROUND OF THE INVENTION

The present invention relates to disposable catheters and, in particular, to sterile catheter apparatus which can be applied manually without direct contact by human hands or other unsterile objects.

Many hospital patients require urethral catheterization and one of the serious problems in the treatment of these patients is to prevent urinary infections. Infections, however, can be substantially reduced by limiting the period of time in which the catheter remains in place or, in other words, by employing an intermittent rather than an inlying technique. Even so, the intermittent technique presents real problems that have greatly restricted its obviously beneficial use. The principal problem arises because of the relative frequent need for catheterization coupled with the requirement that each operation must be conducted with sterile equipment and by trained personnel to assure aseptic cleanliness. These requirements apparently have proven too demanding particularly for hospitals or clinics which are notoriously overcrowded and understaffed.

However, there have been several prior art arrangements which utilize disposable catheters that can be handled aseptically. The aseptic handling is achieved by enclosing the catheter tube in an envelope in such a manner that the tube can be inserted by retracting the envelope while pressing the tube in an outward direction. Since the tube itself is not directly touched, it remains sterile. Also, the disposability of the entire arrangement avoids the need for resterilization.

Such prior art arrangements clearly are advantageous, although unfortunately they have not been adapted and used to any appreciable extent. Apparently the reason for their low use has been that the specific arrangements have been rather impractical, difficult to use and relatively expensive. Further, they do not provide in one unitary package all of the necessary components and materials such, for example, as a sterile lubricant to facilitate insertion or a convenient receptacle for collection of the samples. The need is to provide a catheter package that can be distributed economically to patients with assurance of convenient, noninfectious use as the occasion arises.

### OBJECTS OF THE PRESENT INVENTION

It is, therefore, one of the objects of the present invention to provide a low cost, disposable catheter apparatus including a catheter tube capable of being aseptically handled, a lubricant and a convenient receptacle for collection of samples through the implanted catheter tube.

Another object is to provide a convenient and relatively inexpensive packaging arrangement for such catheter apparatus, the convenience permitting use by relatively untrained personnel.

A further more specific object is to provide a packaging arrangement in which the lubricant and the catheter tube are separately sealed in their own containers which, in turn, are joined so that separation of the two containers permits both to be opened for use.

Another specific object is to provide catheter apparatus in accordance with the foregoing objects, the container of the catheter tube also providing a receptacle for sample collection.

These and other objects which will become more apparent are achieved by providing apparatus including a flexible, transparent, open-ended tubular casing that encloses an elongate flexible catheter tube. One end of the casing is closed to provide a baglike receptacle for sample collection through the tube after it has been implanted. The other end of the casing is joined to a cuplike capping member and, preferably, the

joined ends of the casing and the capping member both are constricted or pinched together for sealably closing the interiors of each of the members. A lubricant or other catheterizing material is contained in the cuplike member and the sealing of this member, as well as the casing member, permits the contents of both of these members to be maintained in a sterilized condition. Separation of the two members permits both to be opened and the contents exposed for use. The caplike member can be squeezed to apply lubricant, while the casing member can be manipulated to progressively work the catheter tube outwardly from the casing to permit its insertion and implantation. The lack of any direct contact by human hands of the tube itself maintains a sterile, aseptic condition of the tube and, most suitably, the extent to which the tube can be worked out of the casing is limited so that a length of the tube remains in the casing to provide a communication between the body cavity and the receptacle portion of the casing.

### BRIEF DESCRIPTION OF THE DRAWINGS

The invention is illustrated in the accompanying drawings of which:

FIG. 1 is a face view showing the transparent package or casing of the catheter apparatus and certain of the components contained in the package;

FIG. 2 is a longitudinal section taken along lines 2—2 of FIG. 1;

FIG. 3 is a section similar to FIG. 2 of the catheter tube portion of the apparatus; and

FIG. 4 is a perspective illustrating the capping member and the manner in which it is used.

### DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 1 and 2, the catheter apparatus is shown enclosed in a transparent, plastic envelope or package generally indicated by numeral 1, the envelope being formed of an elongate casing member 2 and a capping member 3. Ends 4 and 6 of the envelope both are closed by any appropriate means, such as by heat-sealing, so that, in effect, both casing member 2 and capping member 3 are provided with closed ends permitting both of these members to be used as containers in a manner which will be described. The other ends 7 and 8 of the casing and capping members are joined together in such a manner that each of the members forms a separate container. More specifically, end portions 7 and 8 are compressed and separably joined again by a heat-sealing process or the like. To permit separability of the casing member and the capping member, the joined portions of these two members may be scored, perforated or otherwise weakened so that the two members readily can be separated by tearing. Alternatively, a tear strip can be employed although obviously the tear line must not sacrifice sealability which, in turn, assures sterility. The rip or tear line for the members is indicated by numeral 9 of FIG. 1.

Casing member 2 sealably encloses an elongate catheter tube 11 as well as a lock ring 12 which, for reasons to be set forth, is provided to restrain the extent to which catheter tube 11 can be worked outwardly of its casing or, in other words, to assure that a portion of the catheter tube remains within casing 2. A sleeve or ferrule 13 mounted on the trailing end of catheter tube 11 cooperates with lock ring 12 to achieve the desired restraining action. As shown, ferrule 13 is fixedly mounted on the end portion of tube 11 and the ferrule is formed with a reduced diameter portion adapted to fit within the internal diameter of ring 12, the remainder of the ferrule being enlarged so as to provide a flange 14 which abuts ring 12 and restrains further outward movement of the tube. Ring 12 also is fixedly mounted by being joined in an appropriate manner to the plastic casing member.

Catheter tube 11 may be of any conventional type although preferably it should be formed of a smooth-surfaced silastic material which is of low friction material adapted to facilitate use of the tube. Also to facilitate use, the tube should be flexi-

ble although a certain degree of stiffness is needed to assure insertion. In this regard, it no doubt is apparent that the present apparatus primarily is intended as an urethral catheter although the packaging arrangement could with certain modifications be adapted for other catheterizing applications. As an urethral catheter, the tube is hollow and open-ended, the leading end of the tube being slightly enlarged and provided with particular opening 16 which permits flow from the bladder through the tube into the casing.

Cap member 3 provides a separate container coupled to casing member 2 in the manner already described, this member being used to provide a lubricating material facilitating the insertion of catheter tube 11. More specifically, cap 3 is filled with a lubricant 17 which, when the cap is separated from casing member 2 becomes available for use both on the tip of catheter tube 11 and around the entrance to the urethral passage.

Other features of the invention best can be appreciated by considering the manner in which the present catheter apparatus is used. In fabricating the apparatus, the catheterizing components such as tube 11 and lubricant 17 are enclosed in envelope 1 and the envelope heat sealed to provide a tight closure which then can be sterilized in any suitable manner to maintain these components in an aseptic condition. The packaged apparatus then may be marketed, stored and distributed as sterile packages and the notation "STERILE" can, if desired, be marked on the exterior of the package. Also, distribution of the packaged apparatus either can be to hospital personnel trained to perform the catheterizations or relatively untrained personnel, such as patients themselves, can perform the task with very little preliminary instruction. When catheterization is required, the user simply separates the cap member from the casing member by ripping the package along line 9 and the separation causes ends 7 and 8 of these members either to open or to be readily openable. The first step, as has been indicated, is the application of sterile lubricant 17 and, as desired, the lubricant can be applied both to end 16 of the tube and to the urethral passage. Preferably, application of the sterile lubricant to the end of the tube is accomplished as soon as the tip end is exposed, although it may be desirable to apply a small amount of the sterile lubricant to end 7 of casing member 2 prior to initial exposure of tip 16. The manner in which lubricant 17 is applied is illustrated in FIG. 4 where it will be seen that application can be accomplished simply by squeezing cap member 3 to extrude whatever amount of lubricant may be required. Obviously, it is desirable that lubricant 17 be somewhat viscous so that a squeezing action is required for the application.

In a manner intended to be illustrated by FIG. 3, catheter tube 11 can be progressively inserted into the urethral canal for implantation in the bladder of a patient without directly contacting the tube with human hands or other instruments which might produce contamination and destroy its aseptic condition. More specifically, the tip portion of tube 11 can be exposed by grasping the tube through package 2 and moving the tube relative to the package to cause tip 16 either to break through the closed end of the package or, if this end is already open, to pass through the opening. Tip 16 then is inserted in the urethral passage and the tube progressively worked into implanted disposition by gently continuing the forward thrust of the tube relative to casing member 2, the casing member being retracted in the manner shown in FIG. 3 as the progressive insertion is accomplished. The tube, of course, is of sufficient length to extend fully into the bladder of the patient and, when so implanted, the tube may be locked in position by retracting the casing to contact its ring 12 with locking ferrule 13. The apparatus then is in position to receive urine samples which pass through the tube into the rearward portion of the casing, this rearward portion preferably being provided with longitudinal pleats 18 (FIG. 1) to provide a baglike reservoir to receive the sample.

Another distinct advantage of the present apparatus is that it can be manufactured relatively inexpensively and that its

components also can be made from inexpensive materials, these features provide a total package which permits disposability after each use without any particular economic sacrifice. In this regard, it has been pointed out that the present catheter is intended for intermittent catheterizations as opposed to the more conventional inlying Foley-type catheters which, as has been demonstrated in practice, are far more prone to produce infection due entirely to the period of time in which they remain implanted. The particular advantages of the present apparatus are found in the ability to handle the catheter tube aseptically so as to avoid the need for sterilizations or resterilizations upon each use or reuse. Disposability obviously avoids the prior need for resterilization. In addition, the apparatus includes all of the elements necessary for intermittent catheterization, these elements, in addition to the catheter tube itself, being the ready availability of lubricant 17 as well as the availability of a baglike reservoir portion of the casing as a sample collector. A further refinement of the apparatus is to mark the pleated portion of the casing in graduated cubic centimeter indices to provide a visual indication of the volume of the sample. In total, a complete catheterizing package is provided which can be conveniently and easily used in a safe and reliable manner and which, after collection of a sample from its receptacle portion, can be disposed of at minimum expense.

Obviously many modifications and variations of the present invention are possible in the light of the above teachings. It is therefore to be understood that within the scope of the appended claims the invention may be practiced otherwise than as specifically described.

I claim:

1. Disposable catheter apparatus comprising:

a flexible transparent elongate open-ended tubular casing member having one of its ends closed for providing a baglike receptacle portion,  
an elongate flexible catheter tube longitudinally disposed within said casing,  
a cuplike open-ended capping member having its open end portion sized to match the open end portion of said casing member,  
fluid catheterization material carried by said capping member,  
the open ends of the casing and capping members being pressed together to provide a flattened sheetlike multi-ply section common to both members and said section having its plies severably united for sealably closing both of said members,  
whereby the contents of said members can be maintained in a sterilized condition and the catheterization can be conducted by separating said members and reopening said open ends,  
the reopening permitting said sterilized fluid material to be applied for catheterization and said sterile catheter tube to be worked out of said casing for implantation by aseptically manipulating the catheter tube through contact with the casing, said envelope then providing a baglike reservoir for receiving fluids delivered through the implanted catheter tube.

2. The apparatus of claim 1 further including means for positively retaining a portion of the tube within the casing whereby the retained portion provides a conduit communicating with said baglike receptacle.

3. The apparatus of claim 2 wherein said retaining means includes a ferrule fixedly disposed interiorly of said casing and a flanged lock ring carried by said catheter tube, said lock ring mating with said ferrule whereby said flanged portion restrains movement of the tube outwardly of the casing.

4. The apparatus of claim 2 wherein said catheter tube is formed of a smooth low-friction plastic.

5. The apparatus of claim 4 wherein said fluid material is a lubricant adapted to be applied to the catheter tube and the patient for facilitating catheterization.

6. The apparatus of claim 2 wherein said baglike receptacle portion of the casing is expandable to increase its capacity.