United States Patent

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[72] Inventors **Clair E. Cox**
Winston-Salem, N.C.;
Frank Hinman, Jr., San Francio; Andrew Harautuneian, Gardena, Calif.

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[73] Assignee **Pharmaseal Division of American Hospital Supply Corporation**
Glendale, Calif.

[54] **MEDICAL INSTRUMENT WITH OUTROLLING CATHETER**
14 Claims, 8 Drawing Figs.

[52] **U.S. Cl.** **128/2,** 128/262, 128/349
[51] **Int. Cl.** **A61b 5/10,** A61m 25/00
[50] **Field of Search** ..... 128/2, 262, 348—350, 356

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Primary Examiner—Dalton L. Truluck
Attorneys—Larry N. Barger, Robert T. Merrick and Dawson, Tilton, Fallon & Lungmus

ABSTRACT: A medical instrument for positioning an elongated sac or catheter in a pathient's urethra for urinary drainage or bacterial sampling. The elongated sac fits in a bore of a flexible insertion tube. One end of the sac extends from a front end of this tube and is secured to a rigid tubular guide sleeve encircling a portion of the flexible introducer tube. As the flexible insertion tube is pushed forward, the insertion tube extends out of the guide sleeve into the urethra and the sac rolls out over a front end of the insertion tube into contact with the urethra.

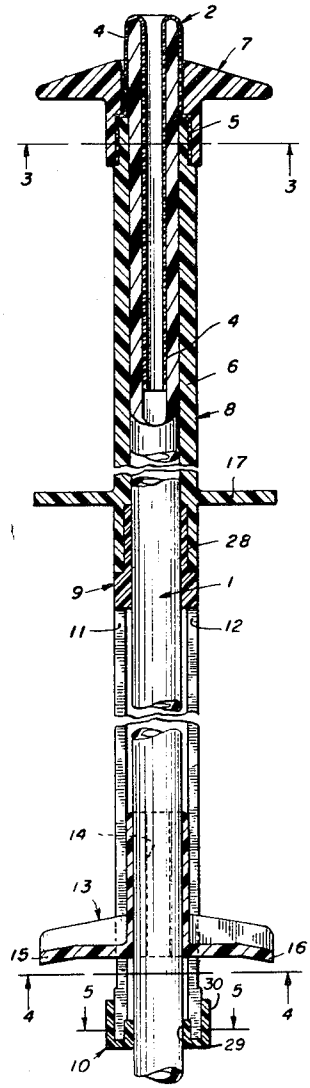


FIG. 1.

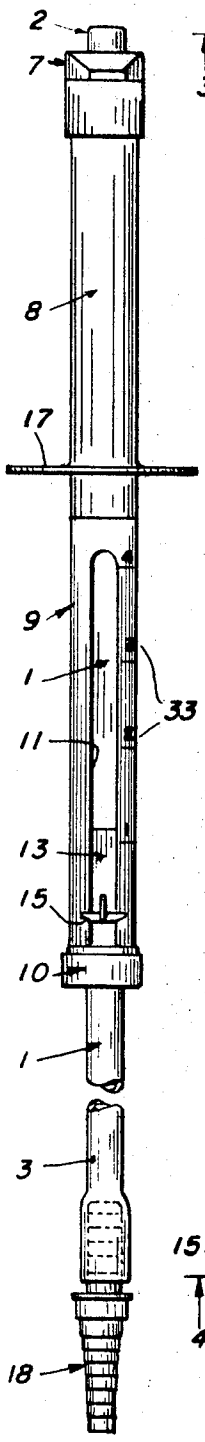


FIG. 2.

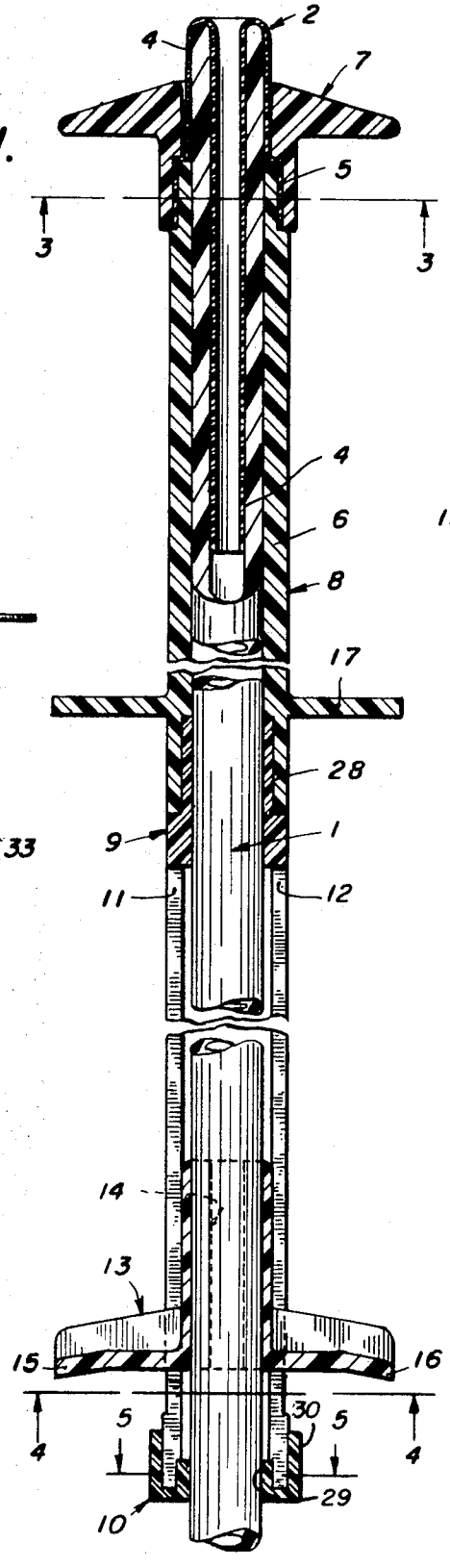


FIG. 3.

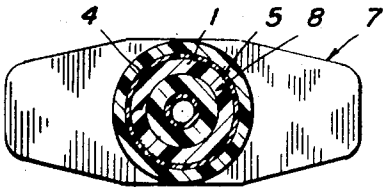


FIG. 4.

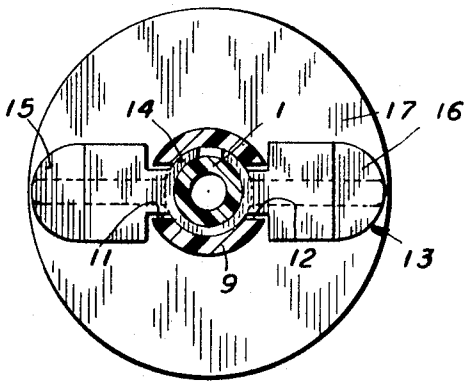
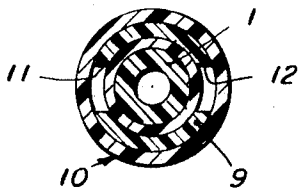


FIG. 5.



INVENTORS
CLAIR E. COX
FRANK HINMAN JR.
ANDREW HARAUTUNEIAN
BY Larry N. Barger
ATTORNEY

FIG. 6.

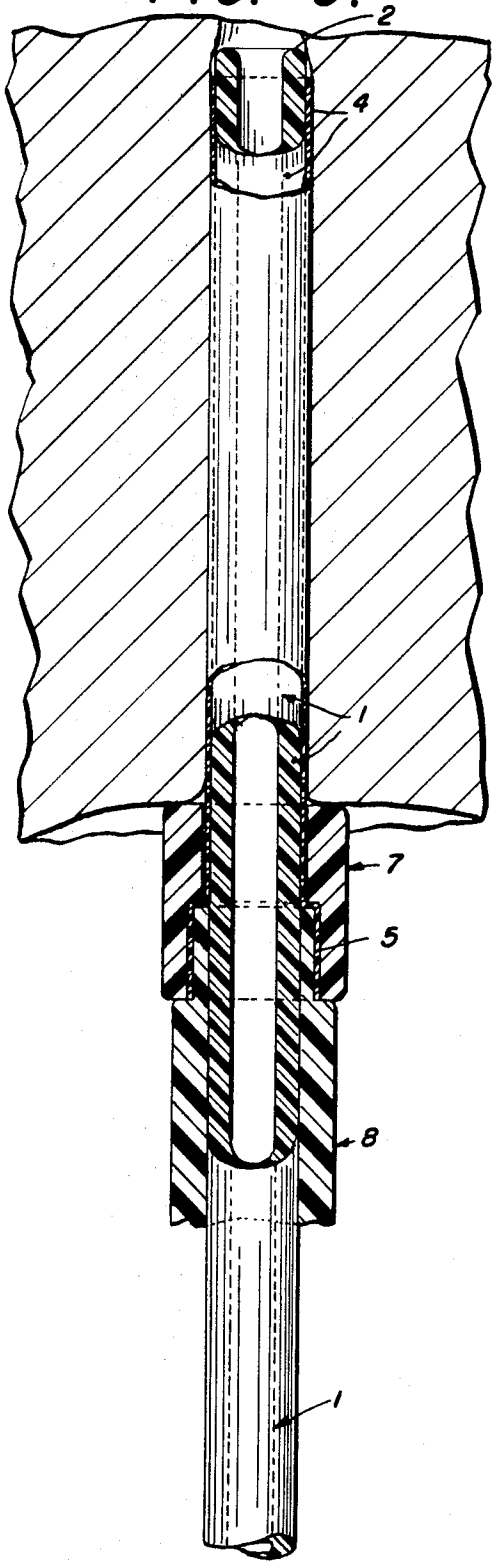
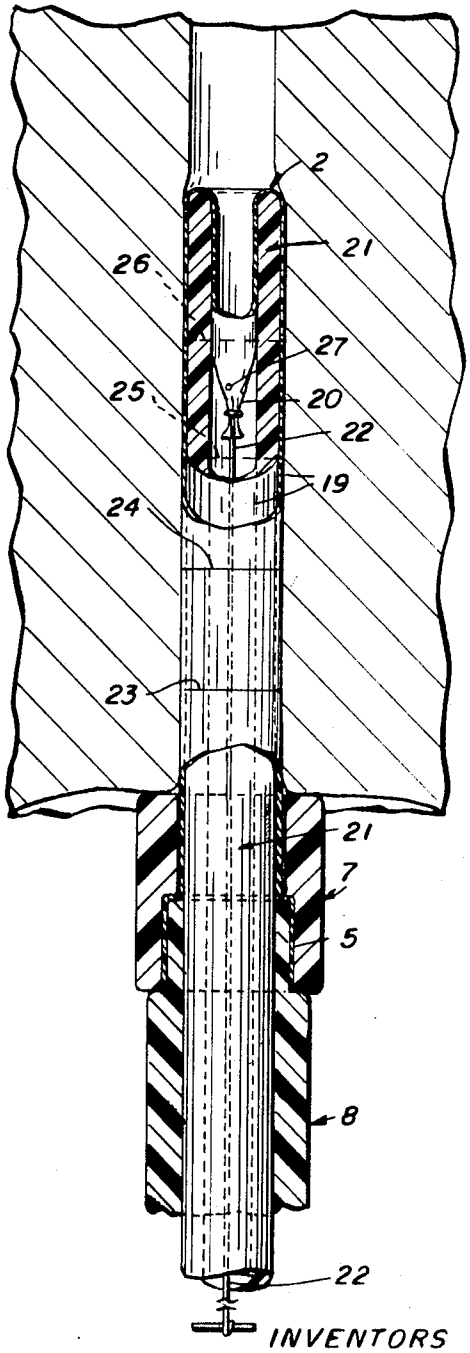
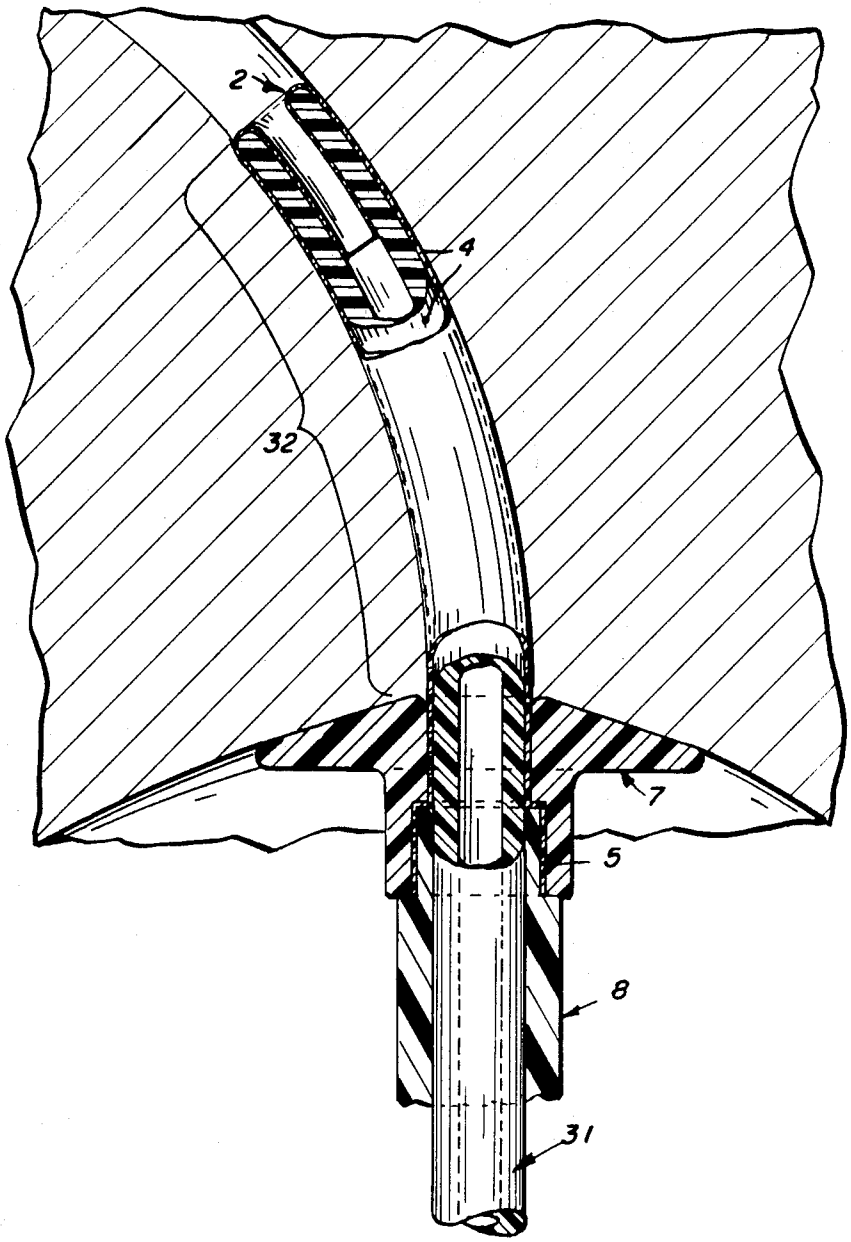


FIG. 7.



INVENTORS
CLAIR E. COX
FRANK HINMAN JR.
ANDREW HARAUTUNEIAN
BY Larry M. Barger
ATTORNEY

FIG. 8.



INVENTORS
CLAIR E. COX
FRANK HINMAN JR.
ANDREW HARAUTUNEIAN
BY Larry N. Barger
ATTORNEY

MEDICAL INSTRUMENT WITH OUTROLLING CATHETER

This invention relates to a medical instrument for everting an elongated sac or catheter and inserting it through an opening and into a body cavity such as the urethra. This is particularly useful for obtaining samples of microorganisms from different areas of the urethra, or for inserting a tube into the urinary bladder without transferring microorganisms from the meatus and distal urethra to other areas of the urinary tract.

Devices with outrolling catheters which accomplish these feats have been proposed in the past. A very early example of such a device is described and illustrated in an article entitled "A New Method for the Prevention of Intraurethral Spreading of Germs Caused by the Insertion of Catheter and Irrigation of the Urethra" by Georg Baller in Dermat. Ztschr. (now Dermatologica) V. 32, p. 39—46 (1921). Work on a similar outrolling catheter device as was done by Henry F. Helmholz, Sr. and reported as "Determination of Bacterial Content of the Urethra: A New Method, with Results of a Study of 82 Men," Journal of Urology, Volume 64, pages 158—166 (1950).

These prior art devices of Baller and Helmholz included a rigid metal insertion tube and a rigid disc with a center hole which slidingly fits over the insertion tube. A flexible rubber sac or cot was attached at one end to the disc. The other end was telescoped into a bore of the metal insertion tube. When the disc was near a forward end of the insertion tube, nearly all the flexible sac was inside the insertion tube. In use, a nurse or physician placed the disc against the urethral meatus. He than then pushed the metal insertion tube through the disc and into the urethra. As the insertion tube advanced, the rubber sac was pulled out of the tube's bore, turned inside out as it rolled over a front end of the insertion tube and was laid down along the urethra.

By visualizing how these outrolling catheter devices work, one can see that the sac or catheter is evaginated during insertion. This is important because it has been found that the first centimeter of the distal area of the urethra often contains a high bacterial count. Areas of the urethra nearer the bladder usually contain few bacteria or may be sterile. With a sterile outrolling catheter device, it is possible to insert the catheter along the entire length of the urethra into the bladder without transferring bacteria, which could cause infection, from the distal to the proximal areas of the urinary tract.

The flexible sac of these devices can be used for either urinary drainage as explained above or can be used for taking bacterial samples at various points along the urethra. In this latter use, these bacterial samples can be used for culture tests in diagnosing a patient's particular urological problem. In this second use, the sac has a pull string tied to an end of the sac within the insertion tube. After the flexible sac has been placed in the urethra, this string is pulled to invert the sac and pull it back into the insertion tube as the device is removed. The sac now has bacterial samples from various points along the urethra, and a physician can identify the bacteria and estimate their concentrations at, for instance, 1, 2, 3 and 4 cm. distances from the urethral meatus.

The foregoing was to explain how the prior art outrolling catheters worked so the present invention could be understood. In the prior art devices a rigid metal tube was used to insert the flexible sac. A rigid metal tube can be painful to a patient, particularly if he moves and the stiff tube in his urethra is cocked to one side. Metal tubes were used despite patient discomfort because they had sufficient columnar rigidity to penetrate the urethra and evert the flexible sac. Flexible plastic insertion tubes have been suggested, but these lack the columnar rigidity of metal tubes and tend to kink and bend when shoved toward the urethra.

The present invention overcomes these difficulties in the previous outrolling catheter devices by providing a flexible plastic insertion tube minimizing patient discomfort, a flexible sac for insertion into the urethra, and a rigid guide sleeve surrounding the flexible insertion tube. The rigid guide sleeve

provides columnar rigidity to the flexible insertion tube but does not itself enter the urethra.

Illustrations of three embodiments of this invention are shown in the attached drawings, in which:

FIG. 1 is a side elevational view of the medical instrument used for inserting a flexible sac into a body cavity;

FIG. 2 is an enlarged longitudinal sectional view partially in section of the medical instrument;

FIG. 3 is a cross-sectional view taken along line 3–3 of FIG. 2;

FIG. 4 is a cross-sectional view taken along line 4–4 of FIG. 2;

FIG. 5 is a cross-sectional view taken along line 5–5 of FIG. 2;

FIG. 6 is a fragmentary longitudinal sectional view of a forward portion of one embodiment of the medical instrument showing it used for urinary drainage;

FIG. 7 is a view similar to FIG. 6 of a second embodiment of the medical instrument showing it being used for obtaining bacterial samples from a urethra; and

FIG. 8 is a fragmentary sectional view of a forward portion of a third embodiment showing a preformed curve in an insertion tube.

Referring to these drawings in detail, FIGS. 1—6 show a first embodiment of the invention particularly suited for inserting a flexible sac into a female patient's urethra without pushing bacteria from the meatus into the bladder. Once inserted, the sac has a flexible insertion tube inside, through which urine can flow. It is important to this invention that the insertion tube be laterally flexible so it can follow any natural contour of the urethra and not cause excessive pain if the patient moves while the insertion tube and sac are in the urethra.

The medical instrument includes a flexible insertion tube 1 with a forward end 2 and a rearward end 3. A thin plastic sac 4 of layflat plastic tubing is telescoped into the insertion tube's bore at its forward end 2 and an end portion 5 of the sac extends out of the insertion tube and is attached to a rigid guide sleeve 6. The sac can be everted and laid down along an inside surface of the urethra by holding guide sleeve 6 and shoving the insertion tube into the urethra.

As mentioned, the instrument includes the rigid guide sleeve 6 surrounding the flexible insertion tube. This guide sleeve is substantially longer than the insertion tube's diameter and has four parts, namely: a forward, generally oval-shaped shield 7 adapted to be pressed against the area surrounding the meatus; a first tubular section 8; a second tubular section 9; and a rear cap 10. All of these parts are joined together to form an elongated rigid member. As shown in FIGS. 1 and 2, the second tubular section 9 has a pair of diametrically opposed slots 11 and 12 providing access to the introducer tube through the guide sleeve 6. A handle 13 is attached to the flexible insertion tube at these slots for urging the insertion tube longitudinally along the guide sleeve. The handle includes a rigid C-chaped tubular segment 14 surrounding the insertion tube and a pair of diametrically opposed thumb pads 15 and 16 integrally joined to the C-shaped tubular segment 14. These thumb pads extend outwardly through the slots 11 and 12.

An operator can easily operate the instrument with one hand by grasping a finger flange 17 on first tubular section 8 and one thumb pad, and thereafter pushing the thumb pad toward finger flange 17. This pushes a forward end of the insertion tube out of the guide sleeve, and thus everts the sac 4 and lays it down along the inside surface of the urethra. Calibrations 33 show how far the insertion tube has been pushed into the urethra. The insertion tube continues into the urethra until sac 4 is entirely pulled out of the insertion tube's bore and the insertion tube extends a short distance beyond the end of the sac as shown in FIG. 6. This insures that the sac will not block the insertion tube's bore and slow down urine flow. The thumb pads abut forward ends of the slots 11 and 12 when the insertion tube is fully inserted, as in FIG. 6. Next, a conduit (not shown) leading to a drainage container is con-

nected to an adapter 18 at the rear of the introducer tube and urinary drainage begins. After the urine in the patient's bladder has been drained, the insertion tube and sac are pulled out of the urethra and discarded.

A second embodiment of the invention is shown in FIG. 7. Here, the medical instrument is intended for use in taking bacterial samples along a female urethra to determine the types and concentration of bacteria at different depths in the urethra. This instrument is identical to the instrument of FIGS. 1—6, except that here a string 22 is tied to the end 20 of flexible sac 19 within the bore of flexible insertion tube 21, and said string extends out through a rear portion of the insertion tube. The sac also has a series of depth marks 23, 24, 25 and 26 to indicate for instance the 1 cm., 2 cm., 3 cm. and 4 cm. positions in the urethra.

In use, this second embodiment is inserted in the same way as the embodiment of FIGS. 1—6, but the sac 19 is not completely pulled out of the insertion tube's bore. Instead, after the sac has been inserted a given distance into the urethra to contact its inner surface and pick up bacterial samples, the sac is pulled back into the insertion tube 21. If desired, a hole 27 can be provided in the sac near where the string 22 is tied to it. This allows urine to flow through the sac so the sac is not filled with urine when it is pulled back into the insertion tube. After the flexible insertion tube and sac have been removed from the urethra, the sac which now has bacterial samples on its inside surface can be cut into 1 cm. segments and tests run to determine the bacterial types and concentrations at various depths in the urethra.

A third embodiment of this invention is shown in the sectional side elevational view of FIG. 8. Here the instrument is the same as the instrument shown in FIGS. 1—6, but the flexible insertion tube 31 has a preformed curved section 32 so it conforms more naturally to the contour of the urethra. To help maintain this curved shape, the guide sleeve can also be curved. This preformed curved section 32 in the insertion tube can be formed by taking a section of flexible extruded tube, bending it to the desired curvature and then heating it in an oven to a temperature below its melting point so the tube takes on a permanent set or curve. As the insertion tube 31 is pushed out of rigid guide sleeve, it smoothly follows the curved urethra as shown in FIG. 8. If desired, the rigid tubular guide sleeve can also be curved.

The medical instruments of these embodiments are made in a similar way. In describing how they are made, it suffices to refer to the version shown in FIGS. 1—6. The insertion tube 1 is made of a flexible polyvinyl chloride tube, and sac 4 is a layflat polyethylene sac which has sufficient flexibility and strength for rolling over the insertion tube's end. To aid in rolling the sac over the insertion tube's end, the inner and outer surfaces of the insertion tube have been coated with silicone oil. To hold the sac to the rigid guide sleeve, the sac has its end portion wedged between shield 7 and first tubular section 8. There is no adhesive bond here so that the sac can be removed if desired. Removal of the sac is important in the second embodiment where the sac contains bacterial samples.

Moving rearwardly from the front shield, the first and second sections 8 and 9 are joined together at a joint 28 which can be a solvent joint. The first section preferably is of a transparent material such as polycarbonate so urine can be observed flowing through the transparent insertion tube. The second tubular section 9 has slots 11 and 12 which extend completely to a rear end of this section, and a cap member 10 with inner and outer skirts 29 and 30 fits over the rear end of tubular section 9 and sealed thereto to hold it in a circular shape.

As mentioned previously, the flexible insertion tube is urged forward along the rigid guide sleeve by a handle 13 which has a C-shaped tube segment 14. During assembly of the instrument, the flexible insertion tube is squeezed into a mouth of the C-shaped tube segment 14. To insure that the handle does not slip on the insertion tube, it is sealed by a solvent or adhesive to the insertion tube.

In the foregoing description of our invention, we have described the instrument as inserting a flexible sac into a female urethra. The invention is also adaptable for inserting a sac in a male urethra merely by making the sac, insertion tube and guide sleeve longer.

Although we have used specific embodiments to describe our invention, it is understood that persons skilled in the art can make certain modifications to the embodiments without departing from the spirit and scope of the invention.

We claim:

1. A medical instrument for everting an elongated sac and inserting it into a body orifice, said instrument comprising:
a flexible insertion tube having a forward and rearward end;
an elongated tubular sac within a bore of the insertion tube,
one end portion of the sac being removably disposed in the bore and extending over the forward end of the inserting tube;
an elongated, rigid guide sleeve substantially longer than the insertion tube diameter and reciprocably embracing a forward section of the insertion tube adjacent the insertion tube's forward end,
said guide sleeve including abutment means at the forward distal end for preventing the guide sleeve from entering a body opening, said tubular guide sleeve keeping the forward section of the insertion tube from laterally bending before and as it enters a body orifice, said sac's other end portion being reversibly secured to rearwardly of the forward distal end of the tubular guide sleeve, the insertion tube being of such a character than when longitudinal force is applied thereon rearward of the forward distal end of the rigid guide sleeve, the insertion tube is urged longitudinally along the bore of the tubular guide sleeve and pushes the forward end of the insertion tube out of the tubular guide sleeve beyond the distal end thereof, thereafter pulling the sac out of the insertion tube's bore, turning the sac inside out on the outer surface of the insertion tube and laying it down along an inside surface of the body orifice.

2. A medical instrument as set forth in claim 1 wherein the instrument has means connected to the insertion tube for urging it longitudinally along the guide sleeve.

3. A medical instrument for everting an elongated sac and inserting it into a body orifice, said instrument comprising: a flexible insertion tube having a forward and rearward end; an elongated tubular sac within a bore of the insertion tube, an end portion of the sac extending from the forward end of the insertion tube; an elongated, rigid tubular guide sleeve encircling a section of the insertion tube adjacent the insertion tube's forward end, which tubular guide sleeve keeps this section of the insertion tube from laterally bending before entering a body orifice, said sac's end portion being secured to this tubular guide sleeve, whereby the insertion tube can be urged longitudinally along an inside of the tubular guide sleeve to push the forward end of the insertion tube out of the tubular guide sleeve, thus pulling the sac out of the insertion tube's bore, turning the sac inside out on an outer surface of the insertion tube and laying it down along an inside surface of a body orifice, the instrument having means connected to the insertion tube for urging it longitudinally along the guide sleeve, the guide sleeve having at least one longitudinal slot and the means for urging the insertion tube along the guide sleeve is a rigid handle attached to the insertion tube and extending outwardly through the longitudinal slot.

4. A medical instrument as set forth in claim 3 wherein the handle includes a rigid C-shaped tube segment fitting over the insertion tube.

5. A medical instrument as set forth in claim 1 wherein the guide sleeve has a pair of diametrically opposed longitudinal slots and the instrument has a handle with a rigid C-shaped tube segment fitting over the insertion tube, said handle also having a pair of integrally attached diametrically opposed thumb pads which extend outwardly through the two elongated slots.

6. A medical instrument as set forth in claim 3 wherein the handle abuts a front end of the slot when the flexible sac is completely pulled out of the insertion tube's bore and a forward end of the insertion tube extends slightly beyond the flexible sac.

7. A medical instrument as set forth in claim 1 wherein the flexible sac inside the insertion tube's bore has a string member attached thereto, said string member extending outwardly through a rearward end of the insertion tube for pulling the sac back inside the insertion tube after it has been inserted into a body cavity.

8. A medical instrument as set forth in claim 1 wherein the insertion tube has an adapter at its rearward end for connecting to a fluid conduit.

9. The medical instrument as set forth in claim 1 wherein the means at the forward distal end of the rigid guide sleeve includes a generally oval-shaped shield.

10. A medical instrument as set forth in claim 3 wherein the rigid guide tube includes a finger flange integral therewith and spaced between the longitudinal slot and the guide tube's forward end.

11. A medical instrument for everting an elongated sac and inserting it into a body cavity, said instrument comprising: a flexible insertion tube having a forward end and a rearward end; an adapter on said rearward end for connection to a fluid conduit; an elongated tubular sac within a bore of the insertion tube and having an end portion of the sac extending from the forward end of the insertion tube; a rigid tubular guide sleeve substantially longer than the insertion tube's diameter fitting around the insertion tube, said tubular guide tube having a shield at its forward end, a pair of longitudinal slots spaced rearward of the shield, and an external finger flange spaced between said shield and slots; a handle including a rigid C-shaped tube segment fitting over the insertion tube and secured thereto, and a pair of thumb pads integrally connected to the C-shaped tube segment and extending outwardly through said slots, whereby an operator can grasp the thumb pads and finger flange and urge the insertion tube out of the tubular guide sleeve, thus causing the sac to be pulled out of the insertion tube, turned inside out on an outer surface of the insertion tube and laid down along an inside surface of a body cavity.

12. A medical instrument as set forth in claim 11 wherein the insertion tube and at least a portion of the guide sleeve are transparent so an operator can observe liquid flow therethrough.

13. The medical instrument as set forth in claim 1 in which said flexible insertion tube includes an intermediate preformed section for accommodating the insertion tube to natural curvatures of a body orifice.

14. The medical instrument as claimed in claim 1 in which the inner and outer surfaces of said insertion tube adjacent the forward end include a lubricant coating for facilitating rolling of the sac over the forward end of the insertion tube.