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3,444,860

**ASEPTIC CATHETER ASSEMBLY WITH
HOLDER INTRODUCER**

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8 Claims

ABSTRACT OF THE DISCLOSURE

An aseptic catheter assembly including a lubricated catheter tube with a collection bag connected to one of the tube end portions and an elongated hollow, open-ended semi-rigid holder-introducer surrounding the tube at its opposite end portion with the tube being slideable therethrough. The assembly further includes a flexible elongated tubular membrane surrounding the tube with one of the membrane end portions being attached to and outwardly around the holder-introducer between the ends of the holder-introducer and the other membrane end portion being attached to and externally around the tube adjacent the tube and bag connection. A removable cap is provided closing the exposed end of the holder-introducer to maintain aseptic integrity of the assembly.

This invention relates to catheters and more particularly to an improved catheter assembly wherein the catheter is maintained in a sterile condition until use.

Under the existing catheterization procedures, the doctor or nurse using the catheter must handle the catheter in directing and introducing the catheter into the urethra and therethrough into the bladder. This handling of the catheter requires the operator to use sterile gloves or instruments; and, even employing these cautionary procedures, there is still a danger of the catheter becoming contaminated.

It is therefore an object of the subject invention to provide a catheter which can be maintained in a sterile condition before use and to collect urine using this catheter under sterile conditions.

Another object of this invention is to provide an improved disposable catheter assembly.

A further object of the instant invention is to provide a means to collect urine from patients under more sterile circumstances.

Still another object of the subject invention is to provide a sterile disposable catheter assembly wherein the catheter itself need not be touched or handled directly by human hands.

The novel features which are believed to be characteristic of this invention are set forth with particularity in the appended claims. The invention itself, however, both as to its organization and method of operation, together with further objects and advantages thereof, may best be understood by reference to the following description taken in connection with the accompanying drawing, in which:

FIG. 1 is a vertical elevation partially in section of a preferred embodiment of the disposable catheter assembly of this invention;

FIG. 2 is a plan view of the clamp used to seal off the neck of the flexible collection container of the invention;

FIG. 3 is a cross-sectional view taken along the line 3-3 of FIG. 1; and

FIG. 4 is a view similar to FIG. 3 of another embodiment of the catheter assembly of this invention.

Referring now to the drawings in detail the disposable catheter assembly of this invention, generally designated by reference numeral 10 is depicted in FIG. 1. The system

comprises a catheter tube 12 having a closed elliptical forward end 14 and terminating at an open rearward end 16. The catheter has a centrally disposed passageway or channel 18 running its entire length and terminating at opening 20 in tube 12 adjacent its forward end 14. The external surface of catheter tube 12 should be smooth, continuous and non-porous. It may be constructed of rubber or a suitable plastic such as polyethylene. The tube should be flexible but have sufficient strength and longitudinal rigidity to permit insertion of the tube unaided by other devices into and through a tortuous passageway within the body without collapsing.

The assembly further comprises a guide, holder or introducer 22 which surrounds and encloses catheter tube 12. This holder 22 is fabricated from a hard rubber or plastic and is of a rigid or semi-rigid construction. The catheter tube 12 which is normally lubricated is slidable within passageway 24 of holder 22. Passageway 24 extends the full length of holder or guide 22 terminating in an opening in the rearward end 26 and an opening in the forward end 27 of guide or holder 22. The purpose of holder 22 is to guide and direct the catheter into the urethral opening of the patient. The holder 22 provides a place where the operator of the catheter may guide and direct travel of the catheter from a point closely adjacent the urethral opening while insuring that the catheter tube itself is not touched. Forward end 27 of holder 22 is provided with a pressure cap 28. This cap 28 is the snap-off, snap-on type and is not in place when the catheter apparatus is in use, but is used when the device is not in use to insure sterility of the catheter tube 12.

A flexible encasement or membrane 30 surrounds and seals catheter tube 12 in a sterile condition rearward of holder 22. This flexible encasement 30 is sealed at 32 to the rearward end 26 of holder 22 and at 34 adjacent the rearward end 16 of catheter tube 12. The material of this membrane or encasement member 30 is of a very thin flexible plastic, rubber or the like such that the catheter tube 12 may be gripped through this encasement member 30 and gradually worked through holder or guide 22 and inward of the urethra. The rearward end of flexible plastic encasement 30 is sealed to the catheter tube 12 at 34. The catheter tube 12 has its rearward end 16 connected to the neck 38 of a sample collector or container 40. The neck 38 is provided with ridges or corrugations 39 along the interior of its upper end to aid in gripping and securing the tube 12 within the neck 38. The bottom end of flexible plastic encasement 30 could be readily sealed to neck 38 instead of the catheter tube 12 if so desired.

The sterile disposable catheter assembly of this invention is provided with a clamp 44 constructed of metal or other suitable hard material like hard rubber or plastic. The purpose of this clamp 44 is to provide a means of sealing the neck 38 of container 40 such that when a sufficient sample of urine has been collected in container 40 the neck 38 may be sealed by the use of this slidable pinch clamp 44. This allows the catheter tube 12, holder 22 and flexible plastic encasement 30 to be removed from the neck 38 of container 40, such that the container 40 holding a sterile sample of urine may be transported to another area for testing and examination. The clamp 44 is of a slidable and pinch type having a cutout portion 46 extending longitudinally through the central portion of the clamp. One end 48 of this cutout portion is of a diameter and size sufficient to accommodate neck 38 in its completely open and expanded size, while the other end 50 of this cutout portion is of a size which will pinch and completely close and seal neck 38 of container 40. Normally clamp 44 will be in a position around neck 38 such that the neck

passes through the larger end 48 of the cutout 46 such as to permit passage of fluid through the neck 38 into container 40. When it is desired to close off and seal neck 38 once the container has the desired amount of urine therein clamp 44 is moved in a sliding sideward direction relative to neck 38 such that neck 38 becomes positioned in the smaller end 50 of cutout 46 of the clamp thus closing and sealing the neck 38 of container 40.

The length of catheter tube 12 may vary over a wide range depending upon the nearness desired of container 40 to holder 22 and flexible plastic encasement 30. Flexible plastic encasement 30 may also vary in dimension but should be at least eight inches in length when the catheter assembly of this invention is to be used with female patients and no less than fourteen inches in length when the catheter is to be employed with male patients. Although the guide holder 22 may vary in dimension it should be sufficiently long such that it can be conveniently gripped in one hand.

Holder or guide 22 of the catheter assembly of this invention is often of a multiple piece construction as is more clearly seen in FIG. 3. As shown in FIG. 3 the guide 22 comprises two pieces, a larger member or section 52 and a smaller wedge shaped member or element 54. The two members 52 and 54 fit together to form a generally solid and rigid to semi-rigid structure encircling catheter tube 12, with the members 52 and 54 engaging one another along cuts or lines 56 and 58 extending from the inner circumference to the outer circumference of the holder and being held in place by a thin cylindrical membrane 60. The membrane 60 is shrunk around the cylindrical sleeve-like guide 22 during the manufacture thereof to securely hold the members 52 and 54 in place. While the members 52 and 54 shown in FIG. 3 are somewhat unequal in size, they could also readily be constructed to be of equal size or even somewhat more unequal in size and still be satisfactory in use. This particular construction of holder 22 of the catheter assembly is employed so that once the catheter tube 12 is in place within the urethra and bladder of the patient, the holder 22 may be removed from the tube 12, this being accomplished by cutting thin membrane 60 and removing members or sections 52 and 54 from the tube. Thus it is seen that holder 22, flexible plastic encasement 30 and container 40 are completely removable from the catheter tube 12 once their functions have been fulfilled, thereby leaving only the tube 12 (now in a stripped condition) in association with and portions thereof in engagement with the patient. In this manner and condition portions of the catheter tube 12 may be retained within the urethra and bladder of the patient and used to further drain the bladder and/or treat the same, such as by administering medications and drugs through the tube and into the bladder.

Another embodiment of the holder of the catheter assembly of this invention is depicted in cross-section in FIG. 4 at reference numeral 22' surrounding and enclosing catheter tube 12. This construction of the guide or holder 22' is one-piece in nature having a small slot or opening 62 extending from the inner circumference to the outer circumference of the holder throughout its entire length. A strip of adhesive type tape 64 extends across the outer opening of the slot 62 throughout the length thereof to give the guide 22' a completely circumferential construction and appearance. Opening or slot 62 may be formed in the holder 22' during the manufacture thereof or may be later cut into a previously formed continuous cylindrical body to result in the guide 22' as depicted in FIG. 4. Once the catheter tube 12 has been inserted into the urethra and bladder, and it is desired to remove the guide or holder 22' therefrom, tape 64 covering the outer opening of the slot 62 is removed and the sides of the slot 62 are spread apart and outward to generally ex-

pand the holder 22' such that the catheter tube 12 may be slipped through the now enlarged opening 62 and the holder 22' freed from the catheter tube 12.

The catheter of this invention is prelubricated and sterile and remains in this sterile condition until used. Because of the economical materials used the catheter assembly of this invention is disposable. Even though the catheter is disposable it may also be easily and readily disconnected from container 40 at neck 38 and resterilized, lubricated and reused. Due to the novel arrangement of this catheter assembly, and in particular holder 22, the assembly may be employed without the use of rubber gloves and without the need of handling the catheter itself. Therefore, not only is the catheter inserted without being directly handled with the liability of contamination from the fingers, but its exposure to the atmosphere with the possibility of contamination, is greatly reduced.

To use the catheter assembly, the cap 28 is removed from the end 27 of holder 22 and the forward end 27 of holder 22 is aligned with and placed adjacent the entrance to the urethra. The operator of the assembly then grasps the flexible plastic encasement 30 and gradually enters the catheter into the urethra by gently pushing forward on the body of the catheter 12 held through the flexible plastic encasement 30. This action is maintained until the end 14 of catheter 12 reaches the bladder thus constituting a duct for fluid discharge through opening 20 and down through passageway 18 of the catheter into container 40 after passing through neck 38. Once a sufficient sample of urine has been collected in container 40 the upper portion of the assembly including the holder 22, flexible plastic encasement 30, and catheter 12 may be removed from container 40 and neck 38 at the neck connection. The catheter 12 is sufficiently flexible to direct the flow of the remainder of urine in the bladder into another suitable receptacle. Once the container 40 has been disconnected from catheter tube 12, slidable pinch clamp 44 may be operated to close the neck 38 of the container and seal the sample of urine therein. The container 40 with the urine sample therein may then be transported to a suitable area for testing, examination and study of the contents. After the bladder has been drained through the catheter tube 12, the tube with the holder 22 and flexible encasement 30 still attached thereto can be removed from the bladder and urethra of the patient; or the catheter tube may be stripped by removing the holder 22 and flexible encasement 30 therefrom as hereinabove described, and be allowed to remain within the bladder and urethra of the patient for further drainage, testing, or treating of the bladder.

While only certain preferred embodiments of this invention have been shown and described by way of illustration, many modifications will occur to those skilled in the art and it is, therefore, desired that it be understood that it is intended in the appended claims to cover all such modifications as fall within the true spirit and scope of this invention.

What is claimed as new and what it is desired to secure by Letters Patent of the United States is:

1. In an aseptic, lubricated catheter assembly the combination comprising a flexible catheter tube having a forward end portion, a rearward end portion and a hollow passageway extending between said end portions and opening outwardly of said tube adjacent said end portions, a collection bag having a neck portion, said catheter tube rearward end portion being releasably connected to said neck portion of said collection bag, a generally cylindrical, semi-rigid holder remote from said bag, said holder having a passageway extending therethrough with said catheter tube slidably disposed therein, a flexible, severable elongated membrane surrounding said catheter tube and attached to one of its end portions to the rearward end portion of said holder and at

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its other end portion to said catheter tube remote from said holder and adjacent the connection between said catheter tube and collection bag, said holder being externally hand grippable to orient the assembly adjacent the urethral opening of a patient for guiding said catheter tube into the urethra, said catheter tube being workable through said flexible membrane to move said tube through said holder and introduce the same through the urethra and into the bladder of a patient, and a cap removably secured to the forward end portion of said holder to maintain said catheter tube in an enclosed and aseptic state.

2. In an aseptic catheter assembly as defined in claim 1, a selectively adjustable clamp mounted on and surrounding said neck portion of said collection bag operable selectively to open and to pinch closed said neck portion of said bag.

3. In an aseptic catheter assembly as defined in claim 1, said holder having an openable, normally closed slit therein to permit lateral removal of the holder from said catheter tube upon opening of said slit, and means temporarily closing said slit to preserve the aseptic integrity of the assembly.

4. In an aseptic catheter assembly as defined in claim 1 wherein said holder comprises a plurality of elements, and releasable means maintaining said elements of said holder closely adjacent one another to form said holder, whereby upon release of said means said elements may be separated to permit removal of said elements from said catheter tube without withdrawal of said catheter tube from a patient and without removal of said collection bag from said catheter tube.

5. In an aseptic catheter assembly as defined in claim 1, said holder including a slot extending throughout the elongated dimension of said holder communicating between said passageway and opening outwardly of said holder, said slot being of a width less than said outer diameter of said catheter tube, said holder being expandable to increase the width of said slot to pass said catheter tube laterally through said slot, and releasable means closing said slot, whereby upon release of said means said holder is readily removable laterally of said catheter tube without withdrawal of said catheter tube from a patient and without removal of said collection bag from said catheter tube.

6. In a catheter assembly comprising an aseptic, lubricated catheter tube having opposite end portions, a collection bag releasably connected to said catheter tube at one of its said end portions, a rigid holder-introducer surrounding said catheter tube at its opposite said end portion, a flexible, severable elongated membrane surrounding said catheter tube and attached at one of its end portions to said holder-introducer and at its other end portion to said catheter tube adjacent the connection between said catheter tube and collection bag, said holder-introducer including a plurality of separable elements, said elements upon separation thereof being radially removable from said catheter tube without withdrawal of said catheter tube from a patient and without removal of said collection bag from said catheter tube, and releasable means maintaining said elements of said holder-introducer closely adjacent to form said holder introducer.

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7. In a catheter assembly comprising an aseptic, lubricated catheter tube having opposite end portions, a flexible collection bag releasably connected to said catheter tube at one of its said end portions, an elongated semi-rigid holder-introducer surrounding said catheter tube at its opposite said end portion, a flexible, severable, elongated membrane surrounding said catheter tube and attached at one of its end portions to said holder-introducer and at its other end portion to said catheter tube adjacent the connection between said catheter tube and collection bag, said holder-introducer including an elongated slot extending longitudinally thereof with a lateral dimension less than the diameter of said catheter tube, said holder-introducer being readily expandable to increase the lateral dimension of said slot to permit passage of said catheter tube therethrough and laterally of said holder-introducer, said holder-introducer being easily removable laterally of said catheter tube without withdrawal of said catheter tube from a patient and without removal of said collection bag from said catheter tube.

8. A catheter assembly comprising an aseptic catheter tube having opposite end portions, a collection bag releasably connected to said catheter tube at one of its said end portions, an elongated hollow, open-ended, semi-rigid holder-introducer surrounding said catheter tube at its opposite said end portion remote from said bag and said catheter tube being slideable therethrough, a flexible elongated tubular membrane having opposite end portions and surrounding said catheter tube, said membrane being attached at one of its said end portions outwardly around said holder-introducer between the ends of said holder-introducer and at its said other end portion externally around said catheter tube remote from said holder-introducer adjacent the connection between said catheter tube and collection bag, a removable cap closing the exposed end of the holder-introducer to maintain aseptic integrity of the assembly, said catheter tube being manipulatable to slide through said holder-introducer by grasping the outside of said membrane.

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DALTON L. TRULUCK, *Primary Examiner*.

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128—295, 2; 206—63.2

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

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It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 3, line 18, after "guide" insert -- or --
Column 5, line 56, the word "radially" should
read -- readily --

SIGNED AND
SEALED
FEB 3 1970

(SEAL)

Attest:

Edward M. Fletcher, Jr.

Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents