

[54] **ANTISEPTIC CATHETER**
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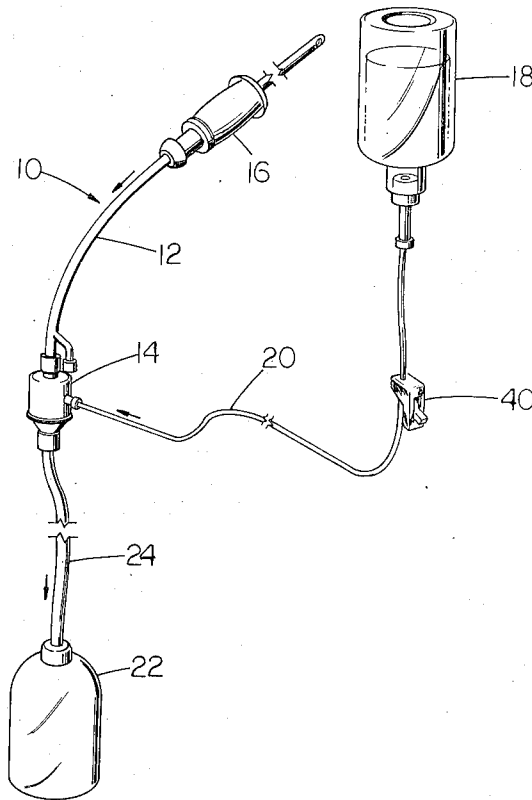
[57] **ABSTRACT**

Medical apparatus and method for preventing infectious organisms from entering the body of a patient through or along a catheter. The apparatus includes a tubular receptacle through which body fluids flow from the catheter to a collecting reservoir, the receptacle adapted in various ways to facilitate introduction of antiseptic compositions from either liquid or solid form into the body fluids to preclude survival therein of infectious organisms. Also disclosed is apparatus for maintaining an antiseptic barrier on the outside of the catheter where it enters the patient's body.

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16 Claims, 7 Drawing Figures



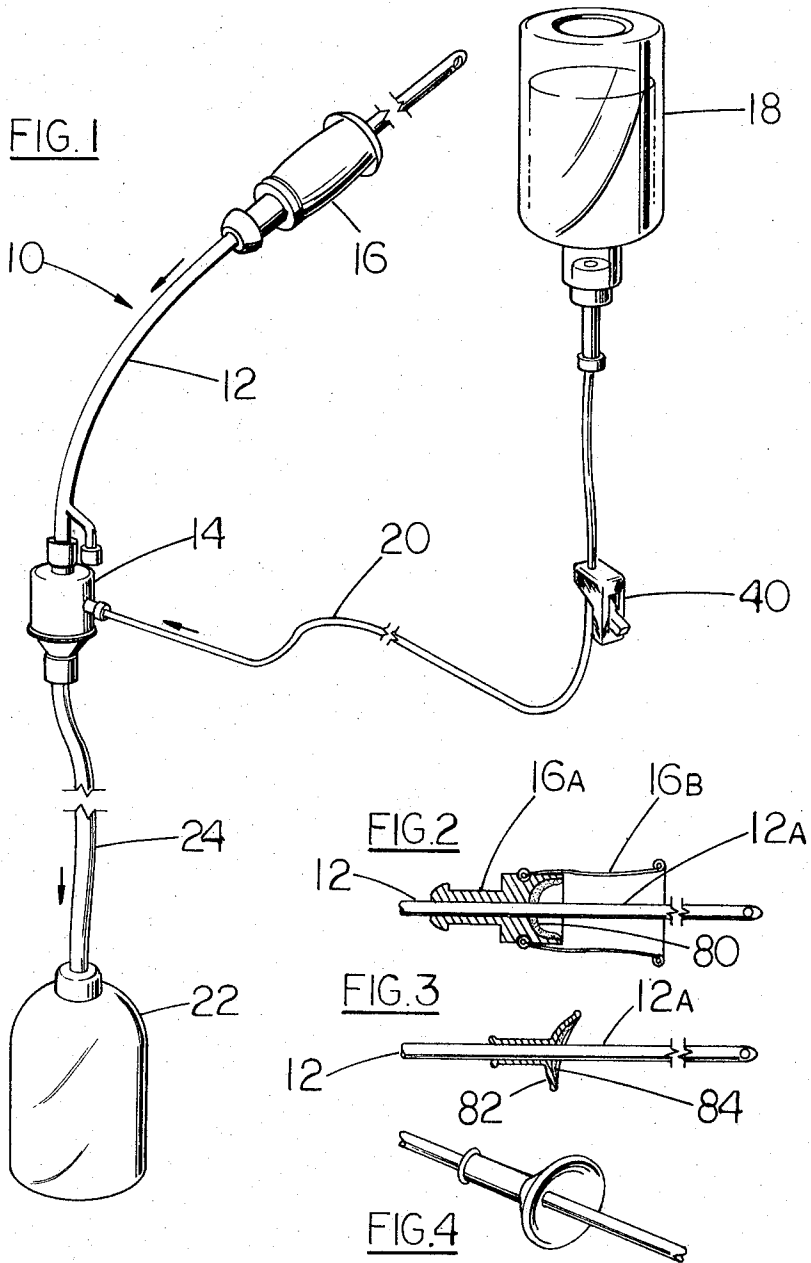


FIG. 6

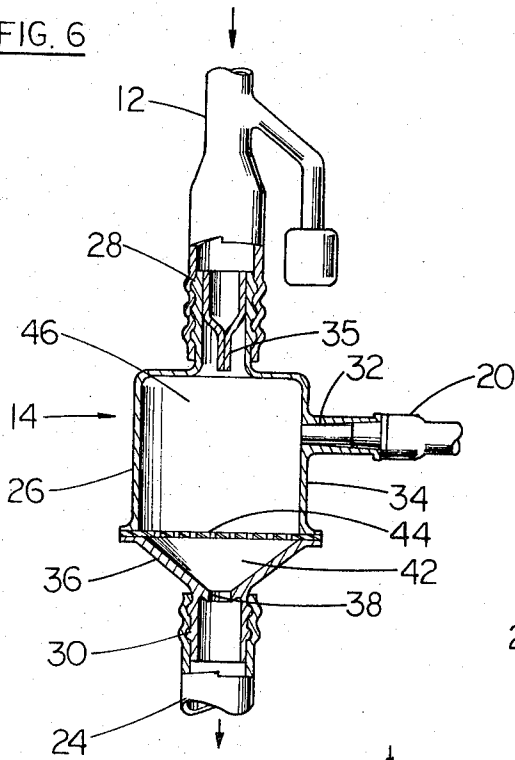


FIG. 5

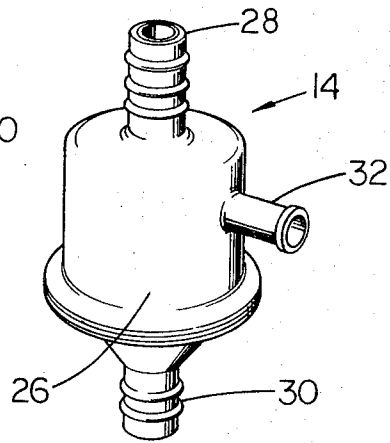
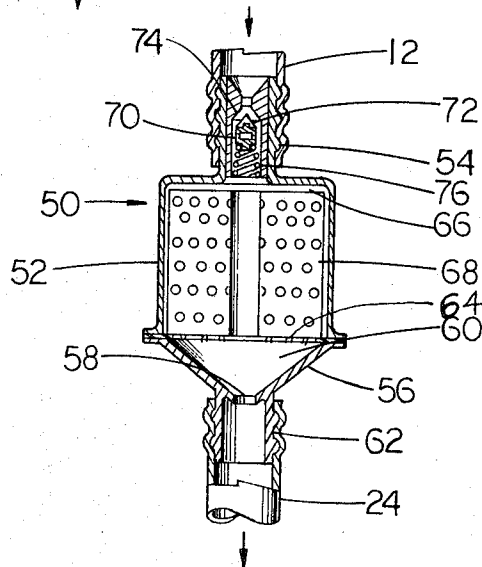


FIG. 7



ANTISEPTIC CATHETER

BACKGROUND OF THE INVENTION

Postoperative patients often require the implantation of a catheter to drain the bladder because shock, induced by the operation, renders the patient unable to release the sphincter muscles which control the release of urine from the bladder. The catheter is used until the patient regains muscular control and can void himself without it. However, the longer the period the catheter is employed, the larger is the risk of infection of the bladder, urethra, and kidneys.

Paraplegic patients, because of injury to the spinal cord, usually have no control over the bladder and must continuously use a catheter of the "in-dwelling" type. The paraplegic is prone to infection, and is almost certain to develop a bladder infection resulting from the use of the catheter. These infections are serious for two reasons.

First, the lack of mobility of the patient reduces the quantity of blood flowing to the lower extremities of the body; i.e., there is a reduced supply of blood carrying antibodies, lymphocytes, and leukocytes because of his lack of physical activity. Therefore, his body is not able to fight the infection effectively.

Secondly, the patient cannot survive without a catheter, for to do so would result in possible uremic poisoning. Most paraplegic patients develop chronic bladder and kidney infections, and in the end succumb to the infection or the toxins produced by the infection which cause failure of the other organs. Therefore, it is safe to predict that most paraplegics will die from an infection which starts in the urethra or bladder as a result of infections introduced by the use of the catheter.

Urine and other body fluids excreted through the urethra are mediums in which a number of organisms can flourish. Therefore, it is easy to recognize that even when the most sterile techniques are employed during the insertion of a catheter, there is still a path through which infectious organisms can enter the body, that being through the inside of the catheter directly into the bladder.

Yet another path by which infectious organisms can enter the body is along the outside surface of the catheter. Although sterile techniques may temporarily eliminate this path during catheter insertion, it is possible for such organisms to migrate along the outside of the catheter when the antiseptic effect of such techniques has worn off.

SUMMARY OF THE INVENTION

This invention comprises an apparatus and method for preventing infectious organisms from entering the body through a catheter. The apparatus comprises a tubular antiseptic receptacle that is interconnected between the catheter's outer end and the drain tube leading from the catheter to its collecting bottle or other reservoir. The receptacle is structured to cause the body fluids flowing from the catheter to come into contact and mix with an antiseptic before they continue into the drain tube, thereby assuring that the fluids in the drain tube prevent migration of infectious organisms into the catheter and ultimately into the patient's body. The antiseptic can be in liquid form, in which case it can be introduced from an external reservoir into the receptacle dropwise or as a slow flow, or it can

be in solid yet soluble form such as a cake or cartridge that is placed in the receptacle where body fluids will pass over or through it. The receptacle further includes a funnel-shaped bottom wall with an outlet opening that causes the antiseptic-body fluid mixture to form a meniscus and then pass through the opening in droplet form, thereby assuring that no infectious organisms in the catheter's drain tube can migrate into the receptacle and on into the catheter without passing through an antiseptic solution. The receptacle also includes a check valve in its inlet portion to prevent backward flow of fluid from the receptacle into the catheter.

The apparatus of this invention additionally comprises antiseptic retainers suitably shaped to fit the contour of the patient's body where the catheter enters it, and having a body-contacting surface adapted to retain an antiseptic ointment or the like in position to seal off entry of infectious organisms along the catheter's outer surface. The catheter extends through these retainers into the body orifice, and the antiseptic composition functions as an aseptic barrier between the outside of the catheter and the orifice entry.

Accordingly, one object of the present invention is to provide an antiseptic catheter for prolonged use in patients without incurring the danger of creating an infection.

Another object of the present invention is the provision of an apparatus and method to introduce an antiseptic into the body fluids emanating from a catheter, thereby to prevent migration of infectious organisms through the catheter into a patient's body.

Yet another object of the present invention is the provision of a means to prevent infectious organisms from entering body orifices along the outside surface of a catheter while it is in functional position.

Further objects and advantages of the present invention will become apparent from the following description thereof, including the several drawings to which it refers.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic view in perspective of an antiseptic catheter apparatus according to the present invention, including a bottle of antiseptic solution and a body fluid collection bottle, plastic bag, or the like, connected to the catheter's antiseptic receptacle by flexible tubing.

FIG. 2 is a longitudinal section through the male antiseptic ointment retainer at the inner end portion of the catheter of FIG. 1.

FIG. 3 is a longitudinal section through an antiseptic ointment retainer on a catheter for use with female patients.

FIG. 4 is an isometric view of the antiseptic ointment retainer of FIG. 3.

FIG. 5 is an isometric view, on an enlarged scale, of the antiseptic receptacle attached to the catheter in FIG. 1.

FIG. 6 is a longitudinal section through the antiseptic receptacle of FIG. 5.

FIG. 7 is a longitudinal section through another form of antiseptic receptacle according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As illustrated in FIG. 1, one embodiment of an anti-

septic catheter assembly 10 according to the present invention comprises a catheter 12, an antiseptic receptacle 14 attached at its upper end to the outer end of the catheter 12, a male type antiseptic ointment retainer 16 through which the inner end of the catheter 12 extends, and a suitable bottle or other antiseptic solution reservoir 18 connected to the antiseptic receptacle 14 by a flexible tube 20. A body fluid collecting bottle 22 or other suitable container is connected through a flexible tube 24 to the lower end of the antiseptic receptacle 14, which bottle 22 functions as a holding reservoir for body fluids flowing from the patient (not shown) through the catheter 12, the receptacle 14, and the tube 24.

The antiseptic receptacle 14, illustrated in greater detail in FIGS. 5 and 6, comprises a main body portion 26 with a top inlet 28 in its upper end, an outlet 30 in its lower end, and a side inlet 32 in its side wall 34 for the admission of antiseptic solution from the bottle 18 and tube 20. The top inlet 28 serves both as a means to admit body fluids into the receptacle 14 and as a means to connect the receptacle to the outer end of the catheter 12. A check valve, such as the flexible rubber lip-type device 35, is secured to the top inlet 28 to prevent fluid flow from the receptacle 14 into the catheter 12.

The lower end 36 of the receptacle 14 is shaped like an inverted cone with a central opening 38 at its apex, thereby to funnel and collect the fluid in the receptacle at the opening where it then drips into the outlet 30. When the flow of antiseptic solution into the receptacle 14 is properly adjusted, as by a conventional intravenous metering device 40 (FIG. 1) in tube 20, sufficient fluid collects in the receptacle's lower conically shaped chamber 42 to assure the maintenance of an aseptic fluid seal across the opening 38 at all times during flow into the tube 24, thereby preventing migration of viable infectious organisms from the tube 24 upward into the receptacle. A perforate screen 44, preferably of stainless steel, separates the conical lower chamber 42 from the receptacle's main or upper chamber 46, and functions to trap material, such as blood clots, that would plug up the opening 38. It should, however, be understood that the screen 44 is optional and can be omitted if desired. Furthermore, as long as an adequate flow of antiseptic solution into the receptacle 14 is maintained, i.e., sufficient to maintain the fluid seal at the opening 38, the conical-shaped lower end 36 can be replaced by a flat end wall (not shown).

In its preferred form, the receptacle 14 is constructed from a clear, hard plastic for simplifying setting the proper flow rate of antiseptic solution into it, observing the fluid level above the opening 38, and periodic checking for buildup of material on the screen 44. The plastic parts can be glued, ultrasonically welded, screwed, or otherwise secured together.

A modified form of the receptacle 14 is illustrated in FIG. 7, this form 50 designed for use with an antiseptic in solid or cake form rather than as a solution. The receptacle 50, which incidentally is interchangeable with the receptacle 14 where solid antiseptics are preferred, is substantially identical in shape with the receptacle 14 except that it has no side inlet. Thus, the receptacle 50 has a main body portion 52 with a top inlet 54 in its upper end, and a lower end 56 shaped like an inverted cone and having an opening 58 at its apex to allow fluid to drip from a lower chamber 60 into the outlet 62. A

perforate screen 64, preferably of stainless steel, extends horizontally between the lower chamber 60 and the main body chamber 66, and supports a cake or cartridge 68 of antiseptic composition that is slowly soluble in the body fluids entering the receptacle through its inlet 54.

A check valve 70 is mounted in the inlet 54 of the receptacle 50 to preclude flow of fluid from the receptacle into the catheter 12. The check valve 70 illustrated in this embodiment comprises a rubber needle valve 72 biased upwardly against a valve seat 74 by a stainless steel or other suitable helical spring 76. Accordingly, the check valve 70 will open in response to fluid pressure above it, i.e., in the catheter 12, but will close if fluid pressure is exerted in the opposite direction. Thus, flow through the receptacle 50 only in the direction of the arrows is constantly assured. It should be understood that other types of check valves suitable for this function also can be used.

Although it is conceivable that the antiseptic catheter of this invention can be used in other body orifices, or in incisions, the principle use for which it is intended is as a bladder drain. For example, it also can be employed as a post operative drain, in which case a suitable antiseptic ointment retainer, to hold the antiseptic ointment against the incision, would be substituted for the male retainer 16.

In order that infectious organisms on the outside of the catheter 12 are prevented from entering the urethra when the catheter is in functional position in a male patient, the antiseptic retainer 16, illustrated in FIGS. 1 and 2, is first slipped over the catheter's inner end portion 12a and coated on the inside with an antiseptic ointment 80. The retainer 16 is comprised of a base portion 16a, and a thin, flexible rubber sheath portion 16b suitably secured to the base 16a. The retainer 16 could, of course, be a one-piece molded article of suitable shape. When in position, the sheath 16b holds the retainer and the ointment 80 in place.

When the patient is female, a suitably shaped retainer such as that illustrated at 82 in FIGS. 3 and 4 is employed. The retainer 82 is coated with antiseptic ointment 84 on the side that will fit against the patient, and then held in place by a sanitary napkin or other appropriate means. In both cases, the antiseptic ointment is retained at the area of contact between the patient's body and the external surface of the catheter, assuring an antiseptic barrier at the juncture.

The antiseptic receptacle 14 (FIGS. 1, 5 and 6) for introduction of antiseptic solutions in the draining body fluid is best suited for patients in the hospital where various intravenous equipment is readily available, such as standard for the bottle 18, flow metering equipment 40 for the bottle 18, and the like. The receptacle 50 (FIG. 7), however, is more suitable for patients not confined to the hospital, as it does not require the necessary equipment for introduction of an antiseptic solution, and can be constructed as a throw-away element for replacement in its entirety, if desired.

The antiseptic cake or cartridge 68 employed in the receptacle 50 (FIG. 6) preferably is an element impregnated with the desired antiseptic in a form that is slowly soluble in the body fluids coming in contact with it. In one form the receptacle 50 is constructed so that it can be opened up and the cake 68 replaced, as when the antiseptic has been dissolved away or, more preferably, at regular intervals to assure proper potency. For exam-

ple, the cake 68 can be a compressed or polymeric pellet containing the antiseptic in a matrix of material such as water-soluble polyvinyl alcohol that will dissolve at a rate proportional to the quantity of urine or other body fluid passing over it, thereby providing a controlled or timed release of the anti-biological agent. Other water soluble polymers presently suitable for this purpose are polyvinylpyrrolidone, hydroxyethyl cellulose, carboxymethyl cellulose, partially hydrolyzed polyvinyl alcohol, and polyethylene oxide. It should be understood that this list of suitable compositions is merely illustrative, and that the invention is not limited thereto.

As will be appreciated, various antiseptic and other biocidal or anti-biotic agents can be successfully employed with the present invention. For example, mercurial compounds, sulfa compounds, broad spectrum antibiotics, phenols, hydrogen peroxide, hexachlorophene, iodine, halogen complexes, betadyne, formalin and formaldehyde, sodium hypochlorite and other halogen salts, acetaldehydes, and many other substances known to have biocidal or anti-biotic properties can be dispersed in the aforementioned soluble polymers and released at a controlled rate, thereby providing aseptic conditions within the catheter's drain or collection tube 24 and the collection bottle 22 for extended periods of time. The time can be controlled by the selection of a polymer having the proper solubility, and it should be apparent that powerful biocides can be used with slowly dissolving polymers while weaker biocides may require a more quickly dissolving polymer to maintain the desired aseptic conditions.

The antiseptic and antibiological agents listed above also can be used in the form of aqueous, alcoholic, or other solutions for controlled rate metering into the catheter's receptacle 14 by conventional intravenous equipment. Other materials providing the necessary antiseptic environment can be prescribed by the attending physician, and added to these listed agents or used in lieu thereof. In each case the solution should have a low vapor pressure so that vapors will not migrate up the catheter 12 into the patient's body.

Although the best mode contemplated for carrying out the present invention has been herein shown and described, it will be apparent that modification and variation may be made without departing from what is regarded to be the subject matter of the invention.

I claim:

1. An apparatus for preventing infectious organisms from entering the body of a medical patient through or along a catheter for removing body fluids, comprising:

- a. a catheter having an inner end portion for insertion into a patient's body and an outer end portion for conducting body fluids to a collection reservoir, and
- b. a means for preventing the migration of infectious organisms through and around said catheter from a body fluid flow collection means to a fluid flow discharge source in said body comprising a receptacle having an antiseptic discharge contacting and mixing means in the path of flow of said fluids

whereby because of said mixture of antiseptic and body fluids infectious organisms in said body fluids are prevented from migrating through the catheter and into the patient.

2. An apparatus according to claim 1 wherein the receptacle includes an inlet for admission of body fluids and an outlet for maintaining a liquid seal between said receptacle and the collection reservoir.

3. An apparatus according to claim 2 wherein the receptacle includes a perforate screen between said inlet and outlet.

4. An apparatus according to claim 2 wherein said outlet comprises an inverted cone-shaped wall with a central opening at the bottom end of said receptacle, said wall thereby functioning as a funnel to collect and conduct the mixture of body fluids and antiseptic to the central opening for subsequent passage therethrough in droplet form.

5. An apparatus according to claim 2 wherein the inlet includes valve means for preventing flow of liquid from said receptacle into the catheter towards its inner end portion.

6. An apparatus according to claim 2 wherein the receptacle includes an inlet for an antiseptic solution.

7. An apparatus according to claim 2 wherein the receptacle includes means for supporting an antiseptic cartridge in its interior for dissolution thereof by body fluids.

8. An apparatus according to claim 7 including an antiseptic cartridge comprising an antiseptic and a water soluble matrix therefor.

9. An apparatus according to claim 8 wherein the antiseptic cartridge is replaceable.

10. An apparatus according to claim 1 including an antiseptic ointment retainer through which the catheter's inner end portion extends, said retainer including means for retaining an antiseptic ointment in place between the catheter and the adjacent surface of a patient's body when the catheter is properly installed in functional position.

11. An apparatus according to claim 10 wherein the ointment retainer includes a flexible sheath portion for use with male patients.

12. An apparatus according to claim 10 wherein the ointment retainer includes a shallow cup portion for use with female patients.

13. A method for preventing infectious organisms from entering a medical patient's body by the way of a catheter connected to a collection reservoir, comprising mixing an antiseptic with discharged body fluids flowing through the catheter to form an antiseptic liquid barrier between the catheter and the body fluid collection reservoir.

14. A method according to claim 13 wherein the antiseptic is in liquid form.

15. A method according to claim 13 wherein the antiseptic is in water soluble, solid form.

16. A method according to claim 13 including establishing and retaining an antiseptic ointment seal between the outside of the catheter and the adjacent surface of the patient's body.

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