

[54] **STERILE CAPS FOR A LIQUID DRAINAGE SYSTEM AND METHOD**

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[22] Filed: **Feb. 20, 1973**

[21] Appl. No.: **333,909**

[52] U.S. Cl. **128/349 R**, 128/295, 206/63.2

[51] Int. Cl. **A61m 25/00**

[58] Field of Search 128/275, 295, 348, 349 R, 128/350 R, 227; 206/63.2, 56 R, 65 R; D83/1

[56] **References Cited**

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Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Powell L. Sprunger

[57] **ABSTRACT**

A pair of sterile nestable closure caps having a female end and a male end, and a method of aseptically protecting the interconnectable ends of first and second tubes in a liquid drainage system with the caps. In the method, the ends of the first and second tubes are disconnected, the end of the second tube is inserted into the female end of the sterile nested caps, and the male end of the sterile nested caps is inserted into the end of the first tube to close the ends of the first and second tubes. The nested caps are then separated, whereby the ends of the disconnected first and second tubes are aseptically closed by the caps.

13 Claims, 11 Drawing Figures

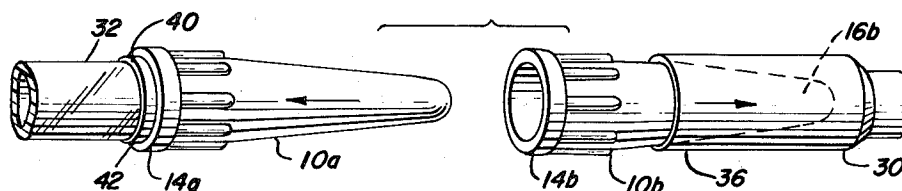


FIG. 1

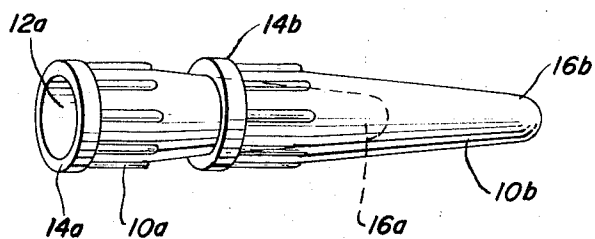


FIG. 2

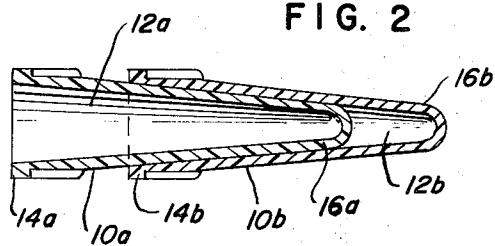


FIG. 3

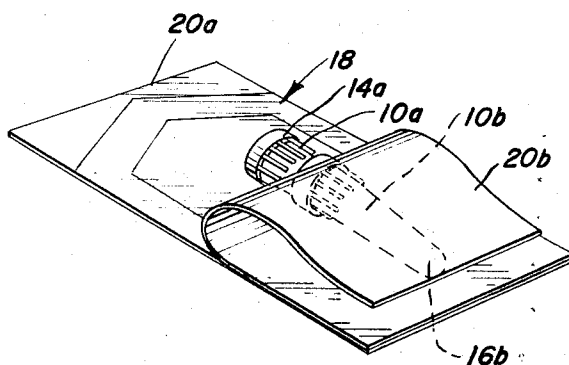


FIG. 4

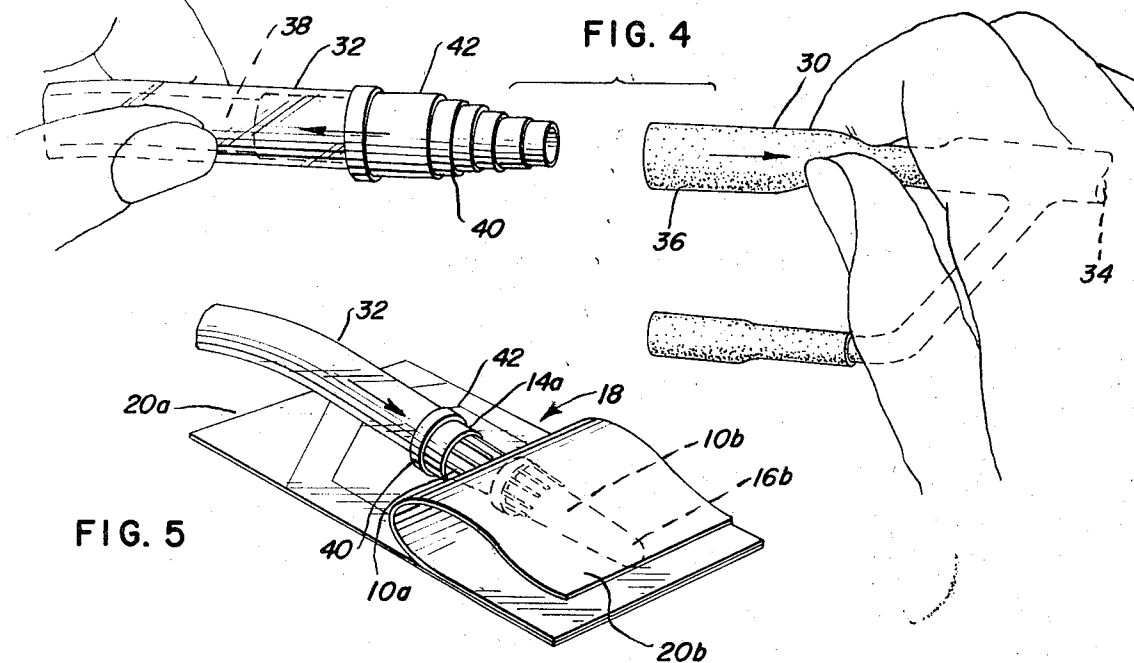
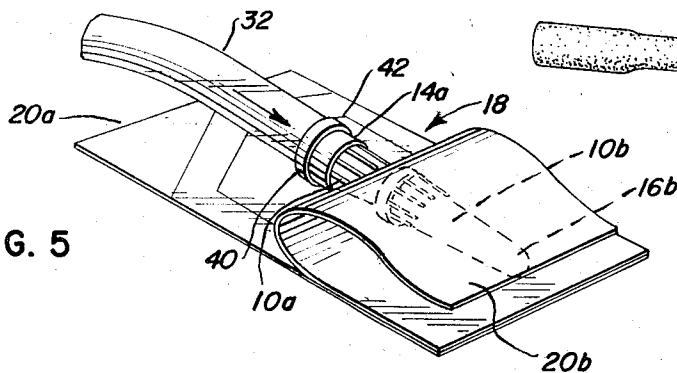


FIG. 5



SHEET 2 OF 2

FIG. 6

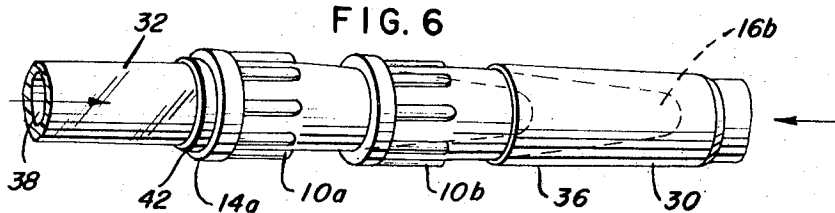


FIG. 7

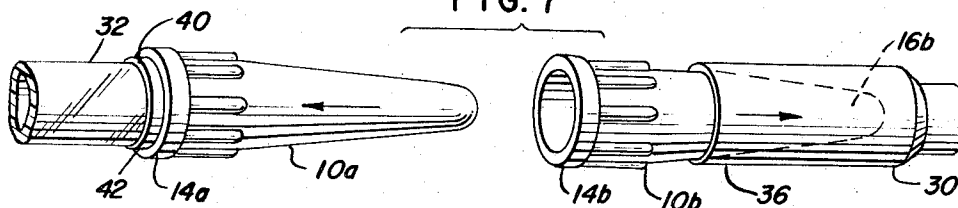


FIG. 8

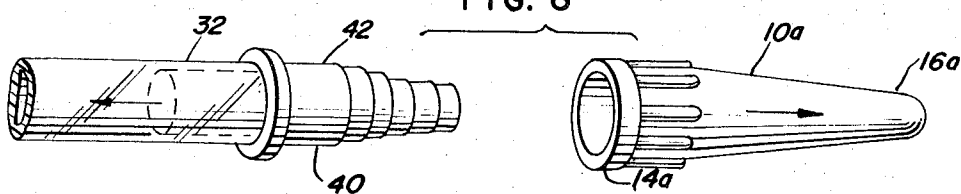


FIG. 9

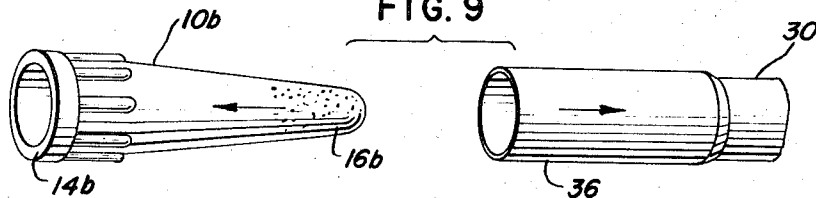


FIG. 10

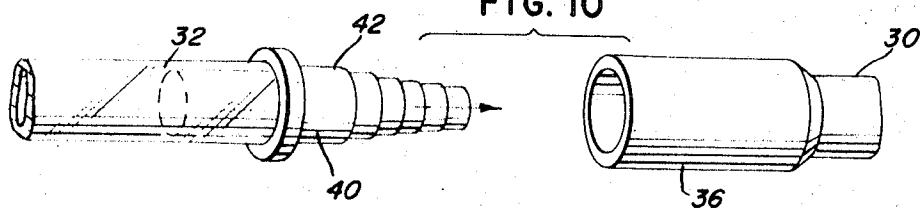
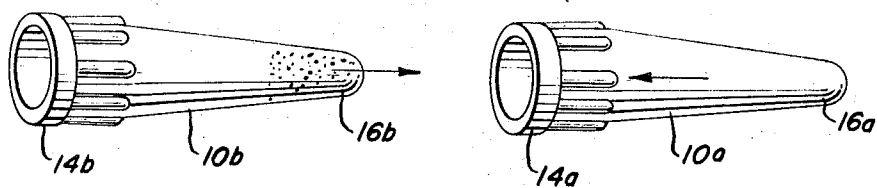


FIG. 11



STERILE CAPS FOR A LIQUID DRAINAGE SYSTEM AND METHOD

BACKGROUND OF THE INVENTION

Various systems for draining a body cavity of a patient are known, such as a urinary drainage system which is used to drain urine from the bladder. In a urinary system in common use, the distal end of a catheter is inserted through the urethra into the bladder with the proximal end of the catheter remaining outside of the patient's body. One end of a drainage tube is connected to the proximal end of the catheter, and urine drains from the catheter through the drainage tube into a collection bag which is connected to the other end of the drainage tube.

It is important to prevent contamination to the drainage system during catheterization, due to possible retrograde movement of bacteria into the bladder which may cause infection in the patient. Accordingly, many of such systems are closed to the atmosphere to exclude bacteria from the systems.

It is sometimes desirable to disconnect the catheter from the drainage tube during catheterization, for example, to permit the patient to leave the bedside without the necessity of carrying the drainage bag. However, difficulty has been encountered in maintaining the systems in a sterile condition during such a procedure, and it is found necessary to protect the ends of the catheter and drainage tube from contamination the time that they are disengaged from each other to prevent contamination to the system.

A catheter plug and shield device is disclosed in Strawn U.S. Pat. No. 3,307,552.

SUMMARY OF THE INVENTION

A principal feature of the present invention is the provision of a pair of sterile caps and a method of aseptically protecting the interconnectable ends of first and second tubes in a liquid drainage system with the caps in a convenient and simplified manner.

The sterile caps of the present invention are nestable, with the nested caps having a female end and a male end. According to the method of the present invention, the ends of the first and second tubes are disconnected, the end of the second tube is inserted into the female end of the sterile nested caps, the male end of the sterile nested caps is inserted into the end of the first tube, and the nested caps are then disconnected.

Thus, a feature of the invention is that the ends of the disconnected first and second tubes are aseptically closed by the caps.

Another feature of the invention is that in a preferred embodiment each of the closure caps has a male end and a female end, such that the male end of either of the caps is nestable in the female end of the other of the caps.

Further features will become more fully apparent in the following description of the embodiment of this invention and from the appended claims.

DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is perspective view of the nestable closure caps of the present invention in a nested configuration;

FIG. 2 is a sectional view of the closure caps of FIG. 1;

FIG. 3 is a perspective view of the closure caps of FIG. 1 as retained in a partially opened sterile package;

FIG. 4 is a fragmentary perspective view of a liquid drainage system showing the proximal end of a catheter being disconnected from the distal end of a drainage tube in the system;

FIG. 5 is a fragmentary perspective view showing the distal end of the drainage tube being inserted into the nested closure caps of FIG. 3;

FIG. 6 is a fragmentary perspective view showing the nested closure caps being inserted into the catheter;

FIG. 7 is a fragmentary perspective view showing the nested closure caps being disconnected from each other;

FIG. 8 is a fragmentary perspective view showing a closure cap being removed from the distal end of the drainage tube;

FIG. 9 is a fragmentary perspective view showing a closure cap being removed from the proximal end of the catheter;

FIG. 10 is a fragmentary perspective view showing the catheter being reconnected to the drainage tube; and

FIG. 11 is a perspective view showing the closure caps being reconnected for disposal.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIGS. 1 and 2, there is shown a pair of nestable closure caps 10a and 10b, which are illustrated in their nested configuration. In a preferred embodiment, each of the closure caps comprises a hollow generally conically shaped member, such that the closure caps 10a and b have cavities or recesses 12a and 12b, respectively, extending from female ends 14a and 14b, respectively, of the caps, while male ends 16a and 16b, respectively, are defined adjacent the other end of the caps. In the nested configuration, the male end 16a of an inner cap 10a is received in the female end 14b of an outer cap 10b, such that the nested caps interengage and are releasably retained together. The nested caps have a female end 14a which is defined by the inner cap 10a and a male end 16b defined by the outer cap 10b. Preferably, both of the caps have the same shape, in order that the male end of either of the caps may be nested in the female end of the other of the caps.

The nested caps may be sterilized and may be aseptically retained in a sterile package known to the art, such as the peel package 18 shown in FIG. 3. The package 18 has a pair of sheets 20a and 20b sealed together adjacent their edges, and one end of the upper sheet is peeled back to expose the female end 14a of the nested caps prior to use, as shown.

The proximal end 36 of a catheter or first tube 30 and the distal end 40 of a drainage or second tube 32 in a liquid drainage system is illustrated in FIG. 4. The catheter 30 has a main lumen 34 extending through the catheter to its proximal end 36, while the drainage tube 32 has a drainage lumen 38 extending through the drainage tube to its distal end 40. During use of the drainage system, the proximal end 36 of the catheter 30 is connected with the distal end 40 of the drainage tube 32 with the lumens 34 and 38 in communication, such

that liquid drains from the catheter 30 through a drainage lumen to a collection bag (not shown). Preferably, the drainage tube 32 has a connector 42 adjacent its distal end 40 to facilitate connectability of the drainage tube with the catheter.

The closure caps are utilized to protect the drainage system from contamination, as described below. First, the sterile package 18 may be opened to expose the female end 14a of the sterile nested caps, as previously described in connection with FIG. 3. Next, the catheter may be pinched by a user's fingers adjacent its proximal end 36 to close the main lumen 34 and prevent further drainage through the catheter, and the ends of the catheter and drainage tube are disconnected, as illustrated in FIG. 4. As shown in FIG. 5, the distal end 40 or connector 42 of the drainage tube 32 is then inserted into the female end 14a of the sterile nested caps. After the distal end 40 of the drainage tube 32 is engaged in the nested caps, the nested caps are removed from the package 18 by withdrawing the drainage tube 32 without the necessity of touching the caps with the user's hands. As shown in FIG. 6, the male end 16b of the nested caps is then inserted into the proximal end 36 of the catheter 30 by pushing the nested caps into this position while the user grasps the drainage tube 32 and catheter 30. Finally, the caps 10a and b are separated by twisting the drainage tube 32 and catheter 30 slightly, relative to each other, and pulling the catheter 30 away from the drainage tube 32, as illustrated in FIG. 7.

Thus, the cap 10a remains on the drainage tube 32 and closes its distal end 40 from the atmosphere to prevent contamination while the drainage tube 32 is disconnected from the catheter 30. Similarly, the closure cap 10b remains in the catheter and closes its proximal end 36 to prevent contamination to the main lumen 34 of the catheter and prevent liquid drainage from the catheter while the catheter is disconnected from the drainage tube. Once the closure caps are in position, as shown in FIG. 7, the patient is free to leave the bedside, for example, to have an X-ray taken, without the necessity of transporting the drainage tube and collection bag with the patient. Since the sterilized caps are removed from a sterile package and are placed in position without the necessity of touching the caps with the hands, it is apparent that the caps are placed on the drainage tube and catheter in an aseptic manner, such as to minimize the possibility of contamination to the system. As previously noted, once the caps are in position, they prevent contamination to the system while the catheter remains disconnected from the drainage tube.

Although the package 18 was described in connection with FIG. 3 as being opened from one end to expose the female end 14a of the nested caps, it is apparent that the opposite end of the package 18 could be opened to expose the male end 16b of the nested caps for use. In accordance with this procedure, the male end 16b of the nested caps is first inserted into the proximal end 36 of the catheter 30, the nested caps are removed from the package 18 by the catheter 30, and the female end 14a of the nested caps is then positioned on the distal end 40 of the drainage tube 32. The caps are then separated from each other, as previously described.

When it is desired to reconnect the catheter 30 to the drainage tube 32, the cap 10a is removed from the dis-

tal end 40 of the drainage tube 32, and the cap 10b is removed from the proximal end 36 of the catheter 30, as shown in FIGS. 8 and 9, respectively. As illustrated in FIG. 10, the distal end 40 of the drainage tube 32 is then inserted into the proximal end 36 of the catheter 30 to establish communication of the lumens 34 and 38 and permit further use of the drainage system. The closure caps 10a and b may then be discarded. However, since the male end 16b of the closure cap 10b may be moist due to drainage of liquid in the main lumen of the catheter while the cap 10b is in place on the catheter, the male end 16b of the closure cap 10b may be inserted into the female end 14a of the cap 10a to cover the moist male end 16b of the cap 10b prior to disposal, if desired.

The closure caps 10a and b may be made of any suitable material, such as plastic. However, if a relatively rigid connector 42 is used on the drainage tube 32, it is desirable to make the inner cap 10a of a softer material than the outer cap 10b and the connector 42. With such a construction of the closure caps, the relatively soft connector 10a readily engages the more rigid connector 42, while the relatively hard cap 10b readily grips the softer inner cap 10a. Thus, in a preferred embodiment, the softer inner cap 10a may be made of a low density polyethylene, while the outer more rigid cap 10b may be made of a medium density polyethylene. However, satisfactory operation of the closure caps 10a and b is also obtained when they are made from identical materials.

The foregoing detailed description is given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, as modifications will be obvious to those skilled in the art.

I claim:

1. A method of aseptically protecting the interconnectable ends of first and second tubes in a liquid drainage system with a nestable pair of sterile caps, with the nested caps having a female end and a male end, comprising the steps of:

disconnecting the ends of the first and second tubes;

inserting the end of the second tube into the female end of the sterile nested caps and the male end of the sterile nested caps into the end of the first tube to close the ends of the first and second tubes;

separating the nested caps, whereby the ends of the disconnected first and second tubes are aseptically closed by the caps.

2. The method of claim 1 wherein the end of the second tube is inserted into the nested caps prior to inserting the nested caps into the first tube.

3. The method of claim 2 wherein the nested caps are retained in a sterile package, and including the steps of:

opening the sterile package; and

removing the sterile nested caps from the opened package with the second tube after inserting the end of the second tube into the female end of the nested caps.

4. The method of claim 1 wherein said first tube comprises a catheter having a main lumen, said second tube comprises a drainage tube having a drainage lumen which communicates with said lumen when the catheter and drainage tube are connected, the distal end of the drainage tube is inserted into the female end of the nested caps, and the male end of the nested caps is in-

serted into the main lumen of the catheter adjacent its proximal end.

5. The method of claim 4 wherein said drainage tube includes a connector adjacent its distal end, and said connector is inserted into the female end of the nested caps.

6. The method of claim 1 wherein each of said caps has a male and a female end, and the male end of an inner cap is nested in the female end of an outer cap.

7. The method of claim 1 including the steps of: removing the caps from the ends of the first and second tubes; and connecting the ends of the first and second tubes.

8. The method of claim 7 including the step of inserting the male end of the cap removed from the first tube into the female end of the other removed cap.

9. A liquid drainage system closure means, comprising:

a catheter having a main lumen and a proximal end;

a drainage tube having a drainage lumen and a connector adjacent its distal end;

a pair of sterile nested closure caps, with the nested caps having a female end removably receiving and closing said drainage tube connector, with the nested caps having a male end removably inserted into the main lumen of the catheter to close its proximal end, and with said caps being separable to aseptically close the ends of the catheter and drainage tube.

10. The drainage system closure means of claim 9 wherein each of said closure caps has a male end and a female end, and the male end of at least one of said caps is separably nested in the female end of the other of the caps.

11. The drainage system closure means of claim 10 wherein each of said caps comprises a hollow generally conically shaped member.

12. The drainage system closure means of claim 10 wherein the closure cap which is nested inside the other cap is less rigid than said other cap.

13. The drainage system closure means of claim 10 wherein the male end of either of said caps is nestable in the female end of the other of the caps.

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