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Murray; Michael G. et al.

### Reusable urinary catheter products

#### Abstract

A reusable urinary catheter (72), comprising a catheter tube (12), a drainage member (22), the proximal end portion of the drainage member being connected to the distal end of the catheter tube, the distal end portion of the drainage member defining a drainage opening (28); a collapsible sleeve (18) surrounding the catheter tube, an introducer attached to the proximal end portion of the sleeve and the distal end portion of the sleeve being attached to the drainage member, the drainage member including channels (23) in fluid communication with the interior cavity of the sleeve, the channels allowing passage of sterilization fluid into and out of the sleeve; a holder (74) having a first port (66) and a second port (68), the introducer being releasably attached to the first port and the drainage member being releasable attached to the second port; and a sterilization fluid located within the sleeve.

**Inventors:** Murray; Michael G. (Ballina, IE), Montes De Oca; Horacio (Ballina, IE), Inglese; Gary W. (Deerfield, IL), Leece; Rebecca M. (Bicester, IE), Balaski; Darcy R. (Castlebar, IE), Clarke; John T. (Galway, IE), O'Mahony; John P. (Ardnacrusha, IE), Sheremetiev; Dmitry (Oranmore, IE), Gamblin; Denise (Leeds, GB), Renehan; Thomas (Ballina, IE), Meaney; Richard J. (Westport, IE), McNulty; Vivienne (Dublin, IE)

**Applicant:** Hollister Incorporated (Libertyville, IL)

**Family ID:** 1000008747833

**Assignee:** Hollister Incorporated (Libertyville, IL)

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*Primary Examiner:* Weiss; Nicholas J.

*Assistant Examiner:* Raymond; Linnae E.

*Attorney, Agent or Firm:* Cook Alex Ltd.

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## **Background/Summary**

CROSS-REFERENCE TO RELATED APPLICATION (1) This application is a National Stage Entry of International Application No. PCT/US2020/036969, filed Jun. 10, 2020, which claims the benefit of U.S. Provisional Application Ser. No. 62/861,130, filed Jun. 13, 2019, all of which are hereby incorporated by reference in their entirety.

### **BACKGROUND**

#### **Field of the Disclosure**

(1) The present disclosure generally relates to urinary catheters. More particularly, the present disclosure relates to reusable urinary catheter products.

#### **Description of Related Art**

(2) Catheters are used to treat many different types of medical conditions and typically include an elongated shaft that is inserted into and through a passageway or lumen of the body. Catheters, and in particular intermittent catheters, are commonly used by those who suffer from various abnormalities of the urinary system, such as urinary retention or incontinence. With the advent of intermittent catheters, individuals with urinary system abnormalities can self-insert and self-remove intermittent catheters several times a day.

(3) Urinary catheters are frequently provided as disposable, single-use items. A user will remove the catheter from a package, use the catheter once, and then dispose of the catheter and the package. Reusable urinary catheters could, thus, be advantageous in reducing the amount of waste created by the use disposable catheters, but there are various challenges associated with the use of reusable catheters (including storage, transport, and sterilization) that must be overcome before widespread acceptance and use of reusable catheters.

### **SUMMARY**

(4) There are several aspects of the present subject matter which may be embodied separately or together in the devices and systems described and claimed below. These aspects may be employed alone or in combination with other aspects of the subject matter described herein, and the description of these aspects together is not intended to preclude the use of these aspects separately or the claiming of such aspects separately or in different combinations as set forth in the claims appended hereto.

(5) In one aspect, a reusable urinary catheter product includes a catheter tube having a proximal insertion end and a distal end. The product also includes a drainage member having a proximal end portion and a distal end portion. The proximal end portion of the drainage member is connected to the distal end of the catheter tube and the distal end portion of the drainage member defines a drainage opening. The product includes a collapsible sleeve surrounding the catheter tube such that the catheter tube is located within an interior cavity that is defined by the sleeve. The sleeve has a proximal end portion and a distal end portion. An introducer is attached to the proximal end portion of the sleeve and the distal end portion of the sleeve is attached to the drainage member, wherein the introducer is releasably attached to the drainage member. A sterilization fluid located within the interior cavity of the sleeve and the drainage member includes channels in fluid communication with the interior cavity of the sleeve. The channels allow passage of sterilization fluid into and out of the sleeve.



(6) In another aspect, a reusable urinary catheter product includes a catheter tube having a proximal insertion end and a distal end. The product also includes a drainage member having a proximal end portion and a distal end portion. The proximal end portion of the drainage member is connected to the distal end of the catheter tube and the distal end portion of the drainage member defines a drainage opening. The product includes a collapsible sleeve surrounding the catheter tube such that the catheter tube is located within an interior cavity defined by the sleeve. The sleeve having a proximal end portion and a distal end portion. An introducer attached to the proximal end portion of the sleeve and the distal end portion of the sleeve is attached to the drainage member. The drainage member including channels in fluid communication with the interior cavity of the sleeve that allow passage of sterilization fluid into and out of the sleeve. A holder having a first port and a second port. The introducer is releasably attached to the first port and the drainage member is releasably attached to the second port. A sterilization fluid located within the sleeve.

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## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

- (1) FIG. 1 is a perspective view of a reusable urinary catheter product according to an aspect of the present disclosure, with the catheter product in a closed loop configuration;
- (2) FIG. 2 is a partial cross-sectional view of the catheter product showing the connection between the drainage member and introducer;
- (3) FIGS. 3-5 are perspective views showing various embodiments of connection elements of the introducer;
- (4) FIG. 6 is a perspective view the catheter product of FIG. 1, showing the catheter product in a generally straight configuration to allow drainage of the sterilization fluid from the catheter product;
- (5) FIG. 7 is a perspective view of the catheter product of FIG. 1, with sterilization fluid being dispensed into the catheter product;
- (6) FIG. 8 is a perspective view of the catheter product of FIG. 1, illustrating the catheter product being placed back into the closed loop condition following use;
- (7) FIG. 9 is a perspective view of the catheter product of FIG. 1, with the drainage member being reconnected to the introducer to form the closed looped configuration for storage and sterilization;
- (8) FIG. 10 is a perspective view of another embodiment of a reusable catheter product according to another aspect of the present disclosure;
- (9) FIG. 11 is a perspective view the catheter product of FIG. 10, showing the catheter product in a generally straight configuration to allow drainage of the sterilization fluid from the catheter product;
- (10) FIG. 12 is a perspective view of the catheter product of FIG. 10, illustrating the introducer being reattached to the holder; and
- (11) FIG. 13 is a perspective view of another embodiment of a reusable catheter product according to another aspect of the present disclosure.

### DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

(12) The embodiments disclosed herein are for the purpose of providing a description of the present subject matter, and it is understood that the subject matter may be embodied in various other forms and combinations not shown in detail. Therefore, specific embodiments and features disclosed herein are not to be interpreted as limiting the subject matter as defined in the accompanying claims.

(13) Reusable urinary catheter products according to the present disclosure and their individual components may be variously configured without departing from the scope of the present disclosure, but in one embodiment, a reusable urinary catheter product **10** is configured as shown in

FIG. 1. In particular, the illustrated product **10** includes a catheter tube **12** having a proximal end portion **14** and a distal end portion **16**. The product **10** also includes a sleeve **18** surrounding the catheter tube **12** wherein the catheter tube **12** is located within an interior cavity **20** defined by sleeve **18**. Prior to use or between uses of the catheter product **10**, a sterilization fluid may be located within the interior cavity **20** of the sleeve **18**. The sterilization fluid contacts the catheter tube **12** and other elements of the catheter product **10** to sterilize the catheter product **10** prior to and/or between uses of the catheter product **10**. As will be explained in more detail below, prior to performing catheterization, the user drains the sterilization fluid from the catheter product **10**. After the sterilization fluid has been drained, catheterization is performed. After catheterization, the user adds sterilization fluid to the catheter product **10** and stores the catheter product **10** until the next use.

(14) Turning back to the catheter tube **12**, the proximal end portion **14** of the catheter tube **12** includes openings or eyes **11** (FIG. 2) that allow liquid to flow therethrough. A drainage member **22** is associated with the distal end portion **16** of the catheter tube **12**. The drainage member **22** may be a funnel and/or a connector that connects to a urine collection bag. The drainage member **22** includes a proximal end portion **24** attached to the distal end portion **16** of the catheter tube **12**. A distal end portion **26** of the drainage member **22** defines a drainage opening **28** (FIGS. 2 and 6) for the drainage of fluids. Referring to FIG. 2, the drainage member **22** also includes one or more channels **23** in fluid communication with the cavity **20** of the sleeve **18**. As will be explained in more detail below, the channels **23** allow the passage of sterilization fluid to and from the cavity **20** of sleeve **18**. That is, the channels **23** allow fluid to be dispensed into the cavity **20**, and also allow fluid to be drained from the cavity **20**. In the illustrated embodiment, the channels **23** extend from the proximal end of the drainage member **22** and are in fluid communication with the drainage opening **28** in the distal end **26** of the drainage member **22**.

(15) As mentioned above, the sleeve **18** surrounds the catheter tube **12** such that the catheter tube **12** is located within an interior cavity **20** defined by the sleeve **18**. The sleeve **18** includes a proximal end portion **30** and a distal end portion **32**. The distal end portion **32** of the sleeve **18** is attached to the proximal end portion **24** of the drainage member **22**. An introducer **34** is attached to the proximal end portion **30** of the sleeve **18**. The proximal end portion **36** of the introducer **34** may include an introducer tip **38** which may be configured to be inserted into the urethral opening prior to insertion of the catheter tube **12**. The introducer tip **38** may include an opening, which may be a reclosable opening **40**. In the embodiments illustrated in FIGS. 2-5, the reclosable opening **40** includes a plurality of flexible petals **41** that are separated by slits **43**. The petals **41** are flexible so as to allow advancement of the catheter tube **12** through opening **40** for insertion of the catheter tube **12** into the urethra. The petals **41** also allow retraction of the catheter tube **12** back into the sleeve **18**, and the petals **41** are resilient so as to reclose opening **40** after the catheter has been fully retracted into sleeve **18**. The introducer **34** also may include a stop or flange **42** that contacts the urinary meatus during insertion into the urethra to prevent over insertion of the introducer tip **38**. The introducer **34** may include a second flange **44** that assists the user in placing the user's fingers in a position to grasping the catheter product **10**.

(16) As shown in FIGS. 1-5, the introducer **34** may be releasably connected or attached to the drainage member **22** so that the catheter product **10** forms in a closed loop configuration. The closed loop configuration could include one or multiple loops or windings. As illustrated in FIG. 2, when the introducer **34** includes an introducer tip **38**, the introducer tip **38** may be inserted into the drainage opening **28** of the drainage member **22**. The introducer **34** may contact the inner surface **46** of the drainage member **22** in a manner that forms a friction fit or snap fit to releasably connect the drainage member **22** and the introducer **34** to each other. The connection between the drainage member **22** and introducer **34** is a liquid tight connection so that the sterilization fluid is contained within the catheter product during storage of the catheter product **10** between uses. Referring to FIG. 2, in the illustrated embodiment, the inner surface **46** of the drainage member **22** includes a

groove or a recess **48** which mates with or accepts flange **42** of the introducer **34** to releasably secure the drainage member **22** and the introducer **34** together. Optionally, the flange **44** of the introducer **34** may contact or mate with the distal end portion **26** of the drainage member **22**, about the area of the opening **28**, to provide a liquid tight seal. When the introducer **34** includes an introducer tip **38**, one of the benefits of this configuration is that the introducer tip is stored in and protected by the drainage member **22**.

(17) FIGS. **4** and **5** illustrate alternative embodiments of attachment mechanisms for releasably attaching the introducer **34** and the drainage member **22**. In FIG. **4**, the proximal end portion of the introducer **34** includes a plurality of protrusions or ribs **45**. For example, the introducer **34** may include opposed protrusions or ribs **45**. The protrusions **45** engage or mate with the inner surface of the drainage member **22** to secure the drainage member **22** and the introducer **34**. Similar to as described above, the inner surface of the drainage member **22** may have a recess or groove that mate with the protrusions. Turning to FIG. **5**, the proximal end **36** of the introducer **34** may include a thread **47** which mates with inner surface of the drainage member **22**. The inner surface of the drainage member **22** may include a complementary threaded portion. The attachment mechanisms **42**, **45** and **47** or any other suitable attachment mechanisms may be incorporated into the flange **44**, instead of being on the insertion tip. Optionally, the flange could be eliminated the attachment mechanism could serve as a stop or flange that contacts the urethral opening.

(18) As mentioned above, prior to use or while the reusable catheter product **10** is stored between uses, a sterilization fluid may be located in the interior cavity **20** of the sleeve **18**. The sterilization fluid contacts the inner and outer surfaces of the catheter tube **12** and introducer **34** and the inner surfaces of the drainage member **22** to sterilize the catheter product **10** between uses. The sterilization fluid may be any suitable biocompatible sterilization fluid. Such fluids may include antimicrobial agents, such as agents that kill bacteria, viruses or other microbes, agents that prevent microbial growth, anti-adherence agents that prevent microbes from adhering to the surfaces, etc. Furthermore, when the catheter tube **12** is a hydrophilic catheter tube that has an outer hydrophilic surface that becomes lubricous when wetted or hydrated, the sterilization fluid may also serve as a hydration fluid that hydrates the hydrophilic surface. The lubricous hydrophilic outer surface assists in inserting the catheter into and retracting the catheter out of the urethra. In other embodiments, the sterilization fluid may include a lubricant, such as oil or water based lubricants that lubricates the outer surface. In yet other embodiments, the user may apply a lubricant just prior to use.

(19) The sterilization fluids may also be a fluid that can be formed into a foam. Such fluids may include a surface tension reducing agent and a foam stabilization agent. The surface tension reducing agent may assist in adding or incorporating gas bubbles into the sterilization fluid to form a foam. In one embodiment, the surface tension reducing agent may be a surfactant or a mixture of surfactants. The surface tension reducing agent may be a foaming agent. The foam stabilizer may slow coalescence of the foam. In one embodiment, the sterilization fluid may include an antimicrobial agent and a surfactant (e.g., sodium dodecyl sulphate or sodium methyl cocoyl taurate) and a stabilizer (e.g., Xanthan gum). The sterilization fluid can be transformed into a foam by homogenizing air with the fluid. The air may be homogenized with the sterilization fluid by agitation of the fluid in the presence of air. The agitation can be a result of the user shaking the catheter product or a result of ordinary movement of the catheter product as the user carries it around. As disclosed in more detail below, in other embodiments, the catheter product may include an agitation mechanism, such as a pump, restriction, homogenizer, etc.

(20) Referring to FIGS. **6-9**, in use, the user disengages the introducer **34** from the drainage member **22**. The drainage member **22** is then held at a location that is lower than the introducer **34** to drain the sterilization fluid from the cavity of the sleeve **18**. The sterilization fluid drains from the cavity of the sleeve **18** through channels **23** in the drainage member **22** (FIG. **2**). In FIG. **6**, the sterilization fluid is drained into a sink **49**. Once the sterilization fluid has been sufficiently drained

from the sleeve **18**, the insertion tip **38** of the introducer **34**, if one is present, is inserted into the urethra of the user. The user then proceeds to advance the catheter tube **12** out of the introducer **34** and into and through the urethra by grasping the catheter tube **12** through the sleeve **18**. The sleeve **18** is flexible and collapsible such that it collapses as the catheter tube **12** is advanced. The catheter tube **12** is advanced through the urethra until the proximal end of the catheter tube **12** reaches the bladder. Urine is then drained from the bladder through the catheter tube **12**.

(21) After urine has been drained from the bladder, the catheter tube **12** is removed from the bladder. The catheter tube **12** is retracted back through the introducer **34** so that the sleeve **18** once again extends over the catheter tube **12** and the proximal end of the catheter tube **12** is within the introducer **34** and/or the cavity **20** of the sleeve **18**. As shown in FIG. 7, a supply of sterilizing fluid **50** is used to add sterilizing fluid to the catheter product **10**. In the illustrated embodiment, sterilizing fluid is dispensed from a bottle **52** into the drainage opening **28** of the drainage member **22**. The fluid may travel through the channels **23** of the drainage member **22** (FIG. 2) and/or through the eyelet **11** of the catheter tube **12** (FIG. 2) into the cavity **20** defined by sleeve **18**. As the fluid enters the cavity **20**, the reclosable opening **40** of the introducer tip **38** prevents the fluid from exiting out of the proximal end of the sleeve **18** or catheter product **10**. After a sufficient amount of sterilization fluid has been dispensed into the catheter product **10**, the catheter product **10** is placed into the closed loop configuration by reattaching the introducer **34** to the drainage member **22** as shown in FIGS. 8 and 9. The catheter product **10** may be manually agitated (e.g., by shaking it) to circulate the sterilization fluid within the cavity of the sleeve **18**. Agitation may also occur as the user carries the catheter with them during every day activities. When the fluid is one that forms a foam, as described above, manual agitation of the fluid results in foaming of the fluid. As shown in FIG. 2, when the introducer **34** is attached to the drainage member **22**, the reclosable opening **40** of the introducer tip **38** serves as an obstruction and/or restriction in fluid path which prevents or restricts the movement of the sterilization fluid. In other embodiments, the introducer tip **38** may be always be open such that the fluid circulates within the closed looped configuration. When the fluid is agitated and the introducer tip includes a reclosable opening, the fluid sloshes against the introducer tip **38** so that the fluid moves move back and forth within the cavity. When a foaming sterilization fluid is used, this obstruction and/or restriction may assist in forming the fluid into a foam. When the user is ready to catheterize again, the user removes the introducer from the drainage member, drains the fluid from the product, and repeats the above discussed catheterization procedure.

(22) FIGS. 10-13 illustrate embodiments wherein the catheter products **60** and **72** include a holder **62** and **74**, respectively, that hold the catheters between uses. The catheter products **60** and **72** include several of the same components as catheter product **10** described above. For example, catheter products **60** and **72** include a catheter tube **12**, sleeve **18**, drainage member **22**, introducer **34**, etc. In the embodiment illustrated in FIGS. 10-12, the holder **62** may also serve as a pump for moving or agitating sterilization fluid within the catheter product **60**. The holder **62** may be an elastic bulb **63** which can be repeatedly squeezed by the user to move and/or agitate sterilization fluid within the catheter product **60**. The bulb **63** includes an inner chamber **64** and a first port **66** and a second port **68** that may be in communication with the inner chamber. The first port **66** is configured for releasable attachment to the introducer **34** and the second port **68** is configured for releasable attachment to the drainage member **22**. The attachments between the ports **66**, **68** and the introducer **34** and the drainage member **22** are preferably fluid tight attachments.

(23) When the fluid is one that may be foamed, squeezing of the bulb **63** agitates the fluid, resulting in the formation of a foam from the fluid. In one alternative embodiment, a sponge **70** may be located within the bulb. When the bulb is compressed, the sponge is also compressed, which may aid in adding air to the fluid. One or both of the ports **66**, **68** may include restrictions or obstructions or one way valves, which also may assist in foaming the fluid. For embodiments in which a sterilization fluid is circulated through the kit, the fluid path may include one or more

filters or screens configured to entrap debris circulating through the fluid path. Each filter or screen may be placed in any suitable location within the fluid path and may be variously configured without departing from the scope of the present disclosure. In an exemplary embodiment, the filter or screen may be provided as a flat mesh with pores that are sized and configured to entrap particulates that may be present in urine. In other embodiments, the filter or screen may be differently configured (e.g., being formed of a woven or non-woven material), including having any pore size and/or porosity. If multiple filters or screens are provided, they may be substantially identical or differently configured and may be positioned at any suitable location with respect to each other. In one embodiment, the filter or screen may be placed in the return loop returning fluid to the pump for recycling. In this embodiment, the filter entraps debris prior to the fluid entering the pump and being returned back into the compartment with the catheter.

(24) Referring to FIG. 11, in use, the drainage member 22 is detached from port 68 of the holder 62 and placed below the introducer 34. The sterilization fluid is drained from the cavity of the sleeve 18 as described above. The introducer 34 is detached from the holder 62 and catheterization is performed as described above. The catheter tube is then retracted back into the introducer and the sleeve once again extends over the catheter tube. Referring to FIG. 12, the introducer 34 may be reattached to the port 66. Sterilization fluid (not shown) may be dispensed into the holder 62 through port 68. The drainage member 22 may then be reattached to port 68. The user may then compress holder 62 to agitate the fluid within the catheter product 60. The sterilization fluid sterilizes the catheter product 60 so it is ready for use the next time the user requires catheterization.

(25) FIG. 13 illustrates another embodiment of a catheter product 72 that includes a holder 74. The holder 74 includes a body 75 having a first port 76 configured for releasable attachment to the introducer 34 and a second port 78 configured for releasable attachment to drainage member 22. The attachments between the ports 76 and 78 and the introducer 34 and drainage member 22 are liquid tight. The body 75 may also include a ring shaped portion 80 that may be used to grasp the catheter product. The holder 74 may also include an electric pump or agitator 82 associated with the port 78 and in fluid communication with drainage member 22. When the drainage member 22 and introducer 34 are attached to their respective ports, the electric pump or agitator may move or agitate the liquid within the catheter product 72.

(26) It will be understood that the embodiments described above are illustrative of some of the applications of the principles of the present subject matter. Numerous modifications may be made by those skilled in the art without departing from the spirit and scope of the claimed subject matter, including those combinations of features that are individually disclosed or claimed herein. For these reasons, the scope hereof is not limited to the above description but is as set forth in the following claims, and it is understood that claims may be directed to the features hereof, including as combinations of features that are individually disclosed or claimed herein.

## Claims

1. A reusable urinary catheter product, comprising: a catheter tube having a proximal insertion end and a distal end; a drainage member having a proximal end portion and a distal end portion, the proximal end portion of the drainage member being connected to the distal end of the catheter tube, the distal end portion of the drainage member defining a drainage opening; a collapsible sleeve surrounding the catheter tube such that the catheter tube is located within an interior cavity defined by the sleeve, the sleeve having a proximal end portion and a distal end portion, an introducer attached to the proximal end portion of the sleeve and the distal end portion of the sleeve being attached to the drainage member, the drainage member including channels in fluid communication with the interior cavity of the sleeve, the channels allowing passage of sterilization fluid into and out of the sleeve; a holder having an inner chamber, a first port, and a second port, wherein the first

- port and second port are in communication with the inner chamber, a proximal end of the introducer being releasably attached to the first port, wherein the introducer is directly coupled within the first port, and a distal end of the drainage member being releasably attached to the second port, wherein the drainage member is directly coupled within the second port; and wherein a sterilization fluid flows through the inner chamber of the holder and interior cavity of the sleeve.
2. The reusable urinary catheter product of claim 1, wherein the holder is at least partially compressible.
  3. The reusable urinary catheter product of claim 2, wherein the holder comprises a bulb, wherein when the bulb is compressed, the sterilization fluid is agitated and moved through the sleeve.
  4. The reusable urinary catheter product of claim 3, wherein a sponge is located within the chamber of the holder.
  5. The reusable urinary catheter product of claim 1, wherein the catheter tube includes a lubricious hydrophilic outer surface and the sterilization fluid hydrates the lubricious hydrophilic outer surface.
  6. The reusable urinary catheter product of claim 1, wherein the sterilization fluid includes a lubricant.
  7. The reusable urinary catheter product of claim 1, wherein the sterilization fluid comprises a foam.
  8. The reusable urinary catheter product of claim 1, wherein fluid moves in a closed fluid path when the holder is compressed.
  9. A reusable urinary catheter product, comprising: a catheter tube having a proximal insertion end and a distal end; a drainage member having a proximal end portion and a distal end portion, the proximal end portion of the drainage member being connected to the distal end of the catheter tube, the distal end portion of the drainage member defining a drainage opening; a collapsible sleeve surrounding the catheter tube such that the catheter tube is located within an interior cavity defined by the sleeve, the sleeve having a proximal end portion and a distal end portion, an introducer attached to the proximal end portion of the sleeve and the distal end portion of the sleeve being attached to the drainage member, the drainage member including channels in fluid communication with the interior cavity of the sleeve, the channels allowing passage of sterilization fluid into and out of the sleeve; a holder having a first port and a second port, a proximal end of the introducer being releasably attached to the first port, wherein the introducer is directly coupled within the first port, and a distal end of the drainage member being releasably attached to the second port, wherein the drainage member is directly coupled within the second port; and a sterilization fluid within the interior cavity of the sleeve.
  10. The reusable urinary catheter product of claim 9, wherein the holder includes an electric pump or agitator for moving or agitating the sterilization fluid within the sleeve.
  11. The reusable urinary catheter product of claim 9, wherein the holder is at least partially compressible.
  12. The reusable urinary catheter product of claim 9, wherein the holder comprises a bulb, wherein when the bulb is compressed, the sterilization fluid is agitated and moved through the sleeve.
  13. The reusable urinary catheter product of claim 9, wherein a sponge is located within a chamber of the holder.
  14. The reusable urinary catheter product of claim 9, wherein the catheter tube includes a lubricious hydrophilic outer surface and the sterilization fluid hydrates the lubricious hydrophilic outer surface.
  15. The reusable urinary catheter product of claim 9, wherein the holder includes a body having a ring shaped portion.
  16. The reusable urinary catheter product of claim 9, wherein the sterilization fluid includes a lubricant.
  17. The reusable urinary catheter product of claim 9, wherein the sterilization fluid comprises a

foam.

18. The reusable urinary catheter product of claim 9, wherein fluid moves in a closed fluid path when the holder is compressed.

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