

TITLE OF THE INVENTION

Luer Cleaner

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This relates to and claims priority from Provisional U.S. Patent Application Serial No. 60/587,790 filed July 14, 2004.

FIELD OF THE INVENTION

[0002] The present invention relates to medical device, and more particularly to an  
The present invention relates to an apparatus for cleaning ~~male threads on~~ a luer connector that is  
attached to a catheter assembly implanted on a patient.

BACKGROUND OF THE INVENTION

(0003) In catheter assemblies such as are used in hemodialysis, proximal ends of the catheters are terminated in luer connectors that are disposed outside of the patient, and the luer connectors enable easy and rapid connection to respective fluid lines of the hemodialysis apparatus in a manner permitting easy and rapid disconnect. Of course, when unconnected to the fluid lines, the ends of the luer connectors are exposed to debris and contamination and they require cleaning and decontamination prior to each connection.

SUMMARY OF THE INVENTION

[0004] The present invention is a luer cleaner that includes a generally hollow body having an open first end, a closed second end, and a longitudinal axis extending therethrough between the first end and the second end. The first end is sized to receive therein the proximal end of the luer

connector and includes a plurality of bristles extending generally toward the longitudinal axis sufficiently to engage the luer connector disposed therein. The second end comprises a compressible reservoir containing a fluid, wherein, when the second end is compressed, the fluid is transmitted from the reservoir toward the first end. When the luer cleaner is inserted over the proximal end of the luer connector and preferably is rotated reciprocally several times about the luer's axis, the bristles engage and mildly scrub the outer surfaces of the luer connector's proximal end, including the male connector threads, to dislodge debris, and the fluid washes and thus cleans and decontaminates the luer connector end when the luer cleaner is removed from the luer connector. The method of the present invention includes: inserting a luer connector proximal end into a luer cleaner open end so that bristles within the luer cleaner engage the luer proximal end outer surfaces to scrub them; compressing the luer cleaner closed second end to force fluid toward the open first end through passageways to wash the luer connector end; and rotating the luer cleaner about the luer connector to scrub and clean it.

[0005] Other embodiments of the luer cleaner provide a frangible capsule within the reservoir at the second luer cleaner end that contains the fluid and that expresses the fluid when crushed; and provide a pair of frangible capsules within the reservoir, that contain the fluid and together express the fluid.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate the presently preferred embodiments of the invention, and, together with the general description given above and the detailed description given below, serve to explain the features of the invention. In the drawings:

[0007] Fig. 1 is a perspective view of a luer cleaner according to a first preferred embodiment of the present invention, with a luer being inserted into the luer cleaner;

[0008] Fig. 2 is an exploded view of the luer cleaner shown in Fig. 1;

[0009] Fig. 3 is a sectional view of the luer cleaner shown in Fig. 1;

[0010] Fig. 4 is an enlarged front view of a scrubber disc shown inside the luer cleaner;

[0011] Fig. 5 is a sectional view of the scrubber disc of Fig. 4, taken along line 5-5 of Fig. 4; and

~~Fig~~[0012] Figs. 6 ~~is a~~ and 7 are sectional ~~view of a luer scrubber~~ views of luer cleaners according to ~~a~~ second preferred embodiment and third embodiments of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

[0013] In the drawings, like numerals indicate like elements throughout. Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention.

The ~~terminology~~terminology includes words specifically mentioned, derivatives thereof, and words of similar import. The following describes preferred embodiments of the invention.

However, it should be understood based on this disclosure, that the invention is not limited by the preferred embodiments described herein.

[0014] Referring now to Fig. 1, a luer cleaner 100 according to a first embodiment of the present invention is shown. The luer cleaner 100 is ~~inserted~~insertable over the proximal end of a luer connector 190 and ~~rotated~~rotatable axially about the luer ~~190. The luer 190 includes male threads 192 that are used to secure the luer 190 to another connection. The luer,~~ Luer connector, or luer, 190 is preferably connected to a medical device, such as a hemodialysis catheter 194, ~~or other.~~ The proximal end of luer 190 includes male threads 192 that are used to secure luer 190 to a second medical device (e.g., a hemodialysis apparatus) having fluid lines each terminating in a corresponding luer connector that

incorporates ~~a luer connection with~~ internal, female threads. Prior to connection of the luer 190 with the ~~other~~second medical device, the ~~luer~~proximal end of luer 190 is inserted into an open end of the luer cleaner 100. As the luer cleaner 100 is rotated about the luer 190, antiseptic fluid contained in the luer cleaner 100 is forced from a reservoir in the luer cleaner 100 such as by manually applied pressure, over the luer 190, to clean debris and other contaminants that may be present on or around the luer threads 192. Also shown, along with Figs. 2 and 3, is a body 160 defining a reservoir 166 for a fluid 168.

[0015] Referring now to Figs. 2 and 3, the luer cleaner ~~100~~100 includes an open end 104, a closed end 106, and a longitudinal axis 107 extending therethrough between the open end 104 and the closed end 106. The open end 104 includes a generally tubular body 108 having a longitudinal passage 110 that extends toward the closed end 106. Preferably, the body 108 is constructed from polyvinyl chloride or some other suitable biocompatible material. The body 108 includes an exterior portion 112 that may optionally include a plurality of gripping ribs 114 extending therefrom, away from the longitudinal axis 107. The gripping ribs 114 allow a user to grip the body 108 during use of the cleaner 100. The interior of the body 108 includes at least one, and preferably two, diametrically

opposed alignment notches 116 that extend from the longitudinal passage 110 away from the longitudinal axis 107.

[0016] The body 108 further includes a guide member 117 that extends partially into the longitudinal passage 110 along the longitudinal axis 107 toward the open end 104. The guide member 117 preferably includes a male luer taper 118 to engage a female luer connection on the luer 190. The guide member 117 prevents fluid from ~~the reservoir that has been forced into the longitudinal passage 110 from~~ entering the catheter 194 through the interior of the luer 190 after the fluid has been forced into the longitudinal passage 110 from the reservoir. The guide member 117 is preferably integrally molded with the body 108, as seen in the ~~cross-section~~cross- section view of Fig. 3.

**[0017]** At least one, and preferably, four passages 119 are disposed within the body 108 between the exterior portion 112 of the body 108 and the guide member 117 (although only two passages 119 are shown in Fig. 3). The passages 119 are preferably parallel to the longitudinal axis 107 and each passage 119 is disposed ninety degrees apart from each adjacent passage 119.

**[0018]** The body 108 also includes an annular ~~rib~~ flange 120 that extends from the body 108, away from the open end 104 of the luer cleaner 100. The ~~rib~~ flange 120 extends outwardly of the passages 119, with a lip 122 being formed between the ~~rib~~ flange 120 and the exterior portion 112 of the body 108.

**[0019]** A tubular ~~connector~~ collar 123, having an approximately "T-shaped" cross section, is fixedly connected to the body 108, distal from the open end 104 of the luer connector 100. The ~~connector~~ collar 123 includes a ~~rib~~ corresponding lip 124 that extends circumferentially ~~around the connector 123,~~ therearound and ~~that~~ is sized to surround and engage ~~the connector 123~~ with the ~~rib~~ flange 120 of the body 108, as is seen in Fig. 3. The connection between the ~~connector~~ collar 123 and the body 108 ~~may be~~ may be an interference fit, a threaded connection, an adhesive-based connection, or some other suitable connection known to those skilled in the art.

[0020] The ~~connector~~collar 123 also includes a ~~connector~~connecting passage 125 that extends through the ~~connector~~

collar 123, generally along the longitudinal axis 107. When the ~~connector~~collar 123 and the body 108 are engaged with each other, a generally circular throughway 126 is formed between the body 108 and the ~~connector~~collar 123 that provides fluid communication between the ~~connector~~connecting passage 125 and the passages 119 in the body 108.

[0021] A scrubber 130 is disposed within the longitudinal passage 110. ~~The scrubber 130~~ and is preferably constructed from at least one, and preferably a plurality, of scrubber discs 131. Details of ~~the~~a scrubber disc 131 are shown in Figs. 4 and 5. ~~Each;~~ each scrubber disc 131 includes an annular ring 132, with each ring 132 having a plurality of scrubber bristles 134 extending therefrom toward the



longitudinal axis 107. Preferably, the rings 132 and scrubber bristles 134 are constructed from polypropylene or some other suitable biocompatible material. The bristles 134 extend sufficiently far toward the center of each ring 132 so as to engage the luer threads ~~192~~ of the luer ~~190~~ when the luer ~~190~~ is inserted into the luer cleaner 100.

[0022] Preferably, the ring 132 for each scrubber disc 131 includes at least one, and preferably two diametrically opposed, alignment posts 136 that extend from the outer perimeter of the ring 132 away from the center of the ring 132. Each post 136 is sized and shaped to fit into ~~the~~ respective alignment notch 116 cut into the body 108. Each post 136 engages the alignment notch 116 in a generally tight, frictional fit so that each ring 132 remains within the longitudinal passage 110 after insertion ~~into the longitudinal passage 110~~ thereinto.

[0023] Each ring 132 also includes at least one, and preferably, a plurality, of ~~through-~~ ~~passages~~ through- passages 140 that allow fluid to pass from one side of each ring 132 to an opposing side of each ring 132. ~~As seen in Fig. 4 four~~ Four through-passages 140 are preferred, as shown in Fig. 4, with each through-passage 140 being disposed at ~~ninety-degree~~ ninety-degree spacings from each adjacent through-passage 140, although those skilled

in the art will recognize that more or less than four through-passages 140 may be used.

However, it is preferred that each ~~through-passage~~through-passage 140 fluidly communicates with a passage 119 in the body 108, so that fluid communication exists between all of the passages 140 and the ~~connector~~connecting passage 125.

[0024] Further, a plurality ~~of radially~~of radially extending channels 142 extends along an exterior of each ring 132 from the outer perimeter of the ring 132 to the inner diameter of the ring 132, with each channel 142 fluidly communicating with a through-passage 140. As can be discerned from Figs. 4 and 5, four channels 142 are disposed at ~~ninety-degree~~ninety-degree spacings apart from each adjacent channel 142, with channels 142 disposed on either side of each ring 132, although those skilled in

the art will recognize that, for each through-passage 140, a channel 142 is preferably disposed on either face of the ring 132.

[0025] With a plurality of rings 132 disposed adjacent one another, as shown in Fig. 23, the radially extending channels ~~142~~ in adjacent rings 132 form radial passages 146 that provide fluid communication between each through-passage 140 and the longitudinal passage 110 to allow fluid to be transmitted through the radial passages 146 to the longitudinal passage 110. Fluid communication is now present between the longitudinal passage 110 and the connector passage 125.

~~A~~[0026] Again referring to Fig. 3, sealing ring 150 is disposed between the array of rings 132 and the open end 104 of the luer cleaner 100. The sealing ring 150 preferably has an internal diameter that is approximately the same as the external diameter of the luer 190 (see Fig. 1) to prevent fluid forced manually from the reservoir 168 within bulbous body 160 and into the longitudinal passage 110, from flowing out of the luer cleaner 100 between the luer ~~190~~ and the body 108 of the cleaner 100. The sealing ring 150 is preferably constructed from ~~Kraton~~KRATON<sup>TM</sup> or other suitable, flexible material, so that the sealing ring 150 generally provides a seal around the luer ~~190~~ when the luer ~~190~~ is inserted into the luer cleaner 100.

[0027] A cap 152 is disposed on the open end 104 of the luer cleaner 100 to retain the sealing ring 150 and the array of scrubber rings 132 within the luer cleaner 100. The cap 152 is preferably annular, with a generally circular central opening 154 that is sized to allow the luer ~~190~~ to be inserted therethrough. The cap 152 is preferably fixedly connected to the body 108, such as with an adhesive, although those skilled in the art will recognize that the cap 152 may be retained by other methods, such as by interference fit, or a threaded connection.

[0028] The closed end 106 of the luer cleaner 100 includes a generally bulbous body 160 constructed from ~~Kraton~~KRATON<sup>TM</sup>, 1064 PVC, or some other suitable, compressible material. The body

160 includes an open end 162 that is fixedly and sealingly connected to the ~~connector~~collar 123 and a closed end 164 disposed away from the open end 162. The interior of the bulbous body 160 defines a compressible reservoir 166. A fluid 168 is disposed within the reservoir 166 such that the reservoir 166 fluidly communicates with the longitudinal passage 110 of the generally tubular body 108 through the ~~connector~~connecting passage 125, the circular throughway 126, the passages 119, the through-passages 140, and the radial passages 146.

[0029] Preferably, the fluid 168 is a fluid having antiseptic properties, such as alcohol. More preferably, the fluid 168 is sufficiently viscous to remain in the reservoir 166 in the absence of a compressive force on the body 160 of the reservoir 166. Such a preferred fluid 168 is isopropyl alcohol in a polymer suspension, such as polyvinyl alcohol, sold commercially by GOJO Industries as PURELL®, although those skilled in the art will recognize that other fluids, including, but not limited to, ~~betadine~~povidone iodine or hydrogen peroxide, or any combination thereof, may be used instead.

[0030] In use, ~~as shown in Fig~~and referring to Figs. 1 and 3, the luer 190, such as on a proximal end of a catheter 194, is inserted into the open end 104 of the luer cleaner 100. The sealing ring 150 engages the external

portion of the luer 190, restricting fluid ~~+56~~166 from being forced out of the open end 104 of the luer cleaner 100.

[0031] After the luer 190 is fully inserted into the open end 104 of the luer cleaner 100, the bulbous body 160 is then compressed, forcing the fluid 168 in the reservoir 166 ~~out of~~from the reservoir 166, ~~through~~ and eventually into the longitudinal passage 110 of the generally tubular body 108 by way of being forced through the ~~connector~~connecting passage 125, the circular throughway 126, the passages 119, the through-passages 140, and the radial passages 146, to the longitudinal passage 110 and thus to

the exterior of the luer 190. The luer 190 is rotated about the longitudinal axis 107 of the luer cleaner 100, in a preferably back-and-forth motion, so that the bristles 134 on the scrubber discs 131, in conjunction with the fluid 168, clean contaminants from the exterior of the luer 190, including the luer threads 192. After several seconds of scrubbing ~~the luer 190~~, the luer ~~190~~ is removed from the luer cleaner 100, and the luer cleaner 100 may be discarded. ~~The luer~~ Luer 190 is now disinfected and may be connected to an external medical device.

[0032] In an alternate embodiment of a luer cleaner 200, shown in Fig. 6, a fluid 268 may ~~be~~ be retained in a frangible container 270 disposed within the reservoir 166. The fluid 268 may be significantly less viscous than the fluid 168 described above with respect to the luer cleaner 100 (Fig. 1). The frangible container 270 prevents the fluid 268 from flowing out of the reservoir 166 prior to use.

[0033] To use the luer cleaner 200, the luer ~~190~~ is inserted into the open end 104 as described above with respect to the luer cleaner 100. The user compresses the reservoir 166 toward the longitudinal axis 107, breaking the frangible container 270, and allowing the fluid 268 to flow from the reservoir 166 and to the longitudinal passage 110 as described above with respect to the luer cleaner 100.

[0034] The frangible container 270 may be constructed from a material that is easily broken open under compression. The fluid 268 may be the same as the fluid 168 described above, or the fluid 268 may be a less viscous fluid, such as, for example, isopropyl alcohol without any suspension.

[0035] In Fig. 7, a third embodiment of luer cleaner 300 is shown. A pair of frangible containers 370 are secured to opposite sides of a tab 372, each containing quantities of fluid 368 that will be expressed into and forwardly through channel 376 of tab 372 when the closed end 360



| ones of frangible containers 370, to enable the user to compress those indicated surfaces to crush  
| and open the frangible containers, which are pressed against tab 372.

| [0036] It will be appreciated by those skilled in the art that changes could be made to the  
embodiments described above without departing from the broad inventive concept thereof. It is  
understood, therefore, that this invention is not limited to the particular embodiments disclosed, but  
it is intended to cover modifications within the spirit and scope of the present invention as defined  
by the appended claims.