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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c). **INVENTOR(S)** Given Name (first and middle Residence Family Name or Surname (City and either State or Foreign Country) [if any]) J. Daniel Raulerson Brewton, AL **Timothy** Schweikert Levittown, PA Additional inventors are being named on the separately numbered sheets attached hereto TITLE OF THE INVENTION (280 characters max) Luer Cleaner Direct all correspondence to: CORRESPONDENCE ADDRESS Joseph E. Maenner Name Company Name Monte & McGraw, P.C 4092 Skippack Pike P.O. Box 650 Address State PA Zip 19474 City Skippack Country USA Telephone 610-584-9400 Fax 610-584-9783 ENCLOSED APPLICATION PARTS (check all that apply) X Specification, 12 pages X Drawings, 5 sheets Other: METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT Applicant claims small entity status. See 37 CFR 1.27. **FILING FEE** X The Commissioner is hereby authorized to charge filing fees or credit Deposit Account AMOUNT (\$) \$160.00 Number 502434 (Attach duplicate copy of this page if paying by deposit account). The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. X No. Yes, the name of the U.S. Government agency and the Government contract number are: Assignee: Date July 14, 2004 Respectfully submitted, **SIGNATURE** Registration No.: 41,964 NAME: JOSEPH/E. MAENNER Docket Number: MED-0080

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

Customer Number 33941

TITLE OF THE INVENTION

Luer Cleaner

FIELD OF THE INVENTION

The present invention relates to an apparatus for cleaning male threads on a luer connector.

BRIEF DESCRIPTION OF THE DRAWINGS

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:

- 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.
 - Fig. 2 is an exploded view of the luer cleaner shown in Fig. 1.
 - Fig. 3 is a sectional view of the lucr cleaner shown in Fig. 1.
 - Fig. 4 is an enlarged front view of a scrubber disc shown inside the luer cleaner.
 - Fig. 5 is a sectional view of the scrubber disc of Fig. 4, taken along line 5—5 of Fig. 4.
- Fig. 6 is a sectional view of a luer scrubber according to a second preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

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 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.

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 over a luer 190 and rotated 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 190 is preferably connected to a medical device, such as a hemodialysis catheter 194, or other medical device that incorporates a luer connection with internal, female threads. Prior to connection of the luer 190 with the other medical device, the 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, over the luer 190, to clean debris and other contaminants that may be present on or around the luer threads 192.

Referring now to Figs. 2 and 3, the luer cleaner 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.

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. The guide member 117 is preferably integrally molded with the body 108, as seen in the cross-section view of Fig. 3.

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.

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

A tubular connector 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 123 includes a rib 124 that extends circumferentially around the connector 123, and is sized to engage the connector 123 with the rib 120 of the body 108, as is seen in Fig. 3. The connection between the connector 123 and the body 108 may be an interference fit, a threaded connection, an adhesive-based connection, or some other suitable connection known to those skilled in the art.

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

A scrubber 130 is disposed within the longitudinal passage 110. The scrubber 130 is preferably constructed from at least one, and preferably a plurality, of scrubber discs 131. Details of the scrubber disc 131 are shown in Figs. 4 and 5. 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 cleaner 100.

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 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.

Each ring 132 also includes at least one, and preferably, a plurality, of 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 through-passages 140 are preferred, with each through-passage 140 being disposed at 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 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 passage 125.

Further, a plurality 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 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.

With a plurality of rings 132 disposed adjacent one another, as shown in Fig. 2, the channels 142 in adjacent rings 132 form passages 146 that provide fluid communication between each through-passage 140 and the longitudinal passage 110 to allow fluid to be transmitted through the passages 146 to the longitudinal passage 110. Fluid communication is now present between the longitudinal passage 110 and the connector passage 125.

A sealing ring 150 is disposed between the 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 to prevent fluid forced from the reservoir 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 KratonTM 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.

A cap 152 is disposed on the open end 104 of the luer cleaner 100 to retain the sealing ring 150 and the 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.

The closed end 106 of the luer cleaner 100 includes a generally bulbous body 160 constructed from KratonTM, 1064 PVC, or some other suitable, compressible material. The body 160 includes an open end 162 that is fixedly connected to the connector 123 and a closed end 164 disposed away from the open end 162. The interior of the bulbous body 160 defines a 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 passage 125, the circular throughway 126, the passages 119, the through-passages 140, and the passages 146.

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 or hydrogen peroxide, or any combination thereof, may be used instead.

In use, as shown in Fig. 1, 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 156 from being forced out of the open end 104 of the luer cleaner 100.

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 the reservoir 166, through the longitudinal passage 110 of the generally tubular body 108 through the connector passage 125, the circular throughway 126, the passages 119, the through-passages 140, and the passages 146, to the longitudinal passage 110 and 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 190 is now disinfected and may be connected to an external medical device.

In an alternate embodiment of a luer cleaner 200, shown in Fig. 6, a fluid 268 may 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. The frangible container 270 prevents the fluid 268 from flowing out of the reservoir 166 prior to use.

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.

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.

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.

CLAIMS

What is claimed is:

1. A luer cleaner comprising:

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,

wherein the first end is sized to receive therein a luer and wherein the first end includes a plurality of bristles extending generally toward the longitudinal axis sufficiently to engage the luer disposed therein; and

wherein 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.

- 2. The luer cleaner according to claim 1, wherein the fluid is an antiseptic fluid.
- 3. The luer cleaner according to claim 1, wherein the plurality of bristles comprises at least one ring disposed in the open end, and wherein the plurality of bristles extend from the at least one ring toward the longitudinal axis.
- 4. The luer cleaner according to claim 3, wherein the at least one ring comprises a plurality of rings.
- 5. The luer cleaner according to claim 1, wherein the reservoir is constructed from
- 6. The luer cleaner according to claim 1, wherein the first end further comprises a collar disposed therein proximate to the second end.

- 7. The luer cleaner according to claim 1, wherein the body further comprises an exterior portion, wherein the exterior portion comprises a plurality of ribs extending therefrom, away from the longitudinal axis.
- 8. The luer cleaner according to claim 1, further comprising a centering post disposed along the longitudinal axis.
- 9. The luer cleaner according to claim 1, wherein the fluid is retained in a frangible capsule.
- 10. The luer cleaner according to claim 1, wherein, in the absence of compression of the reservoir, the fluid is sufficiently viscous to remain within the reservoir.
- 11. The luer cleaner according to claim 1, comprising a means of communicating the fluid from the reservoir to the first end.
 - 12. A method of cleaning a luer comprising:

providing a luer cleaner comprising:

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,

wherein the first end is sized to receive therein a luer and wherein the first end includes a plurality of bristles extending generally toward the longitudinal axis sufficiently to engage the luer disposed therein; and

wherein the second end comprises a compressible reservoir adapted to receive and retain a fluid, wherein, when the second end is compressed, the fluid is transmitted toward the first end;

inserting a luer into the open end, wherein the plurality of bristles engage an exterior of the luer; and

compressing the second end and transmitting the fluid to the luer and to the plurality of bristles.

- 13. The method according to claim 12, further comprising rotating the luer about the longitudinal axis.
- 14. The method according to claim 13, wherein rotating the luer about the longitudinal axis further comprises reciprocatingly rotating the luer in each of two directions.
- 15. A luer cleaner comprising:
 - a generally hollow body having:

from the second end toward the first end.

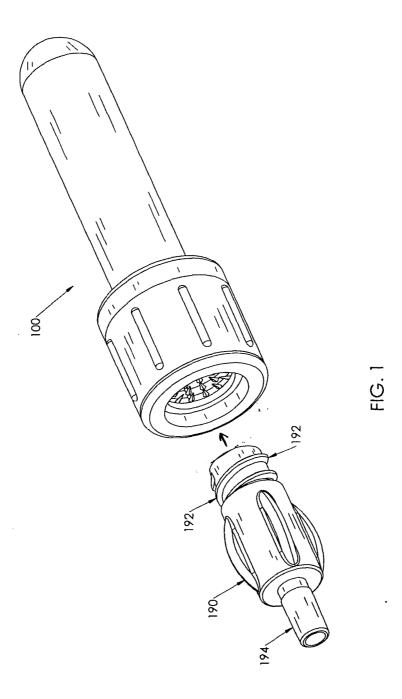
an open first end, a closed second end, and a longitudinal axis extending therethrough between the first end and the second end,

means for scrubbing a luer disposed at the first end; and means for retaining a fluid at the second end and for transmitting the fluid

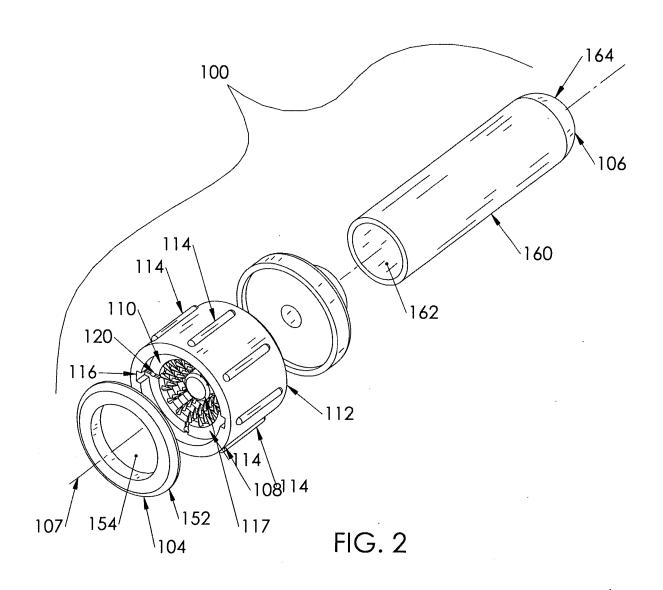
ABSTRACT OF THE DISCLOSURE

A luer cleaner is disclosed. The luer cleaner 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 a luer and includes a plurality of bristles extending generally toward the longitudinal axis sufficiently to engage the luer 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.

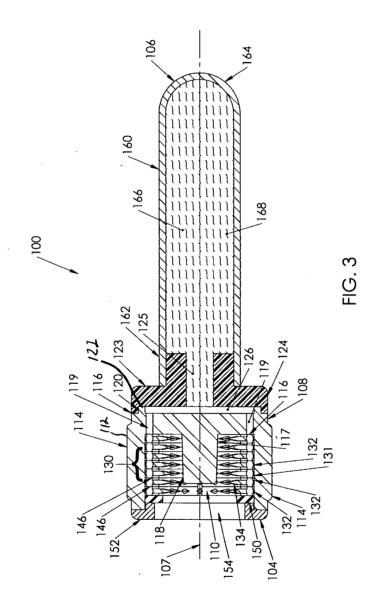
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Title of the Invention: Luer Cleaner
Inventors: Raulerson et al Filing Date: July 14, 2004
Serial No.: Attorney Docket No.: MED-0080
Attorney: Joseph E. Maenner, Monte & McGraw, P.C.
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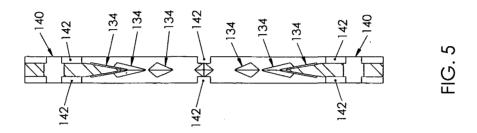
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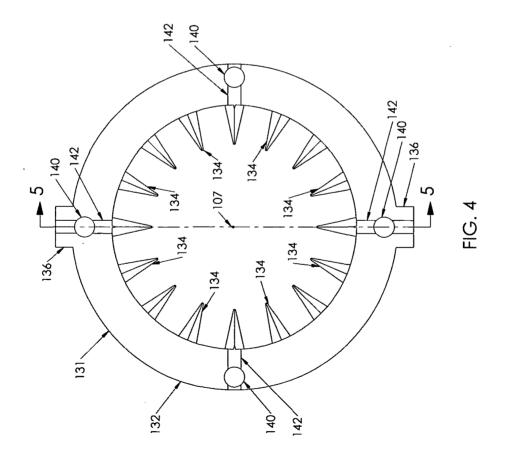


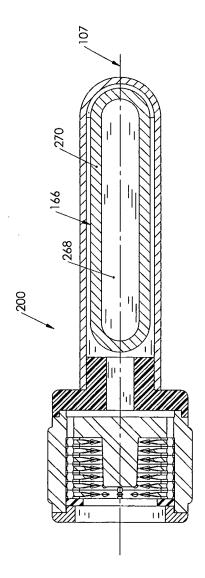
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PATENT	APPLICATION	SERIAL	NO.	

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