(12) UK Patent Application (19) GB (11) 2 063 684 A

(21) Application No **8039079**
(22) Date of filing **1 Oct 1980**
Date lodged **5 Dec 1980**
(30) Priority data
(31) **5748**
27419
(32) **23 Jan 1979**
5 Apr 1979
(33) **United States of America (US)**
(43) Application published **10 Jun 1981**
(51) **INT CL³**
A61M 5/14
(52) Domestic classification
A5R CH
(56) Documents cited
GB 1046684
(58) Field of search
A5R
(60) Derived from Application No. **80/00842** Under Section 15 (4) of the Patents Act 1977
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(54) **Equipment for continuous ambulatory dialysis**

(57) The equipment comprises a dialysis solution bag 10 having a transfer port 12 connected by flexible tubing 22, 30 to patient's tubing 38 leading to a patient's peritoneal cavity. The patient's tubing carries a female connector 36 and the flexible tubing 22, 30 carries a male connector 34, the two connectors forming parts of a luer lock connecting device. A frangible blocking member 40 is provided in the flexible tubing 22, 30 or transfer port 12 to prevent flow from the bag until the member is broken. A particle filter 26 is mounted in the flexible tubing 22, 30.

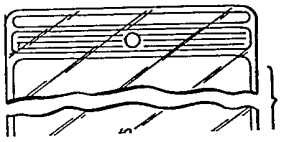


FIG. 1

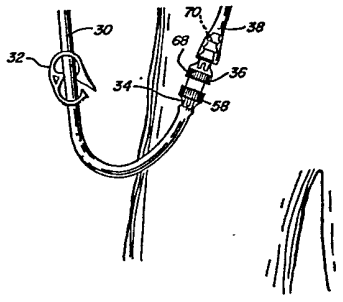
ERRATUM

SPECIFICATION NO 2063684A

Front page, Heading (22) Date of filing *for* 1 Oct 1980 *read* 10 Jan 1980

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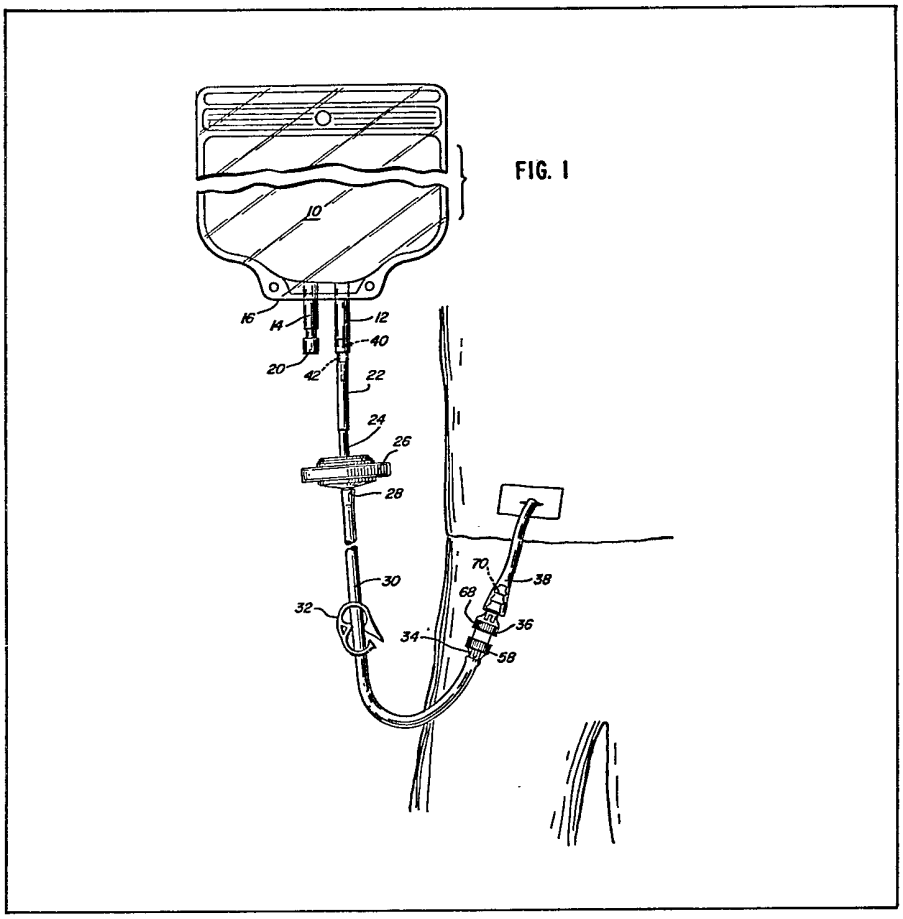


FIG. 1

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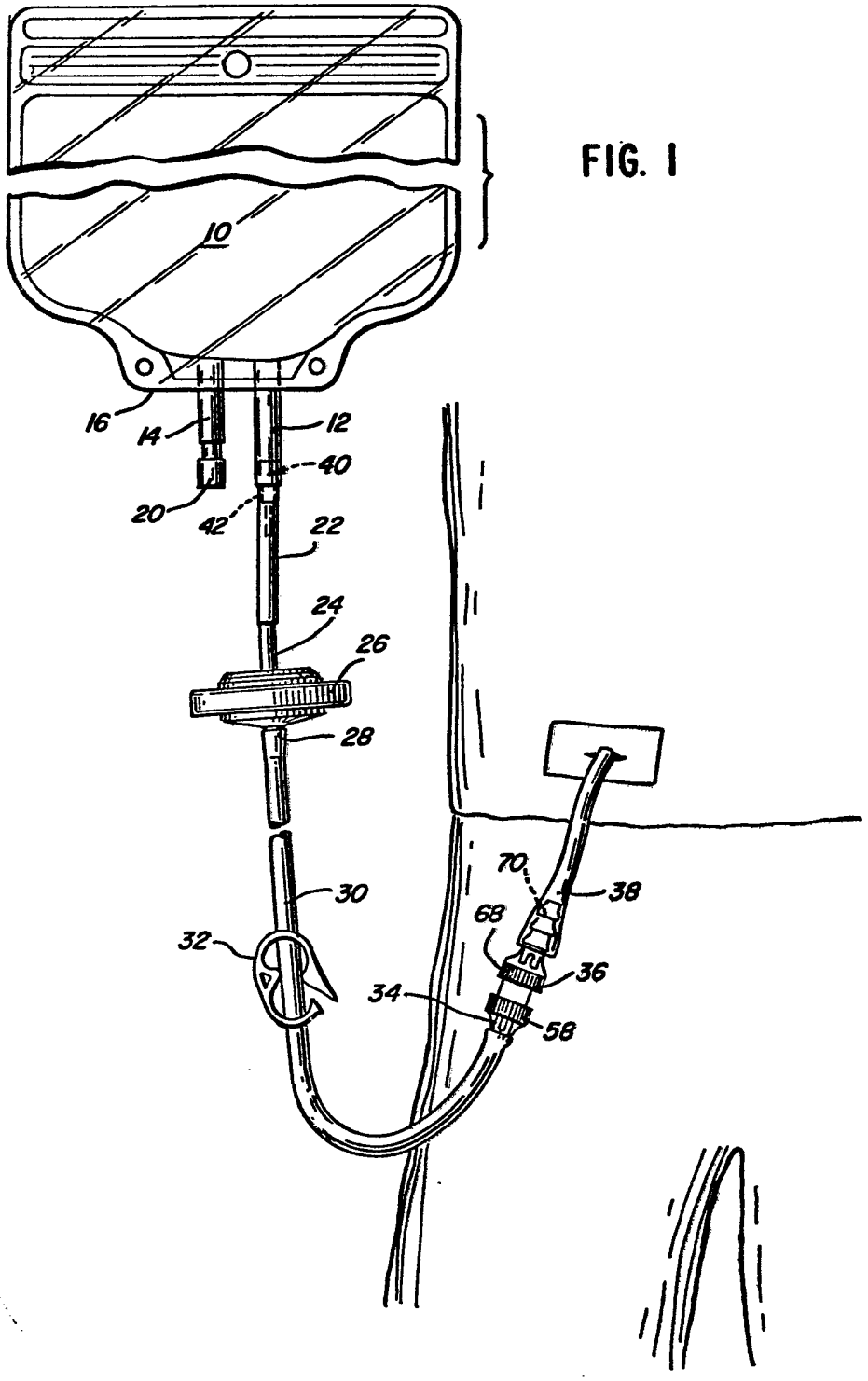


FIG. 1

FIG. 2

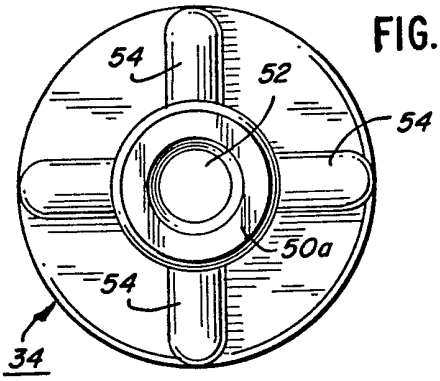
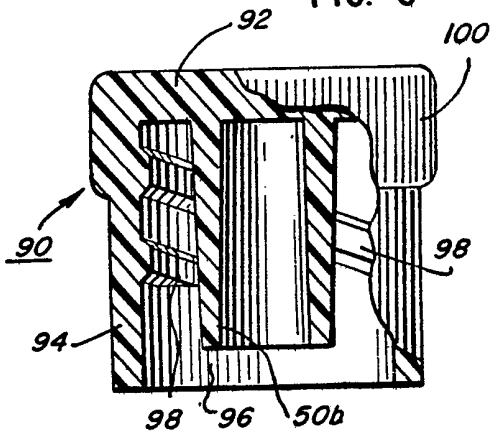


FIG. 8



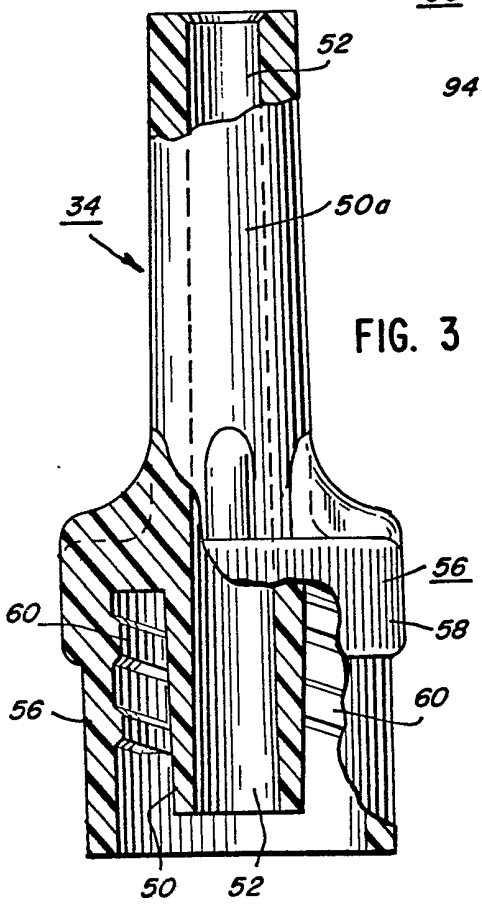
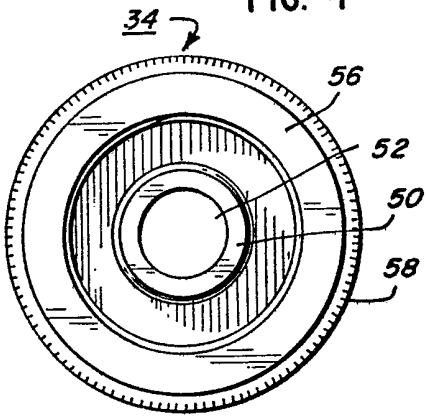


FIG. 3

FIG. 4



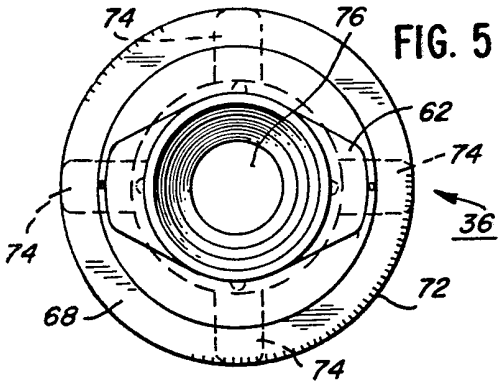


FIG. 5

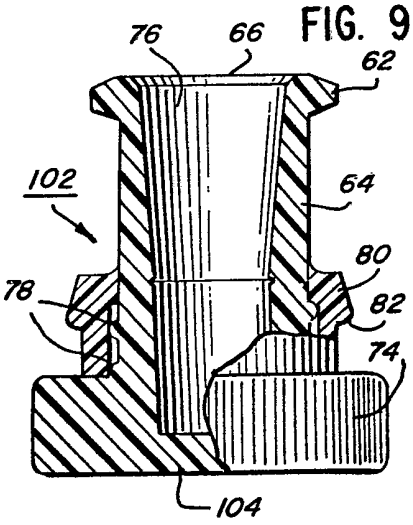


FIG. 9

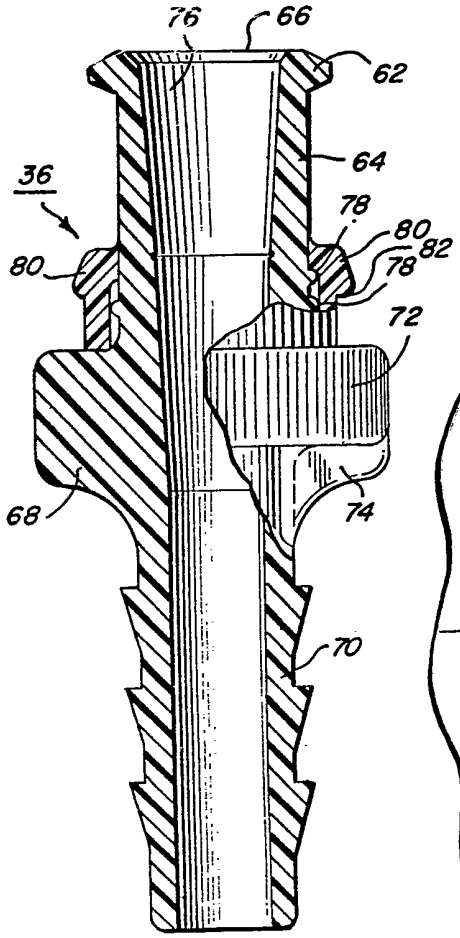


FIG. 6

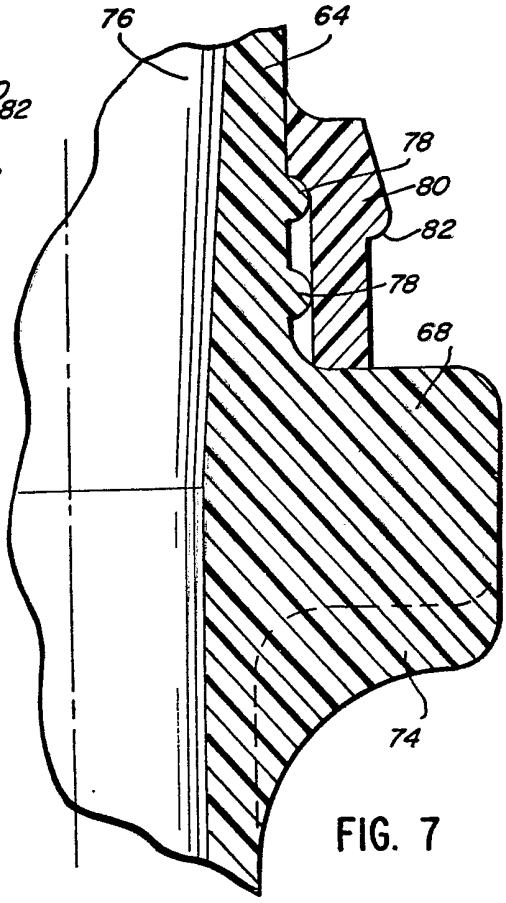


FIG. 7

FIG. 10

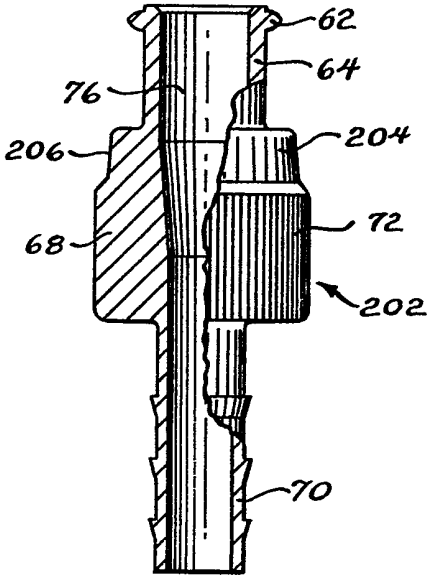
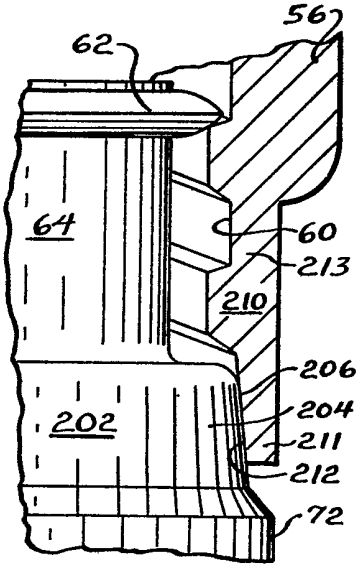

62
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204
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FIG. 11


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SPECIFICATION

Equipment for continuous ambulatory dialysis

This invention relates to equipment for continuous ambulatory peritoneal dialysis in which a dialysis solution is introduced to the peritoneal cavity of the patient, allowed to remain there for several hours and then drained from the patient's peritoneal cavity with this process being repeated on a substantially continuous basis. One manner of achieving this type of dialysis includes the steps of connecting a dialysis solution container to a catheter connected to the patient's peritoneal cavity, unclamping the tubing between the dialysis solution container and the patient's peritoneal cavity so as to allow the dialysis solution to flow from the container to the peritoneal cavity, thereafter reclamping the tubing, allowing the dialysis solution to remain within the patient's peritoneal cavity for several hours, for example, four hours, unclamping the tubing and draining the solution from the patient's peritoneal cavity back to the dialysis solution container, disconnecting the dialysis solution container from the catheter tube and connecting to the catheter tube a fresh dialysis solution container, and repeating the aforementioned steps.

We have discovered that the aforesaid process can be enhanced with the patient having greater freedom of movement if the dialysis solution container is in bag form, particularly a flexible, foldable plastic bag. In this manner, once the dialysis solution has exited the dialysis solution bag, the bag can be folded and carried about by the patient. A very effective connection and disconnection system between the dialysis solution bag and the patient's catheter tube can be achieved by using a luer lock connector system. In this manner, the transfer tube extending from the dialysis solution bag carries a first luer connector and the catheter tube extending from the patient's peritoneal cavity carries a complementary luer lock connector. Such an arrangement is described and claimed in U.K. patent specification No. 2040379.

The present invention provides equipment for continuous ambulatory peritoneal dialysis in which a solution container is coupled via flexible tubing to a patient's tube that communicates with the patient's peritoneal cavity, the equipment comprising a flexible, foldable plastics dialysis solution container having a transfer port extending therefrom; a flexible tube extending from said transfer port and having a connector at its distal end for connecting to a connector carried by the patient's tube; and a frangible member in said flexible tube, said frangible member normally blocking fluid flow in said flexible tube but permitting fluid flow after said frangible member is broken.

Hence the flow of dialysis solution from the dialysis solution bag into the tubing can be prevented until the frangible member is broken.

Reference is now made to the accompanying drawings, wherein:–

Figure 1 is a view of equipment according to the invention including a dialysis bag and tubing connected from the bag to a patient via a luer lock connecting device;

Figure 2 is a rear view of a male connector of the luer connecting device;

Figure 3 is an elevation of the male connector with parts broken away for clarity;

Figure 4 is a front view of the male connector;

Figure 5 is a front view of a female connector of the luer lock connecting device;

Figure 6 is an elevation of the female connector, with portions broken away for clarity;

Figure 7 is a greatly enlarged view of a part of the female connector;

Figure 8 is an elevation, with portions broken away for clarity, of a device for capping the female connector;

Figure 9 is an elevation, with portions broken away for clarity, of a capping device for the male connector of Figure 3;

Figure 10 is an elevation, with portions broken away for clarity of another construction of female connector; and

Figure 11 is an enlarged view of the co-operating portions of the male luer lock connector and the female luer lock connector of Figure 10.

Referring to Figure 1, a dialysis solution bag 10 is shown therein having ports 12 and 14 extending from one side 16 of the bag 10. Port 14 is capped with an injection site 20 in the illustrative embodiment.

Solution container 10 is preferably formed of flexible sheet plastic material that is heat sealed at its edges to form a solution bag. Flexible plastic tubing 22 extends from transfer port 12 and is coupled to the inlet 24 of a particulate filter 26, the outlet 28 of which is coupled to flexible tubing 30 carrying a manually operable clamp 32 in series therewith and having a male luer lock connector 34 at its distal end.

Male luer lock connector 34 is connected to a female luer lock connector 36 which is carried at the distal end of a patient's catheter tube 38 which extends into the patient's peritoneal cavity. Additional details concerning the construction of the luer lock connection system formed by male luer lock connector 34 and female luer lock connector 36 are set forth below and are illustrated in FIGURES 2-9.

A frangible member 40 is positioned in series with transfer port 12 and tubing 22, within the bore defined by the port and tubing. Frangible member 40 blocks fluid flow from transfer port 12 to tubing 22 until the frangible member 40 is broken. Frangible member 40 is preferably formed of a plastic material which fills the flow path of transfer port 12 and tubing 22, but defines a central bore through the plastic material which is sealed by a breakoff member 42. When the member 42 is manually broken, the dialysis solution contained by solution bag 10 can flow through the frangible member 40 and thence through tubing 22 and downstream with respect

The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

thereto. In this manner, the dialysis solution within solution bag 10 is maintained adjacent transfer port 12 until frangible member 40 is broken, and not until the breaking of frangible member 40 can the solution contained within solution bag 10 flow downstream of the frangible member 40.

The filter 26 is a particulate type filter, having a pore size of approximately 5 microns and having a relatively large surface area. It is preferred that the surface area be at least 4 square centimeters and most desirably, about 7 square centimeters. It is also preferred that filter 26 comprise a hydrophilic membrane filter utilizing air venting by hydrophobic membranes.

Clamp 32 may be any type of flexible tubing clamp as is well-known in the art, with it preferably being a type of clamp which may be manually engaged and disengaged, using the thumb and forefinger.

Under certain circumstances, it is believed that certain peritoneal dialysis patients prefer a connection system with respect to the solution container and the patient's catheter tube that does not require the insertion and retraction of a spike connector adjacent the solution container. Unless a spike connector is utilized properly, it is possible that the spike may cause contamination resulting in peritonitis. It has thus been discovered that under certain circumstances the use of the luer connection system of the present invention is advantageous, and achieves a connection that is less likely to be contaminated.

Male luer connector 34 is illustrated in detail in Figures 2-4. Referring to these Figures, the male luer connector 34 comprises a central tubular portion 50 defining an axial bore 52, and with the central tubular portion 50 extending rearwardly to form a circular insert 50*a*. Insert 50*a* is solvent bonded within flexible tubing 30 and extends outwardly by means of a plurality of shoulders 54 to provide an outer sheath 56 which surrounds central tubular portion 50. Outer sheath 56 has a knurled manually-graspable portion 58 and carries internal threads 60. The outer sheath 56 aids in preventing touch contamination during locking and/or unlocking of the luer lock connection system and serves to carry the threads 60 which are engaged by a flange 62 (FIGURE 6) carried by female luer lock connector 36.

Referring to FIGURES 5-7 in which the female luer lock connector 36 is shown in detail, it can be seen that connector 36 comprises a main tubular member 64 having outwardly radially extending flange 62 adjacent its distal end 66. A manually graspable ring 68 surrounds main tubular member 64 and is preferably formed integral therewith, with ring 68 also being formed integrally with a barbed rearward extension 70 for bonded connection within the bore of the patient's catheter tube 38. A knurled portion 72 is provided on the external surface of ring 68 to aid in manually grasping the same. Rearward extension 70 is coupled to ring 68 by means of a plurality of shoulders 74, and the central tubular member 64 and rearwardly extending member 70 define a common axial bore 76.

The flange 62 is shaped and dimensioned so that when male luer lock connector 34 is engaged with female luer lock connector 36, central tubular portion 50 of connector 34 will enter bore 76, and flange 62 will be threaded along threads 60 to form a locking connection.

The diameter of bore 76 tapers inwardly from distal end 76, to a diameter that is smaller than the external diameter of central tubular portion 50, whereby an engagement will result between the external surface of central tubular member 50 and the internal wall of tubular member 64.

Referring to FIGURES 6 and 7 in particular, it is seen that a number of projections or rings 78 are carried by tubular member 64 and an elastomeric member 80 surrounds the tubular member 64 and overlies the projections 78. Elastomeric member 80 has an outwardly extending annular bead 82 utilized for sealing purposes. Thus when male connector 34 and female connector 36 are engaged, elastomeric member 80 will enter outer sheath 56 and a sealing action will occur as a result of annular bead 82 engaging the internal wall of outer sheath 56. In addition to providing an effective seal to prevent contamination, elastomeric member 80 also acts to provide a water tight bacteria barrier which maintains the integrity of the locking connection thus preventing contamination of the luer connection.

If desired, elastomeric member 80 could be swabbed or the chamber defined by the outer sheath 56 could be filled by the patient with a sterilizing agent, such as Betadine. It is preferred that the female luer connector 36, with the exception of elastomeric member 80, be formed in a one-piece integral injection molding construction, and that elastomeric member 80 be formed in a subsequent step in the injection molding process during manufacture of the luer connector. Likewise, in this embodiment it is preferred that the entire male luer connector 34 be formed in a one-piece unitary molded construction.

Referring to FIGURES 10 and 11, an alternative female luer lock connector 202 is illustrated with identical reference numerals indicating the portions of female luer lock connector 202 and male luer lock connector 210 which are identical to portions of female luer lock connector 36 and male luer lock connector 34 respectively.

It can be seen that connector 202 comprises a main tubular member 64 having outwardly radially extending flange 62 adjacent its distal end. Main tubular member 64 is contiguous with a manually graspable ring 204 which extends contiguously rearwardly from the main tubular member 64, with ring 204 also being formed integrally with a barbed rearward extension 70 for bonded connection with a flexible plastic tube such as within the peritoneal dialysis. A knurled portion 72 is provided on the rear external surface of ring 204 to aid in manually grasping the same. Rearward extension 70 is coupled to ring 204, and the main tubular member 64 and rearwardly extending member 70 define a coaxial bore 76.

The male luer lock connector 210 used with the female luer lock connector 202 shown in FIGURE 10, is identical to the male luer lock connector 34 shown in FIGURE 3 with the exception that the front end 211 of the outer sheath 213 or the entire outer sheath 213 is formed of an elastomeric material. This may be

accomplished by separately molding the outer sheath 213 and then attaching it to a male luer connector or by providing a unitary member formed of the elastomeric material desired.

Outer wall portion 204 of female luer lock connector 202 has a rearwardly extending outward taper 206 so that the pressure engagement of the internal wall 212 of outer sheath 213 of the male luer connector 210 and outer wall portion 204 will increase as the male and female connectors are threaded together.

The flange 62 is shaped and dimensioned so that when male luer lock connector 210 is engaged with female luer lock connector 202, central tubular portion 50 of connector 30 will enter bore 76 and flange 62 will be threaded along threads 60 to form a locking connection. The internal wall 212 of outer sheath 213 will engage tapered surface 206 of outer wall 204 snugly, and the engagement will become tighter as the luer connectors are threadedly closed tighter. In this manner, the cooperation of the internal wall of the outer sheath 213 and surface 206 of outer wall 204 is operable for providing a pressure seal-like engagement to prevent leakage and to aid in maintaining a water tight bacteria barrier.

If female luer lock connector 202 is coupled to a catheter tube which extends to the patient's peritoneal cavity, it is desirable that luer lock connector 202 be formed of a more permanent material. To this end, a stainless steel or titanium connector 202 would be satisfactory.

Under certain circumstances, the patient may desire to disconnect the luer lock connection once the dialysis solution has been introduced into the patient's peritoneal cavity. For this purpose, a cap 90 (FIGURE 8) for capping the female luer connector is provided which includes a closed top portion 92 and a downwardly extending sidewall portion 94. Sidewall portion 94 defines a bore 96 which has an identical diameter to the opening defined by outer sheath 56, and the internal wall of sidewall portion 94 carries threads 98 which are identical in size and configuration to threads 60. A central tubular portion 50*b* is also provided. A knurled portion 100 is provided for enabling manual grasping of the cap 90.

Referring to FIGURE 9, a cap 102 for capping the male luer connector is provided that is similar in configuration to female luer connector 36 except that it does not include rear tubular connector 70. Identical reference numerals have been used on the FIGURE 9 cap to represent the portions of cap 102 which are identical to portions of female luer connector 36. It can be seen that instead of bore 76 extending continuously, the bore 76 is capped at its end 104. It should also be realized that male luer lock connector 34 may be carried by the patient's catheter tubing 38 with the female luer lock connector 36 being connected at the distal end of tube 30.

As a result of the cooperation of outer sheath 56 and elastomeric member 80, and as a result of the cooperation of outer sheath 211 and outer taper 206, the luer lock connection system has a touch-contamination prevention feature and also utilizes a sealed closure device when connected to provide a water

CLAIMS

1. Equipment for continuous ambulatory peritoneal dialysis in which a solution container is coupled via flexible tubing to a patient's tube that communicates with the patient's peritoneal cavity, the equipment comprising a flexible, foldable plastics dialysis solution container having a transfer port extending therefrom; a flexible tube extending from said transfer port and having a connector at its distal end for connecting to a connector carried by the patient's tube; and a frangible member in said flexible tube, said frangible member normally blocking fluid flow in said flexible tube but permitting fluid flow after said frangible member is broken.

2. Equipment according to Claim 1, wherein the frangible member comprises a member which fills the bore of the tubing or transfer port and has a central bore a break-off member.

3. Equipment according to Claim 1 or 2, further comprising a particulate filter in series with said flexible tube.

4. Equipment according to Claim 3, wherein said particulate filter has a surface area of at least four square centimeters and includes air venting means.

5. Equipment according to any preceding claim including a patient's tube provided with a connector connectible with that of said flexible tube.

6. Equipment according to Claim 5, wherein said connectors are respectively male and female connectors of a luer lock connecting device.

Printed for Her Majesty's Stationery Office by The Tweeddale Press Ltd., Berwick-upon-Tweed, 1981.
Published at the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.