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(54) Title: CONNECTOLOGY SYSTEM

MATED MALE AND FEMALE CONNECTORS

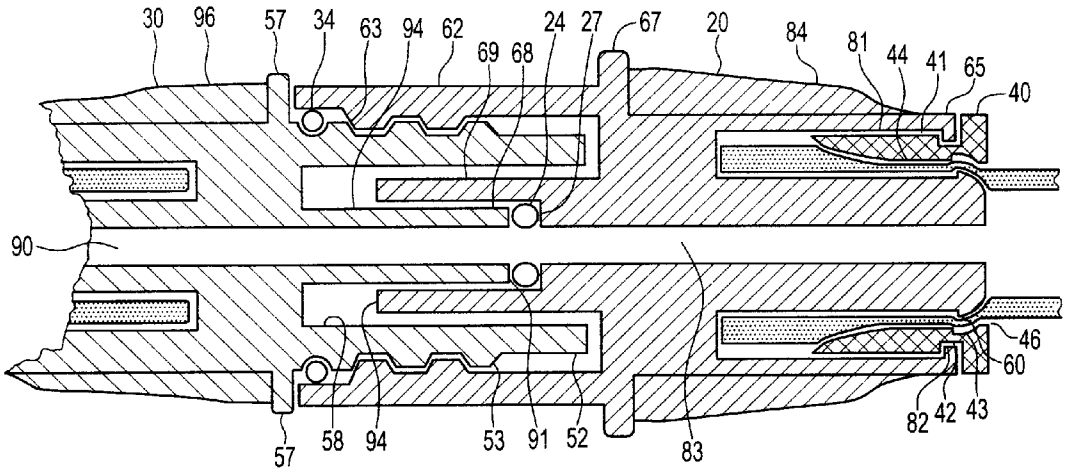

FIG. 10

(57) Abstract: The present invention provides a connectology system comprising a set of mating male connectors and female connectors, the connectors having one or more of the following features: a) two or more independent quarter-turn threads to engage and disengage the connectors; b) a tactile feedback mechanism to indicate completion of engagement and commencement of disengagement; c) flange elements to inhibit touch contamination of the connectors; and d) wing elements to permit application of torque for engagement and disengagement.

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CONNECTOLOGY SYSTEM

Field of the Invention

[0001] The present invention relates to the field of connectology. In particular, it relates to connectology systems for use with peritoneal dialysis (PD) machines.

Background of the Invention

[0002] The natural kidneys function continuously 24 hours a day to maintain the body in a healthy state. They remove nitrogenous waste products and excess fluid, balance electrolytes and generate essential hormones for building red blood cells. When the kidney function drops below a level necessary to sustain life, a person is classified as reaching End Stage Renal Failure (ESRF).

[0003] Dialysis or kidney transplants are the only two accepted treatments for patients with ESRF. Dialysis is the process of transferring accumulated bio-waste from the blood stream into a disposable fluid. It is also used for removing excess fluid from the body and for correcting plasma electrolyte balance. There are two forms of kidney dialysis: Haemodialysis (HD) and Peritoneal Dialysis (PD).

[0004] HD is a complex but rapid procedure, and is the process to which most lay people refer when they speak of dialysis. However, the high annual operating cost and complex infrastructure required for HD make it unsuitable for home use. The ever-increasing demand for home-care and the need for cost containment are favouring the adoption of PD for home care.

[0005] PD makes use of the internal peritoneal membrane to purify the patients' blood. There are two major forms of PD, automated Peritoneal Dialysis (APD) and the manual modality known as CAPD. With both, the blood never leaves the patient's body. Instead, dialysate (dialysis solution) is instilled (FILL) directly into the peritoneal cavity of the patient through a catheter. The dialysate draws soluble waste and excess fluid from the blood contained in the numerous blood vessels in the peritoneal membrane. Osmosis and diffusion are the dominant mechanisms that facilitate this blood cleansing process. In addition, the dialysate balances electrolytes and corrects acidosis of the

blood. This entire process takes place during a fixed time period known as the DWELL. At the end of this period the spent dialysate is removed from the peritoneal cavity (DRAIN) and discarded. This exchange action must be repeated several times during a 24-hour period because the body is continuously producing toxic wastes.

[0006] PD is a very gentle modality. Its slow corrective action closely resembles that of the natural kidney. The operational simplicity, the safety, the elimination of the venipunctures and the low operational costs continue to encourage the growth of this modality. Since PD is not an extracorporeal system, there is no need for large heparinization; an advantage which favors diabetics. However, the need to adhere to a strict aseptic procedure to avoid infection is more important than with HD treatment. The peritoneum membrane is exposed to the external environment every time a catheter is connected to, or disconnected from the solution supply. Hence the potential for infection is high. This potential is a serious limitation to the wide spread acceptance of PD and the route of such infection can usually be traced back to the connectology practice associated with current PD machines.

[0007] Connectology is a dialysis term that describes the connection relationships between a patient's catheter, the machine disposable set (including the transfer set), and the solutions.

[0008] In PD, poor connectology is often the first culprit implicated in peritonitis infection-related events. Poorly designed connectors can lead to improper handling and can result in bacterial contamination and subsequent infection. Thus, the PD connectology is one of the key factors associated with infection control and infection reduction. Complications due to infection may be fatal to the patient and can easily triple the cost of the treatment. Although serious efforts are being centered to produce safe connectology, as yet there is no a single complete connectology system that effectively addresses all the interfaces of PD system in clinical use.

[0009] Two features found in the current connectology art are the use of spikes and threaded connectors. Spiking into dialysis solution bags has many drawbacks, the major one being solution contamination. The procedure of spiking a sterile solution bag can compromise the sterile integrity of the system. Contaminants on the spike are directly

and immediately introduced into the main solution bag. Once introduced into the bag, the glucose, warm temperature and light provide excellent growth environment for bacteria to multiply very quickly. Eventually the contaminants would be infused into the patient. Infection therefore happens very often if extra care is not exercised with spiking. A desirable attribute of a connectology system is to remove the need to spike the solution bag.

[0010] Starting from the patient and moving towards the APD machine there are a number of threaded connectors. The first of these is the bond to transfer set. This first threaded connector mates directly to an adapter (commonly made from titanium) that is inserted at the opening end of the patient's permanent catheter. A satisfactory non-leaking mating between the titanium adapter and this threaded connector should stay intact for 6 months or more. The connector further needs to be compatible with the many chemicals, electrolytes and medications used for PD treatments. The connector material should withstand high sterilization temperatures without deforming or shrinking. Its thread should not generate major friction and be easy to put on. It should not crack under pressure or deteriorate with time because of aging or chemical exposure. Additionally, the connector should come off very easily at the end of 6 months or more time of usage.

[0011] The next connector is bonded to the opposite end of the transfer set. It is a particularly critical connector. This connector must maintain satisfactory mating characteristics during its entire life time. For example, during 6 months time under a CAPD modality of 5 exchanges a day, this connector undergoes screw-in and screw-out a minimum of 5,400 times. It must withstand chemical, electrolyte and medication reactions, withstand stress and strain during connect and disconnect, withstand heat sterilization, provide satisfactory bonding to the transfer set tube, and above all, its performance should withstand aging and discoloration.

[0012] There are many medical connecting systems in use today. The majority employ different connectors of different shapes, different threads, and different sizes for certain applications and/or different components of the same treatment system. For example, one PD system uses an ordinary semi-rigid tube for the outlet of the solution bags. This outlet is mated with a spike transfer set or a spike cassette set. The transfer set is mated

with a multi-turn luer lock connector of different shapes and sizes. The luer lock transfer set connector has exposed fluid path that is susceptible to touch contamination. The transfer set tubing is made of silicone (a material normally used for long life transfer sets). The second connector of the transfer set is made of PVC, ABS and/or polycarbonate. Since silicone cannot be effectively glued to any of these materials, ultrasonic welding is used to attach the second connector to the silicone tubing. However, the connector (hard material) and the silicone tubing (soft and flexible material) have different durometers. Therefore ultrasonic welding does not produce reliable bonding between the connector and the tubing. To compensate a shrinkable overlay is applied over the welding to help secure the tubing to the connector. This bonding technique often fails because of aging and repeated mechanical stress and strain forces during connecting and disconnecting of the transfer set during the six months use and disinfectants have been known to gradually degrade the bonding between the connector and the tubing. A desirable attribute to improve the current art is a more robust method of chemically and mechanically joining the transfer tube to the connector and having an enclosed fluid path that is not susceptible to touch contamination.

[0013] The threading of the second connector of the currently available transfer set requires two or more complete rotations to fully engage and properly seal to the patient line of the dialysis disposable set. The twisting caused by screwing and unscrewing procedure, if not done well, transmits twists to the transfer set and the catheter as well. Mechanical stresses to the catheter due to these manipulations and/or pulling may cause trauma to the exit site of the catheter. This may result in exit-site infection, which is also a major problem of peritoneal access. For safety, the exit-site should be disturbed as little as possible. Trauma to the exit-site may cause leaks of dialysis solution.

[0014] The disposable sets are complemented by disinfecting caps that allow patients to disconnect from and connect to the machine during treatment or at the end of treatment without risk of infection. Disinfecting caps should mate well with the connectors. The cap should ensure that the disinfectant does not dry up during storage and/or between patient disconnections. The caps should come off very easily when being removed. The cap should withstand pressure and stress. The cap should be smooth and small enough to provide comfort to patients wearing it for 6 months or more. The cap should be large

enough to provide easy handling and be removed with minimum force. The design of the cap should be such that the patients do not touch the tip and/or the fluid path during handling (to prevent touch-contamination). Moreover it should be easy for the elderly and vision limited patients to operate safely. Preferably the mating should produce a positive feedback for the patient to know that the cap is properly seated onto the connector. Therefore an effective connectology system should incorporate disposable sets that are complemented by disinfecting caps to allow patients to knowingly disconnect and reconnect safely from the machine without risk of infection during and after treatment.

[0015] It is an object of this invention to partially or completely fulfill one or more of the above-mentioned needs.

Summary of the Invention

[0016] According to an aspect of the present invention there is provided a connectology system comprising a set of mating male connectors and female connectors, the connectors having one or more of the following features: a) two or more independent less than complete turn threads to engage and disengage the connectors; b) a tactile feedback mechanism to indicate completion of engagement and commencement of disengagement; c) flange elements to inhibit touch contamination of the connectors; and d) wing elements to permit application of torque for engagement and disengagement.

[0017] Preferably, the male connectors and female connectors are comprised of an inner tube and an outer tube, wherein the inner tube forms a fluid path for the system and the outer tube shields the inner tube from contact and touch contamination.

[0018] Also preferably, the system further includes a set of male connector caps and female connector caps to cover the male connectors and female connectors when not in use. The system may additionally further include a set of male disinfectant caps and female disinfectant caps to cover and disinfect the male connectors and female connectors when not in use.

[0019] Most preferably, the disinfectant caps contain a disinfectant which is retained inside the disinfectant caps when not in use and released from the disinfectant caps when they are connected to the connectors.

[0020] Thus the system of the preferred embodiments of the invention includes the highly beneficial feature of relying on a single rotation or less, preferably an approximately quarter turn, to securely engage a transfer set to the patient line of the peritoneal dialysis disposable set and/or the solution bags.

[0021] Other and further advantages and features of the invention will be apparent to those skilled in the art from the following detailed description thereof, taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

[0022] The invention will now be described in more detail, by way of example only, with reference to the accompanying drawings of preferred embodiments of the present invention, in which like numbers refer to like elements, wherein:

Figure 1A is a schematic drawing of an APD set up for performing dialysis treatment;

Figure 1B is a schematic drawing of a set-up for performing CAPD or Manual peritoneal dialysis;

Figure 2 is a side view of preferred transfer set according to the present invention;

Figure 3 presents side views of the preferred female and male connectors and, the preferred female and male disinfectant caps;

Figure 4 shows elevation views of female and male covers, vented and non-vented, with the two O-Rings, big and small;

Figure 5A is a sectional view of a non-vented male connector cover and one embodiment of a female disinfectant cap;

Figure 5B is a sectional view of a non-vented male connector cover and alternative embodiment of a female disinfectant cap;

Figure 6A is a sectional view of a non-vented female connector cover and one embodiment of a male disinfectant cap;

Figure 6B is a sectional view of a non-vented female connector cover and an alternative embodiment of a male disinfectant cap;

Figure 7 is a sectional view of the preferred embodiment of Luer Lock connector, with its associated retaining ring and Long Life tubing;

Figure 8 is an exploded sectional view of the female connector, and its associated small O-ring, non-vented cover and retaining ring;

Figure 9 is an exploded sectional view of the male connector and its associated big O-ring and non-vented cover and retaining ring;

Figure 9A is a close-up section view of the male connector and retaining ring of Figure 9;

Figure 10 is a cross-sectional view of mated male and female connectors of Figs. 8 and 9, with tubing attached to the female connector;

Figure 11 is a perspective view of the female connector of Fig. 8;

Figure 11A is a front view of Figure 11;

Figure 11B is a back view of Figure 11;

Figure 12A shows in cross-sectional view the male connector of Fig. 9 with attached tubing, and in process of being disinfected by capping with the female disinfectant cap of Figure 5A;

Figure 12B shows in cross-sectional view the male connector with attached tubing, in process of being disinfected by capping the female disinfectant cap of Figure 5B;

Figure 13A shows in cross-sectional view the female connector with attached tubing, in process of being disinfected by capping with the male disinfectant cap of Figure 6A;

Figure 13B shows in cross-sectional view the female connector with attached tubing in process of being disinfected by capping with the male disinfectant cap of Figure 6B; and,

Figure 14 shows a cross-sectional view of the preferred embodiment of a re-engaged male connector and female connector after said connectors have been disinfected using their respective mating disinfectant caps.

Detailed Description of the Preferred Embodiments

[0023] This invention comprises, in one embodiment, a connectology system for dialysis, that is a complete set of connectors, connector retaining rings, disinfectant caps and associated covers that are necessary for manufacturing, assembling, sterilizing the system and for administering all peritoneal dialysis treatments in a safe and reliable manner. Other embodiments provide individual components of a connectology system for dialysis. A further embodiment is a kit of parts for assembly into a complete connectology system for dialysis. The preferred embodiment of the invention further teaches the art of attaching a connector to a tubing line to provide a reliable bonding structure that can withstand mechanical strains, electrolyte degradation, chemical agent attacks, sterilization methods (heat, gases, electron beam, gamma rays, etc.), disinfectant reactions and long-term applications. It is applicable to both CAPD and APD treatments and also to any medical treatment applications that rely on administering fluid to patients and/or removing fluid from patients.

[0024] Figure 1A shows a typical APD interconnection system. The typical CAPD treatment system, as shown in **Figure 1B**, differs only in the number and complexity of

parts unrelated to the connectology system. Key connectors **1**, **10**, **20**, and **30** are used in the like manner as shown in this diagram.

[0025] Thus in the assembled system according to an embodiment of the invention, in use, connector **1**, most commonly a titanium adapter, is attached to the patient's catheter (not shown). Connector **10,** which is a luer lock connector, and connector **20**, which is a female tube connector, are attached to the opposite ends of the transfer set, illustrated in **Figure 2** hereof. Connector **30,** which is a male connector, is located when in use at the entrance of the patient tubing line of a cassette or the line that is attached to the dialysate solution bags. At the end of the tubing line (or lines) connected to the sterile fluid source, typically a dialysate solution bag, is another similar female tube connector **20a**. At the outlet of the sterile solution bag (or bags, for multiple solution sources) is another similar male connector **30a**. Alternatively, the solution bag outlet using connector **30a** could be connected directly to the transfer set inlet female connector **20** to perform CAPD and/or any manual PD as it is currently practiced.

[0026] Before the system is interconnected as shown in **Figures 1A** or **1B** or in a similar manner for treatment, the individual tubing sets must be manufactured and sterilized. Each connector should be supplied with an appropriate connector cover. The constructions of the respective covers take a specific form depending on the kind of sterilization method used. Sterilization with ethylene oxide requires that the connector covers be vented to allow entry of the gases into the tubing set, and diffusion of the gases out of the tubing set after sterilization is completed. The alternative methods of electron beam and gamma sterilization do not require vented connector covers. For these two sterilization methods, tight fit non-vented connector covers are often preferred over vented connector covers. The connectology system of the preferred embodiment of the invention can use either vented or non-vented connector covers to allow for either type of sterilization to be used.

[0027] In addition to connector covers, matching disinfectant caps are provided in the preferred embodiment, to enable safe, easy and quick disconnection of mating connector parts and connector ends to be disinfected continuously during separations.

[0028] In **Figures 2 – 9** and **11** of the accompanying drawings, the structure and features of the individual components of the connectology system of the preferred embodiment are illustrated and these will be described initially. In Figures **10** and **12 – 14**, the assembly and various steps in the use of the components are illustrated, and this will be described after the structures of the components have been described.

[0029] **Figure 2** shows a typical transfer set, comprising a luer lock connector **10** at one end, for mating with an adapter (typically a titanium adapter) of the catheter (not shown), a retaining ring **11**, a long life tubing (typically silicone or polyurethane) **43**, a retaining ring **40**, a female connector **20**, and a disinfectant cap **31** and its associated O-ring **34**. This is an exit site connection and therefore construction and procedures aimed at inhibiting infections originating from mechanical wear and tear at the point of connection are desirable.

[0030] **Figure 3** shows the female connector **20** and the male **30** adapted for connection thereto, in more detail. It also shows the corresponding disinfectant cap **21** adapted to mate with the male connector **30** for disinfecting purposes, and hence sometimes referred to herein as the female cap. It also shows the corresponding male cap **31,** which is adapted to mate with the female connector **20** for disinfecting purposes. All the components are generally cylindrical. The male connector **30** and the disinfectant male cap **31** each include a large O-ring **34** for creating a seal as discussed below. During operations and/or at the end of treatment, when the male connector **30** is separated (disconnected) from the female connector **20**, the respective disinfectant caps **21, 31** are used to protect the ends and the fluid paths of each connector. The female disinfectant cap **21** is a modification of female connector **20** and the male disinfectant cap **31** is a modification of male connector **30**. The female connector **20** and the male connector **30** have respective outwardly protruding flanges **67** and **57**. The disinfectant caps **21** and **31** have similar outwardly projecting flanges **67a** and **57a** respectively.

[0031] The male connector **30** is provided with a sealing face **58** against which the O-ring **34** is seated. The sealing face **58** is provided with a protuberance **51** at one isolated location. The female connector **20** has a cylindrical shield **62** axially in a direction away from the luer lock **10**. A notch **61** is provided on the end edge **59** of the shield **62** to co-

operate with protuberance **51** on assembly. In similar manner, female cap **21** has a shield **62** and a notch **61**, and male cap **31** has a sealing face **58** and a protuberance **51**.

[0032] With reference to **Figure 4,** associated connector covers **22**, **23**, **32**, and **33** are provided for temporary covering of the ends of the connectors while the connectors are joined to the tubing. **Figure 4** also shows a small O-ring **24** and a large O-ring **34** for assembly with preferred embodiments of the connectors of the invention (**Figures 3, 8 and 9**). Connector covers **32** and **22** are respectively female and male vented connector covers, and have ribs **35**, **25** respectively in their internal surfaces that allow gases to flow in and out of the connectors when the connectors are capped for gas sterilization. Connector cover **33** is a non-vented female cover and connector cover **23** is a non-vented male connector cover. These have no ribs, but instead have a smooth and tight fitting inner lumen that closes the connector's outer surfaces with air-tight seal for gamma and/or electron beam sterilizations. The connector cover **22** is also used to cover the female disinfectant cap **21**, providing a leak proof cover. Likewise the connector cover **33** is used to cover male disinfectant cap **31**. The large O-ring **34** sits at the outer circumference and at the end of the threads of both the tube connector **30** and the disinfectant cap **31**. The small O-ring **24** is located inside of the female tube connector **20** only, as illustrated in **Figure 8** described below.

[0033] Figure 5A shows a cut-away view of the female disinfectant cap **21** and the non-vented connector cover **23**. One method of manufacturing female disinfectant cap **21** is to take female connector **20**, remove the inner cylindrical tube, and extend the hole defined by **69** all the way through the body to terminate at the end of cylindrical tube **65** with a sealed end **66**. A porous sponge **101** or similar material then retains disinfectant solution **102** inside female disinfectant cap **21**. Similarly, **Figure 6A** displays a cut-away view of the male disinfectant cap **31**, the non-vented cover **33**, large O-Ring **34**, disinfectant solution **102** and porous sponge **105**. As with the female disinfectant cap 21, a male disinfectant cap **31** can be manufactured from a male connector 30 with the inner cylindrical hole **58** extended all the way through the whole body to create a single cavity, eliminating the inner cylindrical tubes **91** and **54** (as seen in **Figure 9**), and the single cavity created closed of at the end of **55** by end wall **56**. This cavity is filled with disinfectant **102** and porous sponge **105** (or any appropriate material with a tiny hole or

holes in the material) is placed at the opening to contain the disinfectant inside the cavity. The outside large O-ring **34** is retained. It should be noted here that other kinds of disinfectants (gel, crystal, solid, powder etc.) could be equally used in the same fashion.

[0034] An alternative female disinfectant cap **21** is shown in **Figure 5B**. The porous sponge **101** (from **Figure 5A**) is replaced with a piston **106**. The piston **106** maintains disinfectant **102** in place, and has a channel **108** to permit passage of disinfectant **102** As the male connector is coupled to the female disinfectant cap, piston **102** pushes inward, forcing disinfectant **102** through channel **108** and into the male connector to disinfect it. The equivalent, corresponding male disinfectant cap **31** is shown in **Figure 6B**.

[0035] The piston **102** provides two advantages over the sponge **101**. First, the piston action is much less likely to inadvertently release the disinfectant when not under pressure from the male connector. Second, the disinfectant **102** is under some degree of pressure, allowing it to travel further, including into the tubing to disinfect the tubing coupled to the connector as well.

[0036] The corresponding disinfectant caps **21** and **31** are designed to provide effective disinfecting of both the fluid path and the surrounding protective shields during periods when connectors **20** and **30** are separated (disconnections). Touch contamination from handling the disinfectant caps **21** and **31** is reduced by two built-in features. The first is a circular flange **67** that prevents fingers from sliding forward to touch the outer shield of the connector during the connection phase. The second is that the fluid path and porous sponge **101**, **105** are fully recessed inside an outer shield **62** to prevent contact between fingers and the fluid path and sponges. In addition, the flange **67** prevents individual disinfectant caps from accidentally rolling off sterile trays or surfaces.

[0037] **Figure 7** shows the transfer set luer lock connector **10** that mates with titanium adapter **1** (shown in **Figure 1A**) of the catheter (not shown). The long life tubing **43** passes through the retaining ring **11**, and slides over the inner cylindrical tube of **10**. The retaining ring **11** slides over the long life tubing **43** and is bonded to the inner surface of the outer cylindrical tube of **10**. The retaining ring **11** locks into the inner part of the luer lock connector **10** and mechanically holds the tubing **43** in place with a strong bonding strength. The connector's specifications of the mating end, connector **10**, the inner thread

13, inner luer taper **14**, the fluid path **18** and the tube connector **17**, are designed following luer lock standards and specifications.

[0038] In the known art of producing a transfer set, long life tubing line is slipped over the tail end **17** of the luer lock connector **10**. Because the long life tubing materials (silicone, etc) do not bond very well to the luer lock plastic materials (PVC, ABS, Hytril, etc.) instead of using the standard bonding methods such as high strength glue, UV cured glue, or cyclohexanone, ultrasonic welding is often employed to weld the long life tubing **43** to the outer surface **17** of the tail end of the luer lock. A shrinkable sleeve is then applied over the welded area to protect the bond. Because the two plastic materials are of different durometers (hard and soft), the ultrasonic bonding is not necessarily as strong as would be desired for the intended long-term use of the long life transfer set. The luer lock connector often separates from the long life tubing line, causing leaks and creating means for bacterial contaminations. Therefore, users are encouraged to minimize movement of the welded joint. Regardless, it is common for the life of the weld to be shorter than the expected 6-months usage.

[0039] With reference to **Figures 8** and **9**, which show in more detail preferred embodiments of the female connector **20** and the mail connector **30** respectively,, each male connector **30** is constructed with an external quarter-turn thread **53** and female connector **20** is constructed with an internal quarter turn thread **63** to co-operate therewith, making it easy to achieve proper mating alignment and quick engagement of the connectors. This is of particular importance to reduction of catheter trauma at exit sites. The major complications of catheter exit-site separation are leaks followed by infections. Trauma and tension to exit-sites must be minimized to avoid separation of catheter from the skin. Therefore, the exit-site should be protected from even minimal mechanical disturbances. The quarter-turn threads **53** and **63** reduce twisting that normally generates mechanical strains on connector fittings, transfer sets, catheters and exit-sites.

[0040] The female connector **20** includes an inner cylindrical tube **64** protruding beyond the end opposite from that adapted to receive the male connector **30**, and terminating in a saw-toothed outer ring **60** for attachment to tubing **43**

[0041] **Figure 8** shows an exploded view of the female connector **20**, with internally placed small O-ring **24**, the connector cover (vented **22** or non-vented **23** from **Figure 4**) and retaining ring **40** for securing the connector **20** to a tubing line. **Figure 9** shows a similar exploded view of male connector **30**, with externally placed large O-ring **34** and connector cover (vented **32** or non-vented **33** from **Figure 4**). The retaining ring **40** for securing the connector **20** to a tubing line is shown separated from the connector 20. The retaining rings could be of different materials, could take on other forms of constructions and other methods of attachments and/or bonding could be used to attach them to the respective connectors. A perspective view of the female connector **20** from the front end is shown in **Figure 11**.

[0042] With reference to **Figure 8**, the female connector **20** to be secured to the opposite end of the long life tube **43** from that to which the luer lock connector **10** is attached has a tube connecting end of similar design to that of luer lock connector described above. **Figure 8** shows an exploded view of the female connector **20**, with internally placed small O-ring **24**, the connector cover (vented **22** or non-vented **23** from **Figure 4**) and retaining ring **40** for securing the connector **20** to a tubing line. **Figure 9** shows a similar exploded view of male connector **30**, with externally placed large O-ring **34** and connector cover (vented **32** or non-vented **33** from **Figure 4**). The retaining ring **40** for securing the connector **20** to a tubing line is shown separated from the connector **20** in **Figure 9A**. The retaining rings could be of different materials, could take on other forms of constructions and other methods of attachments and/or bonding could be used to attach them to the respective connectors. A perspective view of the female connector **20** from the front end is shown in **Figure 11**.

[0043] The assembly and interconnection process, as well as the disinfecting, sterilizing process, of the system of the preferred embodiment of the present invention, will now be described with reference to the accompanying drawings.

[0044] To attach the long life tube **43** to the female connector **20**, tube **43** (not shown in **Figure 8**) is slipped over the saw-tooth outer ring **60** and over the entire outer surface of the inner cylindrical tube **64** until seated at the end. Using the same method explained above, the retaining ring **40** is slipped over long life tube **43**, and forced into the inside of

the outer cylindrical tube **65** until the inner ring **82** of the outer cylindrical tube **65** locks into the notch **42** and the notch **43** of the retaining ring **40** lines up with the saw tooth ring **60**, trapping the long life tube **43** in place and the inner surface **45** of the retaining ring **40**, compressing the long life tube **43** firmly against the outer end of the inner cylindrical tube **64**. With the retaining ring **40** locked into the outer cylindrical tube **65**, the outer surface **41** of the retaining ring **40** is ultrasonically welded to the inner surface of the inner surface **81** of the cylindrical tube **65** to form a strong and secure bond. Using this innovative method, all connectors are similarly bonded to their respective tubing accordingly. The retaining ring could also be bonded with glue to the inner side of the outer cylindrical surfaces of the connectors where the fabricating plastic materials are suitable to do so. For example, cyclohexanone may be used when PVC or ABS materials are used to fabricate the connectors **20**, **30** and the corresponding retaining rings **40**.

[0045] To mate the female connector **20** to the male connector **30**, both connectors are easily held in the hand, with fingers safely behind the flanges **57** of the male connector **30** and **67** of the female connector **20**, and the male connector **30** is inserted into the female connector **20** to engage the threading. By twisting the two connectors together for one quarter turn, the two connectors **20**, **30** are firmly engaged with a tactile feedback click when the protuberance **51** of the male connector **30** locks into the notch **61** of the female connector **20** to provide a secure lock-in of the two connectors. This represents a further inventive feature, a tactile feedback mechanism that indicates to the user that the two parts of the connectors are appropriately mated.

[0046] As stated above, during separations of connectors **20** and **30** each mating connector **20**, **30** is covered with corresponding disinfectant cap **21**, **31**. The cap design ensures that the internal fluid path, the external fluid path and the inside of the connector's outer shield are all exposed to adequate disinfectant solution without leaks. It is equally important that when the disinfected mating connectors are reunited, the flushing that follows immediately thereafter is effective to remove the disinfectant solutions from the fluid path before any solution is transferred to the patient. The design of the connectors **20**, **30** and disinfectant caps **21**, **31** accomplish this important procedure effectively and still create a barrier to microorganisms.

[0047] In embodiments of this invention, a method to maintain integrity of attached tubing line to the connector is provided. These embodiments combine friction, tube line compression, a keyed saw tooth ring, and a glued and/or welded additional retaining ring to combat wear and tear at this joint. The tail end of the luer lock connector **10** of this invention is provided with an inner cylindrical tube **17**, terminating with a saw-tooth ring **71**, enclosed by a longer outer second cylindrical tube **15** that terminates with an inner ring **70**. In assembly, the long life tube **43** is slipped all the way over the outer surface of the inner tube **17**. The retaining ring **11**, preferably made of the same material and/or similar material with the same durometer (hardness), is slipped over tube **43** and forced between the inner cylindrical tube **17** and the outer cylindrical tube **15**, compressing tube **43** until the inner ring **70** of the outer tube **15** locks into notch **74** of the retaining ring **11**. At the same time, notch **75** of the retaining ring **11** also aligns itself over the saw-tooth ring **71** of the inner tube **17**, trapping the long life tube onto the saw-tooth ring **71** and the end **72**. The outer surface **73** of the retaining ring **11** is then ultrasonic welded to the inner surface **16** of the outer cylindrical tube **15** to form a strong and long lasting permanent bond. The three mechanical forces, friction, compressive pressure and the keyed saw tooth lock, act in combination with the ultrasonic weld and seals to retain the long life tube in place. In addition the welded section is not exposed to the fluid carrying path and therefore removed from chemical attacks.

[0048] With reference to **Figure 8**, the female connector **20** to be secured to the opposite end of the long life tube **43** from that to which the luer lock connector **10** is attached has a tube connecting end of similar design as that of luer lock connector described above. To attach the long life tube **43** to the female connector **20**, tube **43** (not shown in **Figure 8**) is slipped over the saw-tooth outer ring **60** and over the entire outer surface of the inner cylindrical tube **64** until seated at the end. Using the same method explained above, the retaining ring **40** is slipped over long life tube **43**, and forced into the inside of the outer cylindrical tube **65** until the inner ring **82** of the outer cylindrical tube **65** locks into the notch **42** and the notch **43** of the retaining ring **40** lines up with the saw tooth ring **60**, trapping the long life tube **43** in place and the inner surface **45** of the retaining ring **40**, compressing the long life tube **43** firmly against the outer end of the inner cylindrical tube **64**. With the retaining ring **40** locked into the outer cylindrical tube **65**, the outer

surface **41** of the retaining ring **40** is ultrasonically welded to the inner surface of the inner surface **81** of the cylindrical tube **65** to form a strong and secure bond. Using this innovative method, all connectors are similarly bonded to their respective tubing accordingly. The retaining ring could also be bonded with glue to the inner side of the outer cylindrical surfaces of the connectors where the fabricating plastic materials are suitable to do so. For example, cyclohexanone may be used when PVC or ABS materials are used to fabricate the connectors **20**, **30** and the corresponding retaining rings **40**.

[0049] Figure 10 shows the internal structural details of the male connector **30** following mating connection to female connector **20**. The female connector **20** has an attached tubing line held in place with a retaining ring **40**. The retaining ring **40** is glued or ultrasonically welded to the inside of the female connector **20** as shown. Another tubing line (not shown here) is attached to male connector **30** using a retaining ring in the same manner. This figure also shows the alignment of the internal structures of the two connectors **30** and **20**.

[0050] The outer cylindrical cover **62** of the female connector **20** slides over the large O-ring **34** of the male connector **30**, tightly sealing the inside of the mated connectors from the outside. The inner cylindrical tube **94** of the male connector **30** engages into the inner cylindrical tube **68** of the male connector **20** and compresses the small O-Ring **24** of the female connector **20** against the inner cylindrical step **27** of the female connector **20**. The aligned internal cylindrical holes **90** of male connector **30** and **83** of female connector **20**, define a sealed continuous internal fluid path.

[0051] Figure 12A shows a cross-section of a disconnected male connector **30** with an engaged female disinfectant cap **21**. Screwing the female disinfectant cap **21** onto the opened end of the male connector **30** through one quarter turn twist-locks the two together with a tactile feedback click. The front **91** of the inner cylindrical tube **68** displaces inwards the porous sponge **101** of the disinfectant cap **21**, thereby liberating sufficient disinfectant to enter the fluid path **90** of the male connector **30**. At the same time, both the inner cylindrical tube **68** and the outer cylindrical tube **52** of the male connector **30**, are disinfected accordingly, being continuously bathed in disinfecting fluid. The concentration of the disinfecting fluid surrounding the inner cylindrical tube **68** and

the outer cylindrical tube **52** of the male connector **30** gets stronger with time as more disinfectant diffuses into the cylindrical space defined by the inner cylindrical surface of the female disinfectant cap **21**. The large O-ring provides a secure seal to prevent leaks of fluid to the outside. The corresponding cross-section for a piston-based disinfectant cap is shown in **Figure 12B**.

[0052] Figure 13A shows in cross-sectional view a female connector **20** following disconnection from an engaged male disinfectant cap **31**. During engagement, the inner cylindrical tube **69** pushes inward on the porous sponge **105** of the disinfectant cap **31**, releasing disinfectant **102** into the cylindrical chambers and the fluid path **83** of the female connector **20**. Diffusion of more disinfectant into the closed cylindrical spaces continues with time. The large O-ring **34** of the disinfectant cap **31** seals the disinfectant solution from the outside. The disinfectant cap **31** may stay connected on to the female connector **20** for as long as required. The corresponding cross-section for a piston-based disinfectant cap is shown in **Figure 13B**.

[0053] The large O-ring **34** in a preferred embodiment also gives way easily to a minimum torque when the male disinfectant cap **31** and the female disinfectant cap **21** are being taken off from their respective female connector **20** and male connector **30**.

[0054] Figure 14 shows a cross-section of a male connector **30** following reconnection to female connector **20**. It is to be noted that after internally flushing the reengaged connectors **30** and **20**, disinfectant solution is removed from the aligned fluid paths **90** and **83**. However, the small O-ring **24** of female connector **20**, the internal cylindrical tube **94** of male connector **30**, and the internal cylindrical tube of the female connector **20**, seal off the fluid paths **90** and **83**, from the surrounding disinfectant pool that continues to provide aseptic protection barrier to bacteria. The large O-ring **34** keeps the trapped disinfectant liquid from leaking outside the connectors.

[0055] This concludes the description of a presently preferred embodiment of the invention. The foregoing description has been presented for the purpose of illustration and is not intended to be exhaustive or to limit the invention to the precise form disclosed. Many modifications and variations are possible in light of the above teaching

and will be apparent to those skilled in the art. It is intended the scope of the invention be limited not by this description but by the claims that follow.

What is claimed is:

1. A connectology system, suitable for use in dialysis, comprising male connectors and female connectors, said connectors comprised of an inner tube and an outer tube, such that, when the male connectors and the female connectors are mated, said inner tubes form a fluid path for the system that is recessed from the top of the outer tubes and said outer tubes shield said inner tubes from contact and touch contamination.

2. The connectology system of claim 1, wherein said connectors have one of more of the following features:

one or more independent quarter-turn threads to engage and disengage said connectors;

a tactile feedback mechanism to indicate completion of engagement and commencement of disengagement;

flange elements to inhibit touch contamination of said connectors; and

wing elements to permit application of torque for engagement and disengagement.

3. The connectology system of claim 2, wherein said connectors have all of the following features: a) one or more independent quarter-turn threads to engage and disengage said connectors; b) a tactile feedback mechanism to indicate completion of engagement and commencement of disengagement; c) flange elements to inhibit touch contamination of said connectors; and d) wing elements to permit application of torque for engagement and disengagement.

4. The connectology system according to claims 1-3, wherein a means to maintain integrity of an attached tubing line to the connector combines any multiple combination of: friction, tube line compression, a keyed saw tooth ring, a glued retaining ring and a welded retaining ring.

5. The connectology system of claims 1-4, further including a set of male connector caps and female connector caps to cover said male connectors and said female connectors when not in use.

6. The connectology system of claim 5, wherein the connector caps are vented.

7. The connectology system of claim 5, wherein the set of male connector caps and female connector caps are disinfectant caps.

8. The connectology system of claim 7, wherein said disinfectant caps comprise a cavity containing disinfectant and a retaining element to which permits the disinfectant to be released from said cavity when said disinfectant caps are connected to said connectors.

9. The connectology system of claim 8, wherein the retaining element is a sponge which releases the disinfectant upon contact with the connector.

10. The connectology system of claim 8, wherein the retaining element is a piston containing a channel which allows passage of the disinfectant through the channel upon exertion of force upon the piston.

11. A kit having component parts capable of being assembled into a connectology system, comprising:

a) at least one male connector, each male connector comprised of an inner tube and an outer tube, and having one or more of the following features:

i) one or more independent quarter-turn threads to engage and disengage said connectors;

ii) a tactile feedback mechanism to indicate completion of engagement and commencement of disengagement;

iii) flange elements to inhibit touch contamination of said connectors; and

iv) wing elements to permit application of torque for engagement and disengagement,

b) at least one male connector cap to cover said each male connector;

c) at least one female connector, each female connector comprised of an inner tube and outer tube, and having one or more of the following features:

i) one or more independent quarter-turn threads to engage and disengage said connectors;

ii) a tactile feedback mechanism to indicate completion of engagement and commencement of disengagement;

iii) flange elements to inhibit touch contamination of said connectors; and

iv) wing elements to permit application of torque for engagement and disengagement,

d) at least one female connector cap to cover said each female connector;

whereby the male connectors and the female connectors are mated to each other and said inner tubes form a fluid path for the connectology system that is recessed from the top of the outer tubes and said outer tubes shield said inner tubes from contact and touch contamination.

12. The kit of claim 11, wherein the male connector caps and female connector caps are disinfectant caps.

13. The kit of claim 12, wherein said disinfectant caps comprise a cavity containing disinfectant and a retaining element to which permits the disinfectant to be released from said cavity when said disinfectant caps are connected to said connectors.

14. The kit of claim 13, wherein the retaining element is a sponge which releases the disinfectant upon contact with the connector.

15. The kit of claim 13, wherein the retaining element is a piston containing a channel which allows passage of the disinfectant through the channel upon exertion of force upon the piston.

16. The kit of claims 11-15, further including at least one tubing line and said each male connector and said each female connector further includes a means to integrally attach said tubing line to said connector.

17. The kit of claim 16, wherein the means to integrally attach said tubing line to said connector combines any multiple combination of: friction, tube line compression, a keyed saw tooth ring, a glued retaining ring and a welded retaining ring.

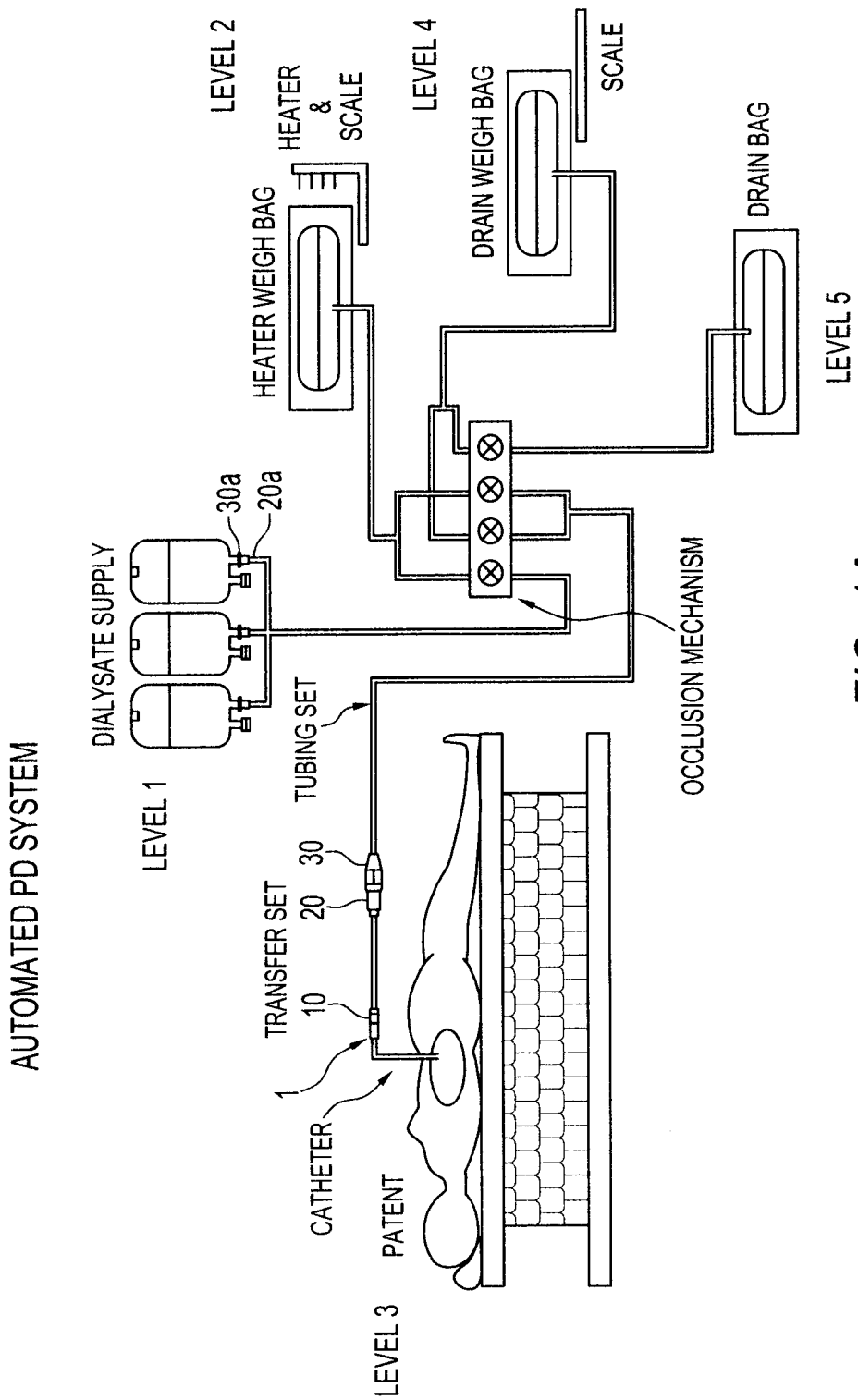
AUTOMATED PD SYSTEM
LEVEL 1
DIALYSATE SUPPLY
30a
20a
TUBING SET
LEVEL 2
HEATER WEIGH BAG
HEATER & SCALE
LEVEL 4
DRAIN WEIGH BAG
SCALE
DRAIN BAG
LEVEL 5
OCCLUSION MECHANISM
TRANSFER SET
30
20
10
1
CATHETER
PATENT
LEVEL 3

FIG. 1A

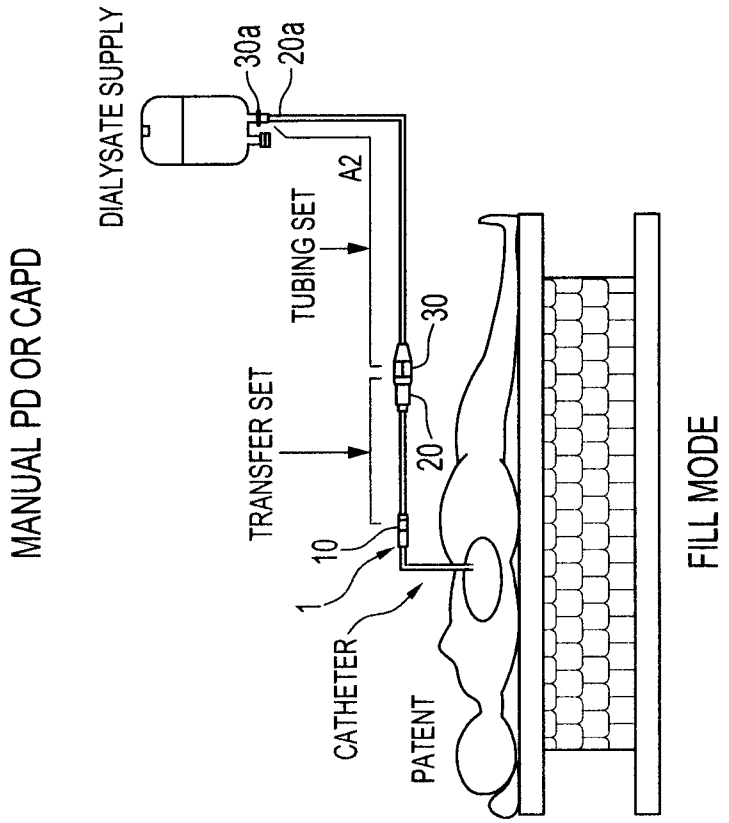
MANUAL PD OR CAPD
DIALYSATE SUPPLY
30a
20a
A2
TUBING SET
30
TRANSFER SET
20
10
1
CATHETER
PATENT
FILL MODE

FIG. 1B

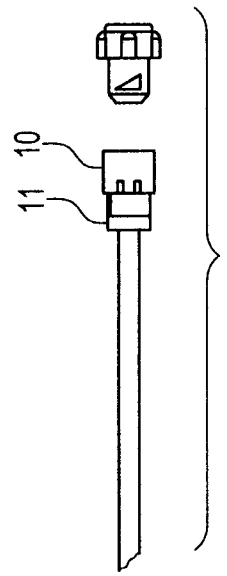

FIG. 2B

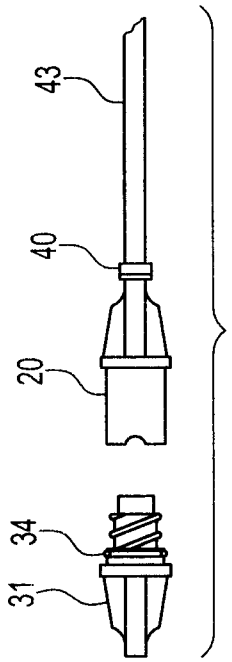

FIG. 2A

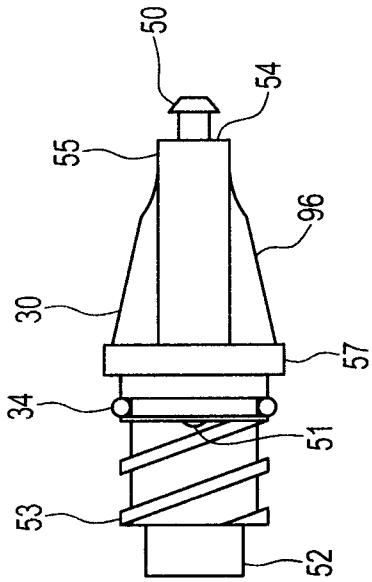

FIG. 3B

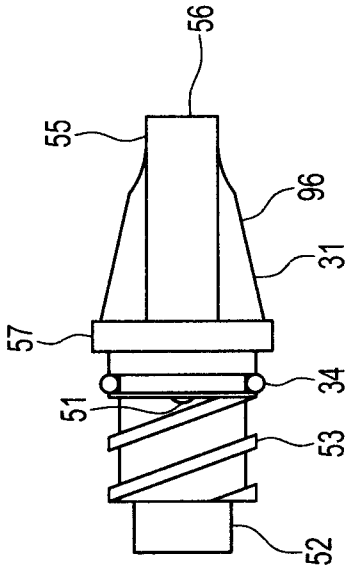

FIG. 3D

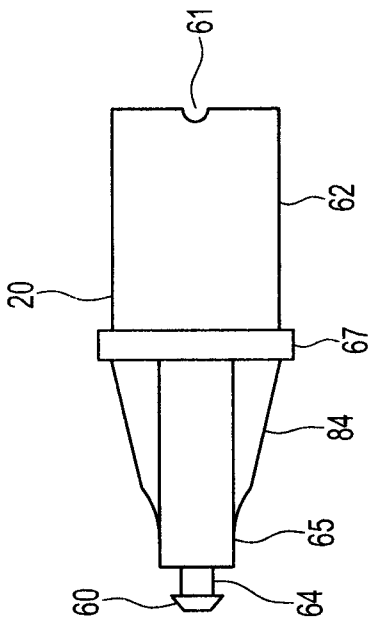

FIG. 3A

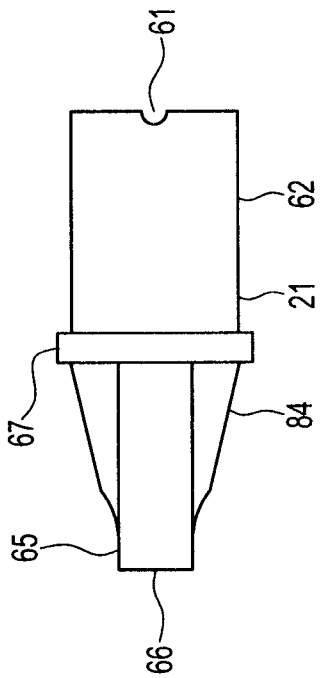

FIG. 3C

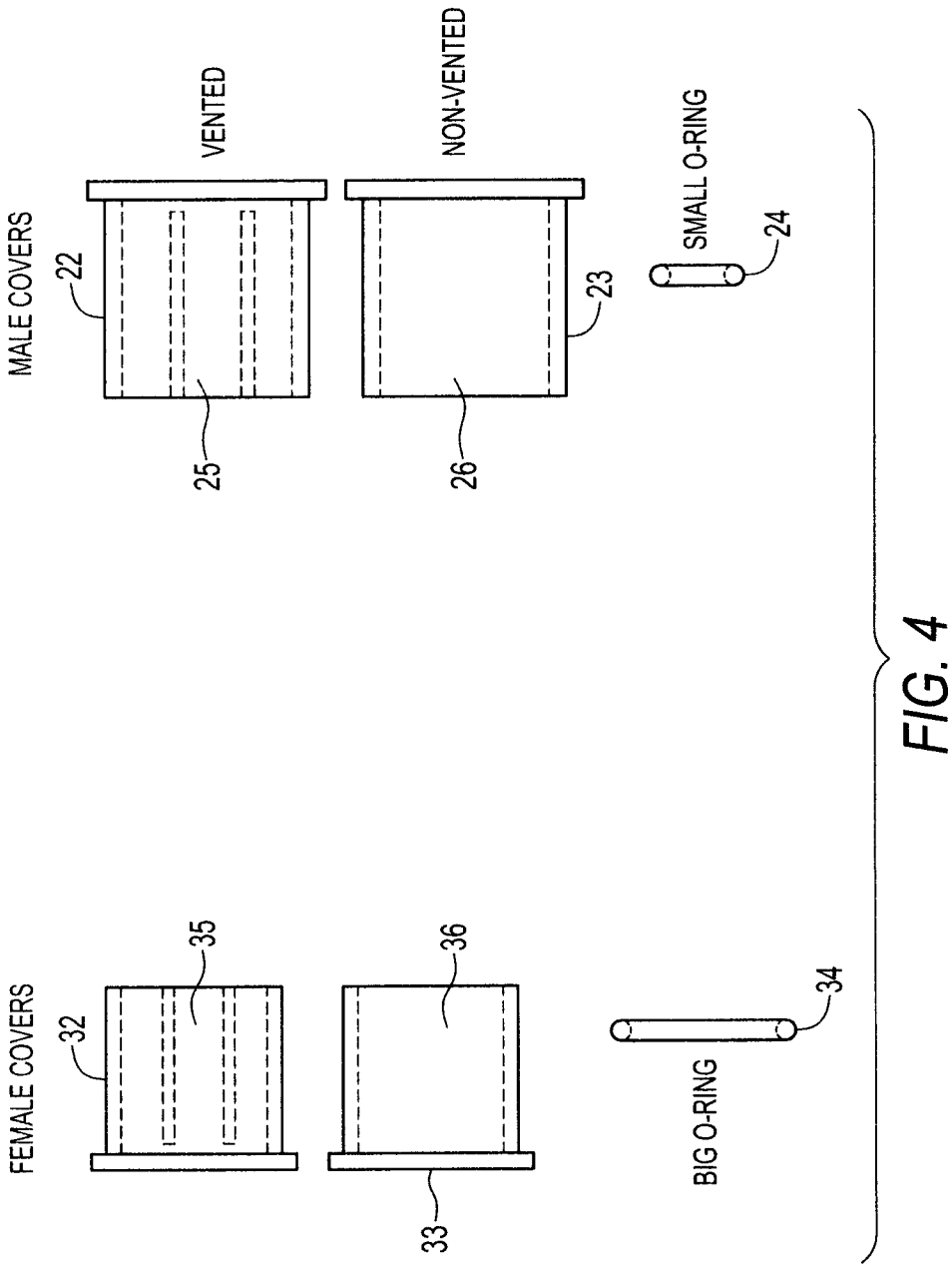
MALE COVERS
22
VENTED
NON-VENTED
SMALL O-RING
24
23
25
26
FEMALE COVERS
32
35
36
34
BIG O-RING
33

FIG. 4

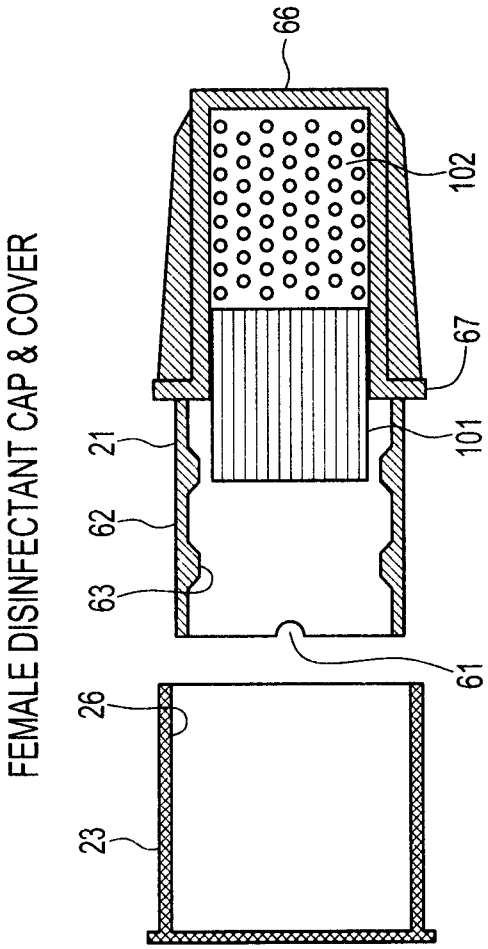

FIG. 5A

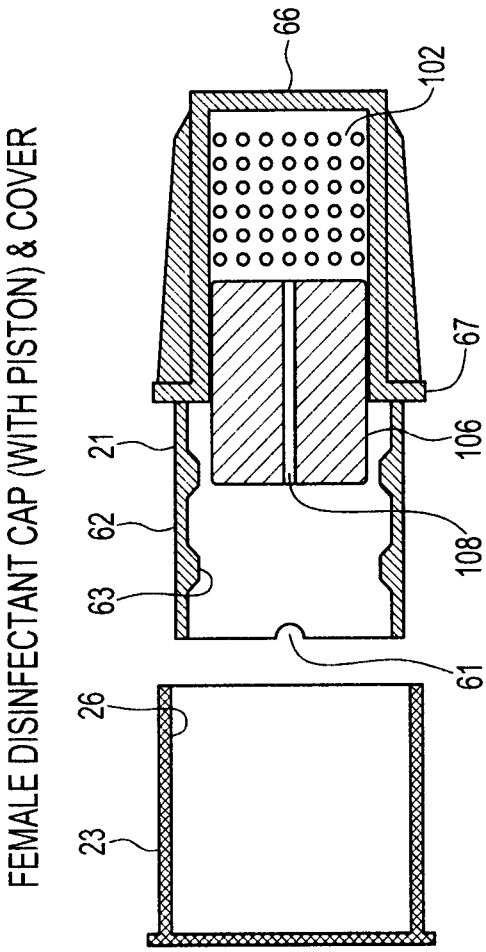
FEMALE DISINFECTANT CAP (WITH PISTON) & COVER
66
102
67
106
108
21
62
63
61
26
23

FIG. 5B

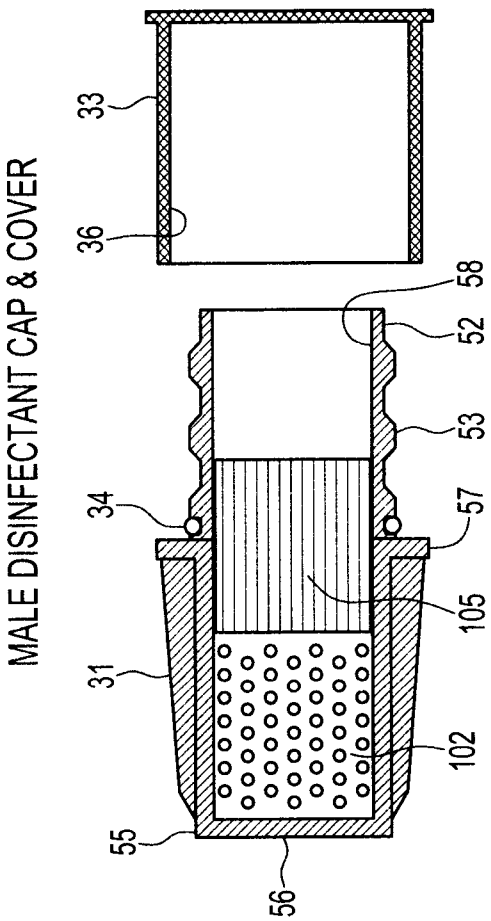
MALE DISINFECTANT CAP & COVER
33
36
58
52
53
34
57
105
31
102
55
56

FIG. 6A

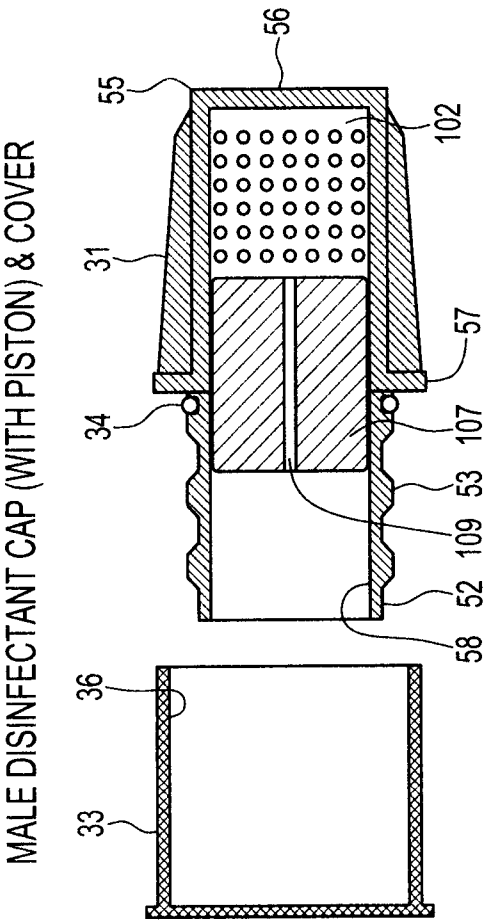
MALE DISINFECTANT CAP (WITH PISTON) & COVER
56
55
102
31
57
34
107
53
109
52
58
36
33

FIG. 6B

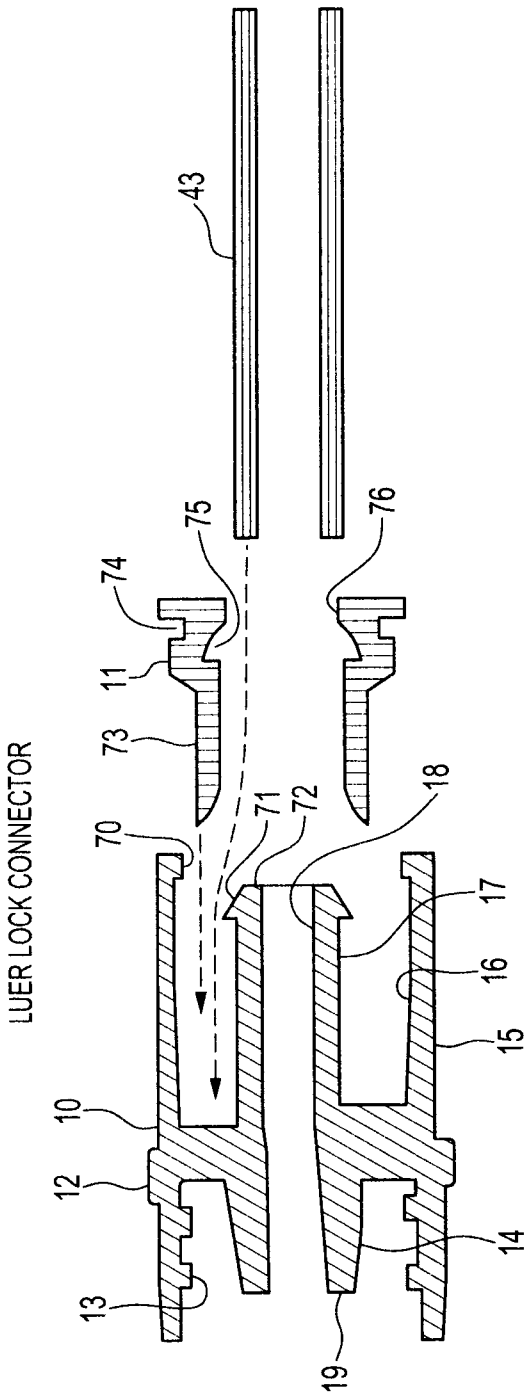
LUER LOCK CONNECTOR
43
75
76
74
11
73
70
71
72
18
17
16
15
10
12
14
13
19

FIG. 7

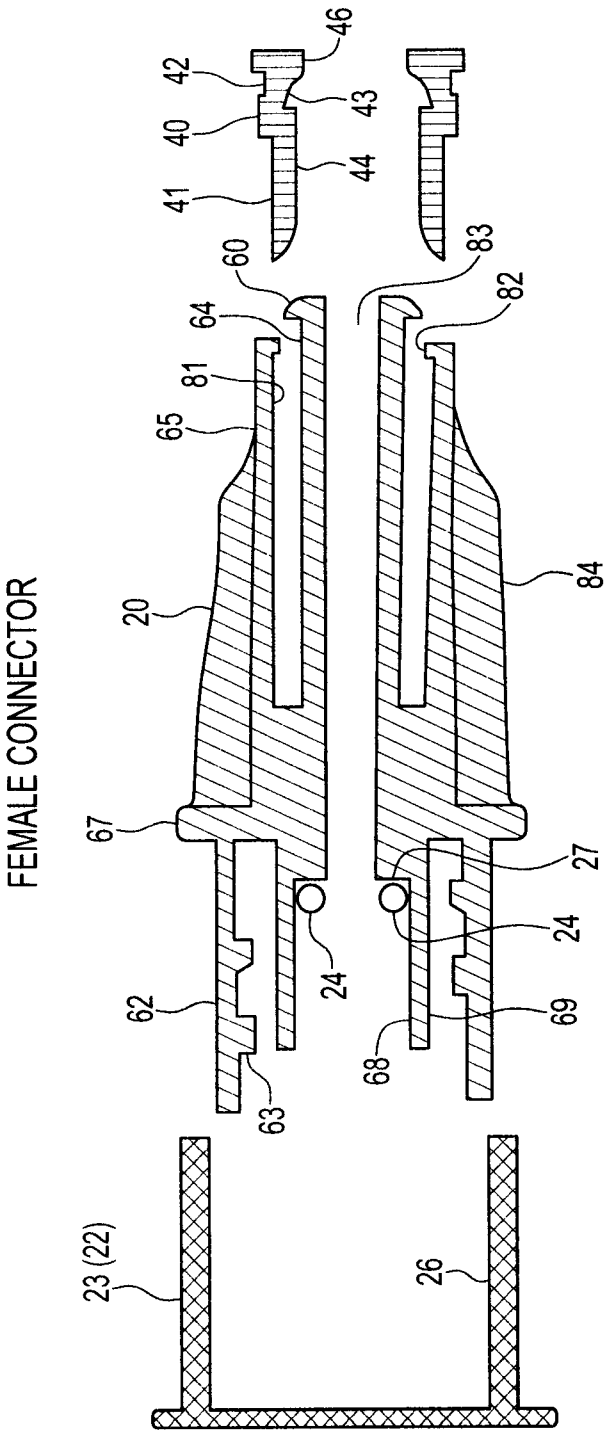
FEMALE CONNECTOR
46
42
43
40
44
41
60
83
64
82
81
65
20
84
67
27
24
24
62
69
68
63
23 (22)
26

FIG. 8

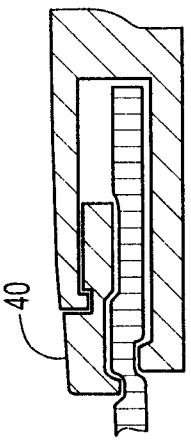
40

FIG. 9A

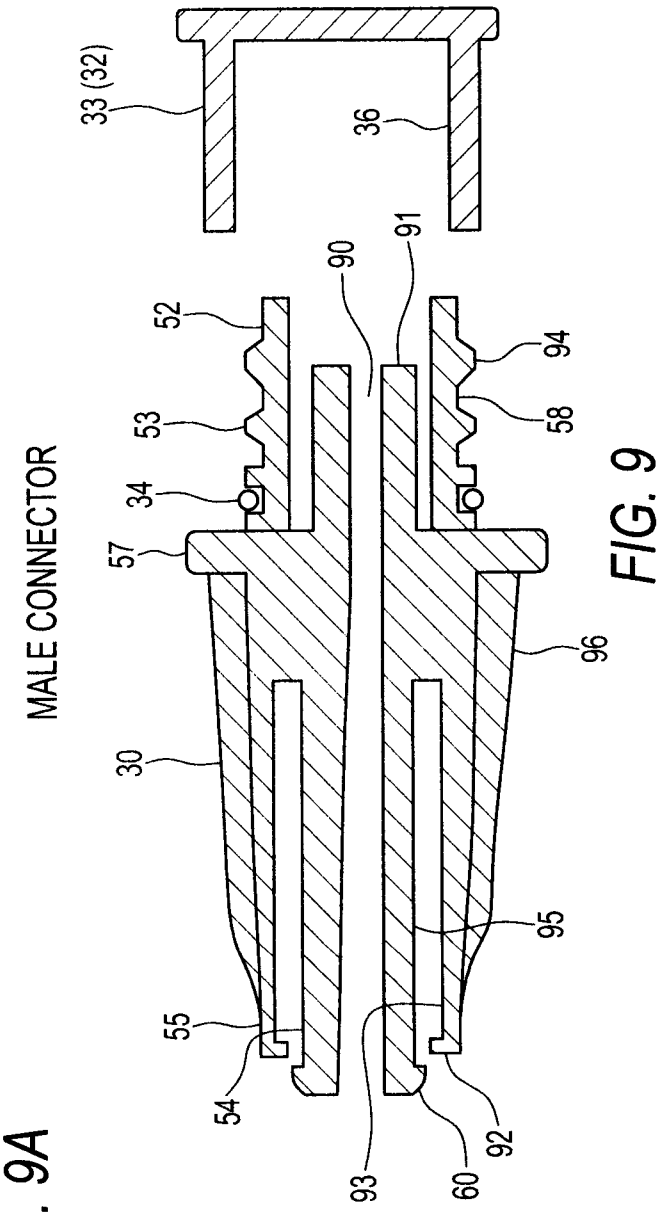
MALE CONNECTOR
33 (32)
36
90
91
52
94
53
58
34
57
96
30
95
55
54
93
60
92

FIG. 9

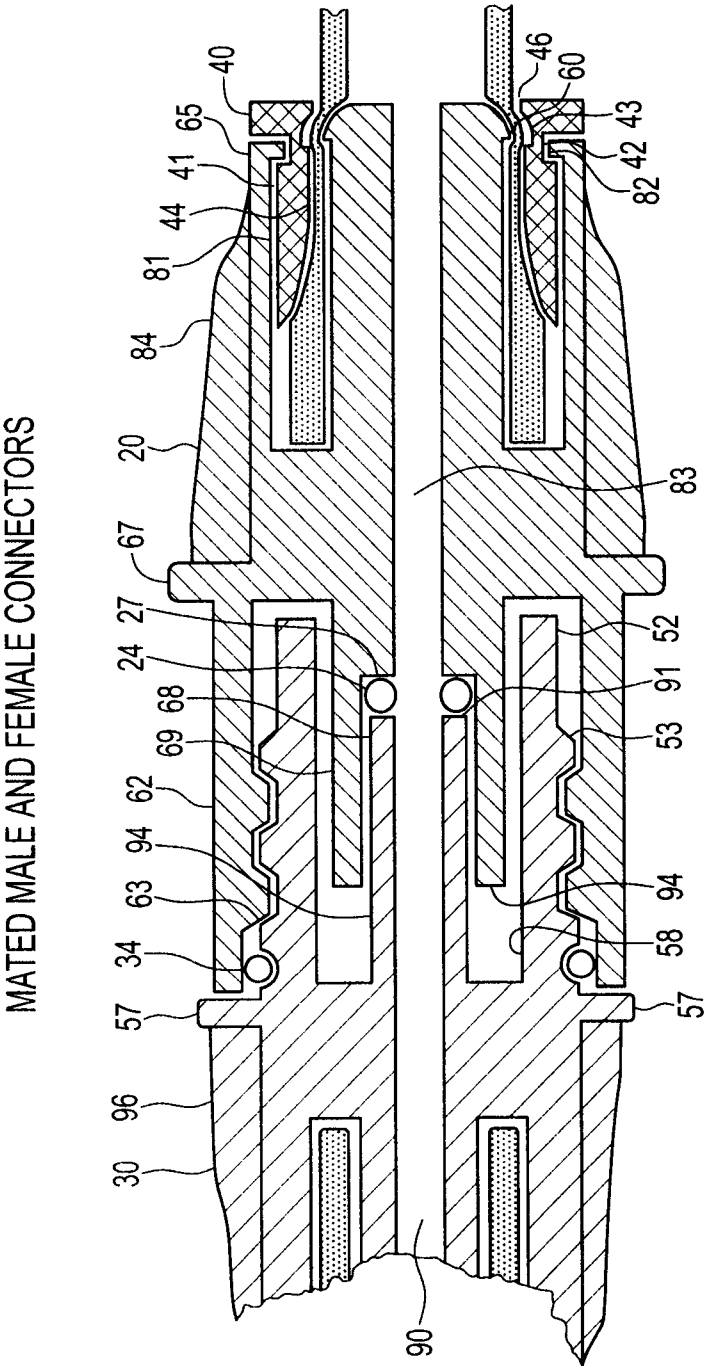
MATED MALE AND FEMALE CONNECTORS
40
65
41
44
81
84
20
67
27
24
68
69
62
94
63
34
57
96
30
90
46
60
43
42
82
83
52
91
53
94
58
57

FIG. 10

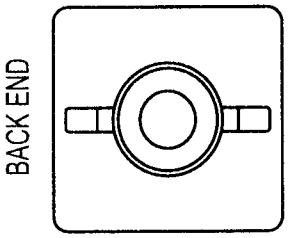

FIG. 1B

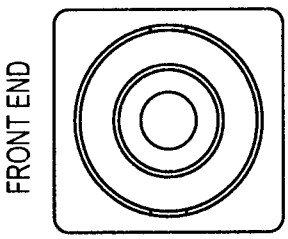

FIG. 11A

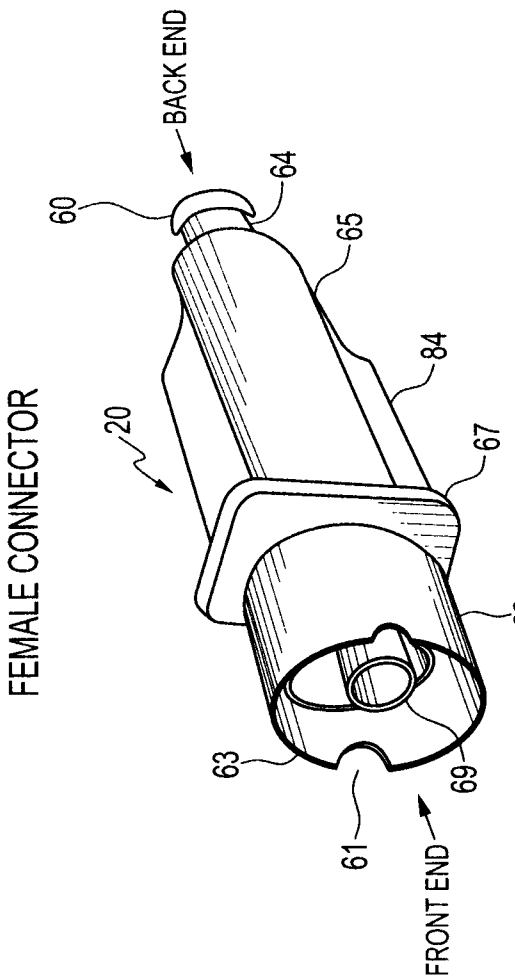

FIG. 11

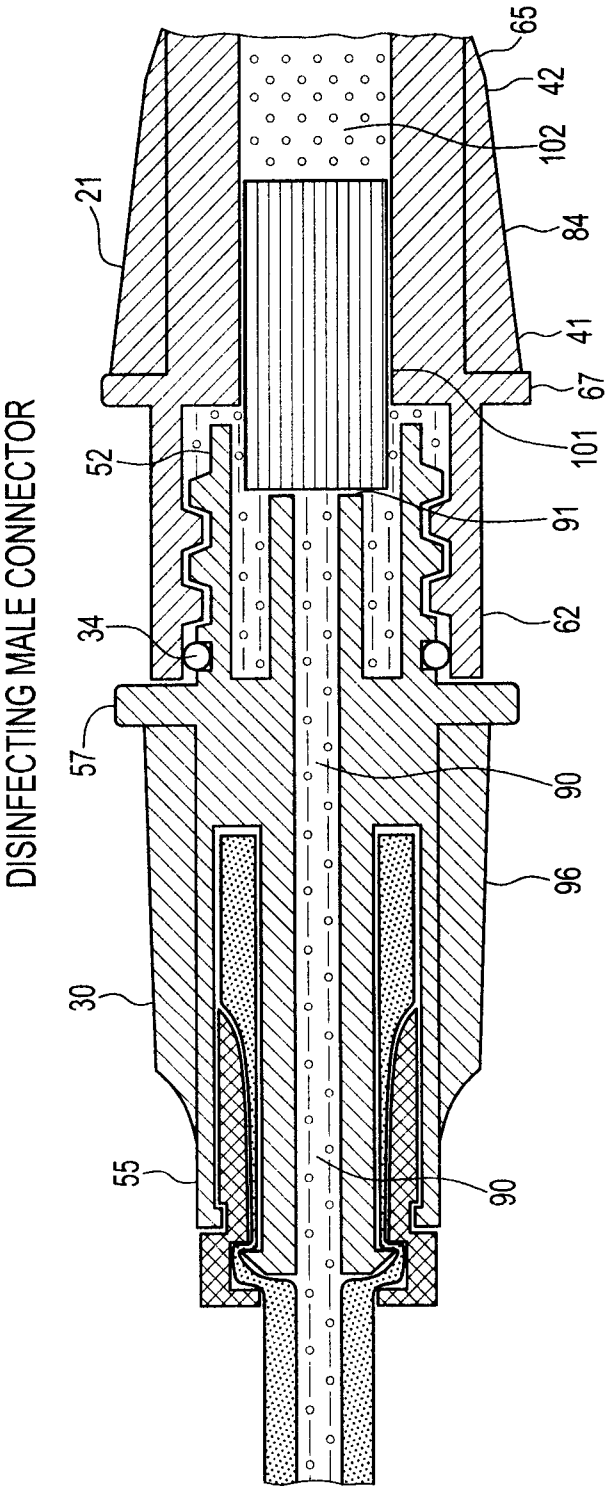
DISINFECTING MALE CONNECTOR
65
42
102
21
84
41
67
101
52
91
62
34
57
90
96
30
55
90

FIG. 12A

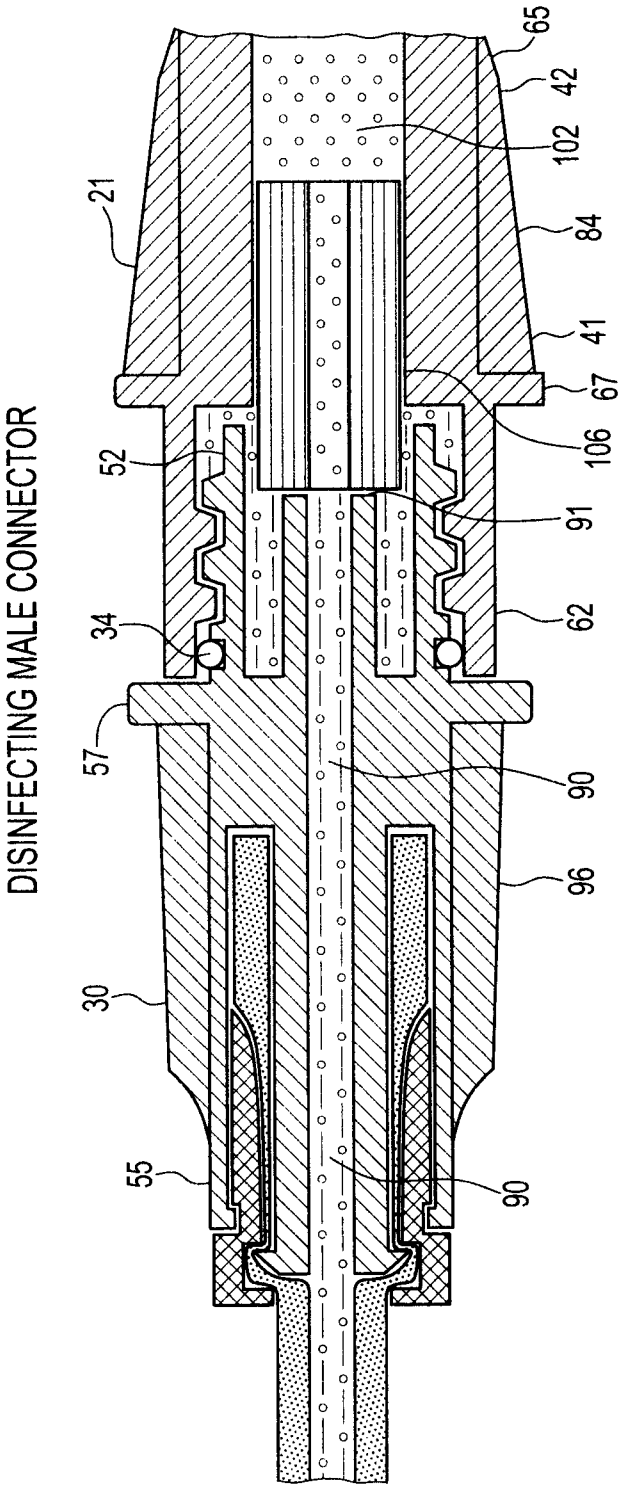
DISINFECTING MALE CONNECTOR
65
42
102
21
84
41
67
106
52
91
34
62
57
90
96
30
55
90

FIG. 12B

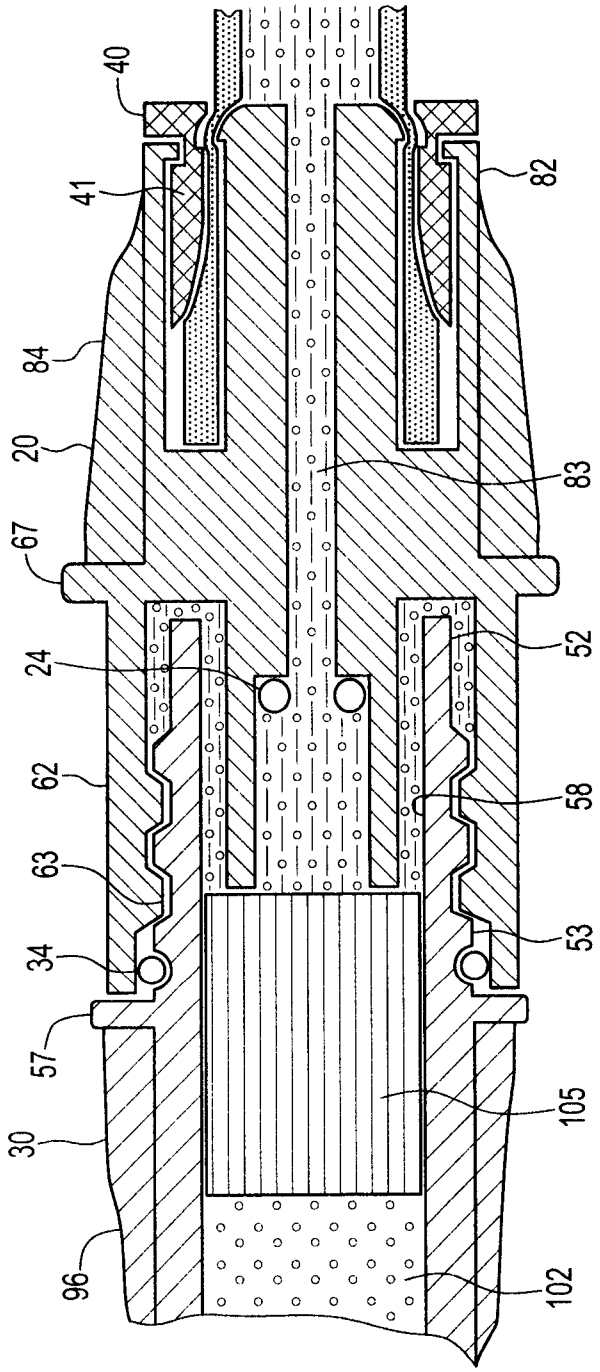
DISINFECTING FEMALE CONNECTOR
40
41
82
84
20
83
67
24
52
62
58
63
53
34
57
105
30
96
102

FIG. 13A

DISINFECTING FEMALE CONNECTOR WITH PISTON CAP

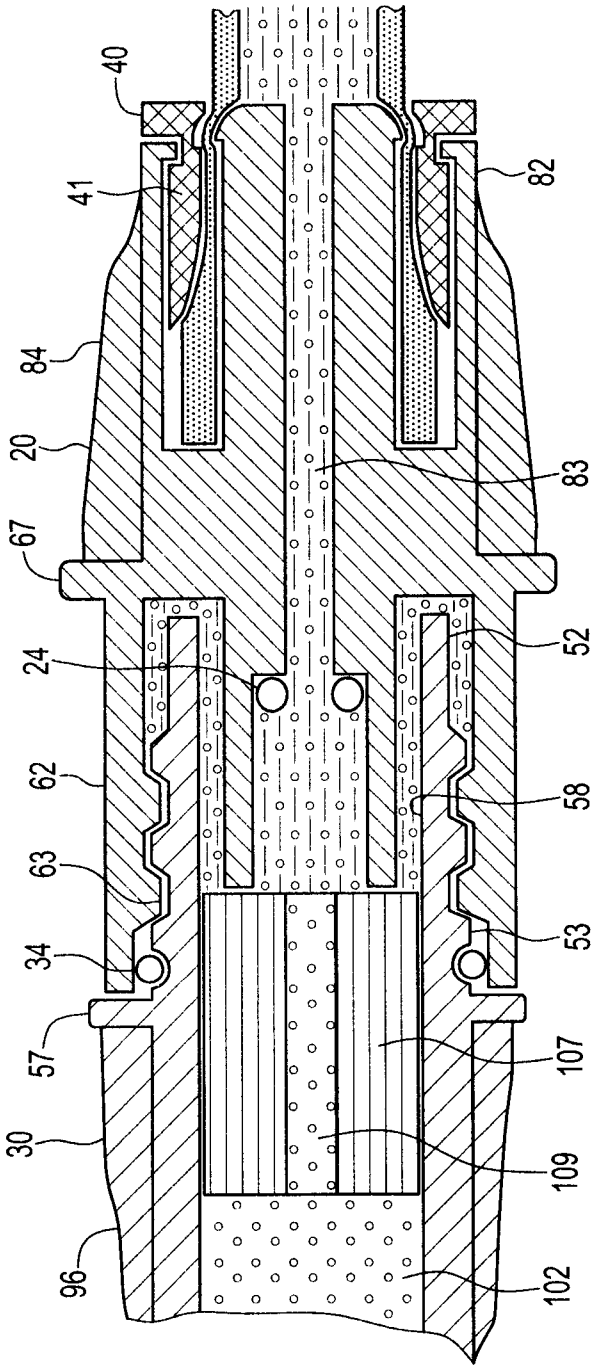

FIG. 13B

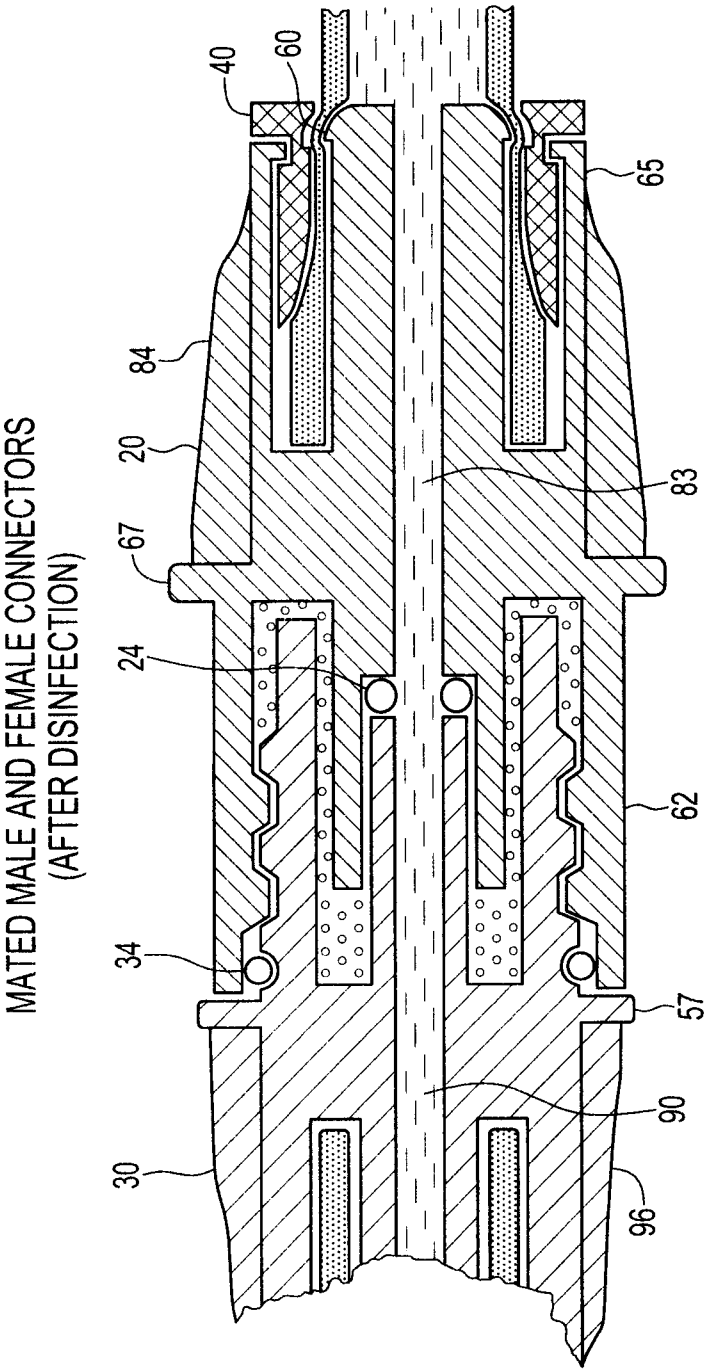
MATED MALE AND FEMALE CONNECTORS
(AFTER DISINFECTION)
40
60
65
84
20
83
67
24
62
34
57
90
30
96

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2008/000164

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61M 39/10*** (2006.01) , ***A61M 39/20*** (2006.01) , *A61M 1/14* (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: ***A61M*** USPC:604

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Databases: Delphion, Espacenet, WEST
Search terms: connector, disinfectant, tactile, torque, luer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6641574 B2 (SEGURA , M.) 4 November 2003 (04-11-2003) *Whole document*	1, 2
Y		3-17
X	US 4810241 A (ROGERS, P.) 7 March 1989 (07-04-1989) *Whole document*	1, 2
Y	US 5591143 A (TROMBLEY, F. et al.) 7 January 1997 (07-01-1997) *col. 1, lines 21-22)*	3
Y	US 5694978 A (HEILMANN, K. et al.) 9 December 1997 (09-12-1997) *Whole document*	5-9, 12-14
Y	US 4432764 A (LOPEZ, G.) 21 February 1984 (21-02-1984) *Whole document*	5-8, 10, 12, 13, 15
Y	US 4588402 A (IGARI, A. et al.) 13 May 1986 (13-05-1986) *col. 6, line 45-47, figure 2*	4, 16, 17

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 April 2008 (17-04-2008)	13 May 2008 (13-05-2008)

Name and mailing address of the ISA/CA	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Jim Triantafillou 819- 934-4268

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2008/000164

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US 6641574B2	04-11-2003	AT 271405T	15-08-2004
		AU 5079000A	28-12-2000
		BR 0011080A	19-03-2002
		CA 2375394A1	14-12-2000
		CZ 20014299A3	12-06-2002
		DE 60012270D1	26-08-2004
		DE 60012270T2	08-09-2005
		EP 1057495A1	06-12-2000
		EP 1057495B1	21-07-2004
		ES 2157799A1	16-08-2001
		ES 2157799B1	01-02-2002
		ES 2225065T3	16-03-2005
		IL 146664D0	25-07-2002
		JP 2003525073T	26-08-2003
		MX PA01012292A	30-07-2002
		PL 195997B1	30-11-2007
		PL 365997A1	24-01-2005
		US 2002038114A1	28-03-2002
		WO 0074768A1	14-12-2000
US 4810241A	07-03-1989	US 4354490A	19-10-1982
		US 4551146A	05-11-1985
		US 4655762A	07-04-1987
US 5591143A	07-01-1997	WO 9422520A1	13-10-1994
US 5694978A	09-12-1997	AT 224217T	15-10-2002
		BR 9505721A	27-05-1997
		CA 2164772A1	10-06-1996
		CA 2164772C	04-12-2001
		DE 9419630U1	02-02-1995
		DE 59510378D1	24-10-2002
		EP 0715864A2	12-06-1996
		EP 0715864A3	12-03-1997
		EP 0715864B1	18-09-2002
		ES 2183848T3	01-04-2003
		JP 2849060B2	20-01-1999
		JP 8215311A	27-08-1996
US 4432764A	21-02-1984	DE 3143329A1	09-06-1982
		DE 3143329C2	21-02-1985
		FR 2493149A1	07-05-1982
		FR 2493149B1	01-02-1985
US 4588402A	13-05-1986	AU 553449B2	17-07-1986
		AU 8930482A	15-09-1983
		BE 894715A1	31-01-1983
		CA 1188943A1	18-06-1985
		DE 3238303A1	29-09-1983
		DE 3238303C2	06-11-1986
		DE 8229004U1	19-05-1983
		DE 8237050U1	19-05-1983
		FR 2522969A1	16-09-1983
		FR 2522969B1	14-08-1986
		JP 1380293C	28-05-1987
		JP 1380295C	28-05-1987
		JP 58152568A	10-09-1983
		JP 58163371A	28-09-1983
		JP 61048382B	23-10-1986
		JP 61050459B	04-11-1986
		SE 453887B	14-03-1988
		SE 453887C	23-06-1988
		SE 8205642A	04-10-1982
		SE 8205642D0	04-10-1982
		SE 8205642L	04-10-1982