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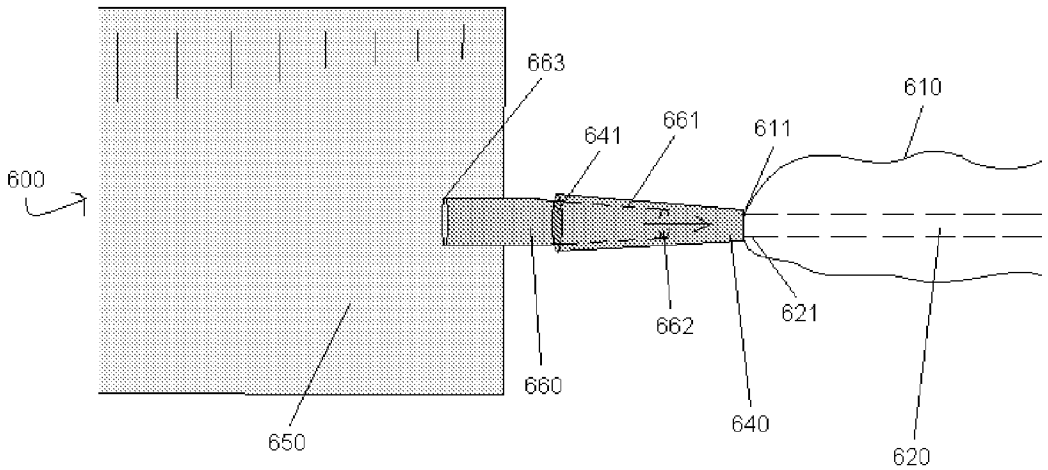

Figure 6

(57) Abstract: A device for connecting a catheter assembly to a collection receptacle is disclosed. The device is situated at a distal portion of the catheter assembly and the connection made may be either temporary or permanent using snap-fit, pressure-fit or other similar mechanism.

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DEVICES FOR CONNECTING CATHETER ASSEMBLY TO COLLECTION RECEPTACLE

[0001] This Patent Application claims priority to U.S. Provisional Patent Application Serial No. 60/902,369, filed February 21, 2007, and is a Continuation-In-Part (CIP) of U.S. Patent Application Serial No. 11/546,293, filed October 12, 2006, the contents of both of which are hereby incorporated by reference in their entirety into this disclosure.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present invention relates to catheter assemblies. More particularly, the present invention relates to devices for connecting a distal portion of a catheter assembly to a collection receptacle.

Background of the Invention

[0003] The urinary catheterization procedure is a common medical practice with the procedure being performed today in both hospital and home settings. In hospital settings today, nurses often perform urinary catheterization procedures using convenience packs, or pre-assembled kits. These convenience packs typically contain a vinyl, red latex rubber, or silicon catheter, a waterproof absorbent underpad, a fenestrated drape, disposable gloves, a sealed packet containing about 22.5 mL of Povidone-Iodine solution, several prepping cotton balls in a disposable tray compartment, a sealed packet containing sterile lubricating jelly, a plastic forceps, a sterile specimen bottle, and a 1000 mL graduated basin. All of these items are packaged together and sterilized.

[0004] To perform the catheterization procedure, a nurse opens the tray, dons sterile gloves and places the drape around the patient's genitalia. The Povidone-Iodine packet is opened and poured over the cotton balls. The packet of lubricating jelly is then opened and squeezed onto a sterile field. The patient's urethral opening is cleansed with the saturated cotton balls, holding each cotton ball with the forceps. Then, the nurse runs the tip end of the catheter, comprising the first inch or two (about 2.5 cm to about 5 cm) of the insertable portion, through the lubricating jelly. The catheter is then inserted into the patient's urethra and advanced until urine begins to flow through the catheter. The urine is drained into the 1000 mL graduated basin and a urine specimen is caught in the specimen bottle if needed. The catheter is then removed and all the aforementioned items are discarded. Care must be taken to maintain sterile procedure in order to reduce the risk of urinary tract infection.

[0005] In order to collect the drained fluid, the 1000 mL graduated basin is typically positioned between the patient's legs during catheterization. Therefore, the basin is susceptible to being struck by a spastic or an uncooperative patient. This can result in spilling of the collected fluid or in making it very difficult for the nurse to perform the catheterization. After the urine is collected, the nurse typically will carry the 1000 mL graduated basin to the toilet and pour out its contents. During this trip, the nurse may spill some of the urine due to difficulty in handling the filled basin or as a result of the nurse's stumbling during her walk from the patient's bed to the bathroom.

[0006] Because multiple steps are involved in the catheterization procedure (*e.g.*, carrying the unwieldy urine filled 1000 mL graduated basin to the toilet)

and meticulous attention to maintain sterile technique is required, a nurse typically spends a significant amount of time (*e.g.*, 10-15 minutes) carrying out each catheterization. This basic procedure is used in virtually every inpatient hospital around the world, and has remained essentially the same for 50 years.

[0007] Thus, there is a need in the healthcare industry for a more convenient and streamlined technique for collecting and disposing the fluid collected from the catheterization process.

SUMMARY OF THE INVENTION

[0008] The current techniques for catheterization are inefficient and inconvenient. In conventional catheterization techniques, the drained fluid is collected in a separate 1000 mL graduated basin which is positioned between the patient's legs. The 1000 mL graduated basin may cause problems for the nurse especially when the patient is spastic or uncooperative since the patient can strike and shift the basin. Also, the basin is unwieldy after it is filled thus making it difficult to carry to the bathroom to empty. The present invention addresses this healthcare problem by providing various techniques for connecting a catheter assembly to a collection receptacle. More specifically, the present invention proposes a device on a distal portion of a catheter assembly in order to facilitate the collection and emptying of the drained fluid.

[0009] In one exemplary embodiment, the present invention is a connecting device for a catheter assembly. The device includes a body situated at a distal portion of a catheter assembly and a collar. The body mates with the collar thereby allowing fluid communication within the catheter assembly while

maintaining a temporary or permanent seal preventing fluid communication with an external environment.

[0010] In another exemplary embodiment, the present invention is a connecting device for a catheter assembly. The device includes a circular body situated at a distal portion of a catheter assembly on or proximal to a urine outlet piece and a collar situated at a proximal portion of a collection receptacle. The circular body mates with the collar thereby allowing fluid communication between the urine outlet piece and the collection receptacle while maintaining a temporary or permanent seal preventing fluid communication with an external environment.

[0011] In yet another exemplary embodiment, the present invention is a catheter assembly. The assembly includes an apertured body situated at a distal portion of the assembly grippable by the operator's hand, a receiving collar situated at a proximal portion of a collection receptacle grippable by the operator's other hand, and a catheter passing through the aperture of the apertured body in fluid communication with the receiving collar.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **Figure 1A** shows a side view of a catheter assembly with a mating stopper with an optional grippable arm at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0013] **Figure 1B** shows a side view of a catheter assembly with a mating stopper with snap protrusions at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0014] **Figure 2** shows a side view of a catheter assembly with mating releases separated by a spring at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0015] **Figure 3** shows a side view of a catheter assembly with a mating cap at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0016] **Figure 4** shows a side view of a catheter assembly with mating connectors at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0017] **Figure 5A** shows a side view of a catheter assembly with mating projections at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0018] **Figure 5B** shows a magnified side view of a catheter assembly with mating projections at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0019] **Figure 6** shows a side view of a catheter assembly with pressure or snap fit mating connectors at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0020] **Figure 7** shows a side view of a catheter assembly with a double pressure or snap fit mating connectors at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0021] **Figure 8** shows a perspective view of a disengaged catheter assembly with ribbed mating connectors at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

[0022] **Figure 9** shows a perspective view of an engaged catheter assembly with ribbed mating connectors at a distal portion of the catheter assembly according to an exemplary embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0023] The present invention provides for catheter and catheter assemblies with connection devices such that the catheter and catheter assemblies are readily attached to and detached from collection receptacles. In particular embodiments and examples presented herein, such catheters are described with respect to urinary catheterization but it must be noted that such connection devices according to the present invention are not limited to urinary catheters alone but may be applicable to any catheter and catheter assembly that could benefit from the use of such connection devices. Furthermore, the present invention allows for an efficient connection of a collection bag and an easier technique for collecting the drained fluid so as to decrease the time required for catheterization and increase the reliability and sterility of catheterization and associated procedures.

[0024] An exemplary embodiment of the present invention as used in catheter assembly **100** is shown in **Figure 1A**. Assembly **100** includes a mating stopper **130** situated at the distal end of the catheter assembly, a catheter **120**, a protective sheath **110**, a distal end **140**, a urine outlet **141**, a collection receptacle **150**, and a mating collar **160**. The mating stopper **130** may be composed of a conventional material commonly used in the catheter arts or more specifically, a rubber or plastic material, so that a substantially tight seal is maintained between the mating stopper **130** and the mating collar **160**. The

mating stopper **130** may be bound via any adhesive technique commonly used in the catheter arts so that it is stationary and unable to translate the length of the assembly **100**. The mating stopper **130** may be of a diameter slightly smaller than of the diameter of the receiving aperture **162** such that the receiving aperture **162** receives and mates with the mating stopper **130** establishing a tight, leak free seal. The diameter of the distal end **140** may be smaller than the diameter of the receiving aperture **162** such that during connection, the distal end **140** resides within the collection receptacle **150** under the mating collar **160**. Optionally, the mating stopper **130** and mating collar **160** may have a magnetic relationship with each other to either enhance the tight seal connection described above, or be a replacement for such a seal. Furthermore, all embodiments described herein may have a magnetic relationship between the mating ends of the distal end of the catheter assembly and the collar of the receptacle to enhance the reversible seal between the two ends.

[0025] The catheter **120** may be composed of a standard material commonly used in the catheter arts or it may be comprised of a hydrophilic material in order to further lubricate the catheter **120**. The protective sheath **110** may be attached to the catheter assembly at attachment site **131** at the distal terminus **111** of the protective sheath **110**. The protective sheath **110** can be attached at attachment site **131** by various adhesive methods known to one having ordinary skill in the catheter art as long as a contamination free seal is maintained. The protective sheath **110** may serve to maintain catheter sterility and provide a chamber for additional lubricant or aqueous solution for the catheter **120**. The attachment site **131** can be situated as shown in

Figure 1A bound to the stopper surface **135** or it can be situated just proximal to the stopper surface **135** or just distal to the stopper surface **135** on the under-side of the mating stopper **130**.

[0026] The proximal tip **121** of catheter **120** may be positioned within the stopper aperture **132** and may extend into the distal end **140** of the catheter assembly. The stopper aperture **132** may be of a diameter slightly larger than the diameter of catheter **120** so that the catheter **120** is able to be positioned as shown in **Figure 1A**. The catheter **120** may be surrounded and enveloped by the mating stopper **130** which keeps the catheter **120** stable and stationary.

[0027] During connection of the catheter assembly **100** to the collection receptacle **150**, the operator may grasp the protective sheath **110** at the distal terminus **111** just proximal to the mating stopper **130** such that the operator's hand or thumb may be butted up against the stopper surface **135** in order to guide the mating stopper **130** into the mating collar **160** of the collection receptacle **150**. With the other hand, the operator may grasp the collection receptacle **150** at the mating collar **160** or at the mating collar attachment site **163**. The operator may guide the distal end **140** and mating stopper **130** towards the receiving aperture **162** of the mating collar **160**. After the distal end **140** passes through the receiving aperture **162** and into the collection receptacle **150**, the operator continues to guide the mating stopper **130** into the receiving aperture **162** until the mating stopper **130** is tightly mated with the mating collar **160** providing a tight, leak free seal. To make this seal, the operator guides the mating stopper **130** into the receiving aperture **162** so that

the stopper surface **135** is at least flush with (*e.g.*, occupying the same horizontal plane) mating collar surface **161**.

[0028] The operator may continue to further guide the mating stopper **130** into the mating collar **160** if so desired but the operator may experience a stoppage point at which an optional grippable arm **133** prevents further guidance by acting as a backstop to further penetration into the receiving aperture **162**. This optional grippable arm **133** thus may serve to prevent the mating stopper **130** from penetrating too far into the receiving aperture **162** making it difficult to detach the mating stopper **130** from the mating collar **160**. Additionally, the optional grippable arm **133** may also serve as a grippable extension which can be used to further manipulate the catheter assembly **100** during attachment and detachment. The optional grippable arm **133** may be connected to the mating stopper **130** via attachment site **134** as shown in **Figure 1A**. The optional grippable arm **133** may be L-shaped as depicted in **Figure 1A** or it may assume any other shape such that it serves the functions as described above.

[0029] After the connection is made between the mating stopper **130** and the mating collar **160**, the drained fluid may flow through the catheter **120** into the distal end **140** out through the urine outlet **141**. The flow of the fluid may be contained and directed into the collection bag **150** since the distal end **140** is cylindrically shaped and the urine outlet **141** is situated within the collection bag **150** and past the mating collar **160**. After the fluid is collected in the collection receptacle **150**, the operator may grasp the optional grippable arm **133** and separate the mating stopper **130** from the mating collar **160** so as to expose the distal end **140** and urine outlet **141** to the external environment.

[0030] Another exemplary embodiment of the present invention incorporated into a catheter assembly **100** is shown in **Figure 1B.** Assembly **100** in **Figure 1B** includes labeled components possessing similar characteristics and parameters as the corresponding labeled components in **Figure 1A**. However, the assembly in **Figure 1B** includes snap wells **151** on the inside surface of mating collar **160**, and snap protrusions **187** on the outer surface of mating stopper **130**. These alternative structures may provide a tighter connection between the mating stopper **130** and the mating collar **160** so as to avoid undesired detachment or translation of the mating stopper **130**. The exemplary embodiment shown in **Figure 1B** may utilize both a physical mating technique (*e.g.*, between the snap protrusions **187** and the snap wells **151**) along with a frictional force technique (*e.g.*, the force observed between the outer surface of mating stopper **130** and the inner surface of mating collar **160** during connection and disconnection) in order to provide a tighter and more secure distal end connection for assembly **100**.

[0031] During connection, the user may grasp the distal terminus **111** of sheath **110** just proximal to attachment site **131** so that the user's hand is adjacent to or on the surface of the mating stopper **130**. With the other hand, the user may grasp the mating collar **160** near mating collar attachment site **163** in such a way as to avoid blocking the receiving aperture **162** while maintaining a stable and secure grip on the mating collar **160**. Then, the user may guide the mating stopper **130** with snap protrusions **187** into the receiving aperture **162** far enough so that the snap protrusions **187** reach the snap wells **151** and mate with them. As the mating stopper **130** is guided into the receiving aperture **162** and into the mating collar **160**, the user may

experience a frictional force opposed to the direction of force being applied by the user. This frictional force may be so strong as to provide a stable and guided introduction of the mating stopper **130** until the snap protrusions **187** reach and mate with the snap wells **151**, but the frictional force may not be so strong so as it to make it difficult and/or unduly burdensome to insert the mating collar **130** into the mating collar **160**. Also, the same frictional force may be observed in the opposite direction during disconnection and may serve to prevent premature disconnection, but it may not be so strong so as to make it difficult and/or unduly burdensome to detach the mating stopper **130** from the mating collar **160**. Thus, during disconnection, the user my exert enough force (*e.g.*, by pulling the mating stopper **130** apart from the mating collar **160**) so as to overcome the opposing frictional force which may be serving to secure the mating stopper **130** to the mating collar **160**.

[0032] In light of the parameters given above regarding the frictional force between the mating stopper **130** and the mating collar **160**, the mating stopper **130** may be of a slightly smaller diameter than the mating collar **160** so as to allow the mating stopper **130** to slide into the mating collar **160** until the snap protrusions **187** reach and mate with the snap wells **151**. The snap protrusions **187** may extend off of the surface of the mating stopper **130** as shown in **Figure 1B**. The mating stopper **130** and the mating collar **160** may be composed of any commonly used flexible material in the catheter arts such that it may function as specified above which may include but is not limited to red rubber or silicon.

[0033] Another exemplary embodiment of the present invention incorporated into a catheter assembly **200** is shown in **Figure 2**, and includes mating

releases **270** situated at the distal end of the catheter assembly, a spring **274**, a catheter **220**, a protective sheath **210**, a distal end **240**, a urine outlet **241**, a collection receptacle **250**, and a mating collar **260**. The mating releases **270** may be composed of a standard material commonly used in the catheter arts. The mating releases **270** may be C-shaped as depicted in **Figure 2** or they may be of any design provided that they abide by the limitations and serve the functions as described below.

[0034] The mating releases **270** have shorter ends **272** and longer ends **271**. The mating releases **270** are connected to each other by a spring **274**. The spring is attached to the mating releases **270** at spring attachments **275**. The spring **274** allows the operator to manipulate the mating releases **270** from a resting state in which the shorter ends **272** project off of the distal end **240** to an engaged state in which the shorter ends **272** are flush with the surface of the distal end **240**. The spring **274** may be of such elastic strength that the mating releases **270** appear as depicted in **Figure 2** in the resting form while at the same time the mating releases **270** experience an amount of resistance such that the operator does not have any difficulty in manipulating the mating releases **270** into their engaged form. During the operator's manipulation of the mating releases **270** for connecting the distal end **240** to the mating collar **260**, the longer ends **271** are grasped and pushed inside the distal end **240** as depicted in **Figure 2** in the direction of the arrows **276** such that the mating releases **270** approach the proximal tip **221**. The longer ends **271** are pushed into the distal end **240** far enough such that the shorter ends **272** are flush with the surface of the distal end **240**. The shorter ends **272** are shorter than the longer ends **271** since the shorter ends **272** only have to be long enough

to catch and mate with the underside of the mating collar **260** in the resting state thus providing a technique for binding the distal end **240** with a collection receptacle **250**. The longer ends **271** may be longer than the shorter ends **272** in order to make it easier for the operator to grasp and manipulate the longer ends **271**. After the operator lets go of the longer ends **271** of the mating releases **270** from an engaged state, the spring **274** may have enough resiliency such that the mating releases **270** resume their resting state as depicted in **Figure 2**.

[0035] Although no exact measurements are required for this exemplary embodiment of the present invention, the following parameters may be met: (1) the distance between the 2 mating releases in their engaged form is greater then the diameter of the catheter **220**; (2) the length of the shorter ends **272** is such that when the mating releases **270** are in a resting state the shorter ends **272** are long enough to extend past a mating collar attachment site **263**; and (3) the length of the mating releases **270** between the shorter ends **272** and the longer ends **271** is at least equal to the height of a mating collar **260** such that when distal end **240** is connected to a mating collar **260** the shorter ends **272** are situated on the underside of a mating collar **260** inside the collection receptacle **250** and the longer ends **271** are situated on top of a mating collar surface **261**.

[0036] During connection of catheter assembly **200** with a mating collar **260** the operator engages the long ends **271**, guides the distal end **240** into the receiving aperture **262** until the shorter ends **272** are situated underneath a mating collar **260** and inside a collection receptacle **250**, disengages the long ends **271** at which point the spring **274** transforms back into its resting state

as shown in **Figure 2** and the shorter ends **272** mate with the underside of a mating collar **260**. Thus, a connection is formed between distal end **240** and receiving collar **260**. During disconnection of the catheter assembly **200** with a mating collar **260** the operator engages the long ends **271,** guides the distal end **240** out of the receiving aperture **262** until the no part of urine outlet **241** is inside the receiving aperture **262**, and then disengages the long ends **271**.

[0037] The proximal tip **221** of catheter **220** may be situated distal to the shorter ends **272** as shown in **Figure 2** in order to avoid contamination of the drained fluid. The parameters for the other component pieces not mentioned for this exemplary embodiment are consistent with the corresponding component pieces disclosed above in the exemplary embodiment shown in **Figure 1** (*e.g.,* the diameter of distal end **240** is smaller than the diameter of receiving aperture **262**, attachment site **231** can be made by various adhesive methods known to one having ordinary skill in the catheter art as long as a contamination free seal is maintained, etc.).

[0038] Another exemplary embodiment of the present invention incorporated into a catheter assembly **300** is shown in **Figure 3**, and includes a mating cap **336** situated at the distal end of the catheter assembly, a catheter **320**, a protective sheath **310**, a distal end **340**, a urine outlet **341**, a collection receptacle **350**, and mating collar **360** with a raised ring **364**. The mating cap **336** may be bound to catheter assembly **300** by any adhesive method commonly used in the catheter arts. The mating cap **336** can be composed of any conventional material commonly used in the catheter arts as long as it can be pliable, and thus easily manipulated to mate with a raised ring **364** of the mating collar **360**. The mating cap **336** may be of a diameter equal to or

slightly larger than the diameter of the raised ring **364**. In this way the mating cap **336** can be guided over the mating collar **360** far enough such that the mating cap **336** mates with the raised ring **364**. Thus, during connection, the operator may grasp the cap surface **337** and snap the mating cap **336** over the raised ring **364**. Since the mating cap **336** may be subjected to strong external forces (*e.g.*, from the operator during connection), the mating cap **336** may be composed of a material capable of withstanding such forces and rebounding to form its original shape as depicted in **Figure 3**. The raised ring **364** may be situated in the same horizontal plane as the mating collar attachment site **363** or just above it (*e.g.*, towards the mating collar surface **361**. An optional grasping tab **338** may be situated on the mating cap **336** in order to provide an extra surface for the operator to grip during connection and disconnection of the mating cap **336** and the mating collar **360**.

[0039] During connection, the operator may grasp the cap surface **337**, guide the distal end **340** into the receiving aperture **362** until the mating cap **336** makes contact with the raised ring **364**. Upon contacting the raised ring **364**, the operator snaps the mating cap **336** over the raised ring **364** such that a tight leak-free seal is made between the mating cap **336** and the mating collar **360**. In the connected arrangement, the collar surface **361** makes contact with the underside of the cap surface **337** and the mating cap **336** occludes the portion of the mating collar **360** from just below the raised ring **364** to the collar surface **361**. During disconnection, the operator may grasp the optional grasping tab **338** in order to open up space between the raised ring **364** and the mating cap **336**. The operator then may pull the mating cap **336** back over the mating collar **360**.

[0040] The mating cap **336** may be bound via any adhesive method commonly used in the catheter arts so that it is stationary and unable to translate the length of the assembly **300**. The parameters for the other component pieces not mentioned for this exemplary embodiment are consistent with the corresponding component pieces disclosed above in the exemplary embodiment shown in **Figure 1** (*e.g.*, the diameter of distal end **340** is smaller than the diameter of receiving aperture **362**, attachment site **331** can be made by various adhesive methods known to one having ordinary skill in the catheter art as long as a contamination free seal is maintained, etc.).

[0041] Another exemplary embodiment of the present invention incorporated into a catheter assembly **400** is shown in **Figure 4**, and includes a mating piece **480** situated at the distal end of the catheter assembly with mating connectors **482**, a catheter **420**, a protective sheath **410**, a distal end **440**, a urine outlet **441**, a collection receptacle **450**, and a mating collar **460** with connection wells **465**. The mating piece **480** has attached to its surface mating connectors **482** at attachment points **484**. The mating connectors **482** can be composed of a conventional material commonly used in the catheter arts such that it can be pliable so the projections **483** of the mating connectors **482** can be pulled up and down without the mating connectors **482** breaking off of the mating piece **480**. The mating connectors **482** can be attached to the mating piece **480** at attachment points **484** via various adhesive methods known to one having ordinary skill in the catheter arts as long as the adhesion can withstand ordinary pulling and pushing forces. The mating connectors **482** may be L-shaped as depicted in **Figure 4** or they may be of any other

design provided that they serve the functions as described below. The mating piece **480** may be the same diameter as the mating collar **460**. Both the mating piece **480** and the mating collar **460** can be composed of any standard material commonly used in the catheter arts. The mating piece **480** may be bound via any adhesive method commonly used in the catheter arts so that it is stationary and unable to translate the length of the assembly **400**.

[0042] The connection wells **465** may be U-shaped indentations on the outside of the mating collar **460** as depicted in **Figure 4**. The connection wells **465** can be made by any cutting techniques known to one having ordinary skill in the catheter arts. They may function to receive the projections **483** of the mating connectors **482** during connection. The connection wells **465** may be deep enough to accept and mate with the projections such that once mated, the projections **483** are locked into the connection wells **465** and any translational or rotational movement of catheter assembly **400** is prevented.

[0043] During connection, the mating piece **480** may be grasped at the mating piece surface **481**, and the mating piece **480** may be guided towards the mating collar **460** such that the projections **483** slide over the mating collar **460** and mate with the connection wells **465** thus connecting the mating piece **480** with the mating collar **460**. The length of the mating connectors **482** may be such that when connected with the connection wells **465**, the underside of the mating piece **480** makes contact with and produces a tight, leak-free seal with the mating collar surface **461**. During disconnection, the operator may grasp any portion of the mating connectors **482** and pull them out of the connection wells **465** such that the projections **483** break a horizontal plane

covering the ridges of the connection wells **465** and the side portions of the mating collar **460**. Once at least one mating connector **482** is pulled out from the connection well **465**, the operator may grasp the mating piece surface **481** and tilt the catheter assembly **400** such that one of the mating connectors **482** is situated in front of the mating collar surface **461**. Then, the operator may tilt the catheter assembly in the opposite direction thereby freeing the mating piece **480** from the mating collar **460**. Finally, the operator may separate the catheter assembly **400** from the mating collar **460** by pulling the assembly out of the receiving aperture **462**.

[0044] The parameters for the other component pieces not mentioned for this exemplary embodiment are consistent with the corresponding component pieces disclosed above in the exemplary embodiment shown in **Figure 1** (*e.g.*, the diameter of distal end **440** is smaller than the diameter of receiving aperture **462**, attachment site **431** can be made by various adhesive methods known to one having ordinary skill in the catheter art as long as a contamination free seal is maintained, etc.).

[0045] Another exemplary embodiment of the present invention incorporated into a catheter assembly **500** is shown in **Figure 5A** and resembles, for example, a locking mechanism used to attach caps onto prescription drug containing bottles. The catheter assembly **500** includes a mating piece **580** situated at the distal end of the catheter assembly with mating projections **585**, a catheter **520**, a protective sheath **510**, a distal end **540**, a urine outlet **541**, a collection receptacle **550**, and a mating collar **560** with locking pieces **566**. The mating projections **585** on the mating piece **580** can be composed of a conventional material commonly used in the catheter arts such that the

mating projections **585** are rigid enough to avoid being broken off from their attachment points **586** on the mating piece **580** during the operator's manipulation of the catheter assembly **500**. The mating projections **585** may be situated on the mating piece **580** in a uniform arrangement such that when the underside of the mating piece surface **581** makes contact with the mating collar surface **561**, the mating **585** projections are dispersed among the locking pieces **566** as shown in **Figure 5B**. Thus, the mating projections **585** on the mating piece **580** along with the locking pieces **566** on the mating collar **560** may both be uniformly spaced apart such that when the mating piece **580** is brought into contact with the mating collar **560** during connection, the mating projections **585** are situated adjacent to the locking pieces **566** as shown in **Figure 5B**. The locking pieces **566** can be composed of a conventional material commonly used in the catheter arts such that the locking pieces are rigid enough to withstand an ordinary amount of friction and pressure. In particular, the tip **567** of the locking pieces **566** may be of such material and width that it does not break off during ordinary manipulation of catheter assembly **500**.

[0046] During connection, the operator grasps the mating piece surface **581** with one hand and guides the mating piece **580** toward the mating collar surface **561** held by the other hand. Thus, the mating piece **580** and the receiving collar **560** may be in physical contact as shown in **Figure 5B**. To complete the connection, the operator may push down on the mating piece surface **581** until the attachment point **586** is situated just below the tip **567** of the locking pieces **566**. While maintaining the same downward force upon the mating collar surface **561**, the operator then may rotate the mating piece **580**

in a clockwise direction such that attachment point **586** is situated just below the tip **567** and in same horizontal plane as the cavity **568** of the locking pieces **566**. This rotational clockwise movement is illustrated in **Figure 5B** by the arrows **569**. Then, the operator may release the grasp on the mating piece surface **581** thereby discontinuing the downward force upon the mating piece surface **581**. The mating projections **585** therefore rebound and slide into the cavity **568** of the locking pieces **566**. To disconnect the mating piece **580** from the receiving collar **560**, the operator applies enough downward force such that the attachment point **586** of the mating projections **585** is situated just below the tip **567** and is far enough out of the cavity **568** to enable counter-clockwise rotation of the mating piece **580**. The operator may rotate the mating piece **580** in a counter-clockwise direction while maintaining the downward force on the mating piece surface **581** such that the mating projections **585** are freed from the cavity **568** of the locking pieces **566**. The operator may then release the mating piece surface **581** thereby allowing the mating piece **580** to rebound to rebound and resume its original position as depicted in **Figure 5B**.

[0047] The cavity **568** may be of such a design such that it is able to receive the mating projections **585**, and in the locked position it is able to securely maintain and prevent movement of the mating projections **585** and hence the mating piece **580** in the absence of the operator's force. The mating collar surface **581** may be of a diameter slightly larger than the diameter of the receiving collar **560** and mating piece **580** such that a gripping top (not shown) is formed thereby enabling the operator to better manipulate the catheter assembly **500**. The diameter of the mating piece **580** may be of a

diameter slightly larger than the diameter of the mating collar **560** such that the mating piece **580** is able to make contact with and extend over the mating collar surface **561** far enough to allow the operator to manipulate the mating projections **585** to connect and disconnect the mating piece **580** with the mating collar **560** as described above. The diameter of the mating piece **580** may be of such a diameter so as to provide a seal between the mating collar **560** and mating piece **580** when the mating projections **585** are situated inside the cavity **568** of the locking pieces **566**.

[0048] Additionally, the inside of the mating piece **580** may contain an inner ring (not shown) made of a standard material commonly used in the catheter arts such that once connected to the mating collar surface **561**, it provides a seal between the mating collar **560** and the mating piece **580**. The inner ring may also be the source of the rebounding mechanism described above. In this embodiment, the inner ring may be of the same diameter as the mating collar **560** such that when in contact with the mating collar surface **561**, the inner ring provides a seal between the mating collar **560** and the mating piece **580**. The inner ring may be attached inside the mating piece **580** at its distal end just above the attachment site **586**. The mating piece **580** may be of a diameter larger than the diameter of the mating collar **560** and ring such that it is able to be connected to the mating collar **560** and locked in place by pushing down on the mating piece surface **581** while rotating the mating piece **580** in a clockwise direction so as to allow the mating projections **585** to enter the cavity **568** of the locking pieces **566**.

[0049] The parameters for the other component pieces not mentioned for this exemplary embodiment are consistent with the corresponding component

pieces disclosed above in the exemplary embodiment shown in **Figure 1** (*e.g.*, the diameter of distal end **540** is smaller than the diameter of receiving aperture **562**, attachment site **531** can be made by various adhesive methods known to one having ordinary skill in the catheter art as long as a contamination free seal is maintained, etc.).

[0050] **Figures 6** and **7** show various exemplary embodiments of the catheter assembly mating connectors. **Figure 6** shows a pressure or snap-fit connection wherein a mating portion of the urine collection bag **660** fits within a distal end **640** of the catheter **620**. The catheter assembly **600** includes a catheter **620**, a protective sheath **610**, a distal end **640**, a urine outlet **641**, a collection receptacle **650**, and a mating insert **660**. The distal end **640** has been adapted to receive the mating insert **660**. The sloping sides of the conically-shaped mating insert **660** can be pressure or snap-fit into the distal end **640**. The distal end **640** is inverse conically-shaped to receive mating insert **660**. Distal end **640** reversibly receives mating insert **660** to form a seal between distal end **640** and mating insert **660**.

[0051] During connection, the operator grasps the base of mating insert **663** with one hand and guides the mating insert **660** toward the distal end **640** held by the other hand. Once inserted, the operator applies pressure to the joint until the mating insert **660** forms a seal against the inner wall of distal end **640**. A snap fit mechanism may be used to snap and hold the pieces together.

[0052] Conversely, the mating portion of the urine collection bag **660** may be designed to accommodate the distal end **640**, rather than fit within it. The result would be the distal end **640** having the insert while mating insert **660**

would actually be a mating receiver, and the distal end **640** would form a seal against the inner wall of mating receiver **660**.

[0053] **Figure 7** shows an exemplary embodiment that utilizes an adaptor **790** to mate both ends of the accompanying components, namely the urine collection bag **750** and the catheter **720**. The catheter assembly **700** includes a catheter **720**, a protective sheath **710**, a distal end **740**, a urine outlet **741**, a collection receptacle **750**, a mating receiver **760** and an adapter **790**. A separator wall **792** positioned centrally on the adaptor **790** presents a maximum engagement length for the ends of the collection bag **750** and catheter **720** and also serves to provide a further seal when engaged. As shown in the figure, both the mating ends of the urine collection bag **760** and the distal end of the catheter **740** may be pressure or snap fit within the adaptor **790**. Conversely, the adaptor may be designed to pressure or snap fit within the ends of the bag **750** and catheter **720**.

[0054] **Figure 8** shows a more detailed view of disengagement of the bag **850** and the catheter **820**, respectively. The mechanism depicted in **Figure 8** is similar to that presented in **Figure 6** in that the male insert **860** and the distal end **840** are mated directly with each other without the use of an intermediary adaptor, as shown in **Figure 7**. In **Figure 8**, the male insert **860** is shown with ribs **862** on an exterior surface towards the male insert opening **861**. The mating ends of the bag **850** and the catheter **860** may be secured together with the aid of the ribbed male insert **860**. Sequential ribs **862** are positioned along the length of the male insert **860** to allow sequentially greater securing between the ends.

[0055] **Figure 9** shows a more detailed view of engagement of the bag **950** and the catheter **920**, respectively. The mechanism depicted in **Figure 9** is similar to that presented in **Figure 6** in that the male insert **960** and the distal end **940** are mated directly with each other without the use of an intermediary adaptor, as shown in **Figure 7**. The mating ends of the bag **950** and the catheter **960** are secured together as shown with the aid of the ribbed male insert **960**.

[0056] Such exemplary mating is shown to be done through pressure or snap mechanisms in these figures. However, other reversible mechanisms are also possible and within the scope of the present disclosure. In any mechanism, the force required to engage or disengage the two mating ends should be sufficient to maintain a seal to allow passage of fluid therethrough during engagement but not be so strong as to prevent the disengagement of the mating ends upon completion of fluid transfer. The materials used should also be flexible enough to allow for reasonable engagement and disengagement forces to be used. In mechanisms that do not require pressure or snap fit, a more rigid material may be used.

[0057] The foregoing disclosure of the exemplary embodiments of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be apparent to one of ordinary skill in the art in light of the above disclosure. The scope of the invention is to be defined only by the claims appended hereto, and by their equivalents.

[0058] Further, in describing representative embodiments of the present invention, the specification may have presented the method and/or process of the present invention as a particular sequence of steps. However, to the extent that the method or process does not rely on the particular order of steps set forth herein, the method or process should not be limited to the particular sequence of steps described. As one of ordinary skill in the art would appreciate, other sequences of steps may be possible. Therefore, the particular order of the steps set forth in the specification should not be construed as limitations on the claims. In addition, the claims directed to the method and/or process of the present invention should not be limited to the performance of their steps in the order written, and one skilled in the art can readily appreciate that the sequences may be varied and still remain within the spirit and scope of the present invention.

WHAT IS CLAIMED IS:

1. A connecting device for a catheter assembly, the device comprising:

a body situated at a distal portion of a catheter assembly; and

a collar, wherein the body mates with the collar thereby allowing fluid communication within the catheter assembly while maintaining a temporary or permanent seal preventing fluid communication with an external environment.

2. The device of claim 1, wherein a collection receptacle is attachable to the collar.

3. The device of claim 1, wherein the body is circular with a diameter slightly smaller than the diameter of the collar such that the body can be situated inside the collar.

4. The device of claim 1, wherein the body has attached to its surface a grippable arm.

5. The device of claim 1, wherein the body includes depressible releases which have a short end and a long end separated by a spring; wherein the short end and the long end are separated by a distance equal to the height of said collar.

6. The device of claim 5, wherein the spring is composed of a metallic or plastic material.

7. The device of claim 1, wherein the body is circular and is of a slightly larger diameter than the collar such that the body can be snapped over the collar.

8. The device of claim 7, wherein the collar includes a raised ring on its surface.

9. The device of claim 7, wherein the circular body has attached to its surface a grippable tab.

10. The device of claim 1, wherein the body includes extensions on its inner or outer surface which mate with receiving structures on the collar.

11. The device of claim 10, wherein the extensions are L-shaped and the receiving structures are indentations capable of securing the extensions when the extensions are inserted into the indentations.

12. The device of claim 10, wherein the extensions are rectangular and the receiving structures are upside-down U-shaped locking pieces capable of securing the rectangular extensions when the extensions are depressed below the locking pieces and rotated into a cavity of the locking pieces.

13. The device of claim 10, wherein the extensions are snap protrusions and the receiving structures are snap wells capable of securing the snap protrusions when the snap protrusions are mated with the snap wells.

14. The device of claim 1, wherein the body and the collar have a magnetic relationship with each other.

15. A connecting device for a catheter assembly, the device comprising:

a circular body situated at a distal portion of a catheter assembly on or proximal to a urine outlet piece; and

a collar situated at a proximal portion of a collection receptacle, wherein the circular body mates with the collar thereby allowing fluid communication between the urine outlet piece and the collection receptacle while maintaining a temporary or permanent seal preventing fluid communication with an external environment.

16. The device of claim 15, wherein the circular body is of a diameter slightly smaller than the diameter of the collar such that the circular body can be situated inside the collar.

17. The device of claim 15, wherein the circular body has attached to its surface a grippable arm.

18. The device of claim 15, wherein the circular body is of a slightly larger diameter than the collar such that said body can be snapped over the collar.

19. The device of claim 18, wherein the collar has attached to its surface a raised ring which mates with the circular body.

20. The device of claim 15, wherein the circular body includes extensions on its inner or outer surface which mate with receiving structures on the collar.

21. The device of claim 20, wherein the extensions are L-shaped and the receiving structures are indentations capable of securing the extensions when the extensions are inserted into the indentations.

22. The device of claim 20, wherein the extensions are rectangular and the receiving structures are upside-down U-shaped locking pieces capable of securing the rectangular extensions when the extensions are depressed below the locking pieces and rotated into a cavity of the locking pieces.

23. The device of claim 20, wherein the extensions are snap protrusions and the receiving structures are snap wells capable of securing

the snap protrusions when the snap protrusions are mated with the snap wells.

24. A catheter assembly, the assembly comprising:

an apertured body situated at a distal portion of the assembly grippable by the operator's hand;

a receiving collar situated at a proximal portion of a collection receptacle grippable by the operator's other hand; and

a catheter passing through the aperture of the apertured body in fluid communication with the receiving collar.

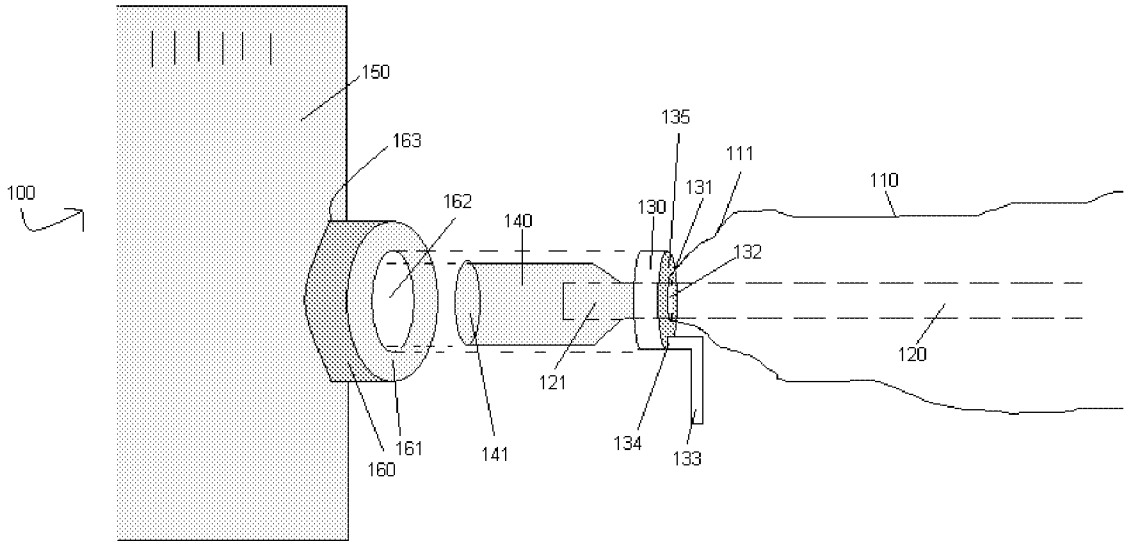

Figure 1A

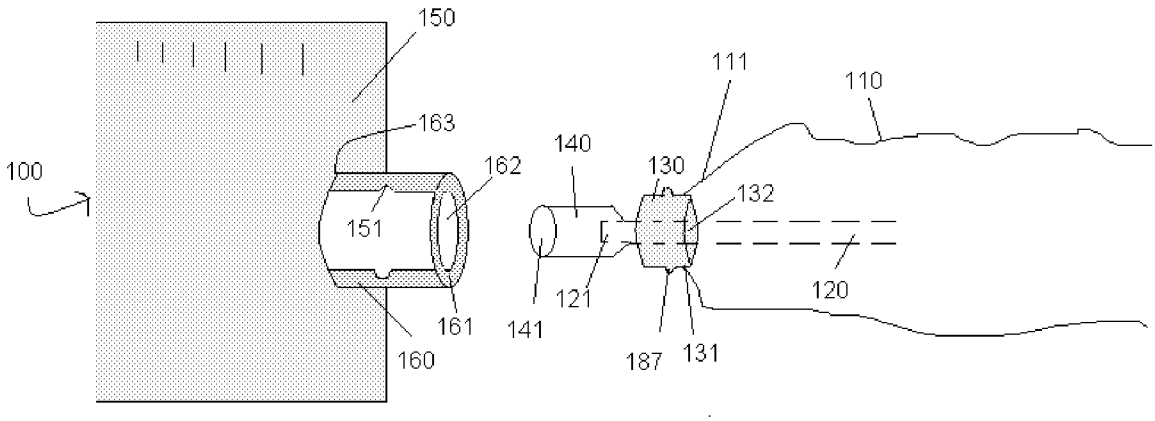

Figure 1B

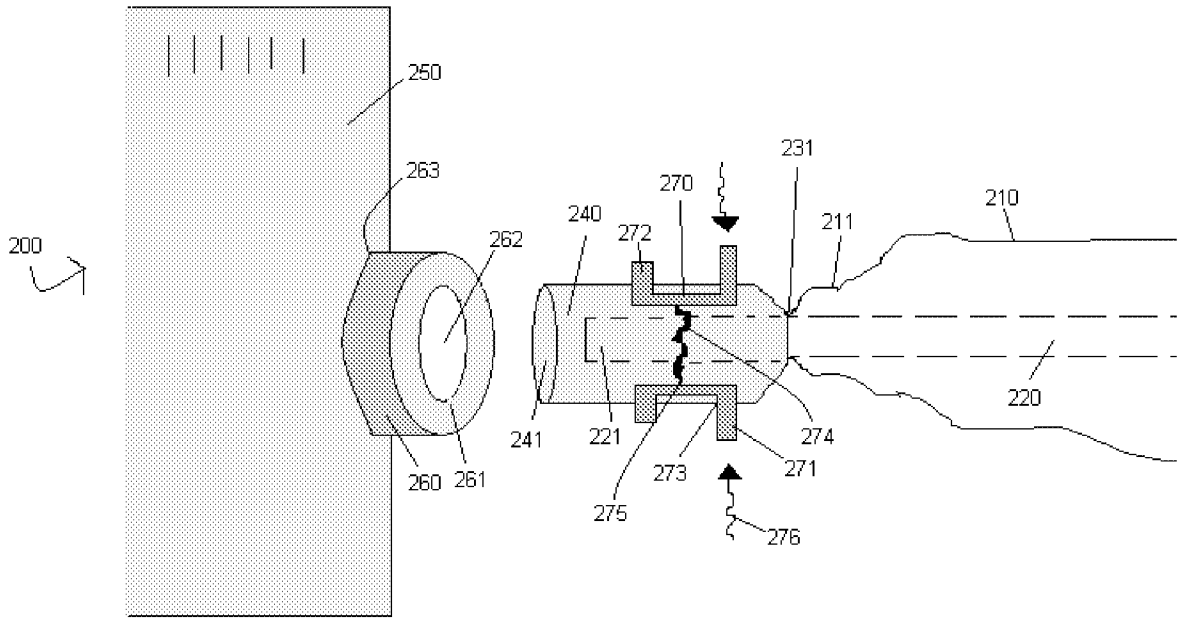

Figure 2

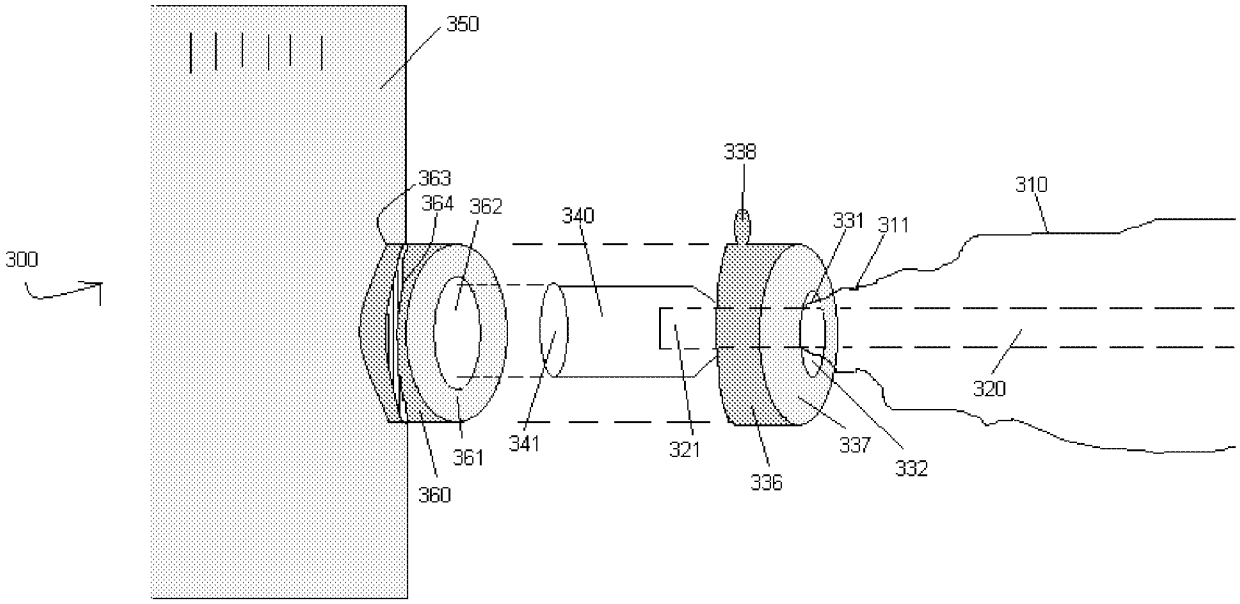

Figure 3

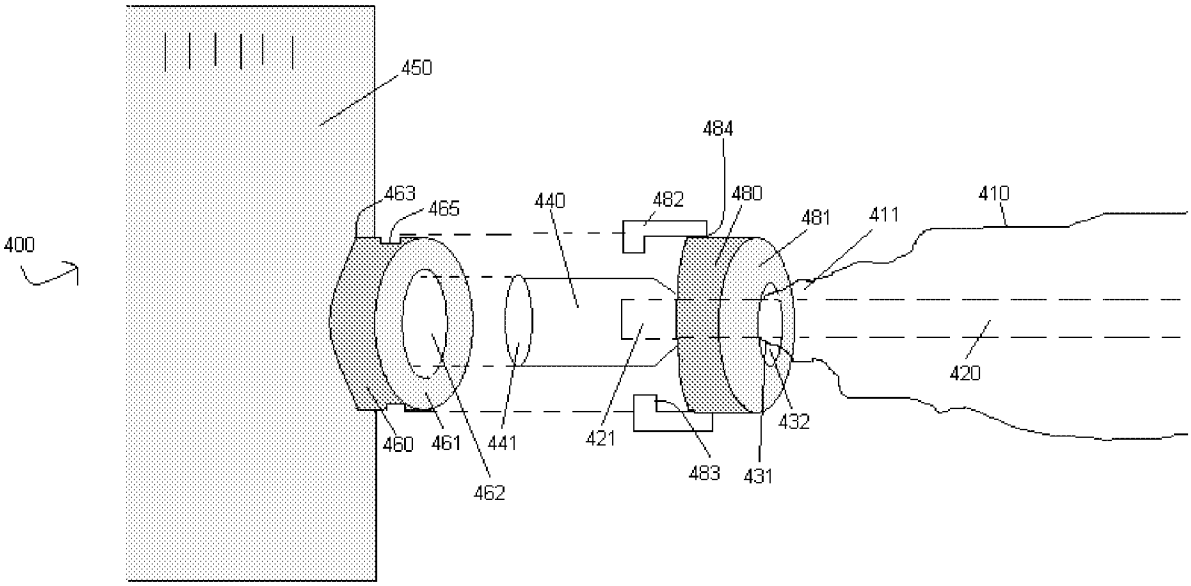

Figure 4

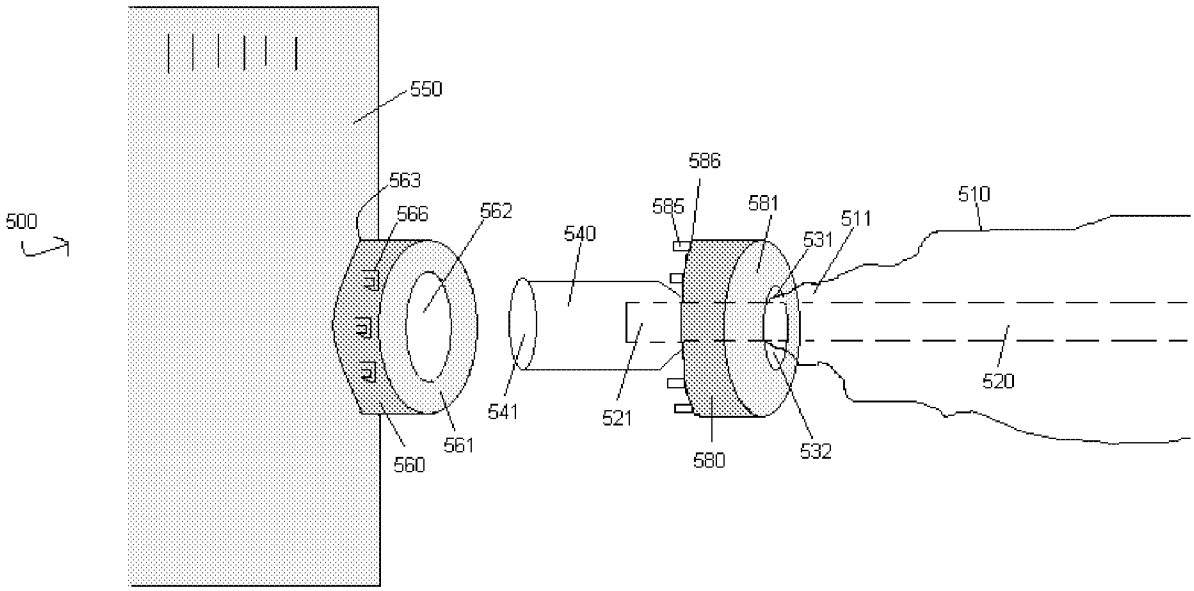

Figure 5A

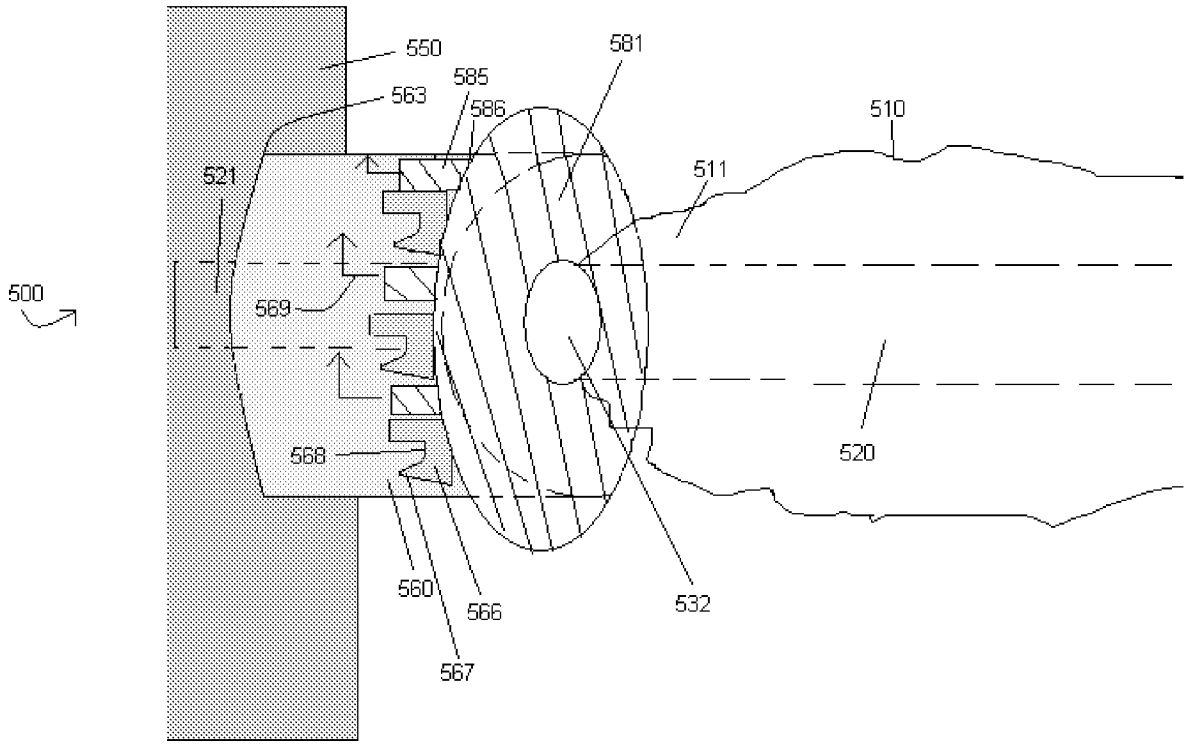

Figure 5B

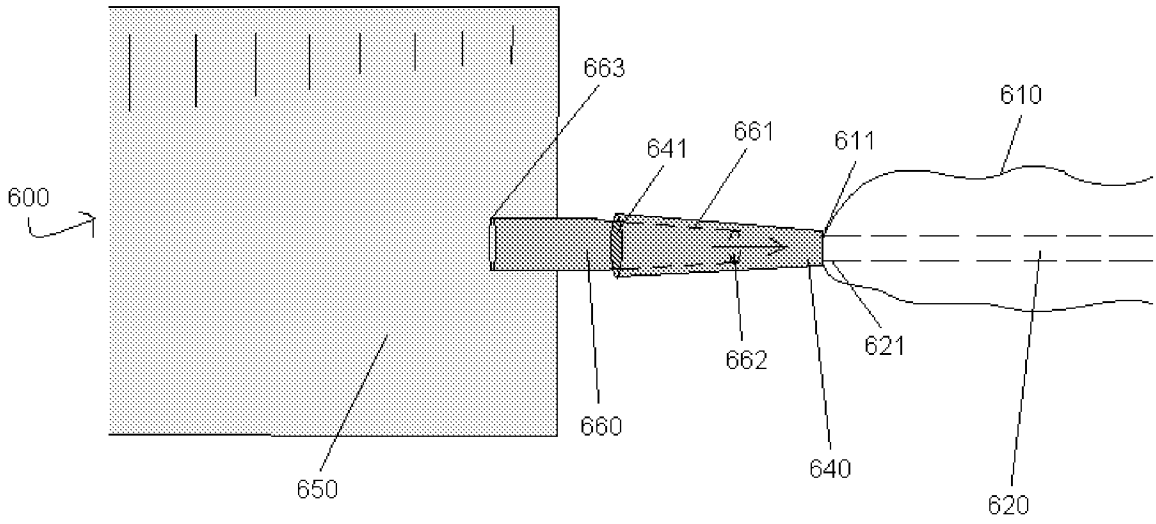

Figure 6

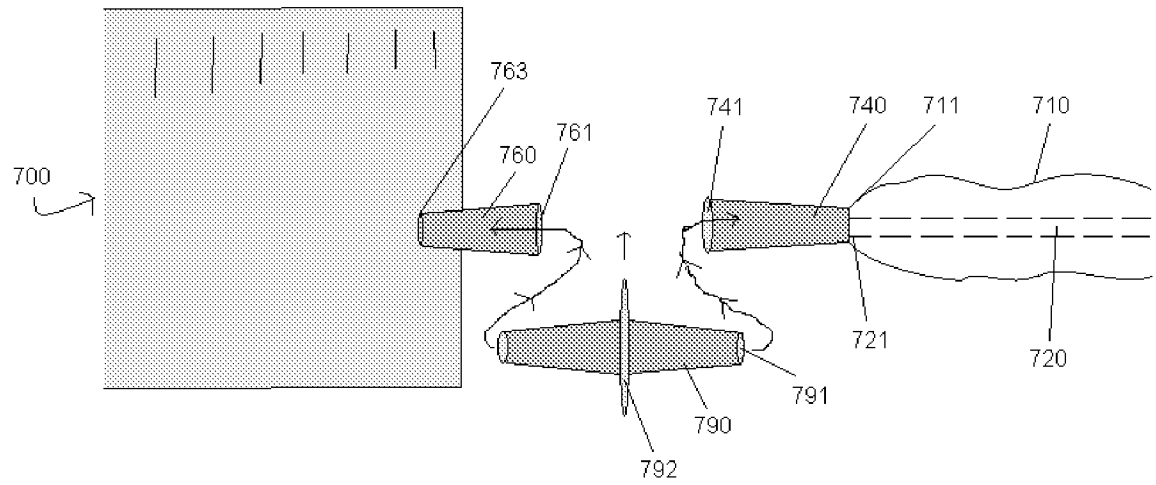

Figure 7

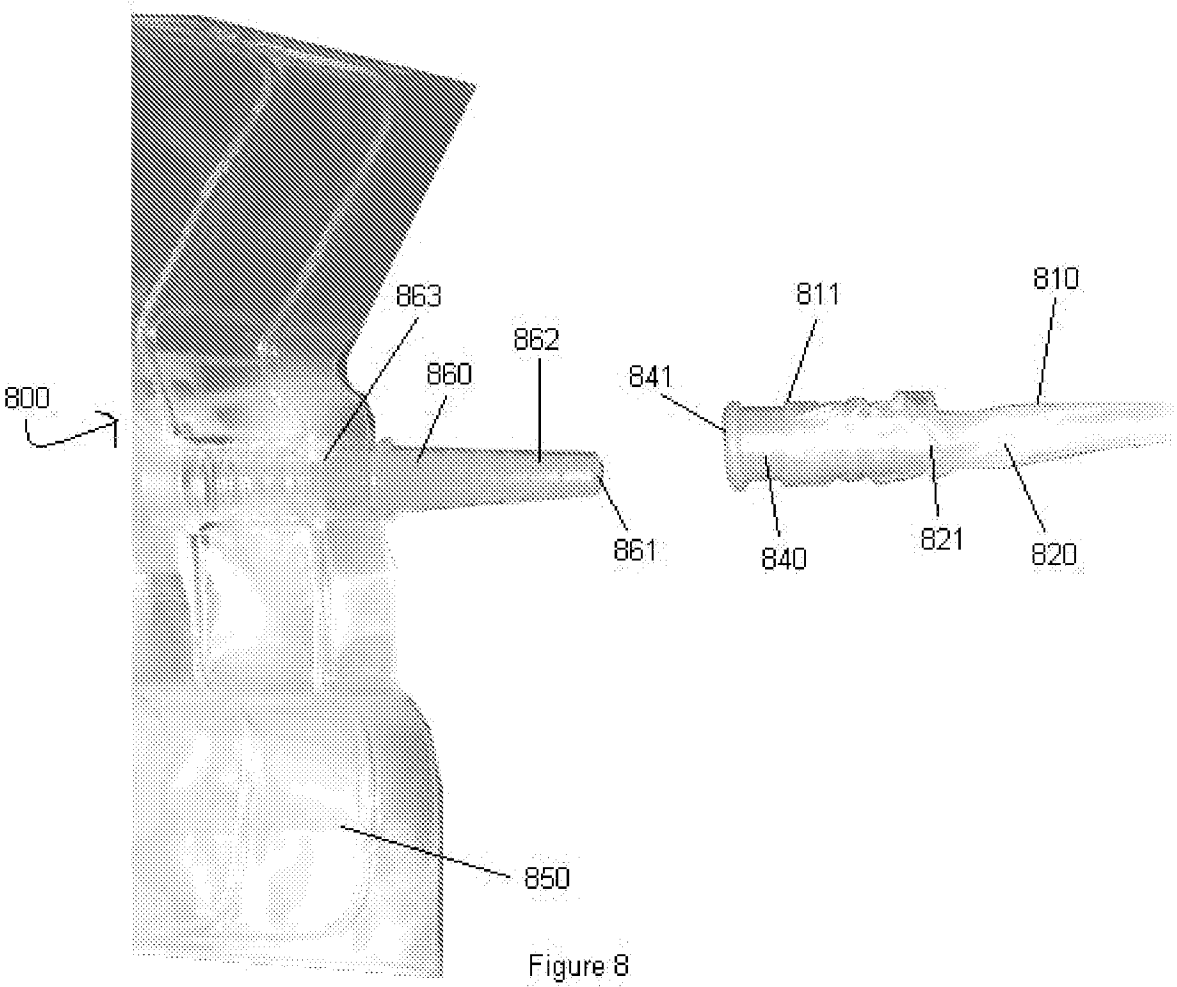

Figure 8

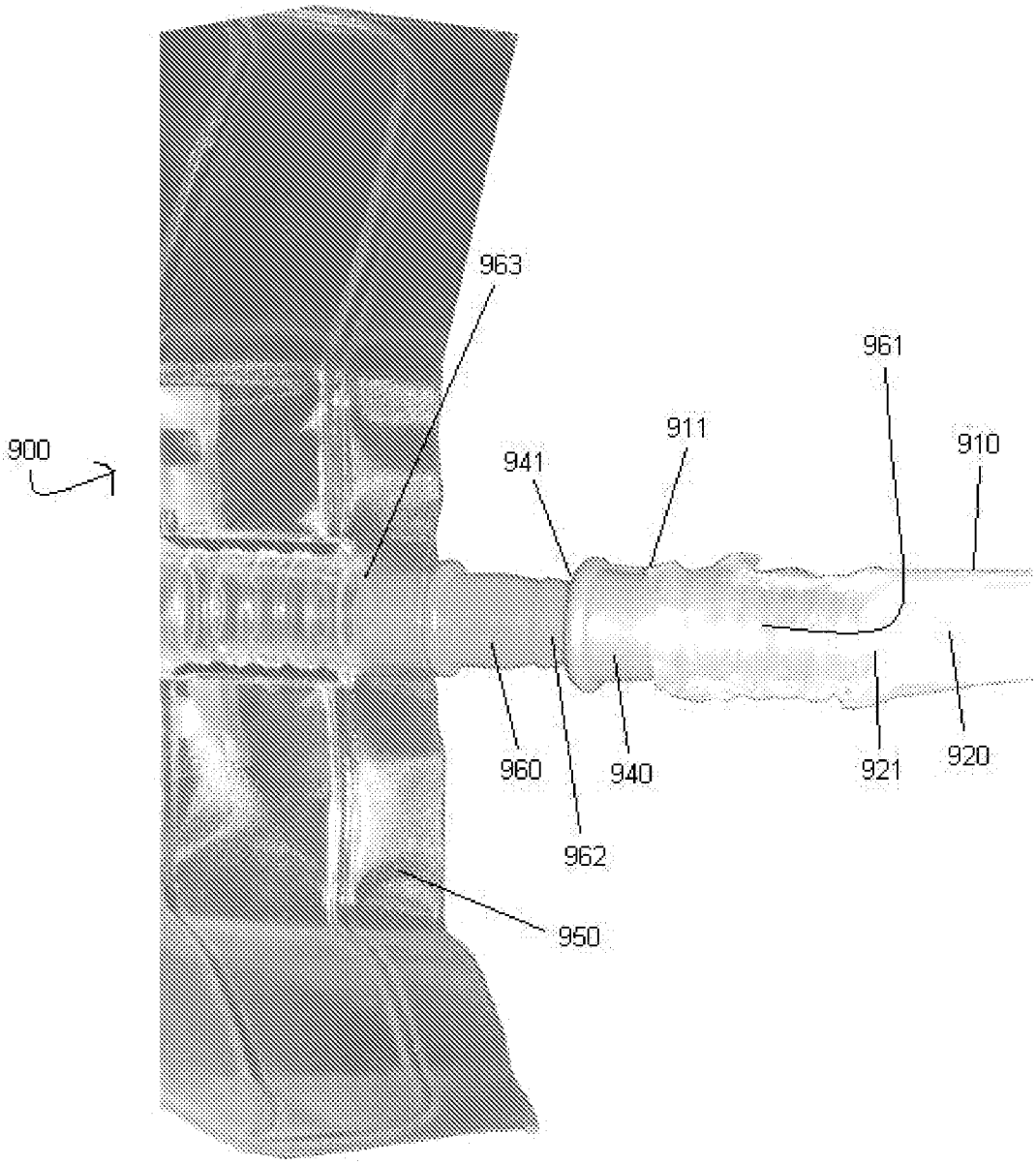

Figure 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/054253

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/00(2006.01)i, A61M 25/16(2006.01)i

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 8: A61M 25/00, A61M 1/00, A61M 27/00, F16L 37/08

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and Applications for Utility models since 1975
Japanese Utility models and Applications for Utility models since 1975

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKIPASS(KIPO internal)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 2005-038414 A (ICU Medical, Inc.) 17 February 2005 See abstract, figure 1 and paragraph [0029].	1-24
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A	US 2003-0018322 A (Tanghoj, Allan and Jensen, Lars Bogelund) 23 January 2003 See the whole document	1-24

☐ Further documents are listed in the continuation of Box C.

☒ 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
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"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
01 JULY 2008 (01.07.2008)	**01 JULY 2008 (01.07.2008)**

Name and mailing address of the ISA/KR
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Facsimile No. 82-42-472-7140

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CHANG, BONG HO
Telephone No. 82-42-481-8289

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