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(54) **Title:** COLLECTION DEVICES FOR CATHETER ASSEMBLIES

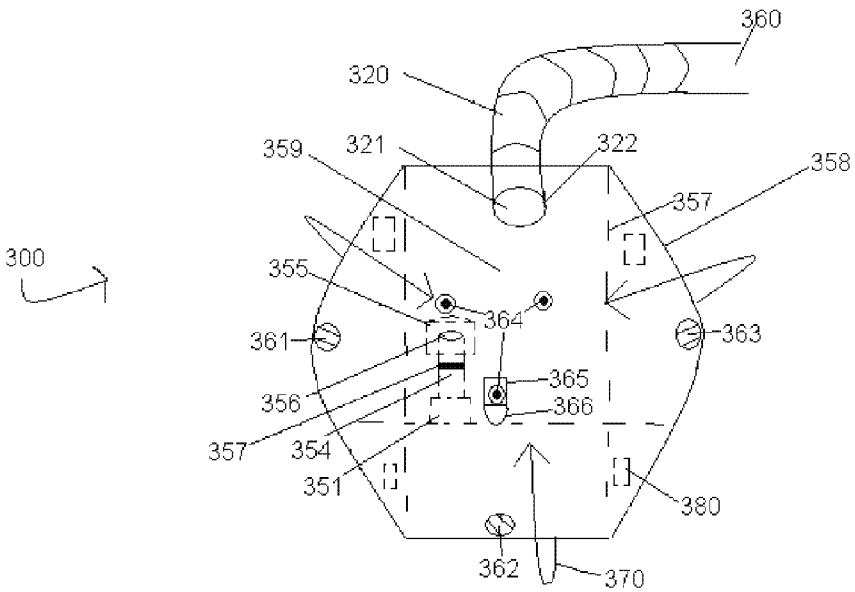


FIGURE 3A

(57) **Abstract:** A collection device for a catheter assembly is disclosed providing for an easier catheterization process and fluid collection with the device capable of being folded from a larger form into a smaller, more mobile form. The collection device may have attached to its top portion a connecting tube capable of being stretched and compressed, thereby allowing the user more flexibility and convenience while catheterized. Additionally, the collection device may contain antiseptic agents, fold lines, a drainage tube, fastening mechanisms, and leg strap holders in order to make the device more convenient to use.

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COLLECTION DEVICES FOR CATHETER ASSEMBLIES

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates generally to catheter assemblies. More particularly, the present invention relates to collection devices for catheter assemblies.

Background of the Invention

[0002] The urinary catheterization procedure is a common medical practice with the procedure being performed today in hospitals, nursing homes, and home settings. When a patient requires a catheter to remain in for a prolonged period of time, an indwelling or Foley catheter is often used. This type of catheter has the benefit of remaining in the bladder for up to one month which decreases the inconvenience of repeated intermittent catheterization. Indwelling urinary catheters are also used in situations where an accurate measurement of urine is required.

[0003] There has been a significant increase in highly resistant bacteria within institutions such as hospitals and nursing homes. Every attempt is being taken to decrease infection by destroying the bacteria. Until that is done, however, attempts must be made to decrease a patient's exposure to such potential harmful bacteria.

[0004] One common complication of indwelling catheters, as a result of infections often by bacteria, is a Urinary Tract Infection (UTI). There have been many attempts to decrease the incidents of urinary tract infections. A very common trend has been to supply the indwelling catheter pre-attached to

a large bedside collection bag. These bedside collection bags are usually of a standard size and can hold up to 2000 mL of urine. The indwelling urinary catheter comes connected to the bedside collection bag to create a "closed system" environment. By not switching from a 2000 mL bedside collection bag to a smaller 500-700 mL leg/day bag, it is hoped that urinary tract infection may be decreased. Every time a urine collection bag is removed from a Foley catheter distal end and replaced with another collection bag, the seal or closed system is broken, and the risk for infection is increased thereby putting the patient at risk.

[0005] Conventional urine collection bags have a drain port located somewhere on the bag. Several times throughout the day the nurse or caretaker is required to open the port and drain the urine into a container for discard. Many times in the hospital setting the patient must get out of bed and walk to the bathroom or shower, or the patient may get out of bed for therapy or exercise. This large 2000 mL bedside collection bag becomes a very significant hindrance to mobility and independence.

[0006] Because infection may arise during catheterization when a large collection bag is replaced by a smaller one and because it is inconvenient to have a large bag attached to a patient when the patient desires to get out of bed, there is a need in the healthcare industry for a sterile and convenient technique for facilitating the catheterization process and being able to effectively transition between a larger collection bag and a smaller leg/day bag.

SUMMARY OF THE INVENTION

[0007] The current techniques for catheterization are inefficient and inconvenient. Infection may arise when an original larger bag is detached, and a smaller leg bag is attached to a distal end of a catheter. The present invention addresses this healthcare problem by providing various devices and techniques to facilitate the catheterization process, and to simplify the transition between a larger collection bag and a smaller leg bag. More specifically, the present invention proposes a foldable collection receptacle with an accordion-like connecting tube, while the collection receptacle is capable of being manipulated between a larger and a smaller form without disconnecting the connecting tube from the collection receptacle.

[0008] In one exemplary embodiment, the present invention is a collection assembly. The assembly includes a collection receptacle; an accordion-like connecting tube attached to the top of the collection receptacle; a drainage port located at a bottom of the collection receptacle; a drainage tube; and a holder; wherein the drainage tube is in fluid communication with the drainage port such that the drainage tube can be manipulated in order to control flow of fluid out of the collection receptacle; and wherein the holder is positioned on the collection receptacle such that a tip of the drainage tube may be stored within the holder when no fluid is being drained from the collection receptacle.

[0009] In another exemplary embodiment, the present invention is a collection device. The device includes a collection receptacle with fold lines; a drainage port located at a bottom of the collection receptacle; and a holder attached to the collection receptacle; wherein the collection receptacle is initially a larger size which can be folded into a smaller size; wherein the drainage tube is in

fluid communication with the drainage port such that the drainage tube can be manipulated in order to control the flow of fluid out of the collection receptacle; and wherein the holder is positioned such that the tip of the drainage tube may be stored within the holder when no fluid is being drained from the collection receptacle.

[0010] In certain exemplary embodiments, an accordion-like connecting tube is also included, and is positioned in between the catheter and the collection receptacle. Such accordion-like property allows a long enough tube to reach a side of the bed and the ability to shorten when worn on the leg. Thus, this connecting tube can extend from a few inches, such as about four inches, to several feet, such as about two feet. Other lengths are also possible and within the scope of the present invention.

[0011] In certain exemplary embodiments, a clamp on the drainage port or tube, or a screw or other flow-arresting device, is included to prevent flow when such drainage port is not in use.

[0012] As used herein and throughout this disclosure, and in order to understand the directional aspects of this invention, "proximal" refers to the section of the device that is closer to the patient's body (*e.g.*, urethra) during catheterization while "distal" refers to the section of the device that is farther away from the patient's body during catheterization.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 shows a side view of a reversible catheter assembly which includes a collection receptacle with a drainage port and clamp according to the prior art.

[0014] Figure 2 shows a front view of a catheter assembly with a collection receptacle which possesses an accordion-like connecting tube, a drainage port, and a drainage tube with an optional clamp according to an exemplary embodiment of the present invention.

[0015] Figure 3A shows a front view of a catheter assembly with a foldable collection receptacle which possesses an accordion-like connecting tube, a drainage port, a drainage tube, and fasteners according to an exemplary embodiment of the present invention.

[0016] Figure 3B shows a rear view of the catheter assembly in Figure 3A but is in the smaller folded position according to an exemplary embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0017] The present invention provides for catheter and catheter assemblies with collection devices such that the operator may more easily transition between a larger collection receptacle and smaller collection receptacle thereby avoiding exposure to infection. In particular embodiments and examples presented herein, such catheters are described with respect to urinary catheterization but it must be noted that such collection 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 collection devices.

[0018] An example of a conventional catheter assembly is shown in Figure 1 as assembly **100**. Assembly **100** includes a collection receptacle **150**, a drainage port **151** with a drainage cover **152**, a mating collar **140**, a catheter

distal end **130**, a mating stopper **111**, a catheter **120**, and a sheath **110**. The collection receptacle **150** may be of any size such that it is be capable of storing a volume between 300 mL and 5 L of fluid. Other volumes are also possible. The collection receptacle **150** is rectangular in shape as shown in Figure 1 or it is any other shape including but not limited to a pouch, an oval, a square, or any other geometric shape that would maximize the volume capacity of the collection receptacle while minimizing the bulkiness of the collection receptacle. The collection receptacle **150** contains a drainage port **151** as shown in Figure 1.

[0019] The drainage port **151** is circular in shape or it is any other shape including but not limited to an oval, a square, or any other geometric shape that would allow for a desired rate of volume flow (*e.g.*, fast or slow) out of the collection receptacle **150** in order to either empty the collection receptacle fully or partially (*e.g.*, to obtain a urine sample). The drainage port **151** is of a size such that it allows for a desired rate of volume flow out of the collection receptacle **150** in order to either empty the collection receptacle fully or partially. The drainage port **151** is located at the distal end (the bottom) of the collection receptacle **150** as shown in Figure 1 such that it is in a position to efficiently and optimally drain the contents of the collection receptacle **150** when the receptacle is filled with urine.

[0020] Assembly **100** also includes a drainage cover **152** covering the drainage port **151**. The drainage cover **152** is of any shape as described above for the drainage port **151** as long as the drainage cover **152** is able to effectively occlude the drainage port **151** when the drainage cover **152** is closed (*e.g.*, mated with the drainage port) thereby preventing any leakage

out of the collection receptacle **150**. The drainage port **151** is attached to the collection receptacle **150** via any appropriate technique such that when the drainage cover **152** is open (*e.g.*, not mated with the drainage port **151**), the drainage cover remains attached to the collection receptacle thereby preventing the operator from misplacing or losing the drainage cover **152** and also allowing the operator to easily close the drainage cover after the desired amount of urine is drained from the collection receptacle **150**. The drainage cover **152** also possesses a grippable tab **153** that is used to open and close the drainage cover.

[0021] Before catheterization, the mating stopper **111** is mated with the mating collar **140** so that the catheter distal end **130** is situated within the collection receptacle **150**. In this way, the urine outlet **131** is positioned within the collection receptacle **150** before the urine is drained into the receptacle. The connection provided by the mating of the stopper and collar is strong enough to effectively resist undesired disconnection before, during, and after the desired amount of fluid is extracted from the patient. After the desired amount of fluid is extracted and/or the catheterization process is completed, the operator may exert sufficient force to disconnect the mating stopper **111** from the mating collar **140** thereby possibly separating the collection receptacle **150** from the catheter distal end **130**. The operator then places the collection receptacle **150** over a specimen bottle or a toilet, and then grasps the grippable tab **153** with one hand and removes the drainage cover **152** from the drainage port **151** thereby allowing the collected urine to flow out of the collection receptacle by way of gravity. Once the desired amount of drained fluid is released (*e.g.*, a sample size or the whole volume of

collected fluid) from the collection receptacle, the operator replaces the drainage cover **152** so that it mates with the drainage port **151**. To close the drainage cover **152**, the user mates the drainage cover **152** with the drainage port **151** (*e.g.*, including but not limited to snapping the cover into the port) firmly enough to provide a leak-free seal between the drainage cover and the port.

[0022] An exemplary embodiment of the present invention incorporated into a catheter assembly **200** is shown in Figure 2, and includes a collection receptacle **250**, a drainage port **251** with a drainage tube **254**, a clamp **257**, a holder **255**, and a connecting tube **220**. The collection receptacle **250** may be pouch shaped as shown in Figure 2 or it may be any shape including but not limited to a rectangle, oval, square, or any other geometric shape such that the volume capacity of the collection receptacle may be maximized while the bulkiness of the collection receptacle may be minimized. The collection receptacle **250** may be of any size or size range, including but not limited to between 300 mL and 5 L. The collection receptacle **250** may contain an antiseptic pellet (not shown) capable of maintaining an internal sterile environment for the collection receptacle. The antiseptic pellet may be a free pellet or it may be "cage" ball pellet capable of releasing its antiseptic agent in a time sensitive fashion. This "cage" ball may be capable of releasing the antiseptic agent constantly over a defined time period (*e.g.*, 1-2 months). Such a time-released pellet may keep the collection receptacle **250** and assembly **200** free of contamination.

[0023] The connecting tube **220** may act as a sterile fluid conduit by allowing a sterile passageway for fluid to drain into the collection receptacle **250** from a

catheter (not shown) connected at attachment site **260**. The connecting tube **220** may contain on its inner surface any antiseptic agent (not shown) capable of maintaining a sterile environment inside its surface and therefore inside assembly **200**. The antiseptic agent may effectively prevent contamination and subsequent patient infection arising from bacteria. The connecting tube **220** may be comprised of any suitable material such that the tube can act like an accordion and be capable of stretching to a length of approximately 4 feet and be capable of compressing to a length of approximately 1 foot or less when so manipulated. The material property that allows such flexibility in length for the connecting tube is similar to that of a bendable plastic straw. The longer length of the connecting tube may be suitably used when the collection receptacle is larger (*e.g.*, 2-5 L) thereby providing maximum length from the patient to the collection receptacle, and a maximum volume for fluid collection (*e.g.*, for when the patient is lying in bed). Alternatively, the shorter length of the connecting tube may be suitably used when the collection receptacle is smaller (*e.g.*, 300 mL) thereby providing a more manageable length from the patient to the collection receptacle, and a more convenient collection receptacle size (*e.g.*, for when the patient is mobile). The connecting tube **220** may be permanently attached to the urine inlet **221** at attachment site **222** via any suitable permanent attachment means known in the catheter art (e.g., heat sealing, clamping, etc.). In this way, a sterile environment may be maintained within catheter assembly **200**. The connecting tube **220** may also be attached permanently to a catheter (not shown) at the proximal end **260** of assembly **200** as described above.

[0024] The drainage port **251** may be situated as shown in Figure 2 at the bottom of the collection receptacle so as to maximize the usability and drainability of the collection receptacle. The drainage port **251** may be rectangular in shape as shown in Figure 2 or it may be any other shape such that the port can effectively and efficiently allow the passage of fluid out of the collection receptacle at a desired rate. Additionally, the drainage port **251** may be of any size. The drainage port **251** may also contain a drainage tube **254** which may effectively provide a conduit for the urine to drain out of the collection receptacle **250**. A base portion of the drainage tube **254** may be attached to and sealed with the drainage port **251** via any attachment method including, but not limited to, heat sealing in order to prevent leakage. The attachment method may allow the drainage tube **254** to be in fluid communication with the drainage port **251** such that the urine may flow out of the collection receptacle and into the drainage tube when the tube is removed from the holder **255** and pointed downward as shown by arrow **271**. The attachment method at urine inlet **221** between the collection receptacle and connecting tube and the attachment of the drainage tube **254** with the drainage port **251** may be such that during urine flow, no urine is able to leak through and thus a leak free seal may be maintained between at the urine inlet **221** and the drainage port **251**. An optional clamp **257** may also be present on the drainage tube **254** to further prevent premature fluid leakage and to allow the user more control over the urine flow. The clamp **257** may encompass the drainage tube **254** and may be comprised of any material and may be formed in any shape such that the clamp is capable of effectively allowing fluid to pass through the drainage tube when it is in an open position,

and then capable of occluding the drainage tube when it is in a closed position (e.g., not allowing fluid to pass).

[0025] At any point during the catheterization, the operator may remove the drainage tube **254** from within the holder **255** thereby exposing the drainage outlet **256**. The drainage tube may be pulled out of the holder **255** just prior to catheterization. The drainage tube **254** may be manipulated by the user to adjust the amount and flow rate of urine allowed to pass through the drainage tube **254**. In order to detach the drainage tube **254** from the holder **255** and therefore drain the collection receptacle **250**, the operator may grasp the drainage tube anywhere along its body and pull down as shown by arrow **271**. This motion may allow the user to bend the drainage tube **254** towards the ground to control urine flow.

[0026] For example, the operator may grasp the drainage tube **254** with one hand by forming a fist around the tube. After pulling down, the operator may rotate his or her wrist away from the collection receptacle to expose the drainage outlet **256**. By varying the magnitude of the twist, the operator may control the flow rate of urine out of the collection receptacle **250**. To stop the flow of urine out of the collection receptacle **250**, the operator may grasp the drainage tube as specified above and may manipulate the drainage tube **254** to an almost horizontal position (*e.g.*, parallel to the floor) or the user may engage the clamp **257**. The operator may then insert the drainage outlet **256** and proximal portion of the drainage tube **254** back into the holder **255**.

[0027] In order to achieve all of these functions and limitations, the collection receptacle **250** may be flexible and not easily broken or ripped, and the drainage tube **254** may also be flexible and capable of manipulation. The

holder **255** may also be flexible and may be attached to the collection receptacle **250** via any attachment means including but not limited to adhesion. The holder **255** may be attached to the collection receptacle at a location such that the drainage tube **254** is able to rest within the holder as shown in Figure 2. Thus, the distance between the holder **255** and the drainage port **251** must be roughly equivalent to the length of the drainage tube in order for the drainage tube **254** to rest within the holder **255** without any support from the operator.

[0028] Yet another exemplary embodiment of the present invention incorporated into a catheter assembly **300** is shown in Figure 3A, and includes an unfolded collection receptacle **358** with fold lines **357,** left fastener **361**, bottom fastener **362**, right fastener **363**, receiving bodies **364**, drainage port **351**, drainage tube **354**, holder **355**, connecting tube **320**, pull attachment **365**, and pull ring **366**. The unfolded collection receptacle **358** as shown in Figure 3A may be of any size such that it is capable of receiving and storing up to 5L of fluid. The receptacle may have fold lines **357** on its surface as shown in Figure 3A such that the unfolded collection receptacle **358** is capable of being folded (*e.g.*, reduced from a size capable of holding up to 5 L of fluid to a smaller size capable of holding less than 5 L of fluid). The fold lines **357** are shown as residing on the same side as the drainage port **351** and drainage tube **354** but this is not a limiting characteristic for this exemplary embodiment and they may be on the other side or on both sides of the collection receptacle. The fold lines **357** may be situated such that the operator is able to fold both sides of the receptacle along with the bottom of the receptacle in the direction shown by arrows **370** while avoiding interfering

with the integrity of the drainage port **351** and the drainage tube **354**. For example, the operator may fold the left side of the receptacle toward the middle of the front side of the receptacle such that the left fastener **361** is brought closer to approximately the center of the front side (*e.g.*, the side opposite the drainage port **351**and tube **354**) and is made to mate with the left receiving body **364**. Then, the operator may fold the right side of the receptacle toward the middle of the front side of the receptacle such that the right fastener **363** is brought closer to approximately the center of the front of the receptacle and is made to mate with the right receiving body **364**. Finally, the operator may fold the bottom of the receptacle toward the middle of the receptacle such that the bottom fastener **362** is brought closer to approximately the center of the front side of the receptacle and is made to mate with the bottom receiving body **364**. After all the fasteners are mated with the receiving bodies, the smaller, more mobile folded collection receptacle **390** is formed as shown in Figure 3B. The leg strap holders **380** may be on the same side as the drainage port **351** as shown in Figure 3A but they may be on the left, right, and bottom flaps of the collection receptacle. Thus, after the smaller collection receptacle is formed (e.g., the flaps are folded over), the leg strap holders **380** are now on the front side of the collection receptacle as shown in Figure 3B and do not interfere with the user's operation of the drainage port **351** and tube **354**. After the folded collection receptacle **390** is formed, the leg strap holders **380** are ready for the leg straps (not shown) to be attached. This sequence of steps as described above does not have to be strictly followed and the right side or the bottom may be folded first, for example.

[0029] The fasteners described above may consist of snapping protrusions that mate with receiving bodies **364** on the front side of the collection receptacle. Once mated, the fasteners and receiving bodies form the mated bodies **367**, **368**, and **369** as shown in Figure 3B. Alternatively, the fasteners may mate with each other. Such a snapping material for the fasteners may be composed of plastic but is not limited to such material. The fasteners may alternatively be composed of magnetic, hook and loop mechanism (such as VELCRO), or other materials that may be reversibly attached to the collection receptacle or to each other so long as the material is able to securely and reversibly bind to the surface of the collection receptacle or to each other. The adhesive force provided via the connection of the fasteners to each other or to the receptacle may be strong enough so as to avoid premature disconnection, but not so strong as to make it difficult for the operator to achieve the desired disconnection.

[0030] Alternatively, a mating plastic zipper-like locking mechanism may be used to seal off different chambers within the unfolded collection receptacle **358** by gently pressing down on the mating plastic zipper components strategically placed along folding lines **357** throughout the unfolded collection receptacle **358**. In such a manner, a user may choose one or more chambers within the unfolded collection receptacle **358** that may be used to collect urine. For example, a user may wish to seal off the two side chambers separated by the two vertical plastic zipper lines places at the folding lines **357**. In such a scenario, urine will only be collected in the center two chambers, center top chamber **359** and the chamber directly below it in the figure. A user may even wish to exclude the lower center chamber as well by pressing and locking the

zipper mechanism horizontally separating the center top chamber **359** and the center lower chamber. In one exemplary embodiment, a U-shaped continuous zipping mechanism may be used to separate one or more chambers.

[0031] With each closing off of a chamber within the collection receptacle, the volume able to receive and store urine is decreased, thus making smaller urine volume measurements easier and more accurate. A gradated visual measurement scale may also be included on the surface of the receptacle (not shown) so that the user may determine the exact volume of urine collected depending on which chambers are being used and which have been excluded by the plastic zipper locking mechanism. Such mechanism may be, for example, similar to one used conventionally in plastic sandwich bags. Because such plastic zipper locking mechanism is reversible, a user may choose to open up a sealed and excluded chamber to allow it to also be used to collect and house urine.

[0032] The center top chamber **359** may be opened and closed via pull ring **366**. The pull ring **366** may be attached to the center top chamber **359** via a pull attachment **365**. The pull ring **366** may be of any shape and configuration such that the user is able to grasp it and pull the sealed portion of the collection receptacle corresponding to the center top chamber **359** sufficiently to release the bound fold lines **357** (*e.g.*, bound in any manner as described above). In this way, the user is able to easily manipulate the size of the collection receptacle from small to large and vice versa. The user may form and undo formed chambers simply by pulling at the opposite sides of the

receptacle at the folding lines **357** which separate a used versus unused chamber, thereby allowing urine to flow into that chamber as well.

[0033] The folded embodiment of the present invention is shown in Figure 3B and is labeled as the folded collection receptacle **390**. The size of the folded collection receptacle **390** (*e.g.*, 300 mL to 1000 mL) may be smaller than the size of the unfolded collection receptacle **358** (*e.g.*, up to 5 L). The ability to convert the unfolded collection receptacle **358** into the folded collection receptacle **390** enables a patient to increase his or her mobility since a larger receptacle (*e.g.*, the unfolded collection receptacle **358**) is typically used for when the patient is in bed while a smaller, and more easily transportable receptacle (*e.g.*, the folded collection receptacle **390**) is typically used for when the patient is out of bed and walking around. Thus, this exemplary embodiment of the present invention may have particular advantages for the use of Foley catheters, or indwelling catheters, wherein the unfolded collection receptacle **358** may be used for the patient while he or she is in bed, and the receptacle can then be folded into the folded collection receptacle **390** if and when the patient desires to get out of bed but does not wish to disconnect the catheter or the collection receptacle.

[0034] In order to increase the convenience and portability of the folded collection receptacle **390**, the receptacle may contain leg strap holders **380** as shown in Figures 3A and 3B and as described above. These straps may be situated such that they do not interfere with the drainage port **351** and drainage tube **354** when the collection receptacle is in the folded form. In this way, the front side of the receptacle may be attached to the patient's leg while the back side of the receptacle, which contains the drainage port and tube,

may be available for the operator to manipulate. The drainage tube **354** may also be attached to the bottom of the receptacle when the receptacle is in the folded form as shown in Figure 3B. The leg strap holders **380** may be attached to the receptacle via any method commonly used and known to one of ordinary skill in the catheter arts (*e.g.*, heat sealing, adhesion, etc.) and the leg strap holders **380** may be made from the same material as the collection bag, or cloth material with VELCRO or rubber, for example, so that they may be reliably and reversibly secured around the leg of the patient.

[0035] The drainage port **351**, the drainage tube **354**, and the holder **355** may effectively serve the same functions and be capable of performing the same operations while being subject to the same parameters as described above in assembly **200** (*e.g.*, drainage port **351** may be use to empty the collection receptacle **350** using the drainage tube **354**, etc.). Additionally, the inner surface of the connecting tube **320** may be coated with an antiseptic agent as described above to prevent contamination. Also, the collection receptacles as described in assembly **300** (*e.g.*, both the unfolded and the folded collection receptacles) may contain an antiseptic pellet in order to maintain sterility as described. Finally, a catheter may be attached at attachment site **360** as described above.

[0036] All of the materials used for the present invention may be comprised of artificial or naturally occurring non-degradable biocompatible polymer or rubber compounds such that the materials used for the present invention serve the functions delineated in this application. Such compounds can include, but are not limited to, polyester based biocompatible polymers, nylon-based biocompatible polymers, latex based biocompatible polymers, Teflon,

polytetrafluoroethylene (PTFE) polymers, polyvinyl chloride (PVC) polymers, silicone polymers, polyurethane polymers, silicone polyurethane polymers, ethylene-vinyl acetate copolymers, polyethylene polymers, and thermoplastic polymers.

[0037] The manufacturing methods that can be employed for the present invention include, but are not limited to, conventional techniques used in the industry to produce similar function products, as apparent to one having ordinary skill in the art.

[0038] 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.

[0039] 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 fluid collection device, the device comprising:

a collection receptacle; wherein the collection receptacle is capable of being reversibly folded to form a smaller collection receptacle.

2. The collection device of claim 1, wherein the collection receptacle is capable of receiving and storing up to about 5 L of fluid.

3. The collection device of claim 1, wherein the smaller collection receptacle is capable of storing between 300 mL and 500 mL of fluid.

4. The collection device of claim 1, further comprising a connecting tube attached to an inlet of the collection receptacle wherein the connecting tube can be stretched to about 4 feet and compressed to about 4 inches.

5. The collection device of claim 1, further comprising an antiseptic coating on an inner surface of the collection receptacle to prevent contamination and maintain sterility.

6. The collection device of claim 1, further comprising an antiseptic pellet within the collection receptacle to maintain sterility.

7. The collection device of claim 1, further comprising a sealing mechanism used to form and maintain independent chambers.

8. The collection device of claim 7, wherein the sealing mechanism involves plastic zipper locking seals.

9. The collection device of claim 7, wherein one of the independent chambers has on its surface a pull ring by which the user can reversibly unseal the independent chamber from the rest of the collection receptacle.

10. The collection device of claim 1, further comprising fold lines wherein the fold lines allow the user to decrease the total size of the collection receptacle.

11. A fluid collection device, the device comprising:

a collection receptacle; and

a sealing mechanism; wherein the sealing mechanism is used to form and maintain independent chambers within the collection receptacle.

12. The fluid collection device of claim 11, wherein the collection receptacle possesses fold lines on its surface to allow the user to fold back the unused portions of the collection receptacle after the independent chambers are formed.

13. The fluid collection device of claim 11, wherein the collection receptacle contains fastening mechanisms on its surface to reversibly form a smaller collection receptacle defined by the boundaries of one of the independent chambers.

14. The fluid collection device of claim 11, further comprising an antiseptic pellet within the collection receptacle in order to prevent contamination and maintain sterility.

15. The fluid collection device of claim 11, further comprising a connecting tube attached to an inlet of the collection receptacle capable of being stretched up to about 4 feet and compressed to about 4 inches.

16. The fluid collection device of claim 15, wherein the connecting tube has an antiseptic coating on its inner surface to prevent contamination and maintain sterility.

17. A fluid collection device, the device comprising:

a collection receptacle containing an antiseptic pellet;

a sealing mechanism; and

fold lines on the surface of the collection receptacle;

wherein the collection receptacle can be folded along the fold lines to form a smaller collection receptacle defined by the boundaries formed by the sealing mechanism.

18. The fluid collection device of claim 17, further comprising a connecting tube attached to an inlet of the collection receptacle capable of being stretched and compressed to different lengths.

19. A fluid collection device, the device comprising:

a collection receptacle with an antiseptic pellet;

a sealing mechanism forming independent chambers;

fold lines on the surface of the collection receptacle;

a connecting tube coated with an antiseptic agent and attached to an inlet of the collection receptacle; and

a drainage tube in fluid communication with a drainage port at the bottom of the collection receptacle;

wherein the collection receptacle can be folded along the fold lines to form a smaller collection receptacle defined by the boundaries delineated by the sealing mechanism; and

wherein the drainage tube is in fluid communication with both the collection receptacle and the newly formed smaller collection receptacle.

20. The fluid collection device of claim 19, wherein the sealing mechanism is comprised of plastic zipper locking seals.

21. The fluid collection device of claim 19, further comprising a holder

wherein the drainage tube may placed when not in use.

22. The fluid collection device of claim 19, wherein the collection receptacle further contains leg strap holders in order to attach the receptacle to the patient's leg.

23. The fluid collection device of claim 19, wherein the size of the smaller collection receptacle is maintained via fasteners attached to the surface of the collection receptacle.

24. The fluid collection device of claim 19, wherein the fasteners are composed of plastic, VELCRO, or magnets.

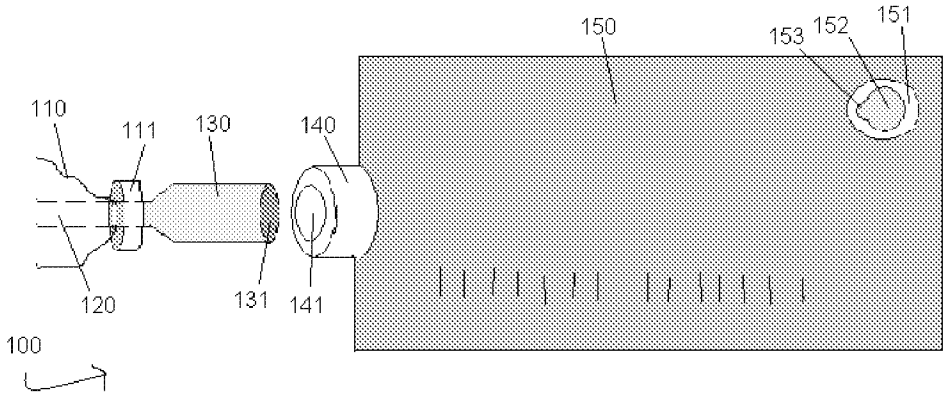


FIGURE 1 (PRIOR ART)

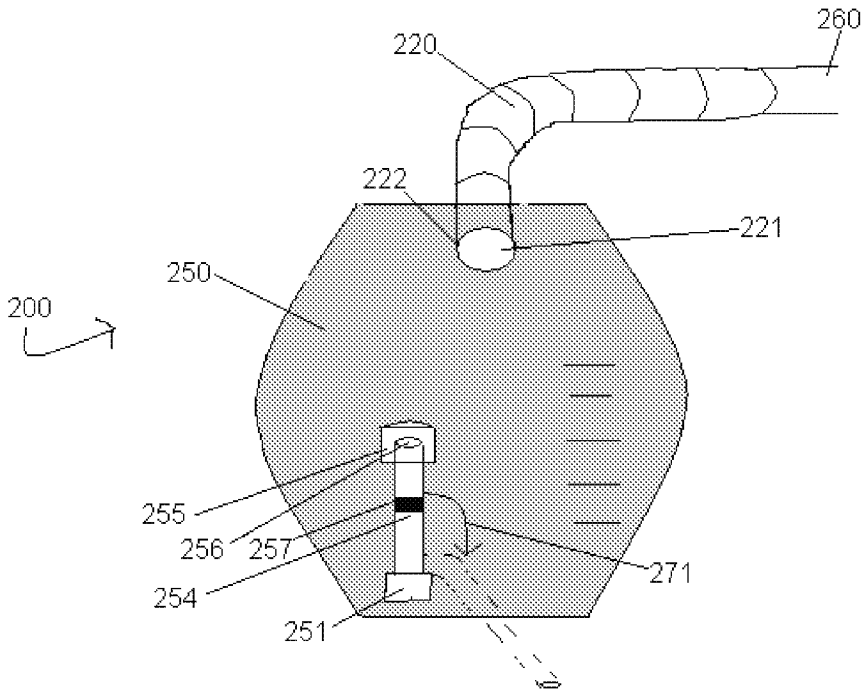


FIGURE 2

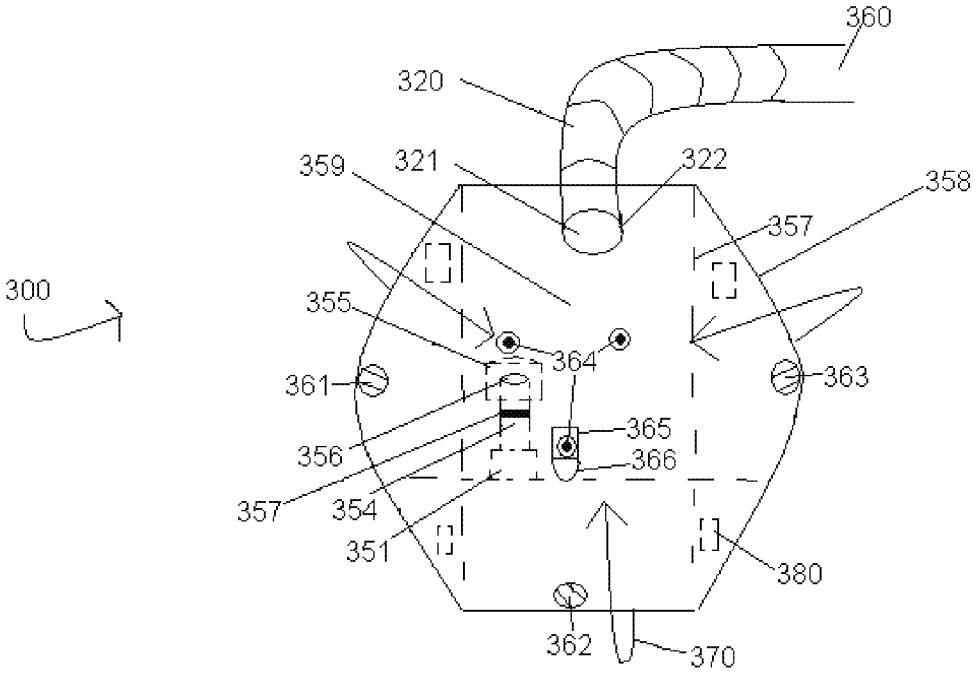


FIGURE 3A

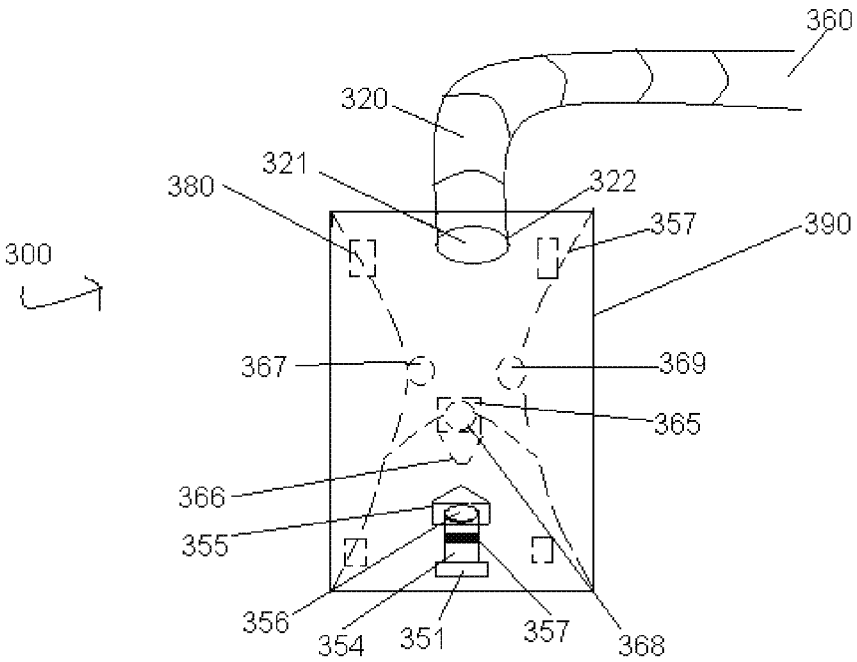


FIGURE 3B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/050890

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/00(2006.01)i, A61M 25/02(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

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

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

eKIPASS, WPI, USPTO, PAJ "catheter, collection device, receptacle, sealing, chamber etc."

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,725,515 A (DONALD J. PROPP, US) 10 Mar. 1998 See the whole document	1-24
A	US 5,147,341 A (RICHARD N. STARKE; RAYMOND G. BIGLER, US) 15 Sep. 1992 See the whole document	1-24
A	US 5,087,251 A (ARNOLD M. HEYMAN et al., US) 11 Feb. 1992 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

"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 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
18 JUNE 2008 (18.06.2008)	**18 JUNE 2008 (18.06.2008)**

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
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Facsimile No. 82-42-472-7140

Authorized officer

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Telephone No. 82-42-481-8150

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/050890

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I, claims 1-10 and 17-24, drawn to a fluid collection device comprising a collection receptacle wherein the collection receptacle can be folded to a smaller collection receptacle.

Group II, claims 11-16, drawn to a fluid collection device comprising a sealing mechanism wherein the sealing mechanism is used to form and maintain independent chambers with a collection receptacle.

The inventions listed as Group I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they are discrete inventions with distinct field of search.

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/050890

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5,725,515 A	10.03.1998	None	
US 5,147,341 A	15.09.1992	WO 9406377 A1	31.03.1994
		EP 0613356 A1	07.09.1994
		CA 2126107 C	03.07.2007
		AU 2586492 A1	12.04.1994
		AU 0666129 B2	01.02.1996
US 5,087,251 A	11.02.1992	None	