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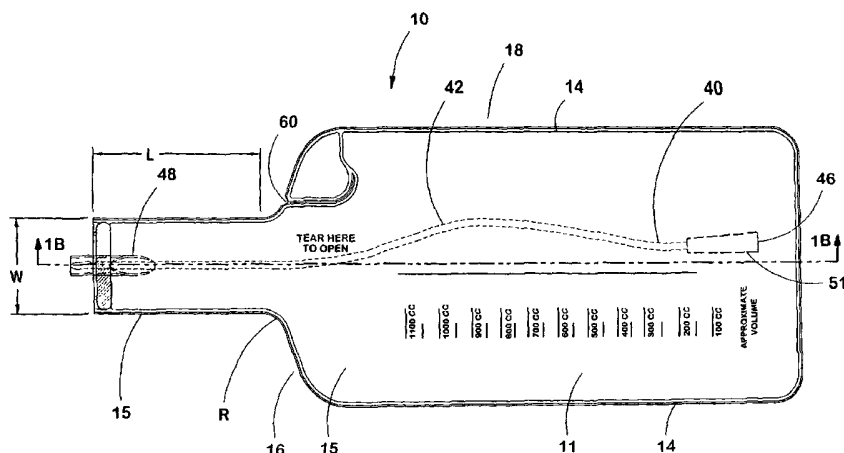
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(54) Title: URINE COLLECTION BAGS FOR URINARY CATHETER SYSTEMS



(57) Abstract: Urine collection bags are provided that include features that facilitate easy insertion of a urinary catheter into a patient's bladder. In some implementations, the urine collection bag is formed of a soft, flexible material that is comfortable when it contacts the user's skin, easy to manipulate, and relatively noiseless during use.

URINE COLLECTION BAGS FOR URINARY CATHETER SYSTEMS

TECHNICAL FIELD

This invention relates to urine collection bags for urinary catheter systems.

BACKGROUND

Urinary catheter systems generally include a long, thin, flexible tube (the urinary catheter) that is inserted into the urethra, past the trigone muscle and into the bladder to withdraw urine from the bladder. Urine flows through the catheter and is collected, e.g., in a urine collection bag. Once urine flow stops, or if the bag is filled, the catheter is removed from the bladder. The catheter is generally lubricated to facilitate insertion. In a closed catheter system, the lubricated catheter is supplied inside the urine collection bag with a urethral introducer tip to prevent human contact/contamination of the catheter as it is inserted into the urethra. The introducer tip is inserted into the patient's urethra, and the catheter is advanced out of the bag by sliding the catheter through the bag using the following procedure. Following insertion of the introducer tip, the user stabilizes the introducer tip with the user's non-dominant hand (i.e., the left hand if the user is right-handed). Next, using his dominant hand, the user holds the catheter through the bag, with his thumb and index finger, just behind the introducer tip, and advances the catheter slowly into the urethra. The catheter is advanced by the user pinching the catheter with his non-dominant hand, while using his dominant hand to retract the bag without retracting the catheter out of the urethra. The user then reduces the finger pressure applied by the non-dominant hand, and repeats the preceding step a number of times until the catheter has been advanced into the bladder and urine is flowing into the bag.

There is a tendency, during this procedure, for the catheter to slip back into the bag as the user is trying to advance it, causing the user discomfort and frustration. This is in part due to the difficulty of gripping the lubricated catheter through the bag material. Many users of urinary catheters have compromised finger strength, due to spinal cord injuries, which only exacerbates the gripping problem. Also, if the bag is formed of

certain materials, moving the bag in this manner may cause a “crinkling” noise that may be embarrassing to the user if the catheter is being used in a public restroom.

SUMMARY

5 The present invention provides a urine collection bag that includes features that facilitate easy insertion of a urinary catheter into a patient’s bladder. In some implementations, the urine collection bag is formed of a soft, flexible material that is comfortable when it contacts the user’s skin, easy to manipulate, and relatively noiseless during use. Thus, the urine collection bag can be used with a minimum of discomfort, and can be used discreetly in public restrooms. In some implementations, the urine
10 collection bag is formed of a material that includes a surface texture that will allow the user to more easily grip the catheter through the bag material. In some implementations, the bag has an elongated neck and smoothly rounded shoulders, to improve user comfort by reducing chafing of the bag against the user’s legs, and eliminating sharp corners that could jab a user.

15 In one aspect, the invention features a urine collection bag for use in a urinary catheter system, including opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, at least one portion including a surface texture having a depth sufficient to increase the flexibility of the plastic sheet material relative to an otherwise identical plastic sheet material without
20 the surface texture.

Implementations of this aspect of the invention may include one or more of the following features. The surface texture can be provided on at least one (e.g., one or both) of the opposed surfaces of the portions. The depth of the surface texture can be selected to provide the plastic sheet material with a hardness of less than about 85 Shore A. The
25 minimum depth of the surface texture can be at least about 25% of the thickness of the plastic sheet material (e.g., from about 25% to 75% of the thickness of the plastic sheet material, or from about 40% to 60% of the thickness of the plastic sheet material). The plastic sheet material can include polyvinyl chloride. The plastic sheet material can have an overall thickness of from about 5 to 10 mils. The surface texture can provide the sheet

material with a hardness of from about 60 to 85 Shore A. The surface texture may be provided on one or both of the portions.

In another aspect, the invention features a urine collection bag for use in a urinary catheter system, including opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed bag, a surface texture being disposed on at least one of the opposed surfaces of the portions.

In some implementations of this aspect of the invention, the plastic sheet material can include polyethylene. The surface texture can be constructed to increase the friction between the opposed surfaces of the portions and a catheter during gripping of the catheter by a patient, relative to the friction exerted by opposed portions of an otherwise identical plastic sheet material without the surface texture. The surface texture may be provided on one or both of the opposed surfaces.

In a further aspect, the invention features a urine collection bag for use in a urinary catheter system including a catheter having an introducer tip for introduction of the catheter into the urethra. The urine collection bag can include opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, the receptacle having an open end through which the catheter can be advanced into the urethra, and, joined to the receptacle at the open end, a braking interface tube constructed to receive and guide the introducer tip, the braking interface tube having a beveled leading edge.

Implementations of this aspect of the invention may include one or more of the following features. The leading edge can be inclined at an angle of from about 15 to 45 degrees. Facing surfaces of the opposed portions of plastic sheet material can include a surface texture. The surface texture can be provided on one or both of the facing surfaces. The braking interface tube can be formed from a polymer selected from the group consisting of polyvinyl chloride, polyurethanes and silicones. The braking interface tube can be formed of a material having a hardness of from about 40 to 80 Shore A. The beveled leading edge can define an open area, and the braking interface tube can be dimensioned and positioned so as to allow a user to place his thumb against a first one of the opposed portions, over the open area, and his index finger on the opposite one of the opposed portions, approximately aligned with the thumb, so that the thumb presses

the first opposed portion directly against the catheter tube, while the index finger presses the opposite opposed portion against a lower surface of the braking interface tube, which in turn presses against the catheter tube. The open area can be substantially elliptical.

In yet another aspect, the invention features a urine collection bag for use in a urinary catheter system including a catheter having an introducer tip for introduction of the catheter into the urethra, the urine collection bag including (a) opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, the receptacle having an open end through which the catheter can be advanced into the urethra; and (b) joined to the receptacle at the open end, a braking interface tube constructed to receive and guide the introducer tip, the braking interface tube being formed of a material having a hardness of from about 40 to 70 Shore A. In some implementations of this aspect of the invention, the braking interface tube is formed of polyvinyl chloride.

The invention also features a urine collection bag for use in a urinary catheter system, including opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, the plastic sheet material being a noiseless material, i.e., a material that makes substantially no audible crinkling noise when the urine collection bag is manipulated during ordinary use.

In another aspect, the invention features a urine collection bag for use in a urinary catheter system, including opposed portions of a polyvinyl chloride plastic sheet material having a thickness of from about 5 to 10 mils, the opposed portions being sealed together around a peripheral edge to define a substantially closed receptacle.

In a further aspect, the invention features a urine collection bag for use in a urinary catheter system, including opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed, substantially bottle-shaped receptacle.

Implementations of this aspect of the invention may include one or more of the following features. The receptacle can include an elongated neck region, having a width of less than about 50 mm. The receptacle can include curved shoulders. The shoulders can have a radius of curvature of from about 0.25 to 1.03 degrees. The receptacle can have a total volume of at least 1000 cc.

The invention also features a urine collection bag for use in a urinary catheter system, including (a) opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, at least one portion including a surface texture having a depth sufficient to increase the flexibility of the plastic sheet material relative to an otherwise identical plastic sheet material without the surface texture, the surface texture being disposed on an interior surface of the receptacle; and (b) an interface tube having a beveled opening constructed to allow a user to apply pressure with an index finger or thumb from an exterior surface of the receptacle and thereby press the surface texture against a urinary catheter disposed within the receptacle to hold the catheter in place while manipulating the sheet material to advance the catheter out of the receptacle.

In some implementations of this aspect of the invention, the sheet material can be a noiseless material, e.g., polyvinyl chloride. The surface texture can be constructed to provide pockets for receiving lubricant. The surface texture can be provided on one or both portions.

In still another aspect, the invention features a urine collection bag for use in a urinary catheter system, including opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, wherein at least one of the portions includes a raised surface texture.

In some implementations of this aspect of the invention, one of the opposed portions may not include said raised surface texture. The portion including the raised surface texture can include a transparent region that does not include the raised surface texture. The transparent region can define a lengthwise stripe or a horizontal stripe.

In another aspect, the invention features a urine collection bag for use in a urinary catheter system, including a reservoir region for containing urine; extending from the reservoir region, an elongated neck region having an end through which a catheter can be introduced into a user's urethra; and extending from a side portion of the neck region, a tear tab constructed so that pulling the tear tab outwardly from the neck region exposes a pour opening through which urine can be drained from the urine collection bag.

In some implementations of this aspect of the invention, the tear tab can include an opening through which the user can insert a finger to pull the tear tab. The tear tab can

include protrusions that facilitate gripping of the tear tab by the user. The tear tab can be configured to be pulled toward the end of the elongated neck region. The urine collection bag can further include a catheter sealed to the bag at the end. The urine collection bag can further include a notched region between the tear tab and the side portion, wherein the notched region is configured to initiate tearing of the tear tab. The urine collection bag of claim 43 further comprising a tab at a distal end of the bag, having an opening through which a user draining the bag can insert one or more fingers.

The invention also features a urine collection bag for use in a urinary catheter system, including a reservoir region for containing urine; extending from the reservoir region, an elongated neck region having an end through which a catheter can be introduced into a user's urethra; and extending from a distal end of the bag, a tear tab constructed so that pulling the tear tab exposes a pour opening through which urine can be drained from the urine collection bag.

In yet another aspect, the invention features a urine collection bag for use in a urinary catheter system, including a reservoir region for containing urine; extending from the reservoir region, an elongated neck region having an end through which a catheter can be introduced into a user's urethra; and extending from a distal end of the bag, a tab having an opening through which a user draining the bag can insert one or more fingers.

Any of the urine collection bags provided herein can include a lubricating material on the inner surface of at least one of the portions. The lubricating material can contain a silicone.

The invention also features closed catheter systems including the urine collection bags described above.

The term "overall thickness", when used herein to refer to a textured film, refers to the thickness of the film including the raised areas of the surface texture (e.g., dimension T_0 in Fig. 4A). If the textured film includes a surface texture having raised areas of different heights, the overall thickness is measured at the highest point on the textured surface.

Other features and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

Fig. 1 is a front planar view of a urine collection bag according to one embodiment of the invention, with a catheter shown in phantom lines within the urine collection bag. Fig. 1A is similar to Fig. 1, except that the cap and catheter guide have been omitted to more clearly show the braking interface tube. Fig. 1B is a cross-sectional view of the bag, taken along line B-B in Fig. 1A (for clarity, the catheter is shown as if it were extended straight along line B-B in Fig. 1A).

Figs. 2-2A are schematic perspective views showing a user of the urine collection bag shown in Fig. 1 advancing the catheter out of the bag.

Figs. 3, 3A and 3B are, respectively, enlarged top, side and end views of a braking interface tube used in the urine collection bag shown in Fig. 1.

Fig. 4 is a highly enlarged, detail top view of the surface texture of a film that is suitable for use in the urine collection bag shown in Fig. 1. Fig. 4A is a highly enlarged detail cross-sectional view of a portion of the bag, illustrating the opposed textured surfaces.

Figs. 5 and 5A are front planar views of urine collection bags according to alternate embodiments of the invention.

Fig. 6 is a front planar view of a urine collection bag according to an alternate embodiment of the invention.

Fig. 7 is a partial front planar view of a urine collection bag according to an alternate embodiment of the invention, similar to that shown in Fig. 6. Fig. 7A shows the urine collection bag of Fig. 7 with the tear tab separated from the bag.

Figs. 8-8C are partial front planar views of urine collection bags according to other alternate embodiments of the invention, having alternate tear tab designs.

Fig. 9 is a front planar view of a urine collection bag according to a further embodiment of the invention.

DETAILED DESCRIPTION

Referring to Figs. 1, 1A and 1B, a urine collection bag 10 includes two opposed portions 11 and 12 of flexible sheet material (Fig. 1B), which are sealed at seams 14 to

provide a substantially closed receptacle 13 for receiving urine flowing from the bladder of a patient. Seams 14 can be sealed, e.g., by ultrasonic welding or heat sealing. Prior to use, a catheter 40 (shown in phantom lines) resides in the urine collection bag 10. The catheter 40 includes a catheter tube 42 with a first end 44 for insertion into the patient's urethra and a second end 46 through which urine from the bladder flows into the bag 10. The first end 44 of the catheter tube 42 includes an introducer tip 47 that resides in a braking interface tube 48 that is welded to the base of the introducer tip 47. The function of braking interface tube 48 will be described in detail below. The second end 46 of the catheter tube 42 includes a rigid, non-deformable stop member 51 designed to prevent the catheter 40 from slipping out of the bag 10 through the interface tube opening 50 when the catheter is in use. A cap 43 is provided to seal the bag before and after use.

The receptacle 13 may be substantially "bottle-shaped", i.e., it has an elongated, relatively narrow neck region 15, shoulders 16, and a relatively wide reservoir region 18. The neck region 15 preferably has a width W (Fig. 1A) of less than about 5 cm, more preferably from about 4 to 6 cm, and a length L of at least about 8 cm, more preferably about 8 to 12 cm. Shoulders 16 are smoothly curved, and preferably have a radius of curvature R of from about 0.25" to 1.03". This shape has been found to generally improve user comfort by minimizing chafing and discomfort that can result from sharp edges and corners. While the receptacle may have any desired volume, the receptacle generally has a volume of at least 1000 cc.

Preferably, as shown in Figs. 4 and 4A, the inner surfaces 20, 22 of the portions 11, 12, include a surface texture, e.g., a diamond shaped pattern as shown in Fig. 4. The surface texture provides the inner surfaces with a plurality of depressed areas 24 which have a thickness T that is reduced relative to the overall thickness T_o of the sheet material. The surface texture of the sheet material serves two purposes. First, the depressed areas 24 function as hinge points, significantly increasing the flexibility of the sheet material. This increase in flexibility is advantageous if the sheet material to be used is inflexible, and/or if it is desired to use a relatively thick sheet material, e.g., for ease of processing or strength considerations. Second, the surface texture improves the ability of the user to grip the catheter through the bag when advancing the catheter as described above in the Background section. As discussed above, it is often difficult for a user to grasp a

slippery, lubricated catheter through the sheet material. Providing a surface texture increases the surface area that is available, improving gripping. Moreover, during gripping the depressed areas 24 act as storage pockets to receive the lubricant, and the raised areas in between act as pressure points that grip the catheter.

5 The surface texture is preferably on the inner surfaces 20 and 22 in order to provide this improved gripping; however, the surface texture can be provided on both the inner surfaces and the outer surfaces 28 and 30, or only on the outer surface if the improved gripping feature is not required.

10 The depth of the surface texture, i.e., the difference between T_o and T , will depend upon the degree of increased flexibility that is desired, which will in turn generally depend on the stiffness of the sheet material prior to imparting the surface texture. The two primary variables that will affect the stiffness of the sheet material are the thickness of the sheet material (T_o) and its hardness. The thicker and the harder the material, the stiffer it will be in use. Generally, it is preferred that the surface texture have a depth of
15 at least 25% of the thickness T_o , and preferably from 40 to 60%. If the plastic sheet material has an initial hardness (prior to imparting the surface texture) of from about 60 to 80 Shore A, and a thickness of from about 5 to 10 mils, the depth will generally be from about 40 to 60%. If increased flexibility is not required, e.g., if a flexible material such as polyethylene is used, the depth of the surface texture need only be sufficient to provide
20 improved gripping.

25 Preferred plastic sheet materials include extrudable thermoplastics such as polyvinyl chloride (PVC), high and low density polyethylenes, and polypropylenes. PVC is preferred in some implementations, due to its flexibility, softness, ease of processing, and biocompatibility and hypoallergenic qualities. A suitable PVC is 78 Shore A Polyvinyl Chloride PVC 2222 FS/1-78 Clear 0202, commercially available from Alpha Gary corporation. Suitable plastic sheet materials are manufactured with grades of polymer suitable for human contact. Preferably, after the surface texture is imparted the sheet material has a hardness of from about 60 to 85 Shore A, more preferably about 75 to 81 Shore A. The hardness of the material will determine, in addition to its flexibility, the
30 amount of "crinkling" sound that is produced when the bag is manipulated. If the sheet material is too hard, the bag will tend to make an undesirable amount of noise when used,

and may be difficult to manipulate. If it is too soft, the material may have a tendency to elongate under a load, thus distorting the accuracy of the bag markings for fluid intake measurement. Some polyethylenes tend to be “noisy” when used in bags. If polyethylene is used, it is preferred that a relatively quiet grade be selected.

5 Generally, preferred sheet materials have a thickness of from about 5 to 10 mils. If the sheet material is too thin, it may be difficult to form seal 14 (seal the edges of the portions to form the receptacle), while if it is too thick it may be difficult to obtain a desired flexibility.

10 A suitable surface texture is shown schematically in Figs. 4-4A. This surface texture is formed of a criss-crossed arrangement of linear depressed areas, creating a pattern of generally diamond-shaped raised areas. Many other surface textures may be used, provided the desired degree of flexibility and/or gripping is provided. Other suitable surface textures can be readily determined by those skilled in the art, and include any texture that can be applied to the surface of a metal roll, including but not limited to

15 squares, rectangles, triangles, ellipses, polygons, circles, crystals, snowflakes.

 The surface texture may be imparted by extruding the sheet material and then passing it between a set of textured rollers prior to winding it up on a take-up roll, or using any other desired technique.

 If the surface texture tends to render the bag translucent or opaque, it may be

20 desirable to provide a transparent region (e.g., a clear window) in one or both of portions 11 and 12. (The degree of visibility through the textured film will generally depend on the depth of the texture, the clarity of the plastic and the manufacturing process used.) This may be accomplished by, for example, selectively texturing the film in the machine direction during the film extrusion process. To simplify processing, the window may be

25 in the form of a continuous clear stripe, e.g., longitudinal stripe 200 in Fig. 5 or width-wise stripe 200A in Fig. 5A.

 This window allows the user to improve his view of his urine and evaluate whether it is too dark, cloudy, or has particulate matter floating in it, indicating that the user should drink more water as a first line of defense against a urinary tract infection

30 (UTI). Having a visual warning can often allow the user to ward off a UTI by taking early countermeasures.

An alternative to a clear window or stripe is to texturize only one of the portions 10, 12, and leave the other portion untextured. While it is preferred that at least one of the portions be texturized, in some embodiments both portions may be untextured.

Moreover, the tear seam 60, shown on the side of the reservoir region 18 in Fig. 1, may be positioned in other areas of the bag, to facilitate draining of urine from the bag. For example, as shown in Fig. 6, a tear tab 202 may be positioned on the neck region 215 of the bag. This positioning allows a pour opening 204 (Fig. 7A) to be provided on the side of the neck region, rather than on the side of reservoir region 18, as would be the case in the embodiment shown in Fig. 1.

Preferably, the tear tab 202 is detachably joined to the neck 215 by a recessed groove 201 which allows the tear tab to be smoothly torn towards the user (out of the page, in Fig. 7) to the position shown in Fig. 7A, resulting in pour opening 204. Tearing is initiated at a notch A (Fig. 7). Pour opening 204 generally has a nominal length of from about 0.75 to 1.25 inch, resulting in an opening having a diameter of about 0.45 to 0.8 inch, assuming the opening to be circular (in practice, it is typically somewhat elliptical).

Providing the pour opening on the neck of the bag generally allows the user or a caregiver to drain the bag by holding the reservoir region and tilting the pour opening downward. Using one hand to drain the bag allows a wheelchair-bound patient to use the other hand to hold onto his wheelchair. The positioning of the tear tab on the side of the neck, with the tear direction being away from the patient, allows the patient to use the weight of the urine-filled bag to his advantage, rather than against him as would be the case with other tear tab locations.

An alternate arrangement that allows the bag to be drained using one hand is to position the tear tab at the bottom of reservoir region 18. In this case, the user would generally grasp the neck region to drain the bag.

The tear tab may have any desired design. Examples of suitable designs that allow easy removal of the tear tab (as shown in Fig. 7A), while preventing inadvertent removal and bag leakage, are shown in Fig. 6, 7 and 8-8C. The tear tab may have a hole through which the user may insert his finger to pull the tab, e.g., holes 206 in Figs. 6, 7, 8 and 8C. The tear tab shown in Fig. 8C includes a recessed area 207, to facilitate gripping.

Alternatively, the tear tab may include raised ribs or other structures to assist the user in gripping the tab, e.g., ribs 208 in Figs. 8A and 8B.

The urine collection bag may also include features designed to make the bag easier to hold during emptying, particularly when the user needs to hold the bag with only one hand. For example, as shown in Fig. 9, the bag may include a tab 210 at its distal end 212, with an opening 214 through which the user can insert one or more fingers to hold the bag during draining.

One or both of the inner surfaces of the portions may include a lubricating material, e.g., a coating or layer, to prevent the inner surfaces from adhering to each other. For example, it may be useful to include a lubricating material if one or both of the inner surfaces are untextured and or if the plastic used has a tendency to adhere to itself. Suitable lubricating coatings include silicones, for example silicone oils such as dimethyl silicone oil. The lubricant should generally be applied to the portions in a manner so that bonding of the portions together during formation of the bag will not be deleteriously affected. For example, the lubricant may be applied to the inside of the bag after the bag is formed, e.g., by spraying it into the bag, or may be printed onto the sheet material prior to formation of the bag with the areas that are to be welded together left free of lubricant.

The Braking Interface Tube

To use the urinary catheter 40, the introducer tip 47 is inserted into the patient's urethra, and the catheter is advanced out of the urine collection bag 10 by sliding the catheter through the bag using the following procedure. Following insertion of the introducer tip 47, the user stabilizes the introducer tip with the user's non-dominant hand 102, as shown in Fig. 2. Next, using his dominant hand 100, the user holds the catheter tube 42 through the bag, with his thumb and index finger, about 1 to 2 inches behind the braking interface tube 48 (discussed below), and advances the catheter tube 42 slowly into the urethra. As shown in Fig. 2A, the catheter tube 42 is advanced by the user squeezing the catheter tube 42 with his non-dominant hand 102, while using his dominant hand 100 to retract the bag 10 without retracting the catheter tip 44 out of the urethra. The user then reduces the finger pressure applied by the non-dominant hand, and repeats

the preceding step a number of times until the catheter has been advanced into the bladder and urine is flowing into the bag.

During this procedure, the non-dominant hand grasps the catheter tube 42 using the braking interface tube 48. The braking interface tube 48 includes an opening 50
5 having a beveled leading edge that is inclined at an angle A (Fig. 3A) of from about 15 to 45 degrees from the horizontal H (a horizontal line taken along the upper surface 52 of braking interface tube 48 at the apex X' of the beveled leading edge. If the beveled edge is formed by cutting the tube, angle A will typically vary to some extent from the angle at which the tube is cut, due to flattening and distortion of the soft tube during cutting.

10 This beveled leading edge provides a generally elliptical open area 54. When the user grasps the catheter tube 42 with the non-dominant hand, the user places his thumb against the bag portion 11, over either the open area 54 or the upper surface 52, and his index finger on the opposite side of the bag, against bag portion 12, approximately aligned with the thumb. Thus, the thumb presses the bag portion 11 directly against the
15 catheter tube 42, while the index finger presses the bag 12 against a lower surface 56 of the braking interface tube, which in turn presses against the catheter tube 42. When the user desires to stop the movement of the catheter tube, the user presses the thumb and index finger together to squeeze the braking interface tube against the catheter tube. The inventor has found that the beveled geometry of the braking interface tube, and the
20 manner in which it is positioned, allows the user to securely grasp the catheter tube 42 through the bag during step (b), providing a "braking" effect which generally prevents the tube from slipping back into the bag during this step. The ability to effectively brake the catheter tube during advancement improves user comfort and ease of insertion. Also, the beveled edge of opening 50 acts as a contoured stop to allow complete advancement of
25 the catheter using the textured film, without an abrupt stopping point. This feature maximizes stroke length (the distance the catheter can be moved during a single advancement step) and control of the catheter during the insertion process.

The beveled edge of the tube also acts as a leak resistant seat for the small diameter of the deformable stop member 51 when the catheter is completely extended out
30 of the bag. Due to this sealing feature, leakage of fluid out of the introducer tip onto the patient and the patient's clothes or bedding is minimized or eliminated altogether. Due to

the presence of lubricant, the deformable stop member 51 can be easily disengaged from the beveled edge when the user desires to do so.

A braking interface tube 48 can be provided in a urine collection bag that does not include the textured surfaces described above. However, it is preferred that the bag
5 include both of these features, since the textured surface enhances the braking effect that is provided by squeezing the braking interface tube and the flexible sheet material.

Suitable materials for the braking interface tube include resilient thermoplastics such as PVC, polyethylene, polyurethanes, silicones and coextrusions of these materials. A preferred material is PVC, a suitable grade of which is medical grade USP Class VI,
10 commercially available from Alpha Gary Corporation, as product no. 2222C-65.

Preferred materials have a hardness of less than about 80 Shore A, more preferably from about 40 to 80 Shore A, and most preferably from about 50 to 70 Shore A. Generally, the tube will have a wall thickness of from about 0.89 to 1.02 mm. Typically, the thicker the wall thickness, the softer the tube material should be. The hardness and wall thickness
15 are selected so that the user can easily pinch the walls of the braking interface tube together with finger pressure to grip the catheter tube as stated above.

Using the Closed Catheter System

To obtain a urine sample, the catheter 40 is advanced through the braking
20 interface tube 48 and out of the introducer tip 47, as discussed above, and is inserted into the urethra of the patient. The catheter 40 is then gradually moved into the urethra until the catheter reaches the bladder and urine begins to flow into the bag 10. Following use, the bag 10 may be torn at a tear seam 60 at the base of the bag neck on the shoulder. The urine in the bag 10 may then be poured from the bag into a sample collection vessel for
25 analysis.

It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims.
30 Other aspects, advantages, and modifications are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A urine collection bag for use in a urinary catheter system, comprising:
opposed portions of plastic sheet material that are sealed together around a
peripheral edge to define a substantially closed receptacle;
5 at least one of the portions including a surface texture having a depth sufficient to
increase the flexibility of the plastic sheet material relative to an otherwise identical
plastic sheet material without the surface texture.
2. The urine collection bag of claim 1 wherein the surface texture is provided on
10 at least one of the opposed surfaces of the portions.
3. The urine collection bag of claim 1 wherein the depth of the surface texture is
selected to provide the plastic sheet material with a hardness of less than about 85 Shore
A.
15
4. The urine collection bag of claim 1 wherein the depth of the surface texture is
at least about 25% of the thickness of the plastic sheet material.
5. The urine collection bag of claim 4 wherein the depth of the surface texture is
20 from about 25% to 75% of the thickness of the plastic sheet material.
6. The urine collection bag of claim 5 wherein the depth of the surface texture is
from about 40% to 60% of the thickness of the plastic sheet material.
- 25 7. The urine collection bag of claim 1 wherein the plastic sheet material
comprises polyvinyl chloride.
8. The urine collection bag of claim 1 wherein the plastic sheet material has an
overall thickness of from about 5 to 10 mils.

30

9. The urine collection bag of claim 3 wherein the surface texture provides the sheet material with a hardness of from about 60 to 85 Shore A.

10. A urine collection bag for use in a urinary catheter system, comprising:
5 opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed bag;
 a surface texture disposed on at least one of the opposed surfaces of the portions.

11. The urine collection bag of claim 10 wherein the plastic sheet material
10 comprises polyethylene.

12. A urine collection bag for use in a urinary catheter system including a catheter having an introducer tip for introduction of the catheter into the urethra, the urine collection bag comprising:
15 opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, the receptacle having an open end through which the catheter can be advanced into the urethra; and
 joined to the receptacle at the open end, a braking interface tube constructed to receive and guide the introducer tip, the braking interface tube having a beveled leading
20 edge.

13. The urine collection bag of claim 12 wherein the leading edge is inclined at an angle of from about 15 to 45 degrees.

14. The urine collection bag of claim 12 wherein at least one of the facing
25 surfaces of the opposed portions of plastic sheet material includes a surface texture.

15. The urine collection bag of claim 12 wherein the braking interface tube is formed from a polymer selected from the group consisting of polyvinyl chloride,
30 polyethylene, polyurethanes, silicones and coextrusions thereof.

16. The urine collection bag of claim 12 or 15 wherein the braking interface tube is formed of a material having a hardness of from about 40 to 80 Shore A.

17. The urine collection bag of claim 12 wherein the beveled leading edge defines
5 an open area, and the braking interface tube is dimensioned and positioned so as to allow a user to place his thumb against a first one of the opposed portions, over the open area, and his index finger on the opposite one of the opposed portions, approximately aligned with the thumb, so that the thumb presses the first opposed portion directly against the catheter tube, while the index finger presses the opposite opposed portion against a lower
10 surface of the braking interface tube, which in turn presses against the catheter tube.

18. The urine collection bag of claim 17 wherein the open area is substantially elliptical.

19. A urine collection bag for use in a urinary catheter system including a
15 catheter having an introducer tip for introduction of the catheter into the urethra, the urine collection bag comprising:

opposed portions of plastic sheet material that are sealed together around a
peripheral edge to define a substantially closed receptacle, the receptacle having an open
20 end through which the catheter can be advanced into the urethra; and

joined to the receptacle at the open end, a braking interface tube constructed to receive and guide the introducer tip, the braking interface tube being formed of a material having a hardness of from about 40 to 70 Shore A.

20. The urine collection bag of claim 19 wherein the braking interface tube
25 comprises polyvinyl chloride.

21. A urine collection bag for use in a urinary catheter system, comprising:
opposed portions of plastic sheet material that are sealed together around a
30 peripheral edge to define a substantially closed receptacle;
the plastic sheet material being a noiseless material.

22. A urine collection bag for use in a urinary catheter system, comprising:
opposed portions of a polyvinyl chloride plastic sheet material having an overall
thickness of from about 5 to 10 mils, the opposed portions being sealed together around a
5 peripheral edge to define a substantially closed receptacle.

23. A urine collection bag for use in a urinary catheter system, comprising:
opposed portions of plastic sheet material that are sealed together around a
peripheral edge to define a substantially closed receptacle;
10 the receptacle being substantially bottle-shaped.

24. The urine collection bag of claim 23 wherein the receptacle includes an
elongated neck region, having a width of less than about 50 mm.

15 25. The urine collection bag of claim 23 or 24 wherein the receptacle includes
curved shoulders.

26. The urine collection bag of claim 25 wherein the shoulders have a radius of
curvature of from about 0.25 to 1.03 degrees.

20 27. The urine collection bag of claim 23 wherein the receptacle has a total volume
of at least 1000 cc.

28. A urine collection bag for use in a urinary catheter system, comprising:
25 opposed portions of plastic sheet material that are sealed together around a
peripheral edge to define a substantially closed receptacle;
at least one of the portions including a surface texture having a depth sufficient to
increase the flexibility of the plastic sheet material relative to an otherwise identical
plastic sheet material without the surface texture, the surface texture being disposed on an
30 interior surface of the receptacle; and

an interface tube having a beveled opening constructed to allow a user to apply pressure with an index finger or thumb from an exterior surface of the receptacle and thereby press the surface texture against a urinary catheter disposed within the receptacle to hold the catheter in place while manipulating the sheet material to advance the catheter
5 out of the receptacle.

29. The urine collection bag of claim 28 wherein the plastic sheet material is a noiseless material.

10 30. The urine collection bag of claim 29 wherein the noiseless material comprises PVC.

31. The urine collection bag of claim 10 wherein the surface texture is constructed to increase the friction between the opposed surfaces of the portions and a
15 catheter during gripping of the catheter by a patient, relative to the friction exerted by opposed portions of an otherwise identical plastic sheet material without the surface texture.

32. The urine collection bag of claim 31 wherein the surface texture is
20 constructed to provide pockets for receiving lubricant.

33. A closed catheter system comprising:

a urine collection bag including opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle, at
25 least one of the portions including a surface texture having a depth sufficient to increase the flexibility of the plastic sheet material relative to an otherwise identical plastic sheet material without the surface texture; and

a catheter disposed within the bag;

the urine collection bag being constructed to allow the catheter to be advanced
30 from the bag by a user.

34. A closed catheter system comprising:

a urine collection bag including opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed bag;

5 a surface texture disposed on the at least one of the opposed surfaces of the portions; and

a catheter disposed within the bag;

the urine collection bag being constructed to allow the catheter to be advanced from the bag by a user.

10 35. The closed catheter system of claim 34 wherein the surface texture is constructed to increase the friction between the opposed surfaces of the portions and the catheter during gripping of the catheter by a patient, relative to the friction exerted by opposed portions of an otherwise identical plastic sheet material without the surface texture.

15 36. The closed catheter system of claim 35 wherein the catheter is lubricated.

37. The closed catheter system of claim 36 wherein the surface texture is constructed to provide pockets for receiving lubricant.

20 38. A urine collection bag for use in a urinary catheter system, comprising: opposed portions of plastic sheet material that are sealed together around a peripheral edge to define a substantially closed receptacle; at least one of the portions including a raised surface texture.

25 39. The urine collection bag of claim 38 wherein one of the opposed portions does not include said raised surface texture.

30 40. The urine collection bag of claim 38 wherein said portion including said raised surface texture includes a transparent region that does not include said raised surface texture.

41. The urine collection bag of claim 40 wherein said transparent region defines a lengthwise stripe.

5 42. The urine collection bag of claim 40 wherein said transparent region defines a horizontal stripe.

 43. A urine collection bag for use in a urinary catheter system, comprising:
a reservoir region for containing urine;
10 extending from the reservoir region, an elongated neck region having an end
through which a catheter can be introduced into a user's urethra; and
 extending from a side portion of the neck region, a tear tab constructed so that
pulling the tear tab outwardly from the neck region exposes a pour opening through
which urine can be drained from the urine collection bag.

15 44. The urine collection bag of claim 43 wherein the tear tab includes an opening
through which the user can insert a finger to pull the tear tab.

 45. The urine collection bag of claim 43 wherein the tear tab includes protrusions
20 that facilitate gripping of the tear tab by the user.

 46. The urine collection bag of claim 43 wherein the tear tab is configured to be
pulled toward said end of said elongated neck region.

25 47. The urine collection bag of claim 43 further comprising a catheter sealed to
the bag at said end.

 48. The urine collection bag of claim 43 further comprising a notched region
between said tear tab and said side portion, wherein said notched region is configured to
30 initiate tearing of the tear tab.

49. The urine collection bag of claim 43 further comprising a tab at a distal end of the bag, having an opening through which a user draining the bag can insert one or more fingers.

5 50. A urine collection bag for use in a urinary catheter system, comprising:
a reservoir region for containing urine;
extending from the reservoir region, an elongated neck region having an end
through which a catheter can be introduced into a user's urethra; and
extending from a distal end of the bag, a tear tab constructed so that pulling the
10 tear tab exposes a pour opening through which urine can be drained from the urine
collection bag.

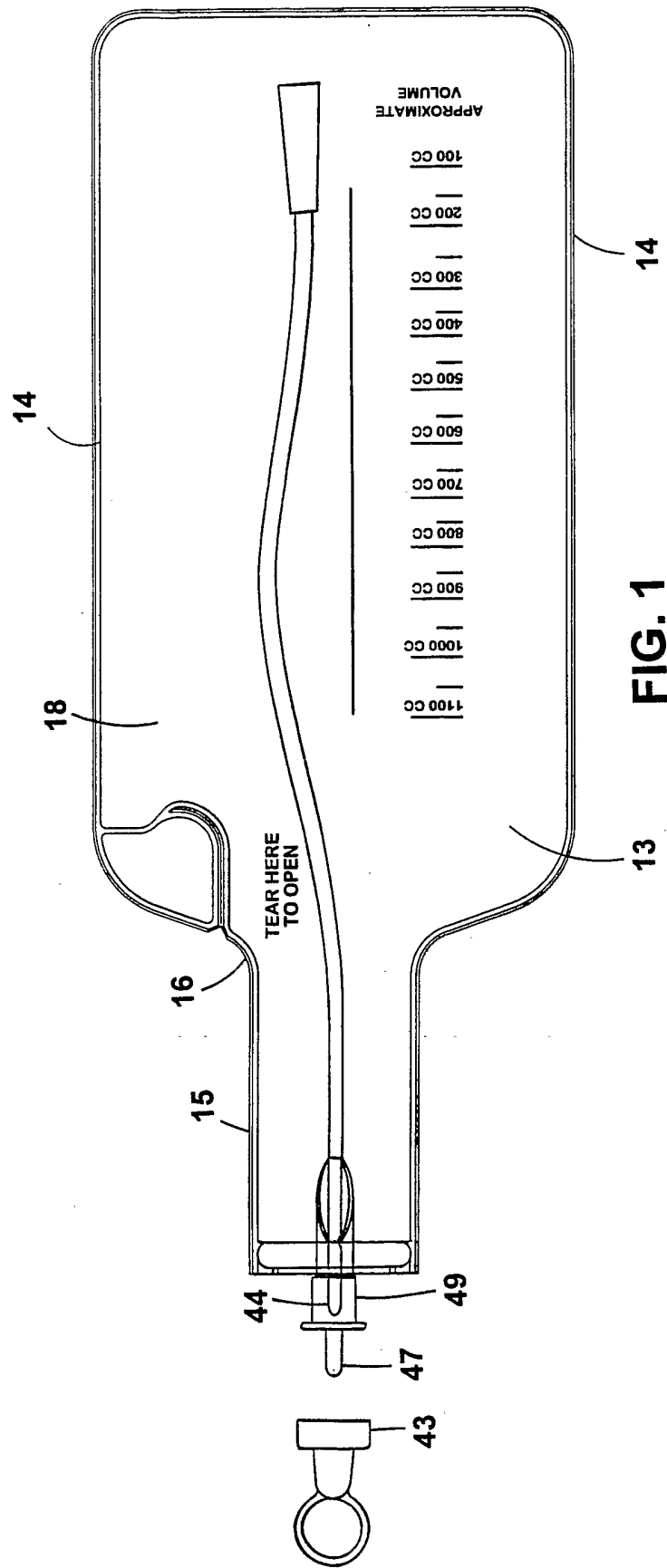
51. A urine collection bag for use in a urinary catheter system, comprising:
a reservoir region for containing urine;
15 extending from the reservoir region, an elongated neck region having an end
through which a catheter can be introduced into a user's urethra; and
extending from a distal end of the bag, a tab having an opening through which a
user draining the bag can insert one or more fingers.

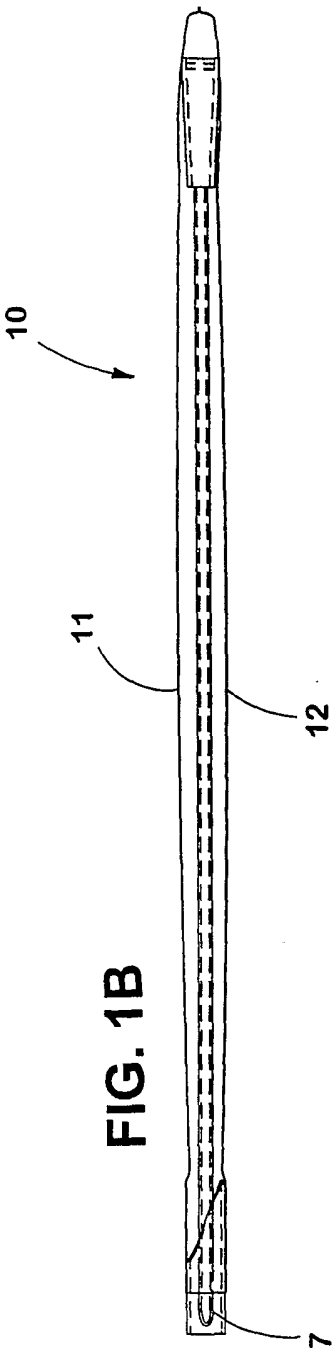
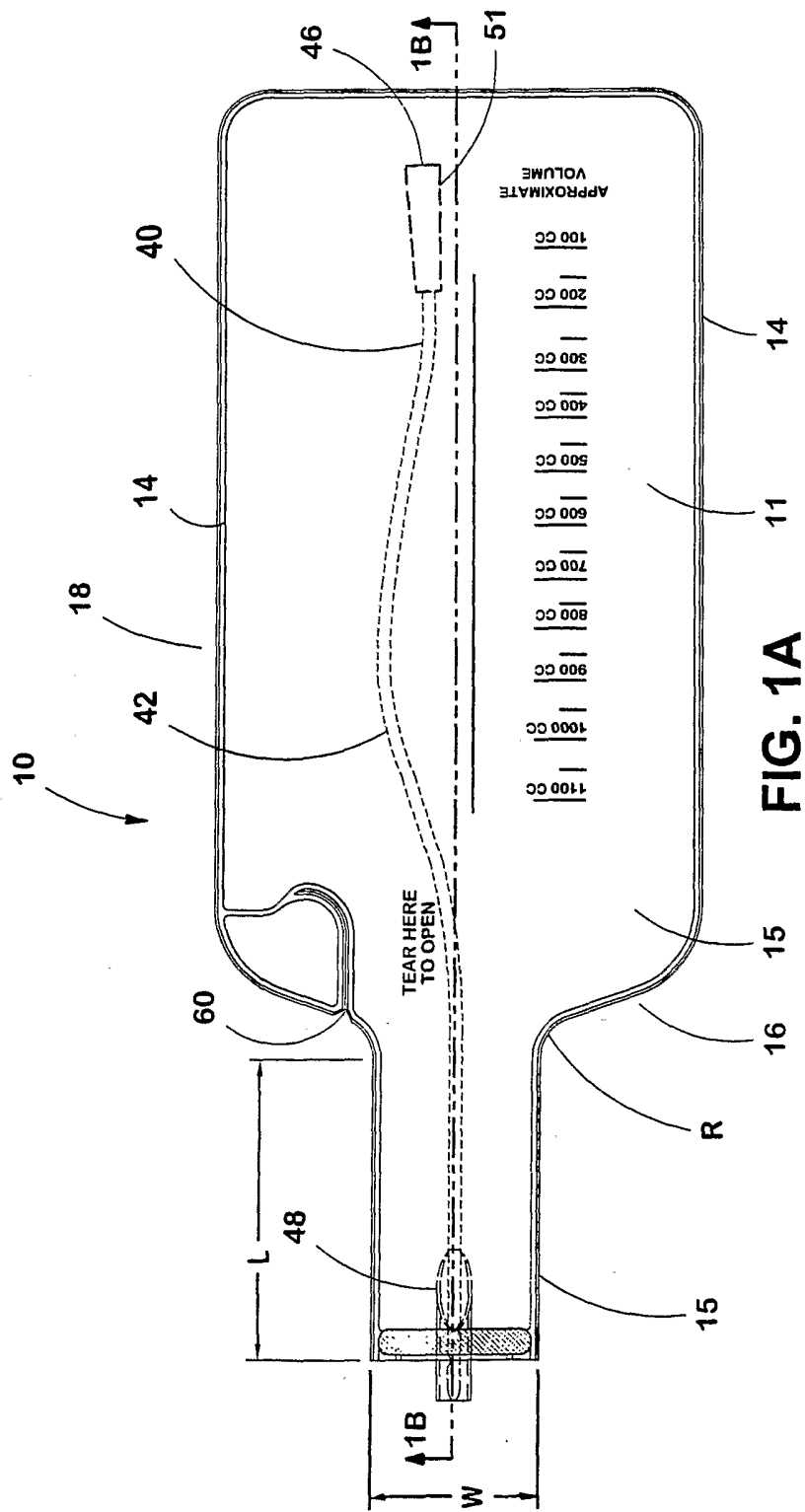
20 52. The urine collection bag of claim 1, 10, 28, 33 or 34 wherein both portions
include a surface texture.

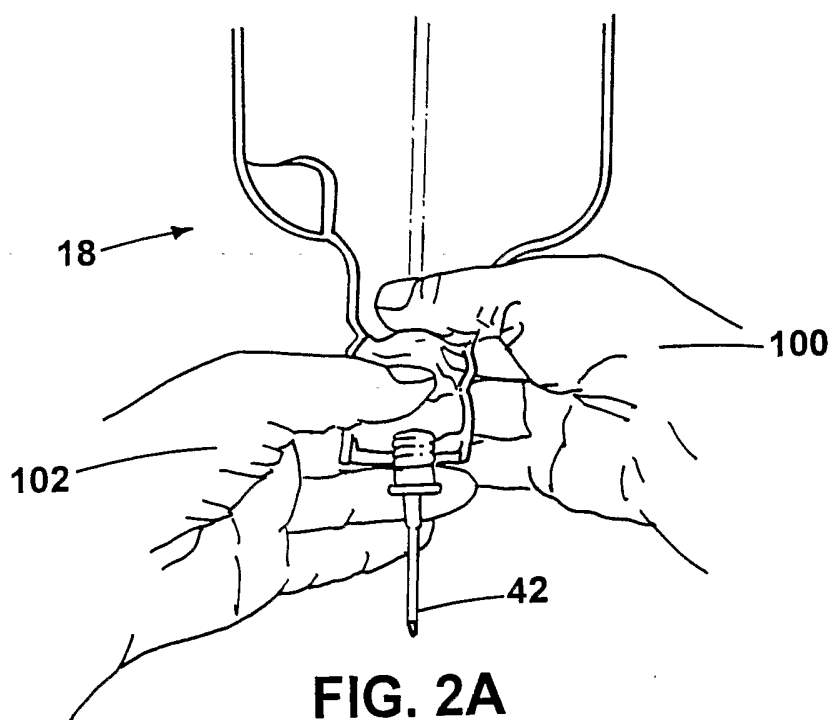
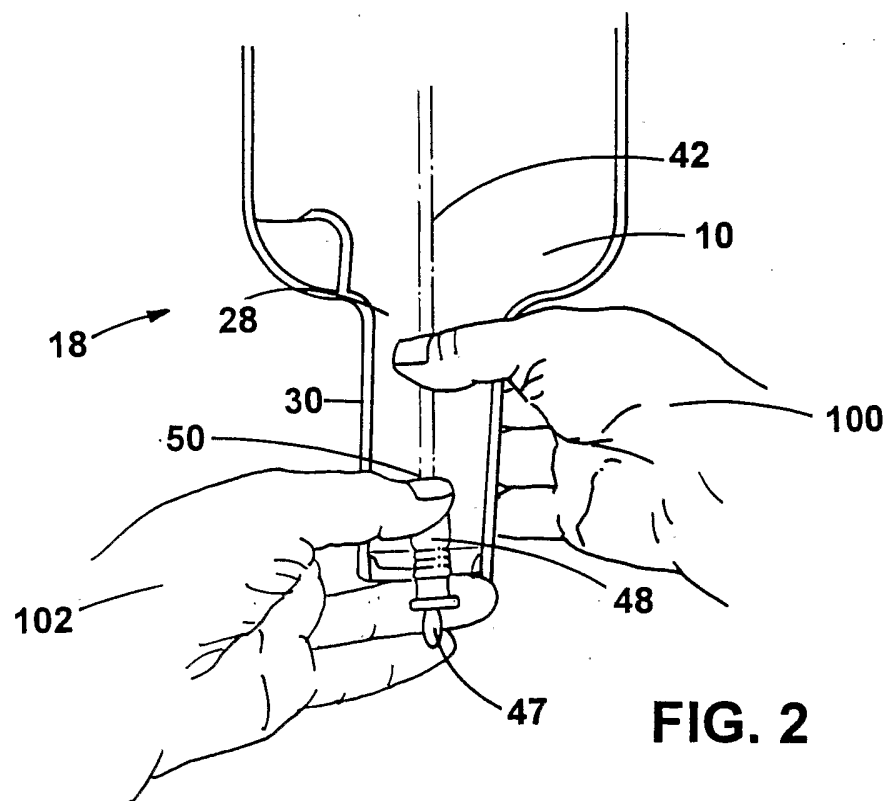
53. The urine collection bag of claim 1, 10, 28, 33 or 34 wherein one of the
portions is untextured.

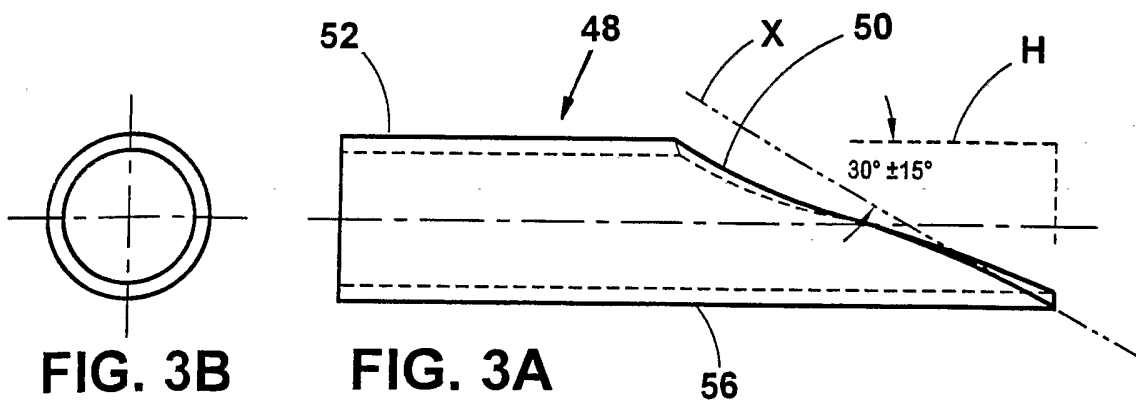
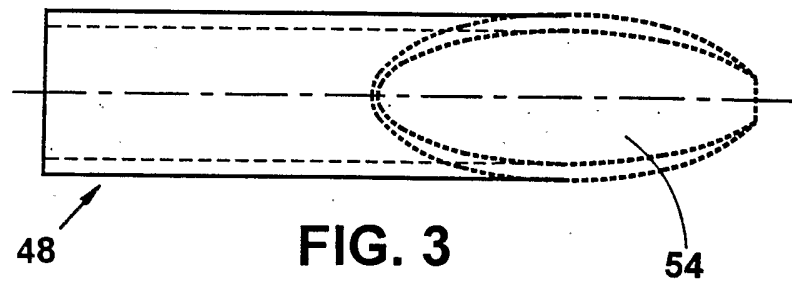
25 54. The urine collection bag of claim 1, 10, 12, 19, 21, 22, 23, 28, 33, 34, 38, 43,
50 or 51 wherein at least one of the portions includes a lubricating material on its inner
surface.

30 55. The urine collection bag of claim 54 wherein the lubricating material
comprises a silicone.









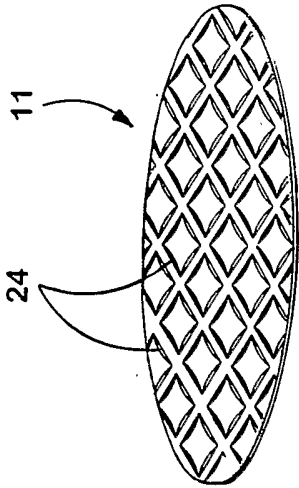


FIG. 4

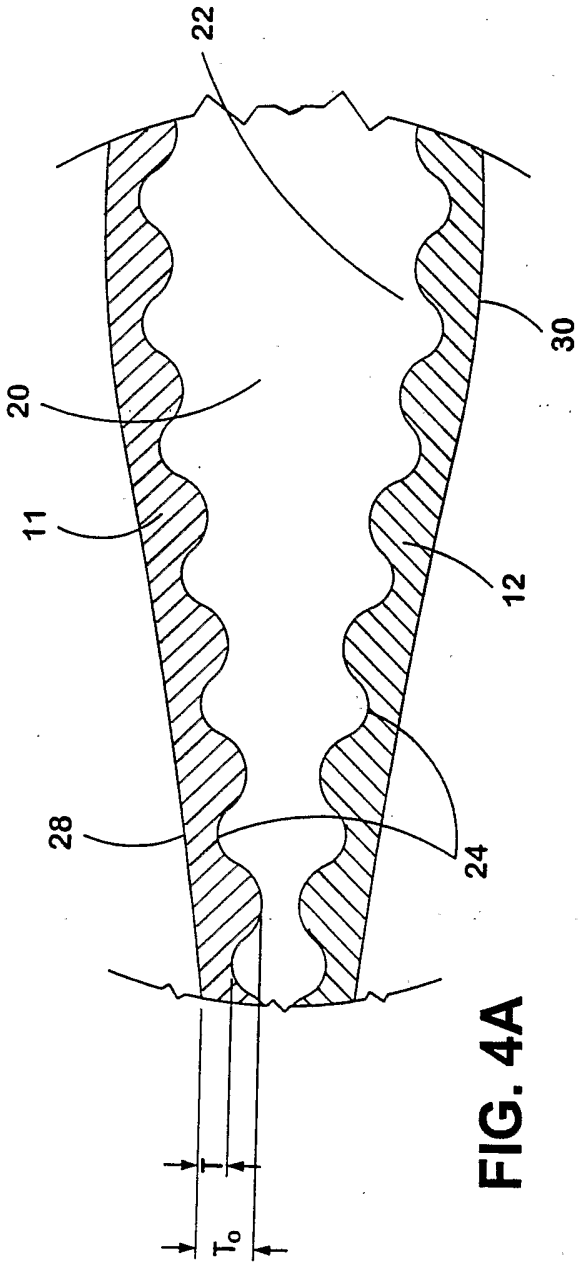


FIG. 4A

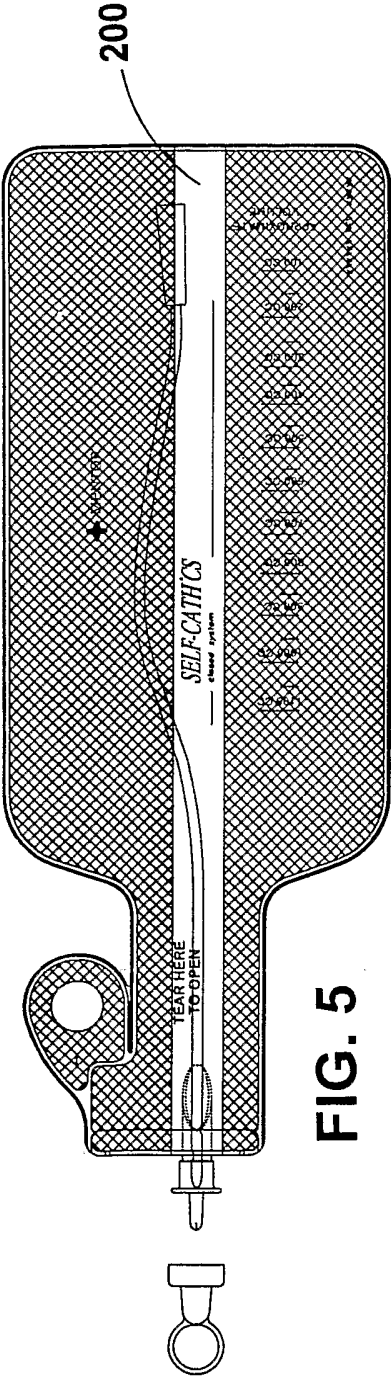


FIG. 5

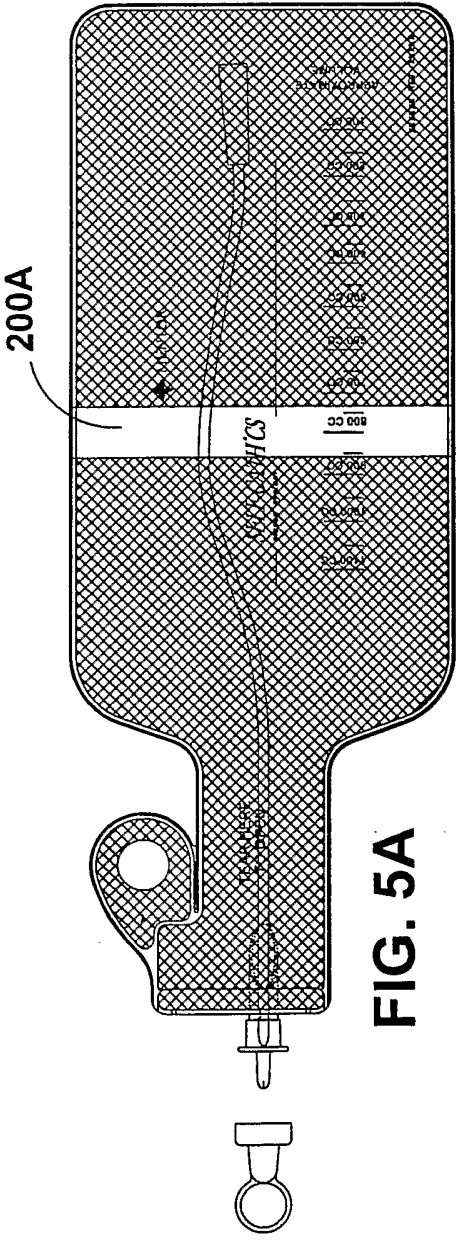


FIG. 5A

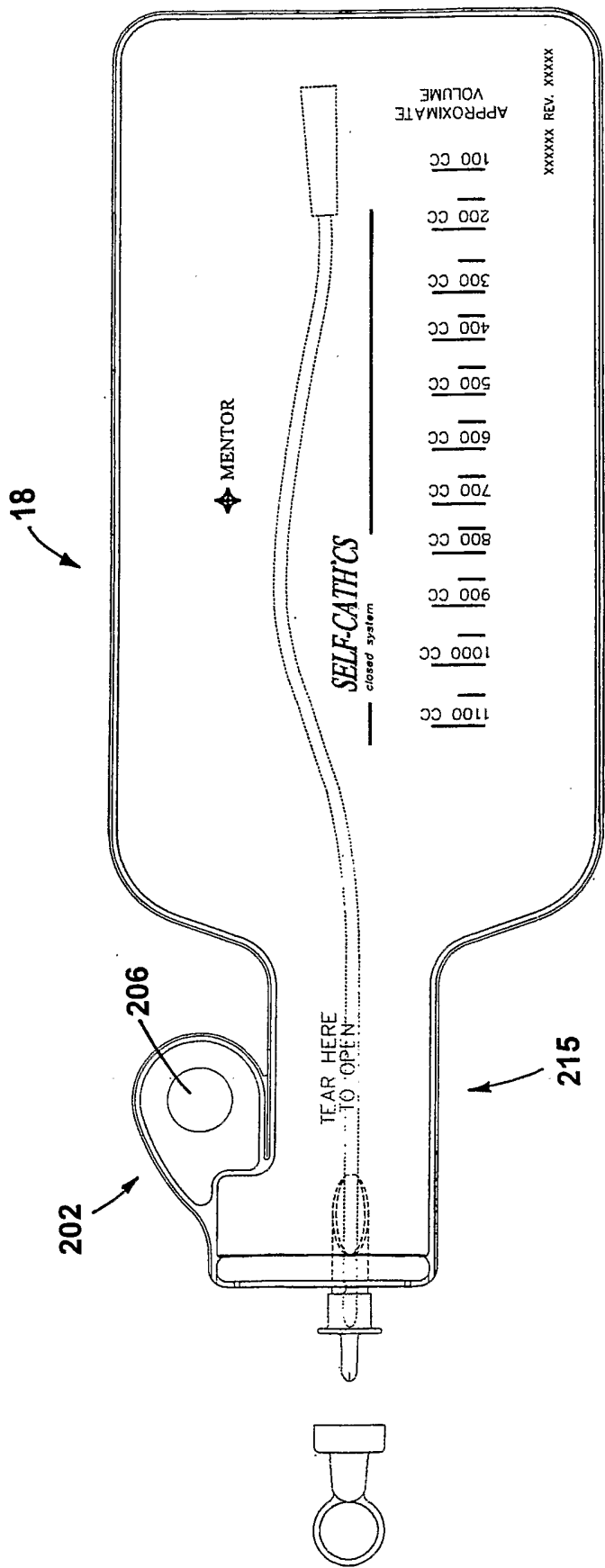
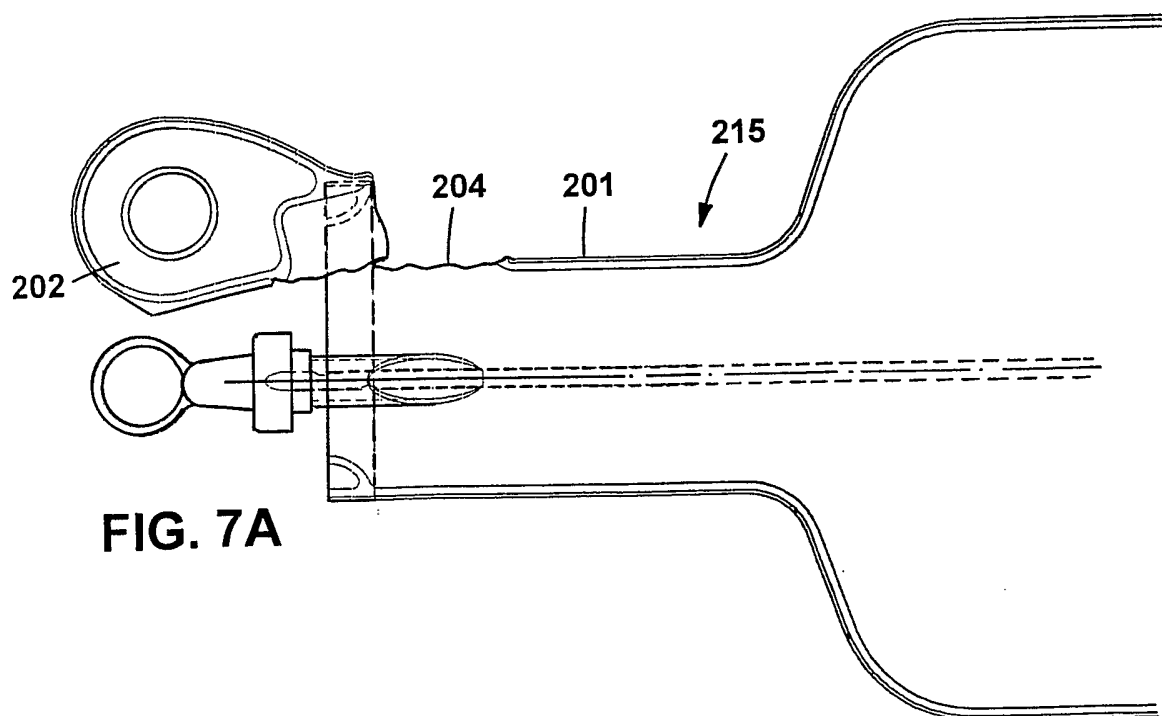
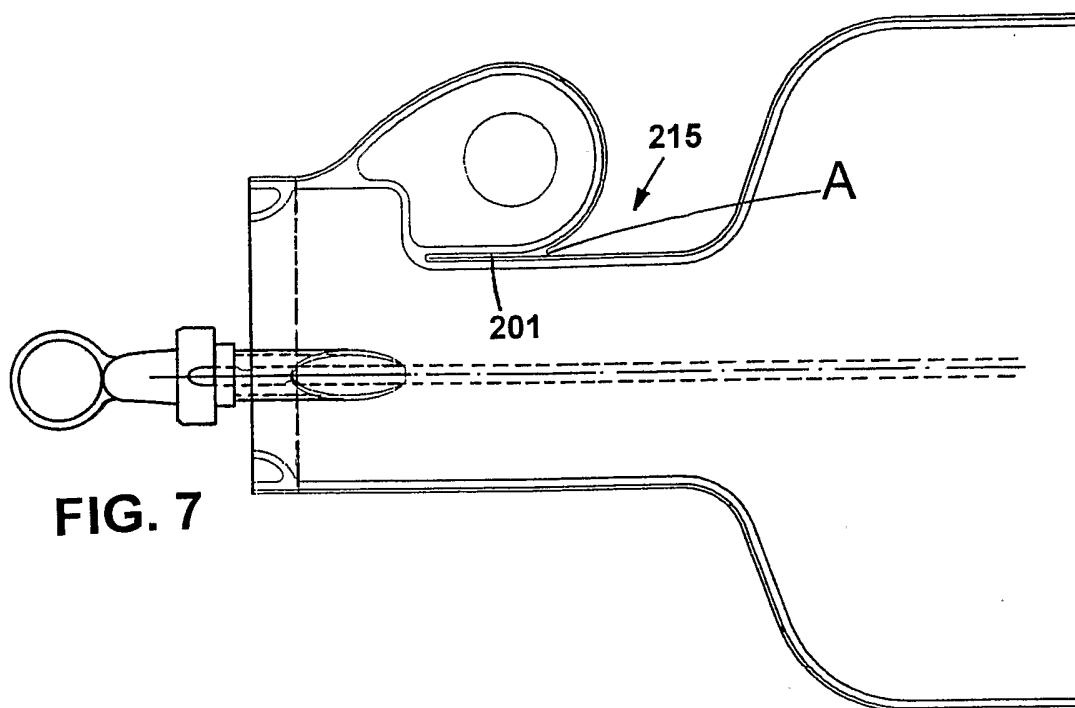


FIG. 6



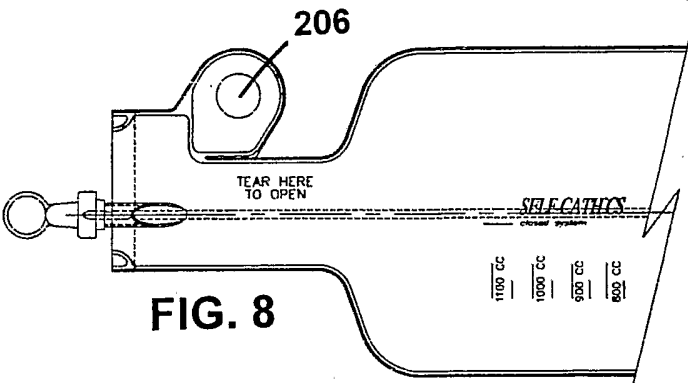


FIG. 8

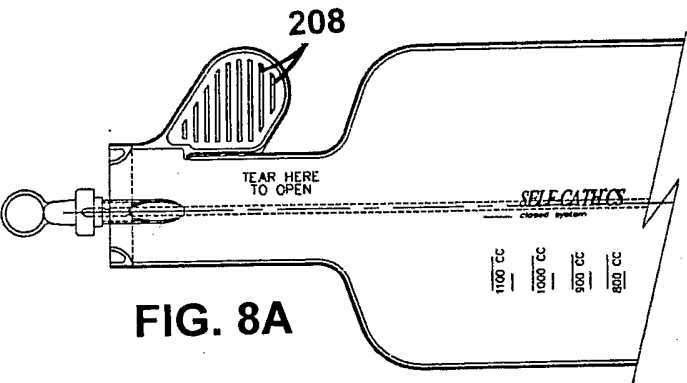


FIG. 8A

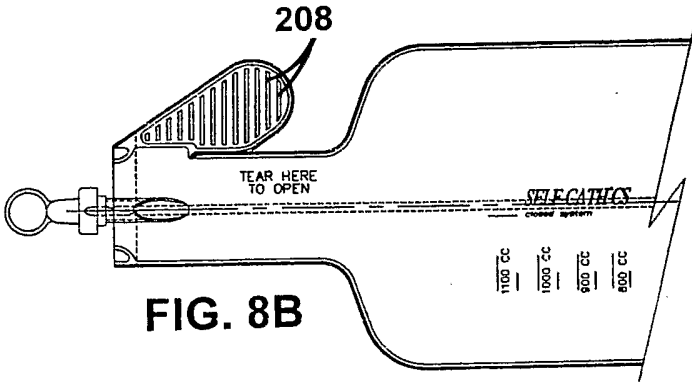


FIG. 8B

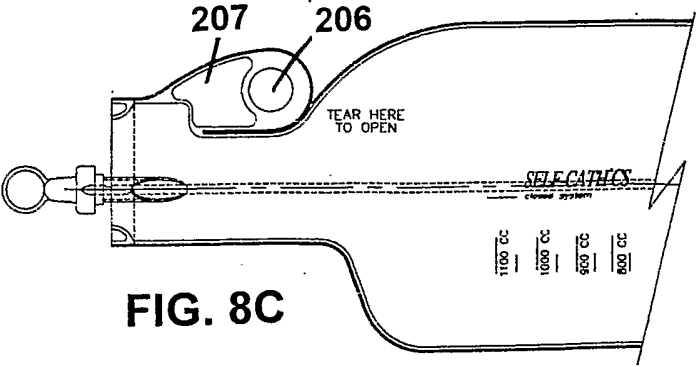


FIG. 8C

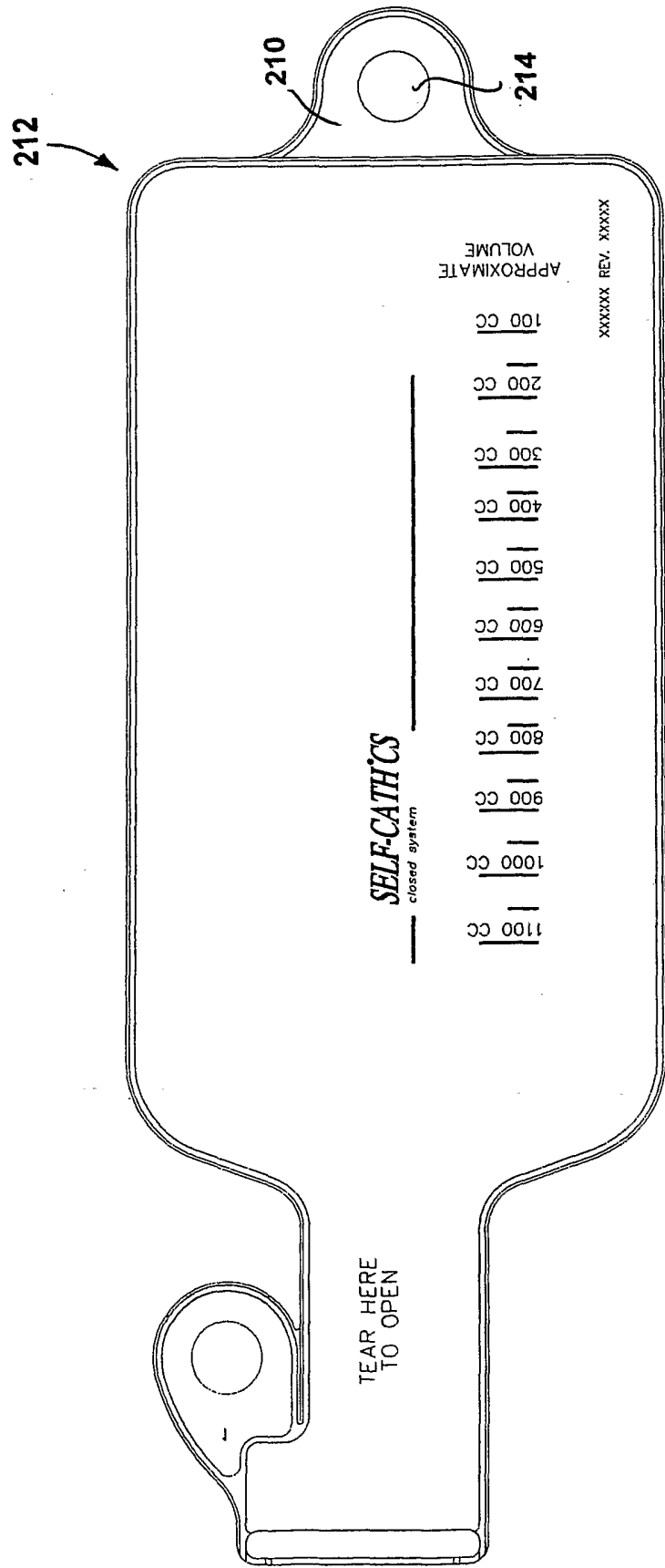


FIG. 9