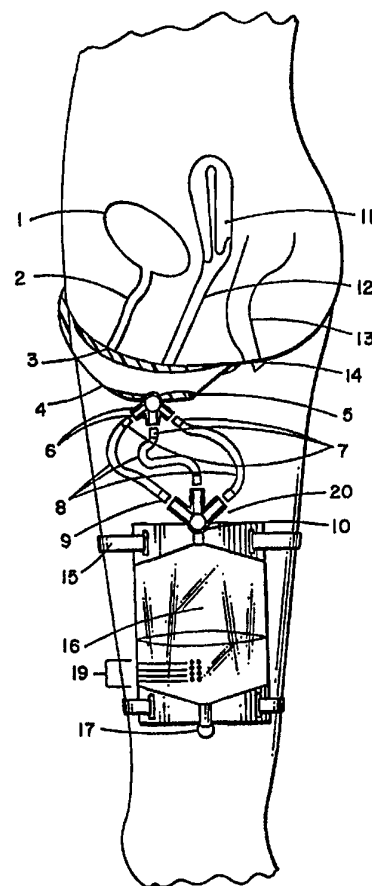




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b>  <b>A61M 1/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 96/00096</b>  <b>(43) International Publication Date:</b> 4 January 1996 (04.01.96)
<b>(21) International Application Number:</b> PCT/US95/07702  <b>(22) International Filing Date:</b> 22 June 1995 (22.06.95)  <b>(30) Priority Data:</b> 08/265,245      24 June 1994 (24.06.94)      US  <b>(60) Parent Application or Grant</b> (63) Related by Continuation US      08/265,245 (CIP) Filed on      24 June 1994 (24.06.94)  <b>(71)(72) Applicant and Inventor:</b> SALTZ, Joan [US/US]; 303 County Road - 881, Crane Hill, AL 35053 (US).  <b>(74) Agent:</b> BEUSSE, James, H.; Hobby & Beusse, Suite 375, 157 E. New England Avenue, Winter Park, FL 32789 (US).		<b>(81) Designated States:</b> AU, CA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> EXTERNAL URINARY RECEPTACLE  <b>(57) Abstract</b>  <p>The invention is an external urinary receptacle for use by human individuals, especially females, which provides swivel portions (5, 10) for comfort and ease of use. The invention may be applied by a user or medical personnel applying it to a patient. It may be used at desired periods of time or worn for extended periods of time. It also provides a snug fitting cup-like device (4) for receiving urine which inhibits infection, rash and chaffing by providing sufficient draining, and which inhibits leakage. The device also includes tubing (8) with quick disconnects (7, 9) attached to a bag (16) containing a drain (17), and optionally volumetric markings (19).</p>		



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**EXTERNAL URINARY RECEPTACLE**FIELD OF THE INVENTION

The present invention is an external urinary receptacle designed to be easily used and comfortably worn by women and men. This application is a continuation-in-part of U.S. Application ,  
5 Serial No. 08/265,245, filed June 24, 1994.

BACKGROUND OF THE INVENTION

There are numerous known devices used by individuals who, for a number of reasons, may have an inability to voluntarily void, including external  
10 catheters, bedpans, diapers, and adult undergarments. Each serve similar function.

Bedpans are large, bowl-like receptacles for the capture of urine and other human waste. Assistance is often required to place them  
15 underneath the posterior of bedridden user and the user must be substantially immobile during use. Emplacement may also be uncomfortable because the use requires moving the user, who is often a patient, and sometimes results in chaffing and  
20 sores of users. Moreover, the bedpans must be cleaned after each use.

Diapers and adult undergarments generally comprise fabric pants or wraps for receiving urine and other human waste. They are worn around the

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pelvis of the user, underneath all other garments. Although permitting mobility, garments of this type are bulky and require frequent changing. In addition, diaper-like garments do not entirely  
5 remove moisture from the area around the user's genitalia, creating the potential for chaffing, infection, or rash.

It has been suggested that external catheters which drain urine away from the genitalia and  
10 deposit it in a containment area be employed. However, external catheters generally include tubes used to transport fluids away from the genitalia which must be maintained in a proper orientation during use to prevent back-up of the fluid flow,  
15 particularly if the external catheter is used in mobility. External catheters require sterile conditions for insertion and also require frequent flushing. Their use may also cause infection.

Others have suggested various forms of external  
20 urinary receptacles for use by individuals who, for a number of reasons, may have an inability to voluntarily void and may have urinary incontinence, both for use during periods of illness or incontinence or when occupational circumstances make  
25 it inconvenient, if not impossible to void at will. By and large these devices are cumbersome, relatively expensive and do not assure that the portion of the device in close proximity to the body will in use evacuate fluid away from the body.

30 SUMMARY OF THE INVENTION

The object of the invention is to provide an external urinary receptacle for use by human individuals, particularly females, which is

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convenient to use and comfortable to wear.

The present invention overcomes the problems of the past by providing an external urinary receptacle, preferably made out of sterile materials, which includes a cup-like device which can fit the anatomy, result in a negative pressure chamber to draw the fluid away from the surface, and which is connected to a collection container via a flexible tube. Using universal connection members, such as swivel joints, permits the tube, container, and cup-like device to move in a wide range of directions. This range of motion allows the components of the device to be comfortable positioned on the wearer during all body positioning and will tend not to pull or tear nor likely bind around the user. This permits the present invention to be used in a releasably affixed state during a variety of physical activities. Moreover, for a bed ridden and/or generally immobilized individual, the device of the present invention will remain operative despite significant repositioning of the body during treatment or to prevent bed sores. It can also be used in a non-affixed mode by a patient who hand emplaces and retains the cup-like genitalia-covering portion over the genitalia during evacuation.

The genitalia-surrounding, cup-like portion includes a concave portion of any suitable material with an aperture located at the low point of its concavity. The perimeter is preferably malleable to permit a close seal thereabout which not only facilitates the capture and draining of urine but also promotes a more comfortable fit. When a seal is created between the cup-like device and the skin of the user, negative pressure exists within the

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cup-like device, providing a vacuum effect, causing the fluid to drain out of the device, regardless of the orientation of the device, and preventing dispersal of fluid over the skin. In turn, maceration, skin infection, rashes and other consequences of stagnant urine remaining on skin are avoided.

One end of a swivel joint is located on the cup-like device, at the aperture in the device. The swivel joint effect may be provided by any suitable means such as a bellows or a hollow ball-and-socket design which permits affixation to the cup-like device at one end and the tubular conduit to the collection container at its other end. The hollow tube is of a length sufficient to permit the desired location of the collection receptacle which will either be carried by and secured to the user along a lower extremity such as a leg, or in the case of a bed ridden individual, to the hospital bed or the like. It extends away from the cup-like device and preferably is detachably connected to an end of the tube for removal and draining. If the device of the invention is a one-time disposable unit, then permanent affixation, such as by adhesive connections, may be desirable.

The collection receptacle may be any suitable water-tight vessel such as a plastic bag or the like or a contoured, rigid plastic container. The collection receptacle preferably has two openings, each located on an end opposite the other, one on top, the other on the bottom. The opening on the bottom is a drain, used to empty the contents of the collection receptacle. Alternately, the entire collection receptacle may be removed and emptied or disposed of. The drain is detachably plugged with

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a stopper to facilitate containment of fluid when it is installed, and the draining of fluid when it is removed. Also, the collection receptacle may be translucent and graduated to permit the measurement and recordation of the amount of fluid contained therein. For some usages, such as hospital uses, the collection receptacle may be removable with the cup-like device and tubing being disposable. In other embodiments, the entire device may be disposable. In those embodiments, the tube may provide for demounting via a quick release mounting devices located on each of its ends. The quick release mounting and demounting devices allow easy attachment/detachment of the components of the invention, for easy replacement, cleaning and emptying.

In either case, preferably a second swivel joint, also generally of the same type as heretofore described, is mounted on the collection receptacle, over the top opening. For example, if a ball joint is used, the ball portion of the joint is located in the socket created by the top opening. The hollow tube protrudes away from the container and is detachably connected to an end of the tube opposite that of the cup-like device. The tube which runs between the cup-like device and the collection container may be made of any suitable material such as flexible plastic material. Preferably, it is a thin material. In an alternate embodiment, a spring-like, body-engaging perimeter member extends about and is contained within the perimeter of the cup-like device. The spring is placed in compression when it is brought against the body of the user. As the spring is urged by its memory to return to its original shape it urges the perimeter

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into intimate contact with the skin of the user. This assists in forming a snug seal between the cup-like device and the user's skin and promotes the water-tightness of the device, this further facilitates the provision of negative pressure within the cup-like device. The cup-like device being slightly squeezed during emplacement and as part of the closed system assembly of the cup-like device, tubing and closed collection receptacle enhances drainage, deters leakage and inhibits skin irritation.

If desired, ruffles may extend along the body-engaging perimeter of the cup-like device with the ruffles being made of or treated so as to be tacky and malleable material to provide a releasable grip between the ruffled edges and the skin of the user. This improves the seal and as well enhances comfort as the excess material of the ruffles assists in the self-adjusting of the perimeter to the anatomical reshaping of the emplacement area due to movement of the user.

Further, the cup-like device, may be made of luminous materials to facilitate ease of location and use at night as the luminous materials allow various parts of the invention to be seen and placed in accessible and easily located positions at low light or in a dark room.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the preferred embodiment of the invention as worn by a human female with portions of certain female internal organs shown in schematic presentation. Further, tube 8, quick disconnects mounts 7 and 9, and hollow



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pipes 6 and 20 are shown in three different positions to illustrate the range of motion of five components;

FIG. 2 is a top view of the cup-like device;

5        FIG. 3 is a sectional view along line 1-1 of FIG. 2;

FIG. 4 is a bottom view of the cup-like device as used by a human female;

10       FIG. 5 is a side view corresponding to FIG. 1 showing an alternate embodiment of the invention;

FIG. 6 is a side view of the cup-like device shown in FIG. 5; and

FIG. 7 is a top view of the device shown in FIG. 6.

15        DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, cup-like device 4 is made of sterile, pliable plastic or other suitable material. Cup-like device 4 is shaped to follow the form of the human female vulva and is concave to facilitate receipt and draining of urine. The concavity is of a depth which will snugly, yet comfortably cover the genitalia of the female user. The cup-like device 4 is of a length sufficient to cover urethra opening 3 and has a circular aperture located within its perimeter, at a point in the longitudinal center of the device and at the bottom of the concavity, to facilitate draining. Swivel joint 5 is a ball-and-socket type swivel which is hollow and has a hollow pipe 6 extending from one end of the swivel. Swivel joint 5 is joiningly attached, at an end opposite hollow pipe 6, to cup-like device 4 over the aperture. As discussed, other devices to permit a wide range of movement,

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such as a bellows device (see FIGS. 5-7) may be employed.

5 Tube 8 has two quick disconnect mounting devices 7 and 9, one being located on each end of tube 8. Tube 8 is connected at an end to hollow pipe 6 via quick release mounting device 7. Tube 8 is of a length sufficient to reach a liquid container mounted on the leg of the human female user of the invention.

10 Bag 16 is a translucent plastic or other similar material bag, much like those used for delivery of intravenous fluids. Bag 16 has openings on two ends of the bag. Swivel joint 10 is a ball-and-socket type swivel which is hollow and has a  
15 hollow pipe 20 extending from one end of the swivel. Bag 16 is joiningly attached to swivel joint 10, at an end opposite hollow pipe 20, over the top opening. The other opening of bag 16 is on the bottom of bag 16. Drain 17 is a stopper device of  
20 a size sufficient to fit snugly with and around the bottom opening. The bottom opening is plugged by drain 17, which is removably attached to bag 16, in and around the bottom opening. Tube 8 is connected at a free end to the hollow pipe via quick release  
25 mounting device 9.

Straps 15 loop through the edges of bag 16, so as not to interfere with the fluid containment function of the bag. Straps 15 are wrapped around a leg of the user to support the bag and facilitate  
30 mobile use of the invention.

Alternately, referring to FIG. 2, spring 22 extends along and is contained within the perimeter. The spring provides structural support to the cup-like device. Spring 22 is placed in compression  
35 when it is brought against the body of the user. As

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spring 22 is urged by its memory to return to its original shape, it pushes against the skin of the user. This forms a snug seal between cup-like device 4 and the user's skin and promotes the water-tightness of the device, thus preventing leakage.

In addition or in lieu of spring 22, ruffles 18 may extend along the perimeter of the cup-like device 4. The ruffles are made of tacky, malleable material to provide a releasable grip effect between cup-like device 4 and the skin of the user and a more comfortable fit. This releasable grip effect promotes a water-tight seal between the cup-like device and the skin of the user, thus preventing leakage.

In use by a human female, cup-like device 4 is placed over the genitalia of the female user. It may then simply be held there by the user or attendant medical personnel until the voiding process is complete. Alternately, cup-like device 4 is placed over the genitalia of the female user, then panties or other undergarments are then put on over cup-like device 4 to provide support and hold it in place. An end of tube 8 is attached to hollow pipe 6 via quick disconnect mount 7. This provides a water-tight seal between cup-like device 4 and tube 8. Tube 8 is fed down through a leg opening of the panties or undergarments. Bag 16 is strapped, using straps 15 to a leg of the user which corresponds to that where the tube is being fed. The free end of the tube 16 is attached to hollow pipe 20 via quick disconnect mount 9.

Alternately, detachable fabric attachment devices may be used to further secure cup-like device 4 in place within an undergarment. Detachable fabric attachment devices (not shown),

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such as Velcro® Brand releasable strips, may be adhesively affixed on the convex side of cup-like device 4 to facilitate detachable attachment between cup-like device 4 and the undergarment, as long as the garment is felt-like and will attach to Velcro® Brand releasable strips, else corresponding Velcro® Brand releasable strips mounted inside the undergarments will be also required to insure security.

Alternately, cup-like device 4 may be strapped in place. Instead of being supported by undergarments, a garter-type belt may be strapped over or fed through a loop in cup-like device 4. Then the garter belt may be looped around the waist of the user, providing support for cup-like device 4 and holding it in place.

Alternately, the invention may be adapted for use by human males. Cup-like device 4 may be shaped to follow the form of the human male genitalia. Cup-like device 4 may be of a concavity of sufficient depth to snugly, yet comfortably cover the genitalia of a human male.

In use by a human male, cup-like device 4 is placed over the genitalia of the male user. It may then simply be held there by the user or attendant medical personnel until the voiding process is complete. Alternately, cup-like device 4 is placed over the genitalia of the male user, then briefs or other undergarments are then put on over cup-like device 4 to provide support and to hold it in place. An end of tube 8 is attached to hollow pipe 6 via quick disconnect mount 7. This provides a water-tight seal between cup-like 4 and tube 8. Tube 8 is fed down through a leg opening of the briefs or undergarments. Bag 16 is strapped, using straps 15

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to a leg of the user which corresponds to that where the tube is being fed. The free end of tube 16 is attached to hollow pipe 20 via quick disconnect mount 9.

5 Alternately, detachable fabric attachment devices may be used to further secure cup-like device 4 in place within an undergarment. Detachable fabric attachment devices (not shown), such as Velcro® Brand releasable strips, may be  
10 adhesively affixed on the convex side of cup-like device 4 to facilitate detachable attachment between cup-like device 4 and the undergarment, as long as the garment is felt-like and will attach to Velcro® Brand releasable strips, else corresponding Velcro®  
15 Brand releasable strips mounted inside the undergarments will be also required to insure security.

Alternately, cup-like device 4 may be strapped in place. Instead of being supported by  
20 undergarments, a garter-type belt may be strapped over or fed through a loop in cup-like device 4. Then the garter belt may be looped around the waist of the user, providing support for cup-like device 4 and holding it in place.

25 Alternately cup-like device 4, and/or tube i, and/or bag 16 may be made of luminous materials to facilitate ease of use at night for the user or medical personnel applying the invention to a patient. Luminous materials allow various parts of  
30 the invention to be seen and placed in comfortable positions, without the need for getting up to turn on the lights at night or in a dark room.

Referring to FIGS. 5-7, there is shown an alternate embodiment of the present invention in  
35 which tube 8 and its pivotable connections have been

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replaced by a flexible coupling 8A. The flexible coupling may take the form of the previously mentioned bellows type coupling and is attached at each end, respectively, to the cup-like device 4 and  
5 bag 16. In this form, the tube 8A is flipped over a pre-formed drain 24 exiting from the cup-like device 4 and a similar inlet tube 26 on the top of the bag 16. Preferably the bag 16 may be a flexible bag, but as shown in FIG. 5, the bag may be replaced  
10 by a less flexible plastic container having outer volumetric markings 19. This form of flexible coupling 8A eliminates the need for the swivel type coupling devices shown in FIG. 1. FIG. 7 also shows a liner pad 28 which may be coated with a cement  
15 enabling it to be glued onto the cup-like device 4 and provide a means for attaching the device 4 to the person's skin using the same cement on an opposite side of the pad.

It should be noted that use of various other  
20 materials, various modifications in the configuration, and the other similar modifications and variations to which the invention is susceptible, may be practiced without departing from the scope, intent, and teaching of the claims.

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## CLAIMS

WHAT IS CLAIMED IS:

1. A urinary receptacle comprising:

a pliable cup-like device, having a shaped perimeter adapted to be emplaced against a user's skin in the vicinity of the genitalia and, when  
5 emplaced, extends about a perimeter of the genitalia;

an exit orifice within said cup-like device by which urinary discharge can be evacuated from said cup-like device;

10 a conduit means, of a desired length, having a first end and a second end, said first end, operably linked to said exit orifice so as to permit flexible movement; and

a collection container, operably linked to the  
15 second end of said conduit means so as to permit flexible movement, said collection container, conduit means and cup-like device, when in operative engagement, forming a closed receptacle such that flexing said cup-like device upon emplacement  
20 establishes negative pressure therein.

2. The urinary receptacle of claim 1 wherein the cup-like device is shaped to generally follow the perimeter of a female vulva and has a concavity, the concavity being of a depth which will snugly,  
5 yet comfortably cover the genitalia of the female user.

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3. The urinary receptacle of claim 1 wherein the cup-like device is shaped to follow the perimeter of an area to enclose the entire male genitalia and has a concavity, the concavity being  
5 of a depth which will snugly, yet comfortably cover the genitalia of a male user.

4. The urinary receptacle of claim 1 wherein the cup-like device contains a spring-like device running along and contained within the perimeter of the cup-like device.

5. The urinary receptacle of claim 1 wherein the cup-like device contains ruffles along the perimeter.

6. The urinary receptacle of claim 5 wherein the ruffles are made of a tacky, malleable material.

7. The urinary receptacle of claim 5 wherein the ruffles are coated with a material which renders the ruffles tacky.

8. The urinary receptacle of claim 1 wherein the container is a translucent plastic bag of a desired configuration and capacity.

9. The urinary receptacle of claim 1 wherein the cup-like device, conduit means, and container are made of luminous materials.

10. The urinary receptacle of claim 8 wherein the container has graduated markings of liquid measure along a side of the container.



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11. The urinary receptacle of claim 1 wherein the cup-like device has detachable fabric attachment devices joiningly affixed to the cup-like device on a convex side of the cup-like device.

12. A urinary receptacle comprising:

5 a pliable cup-like device, having a shaped perimeter adapted to be emplaced against a user's skin, in the vicinity of the genitalia and, when emplaced, extend about the perimeter of the genitalia;

an exit orifice within said cup-like device by which urinary discharge can be evacuated from said cup-like device;

10 a first flexible joint, with an opening of a dimension substantially equal to that of the exit orifice, operably linked to said exit orifice so as to permit flexible movement at said first joint;

15 a conduit means, of a desired length, with an interior dimension substantially equal to the dimension of the opening of the first joint, having a first end and a second end, said first end, operably linked to said first swivel joint;

20 a second flexible joint, with an opening of a dimension substantially equal to that of the interior dimension of the conduit means, operably linked to said second end of the conduit means so as to permit flexible movement at said second joint; and

25 a collection container, operably linked to the second joint opposite the conduit means so as to permit flexible movement.

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13. The urinary receptacle of claim 12 wherein the cup-like device is shaped to generally follow the perimeter of a female vulva and has a concavity, the concavity being of a depth which will snugly, yet comfortably cover the genitalia of the female user.

14. The urinary receptacle of claim 12 wherein the cup-like device is shaped to follow the perimeter of an area to enclose the entire male genitalia and has a concavity, the concavity being of a depth which will snugly, yet comfortably cover the genitalia of a male user.

15. The urinary receptacle of claim 12 wherein the cup-like device contains a spring-like device running along and contained within the perimeter.

16. The urinary receptacle of claim 12 wherein the cup-like device contains ruffles along the perimeter.

17. The urinary receptacle of claim 16 wherein the ruffles are made of a tacky, malleable material.

18. The urinary receptacle of claim 16 wherein the ruffles are coated with a material which renders the ruffles tacky.

19. The urinary receptacle of claim 12 wherein the swivel joints are of a ball-and-socket-type configuration.

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20. The urinary receptacle of claim 12 wherein the swivel joints are of a bellows-type configuration, the joints being made of a moveable, elastic material.

21. The urinary receptacle of claim 12 wherein the container is a translucent plastic bag of a desired configuration and capacity.

22. The urinary receptacle of claim 12 wherein the cup-like device, conduit means, and collection container are made of luminous materials.

23. The urinary receptacle of claim 21 wherein  
5 the container has graduated markings of liquid measure along a side of the container.

24. The urinary receptacle of claim 12 wherein the cup-like device has detachable fabric attachment devices joiningly affixed to the cup-like device on a convex side of the cup-like device.

25. The urinary receptacle of claim 12 wherein the first end of the conduit means is detachably attached to the first swivel joint, and the second end of the conduit means is detachably attached to  
5 the second swivel joint.

1 / 2

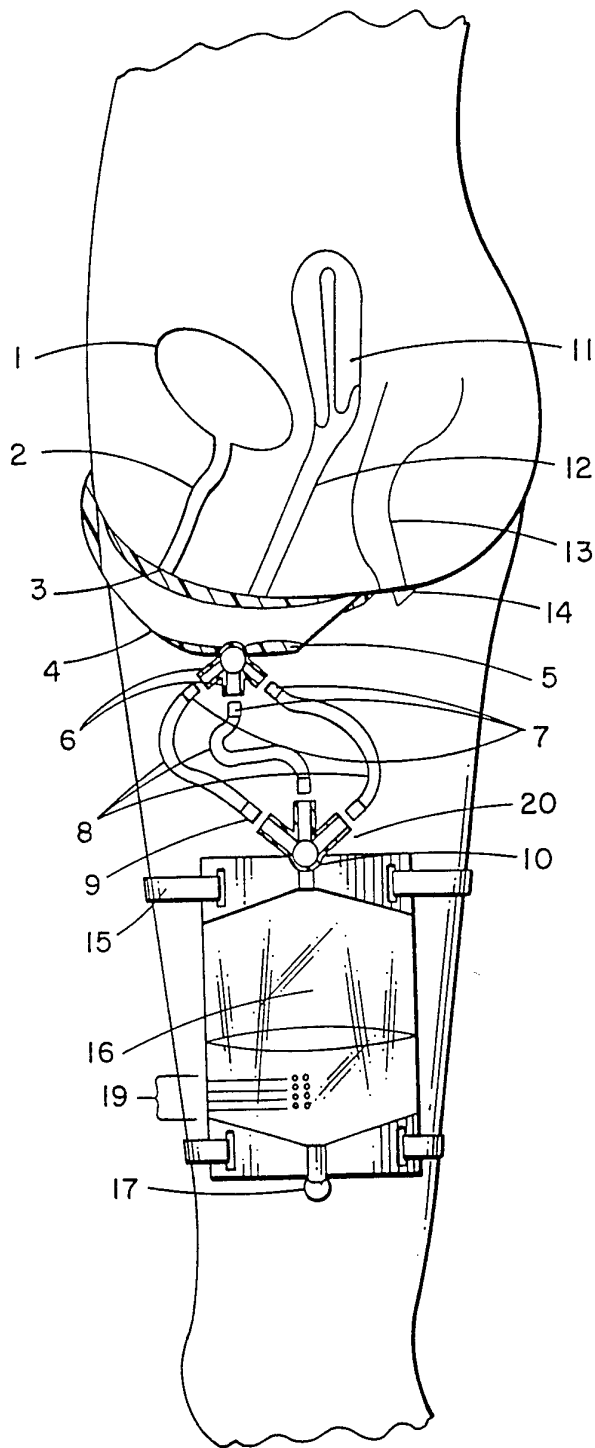


FIG. 1

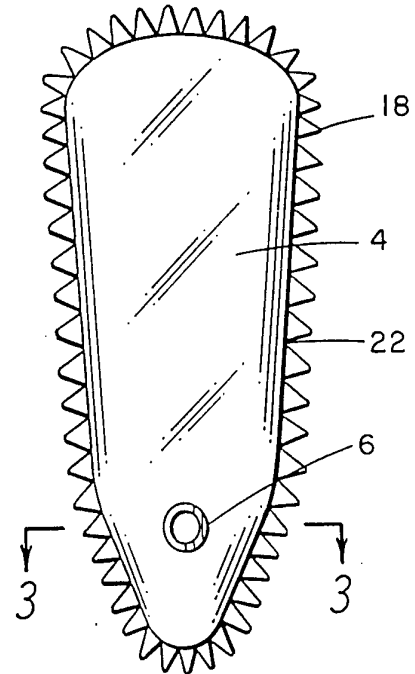


FIG. 2

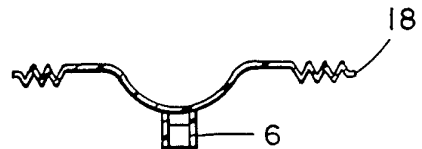


FIG. 3

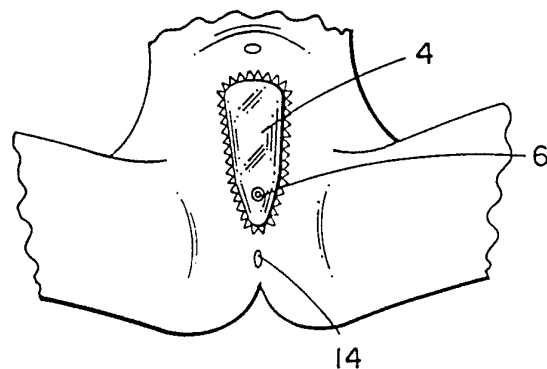


FIG. 4

2 / 2

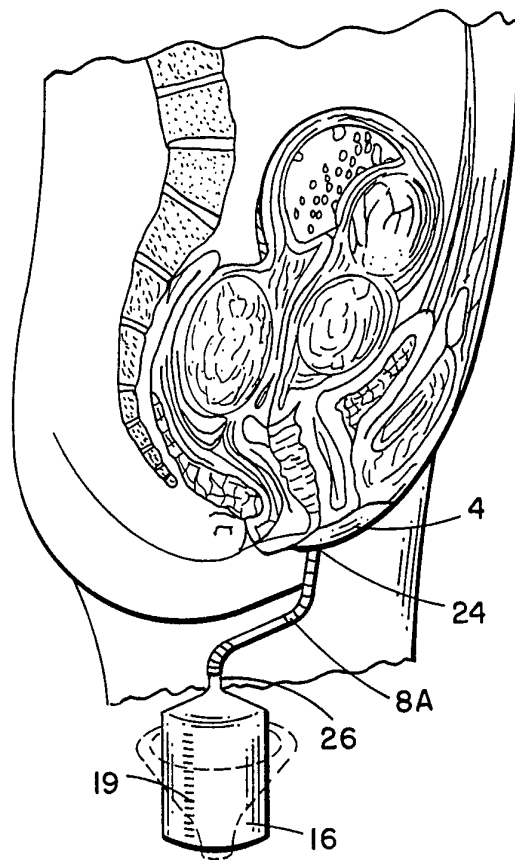


FIG. 5

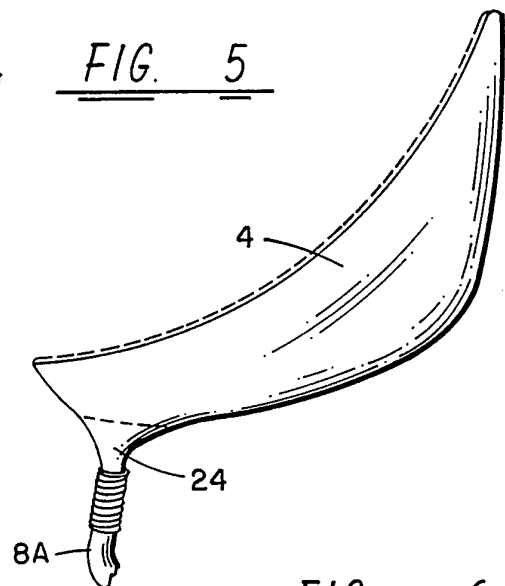


FIG. 6

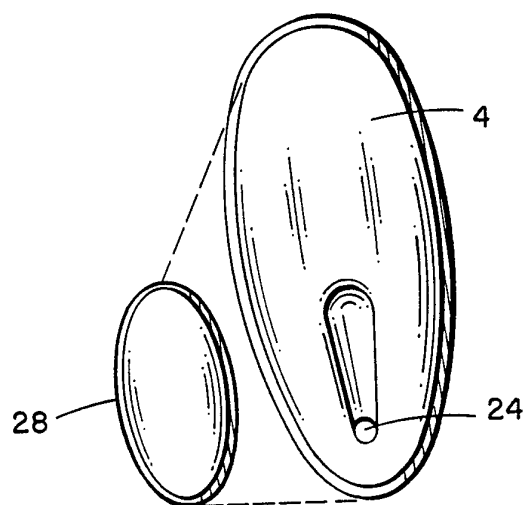


FIG. 7

## INTERNATIONAL SEARCH REPORT

 International application No.  
PCT/US95/07702

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 01/00

US CL : 604/327

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)

U.S. : 4/144.3; 128/844; 285/261; 604/326-331, 347, 349-353

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,233,978 (HICKEY) 18 November 1980, see Abstract and Fig. 5.	1, 2 ----- 3-11, 13, 14
Y	US, A, 4,563,183 (BARRODALE ET AL.) 07 January 1986, see column 4 lines 1-18, and Figs. 1 and 3.	5-7, 16-18
Y	US, A, 3,661,143 (HENKIN) 09 May 1972, see column 4 line 38.	8, 10, 21, 23
Y	US, A, 5,018,532 (ETHEREDGE, III) 28 May 1991, see Abstract.	9, 22
Y	GB, A, 2,126,902 (TOKARZ ET AL.) 04 April 1984, see page 3, column 1 lines 92-102.	11, 24

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"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
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"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 07 SEPTEMBER 1995	Date of mailing of the international search report 26 SEP 1995
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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US95/07702

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,846,816 (MANFREDI) 11 July 1989, see column 3 lines 39-56.	12-25
Y	US, A, 344,202 (J. T. ROBB) 22 June 1886, see Fig. 2.	19