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Broerman

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[45] **June 19, 1973**

[54] **MALE URINAL DEVICE**

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[21] Appl. No.: **183,589**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 8,819, Feb. 5, 1970, Pat. No. 3,608,552.

[52] **U.S. Cl.** **128/295**
[51] **Int. Cl.** **A61f 5/44**
[58] **Field of Search** 128/283, 294, 295

[56] **References Cited**

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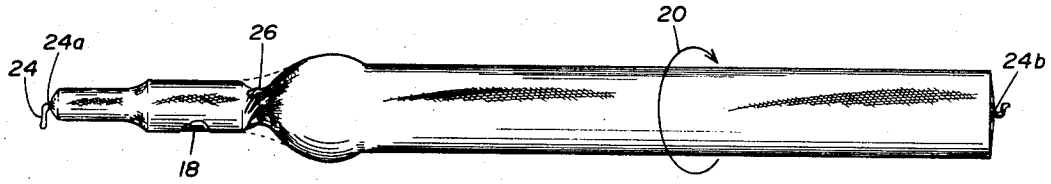
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Primary Examiner—Charles F. Rosenbaum
Attorney—Richards, Harris & Hubbard

[57] **ABSTRACT**

A male urinal device is provided. The device comprises a fabric base, tubular, expansible, liquid-conveying sheath adapted to receive the penis and be affixed thereto in fluid-tight relation, and includes a constricted downstream outlet section which is pivotally flexible at the point of constriction of the sheath by the action of an internal twist of the reinforcing fibrous tube. A fluid coupling member is contained within the outlet section. The fiber sheath is preferably impregnated with a silicone rubber, and in one embodiment of the invention is attached to the body with silicone resin adhesive.

4 Claims, 9 Drawing Figures



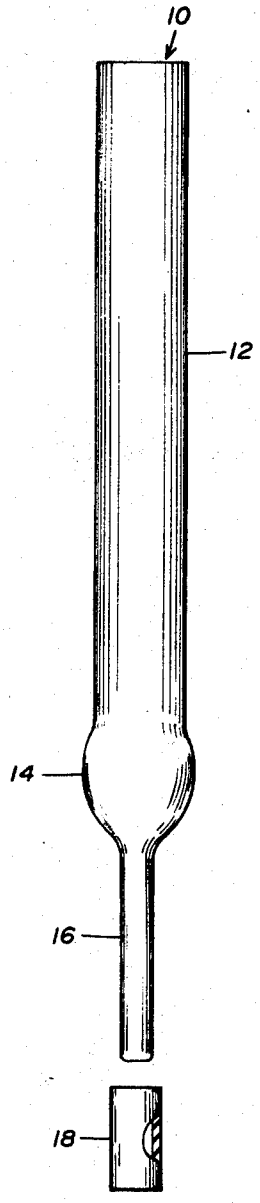


FIG. 1

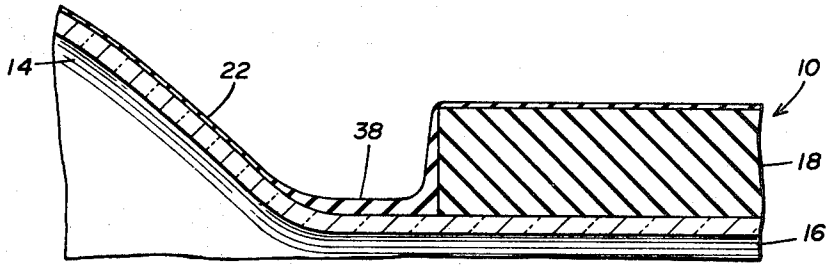


FIG. 2

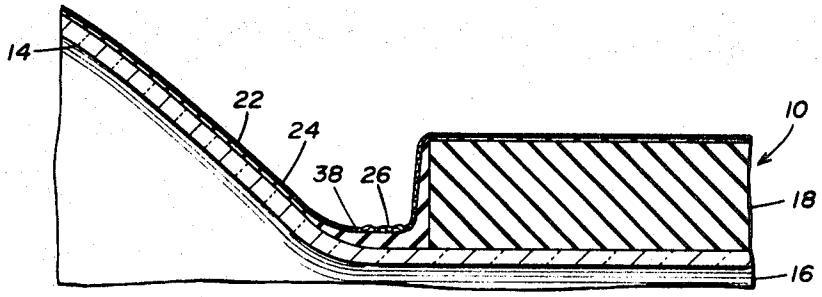


FIG. 4

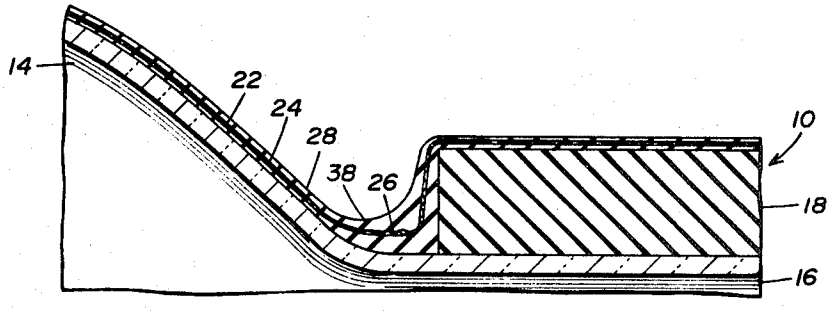


FIG. 5

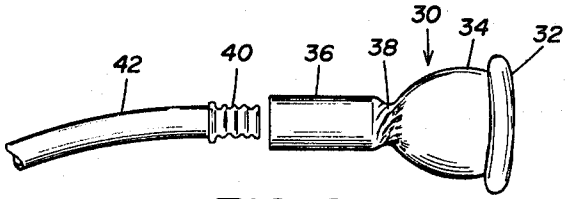


FIG. 6

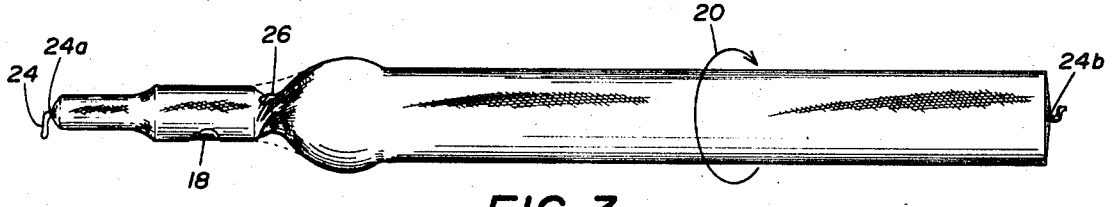


FIG. 3

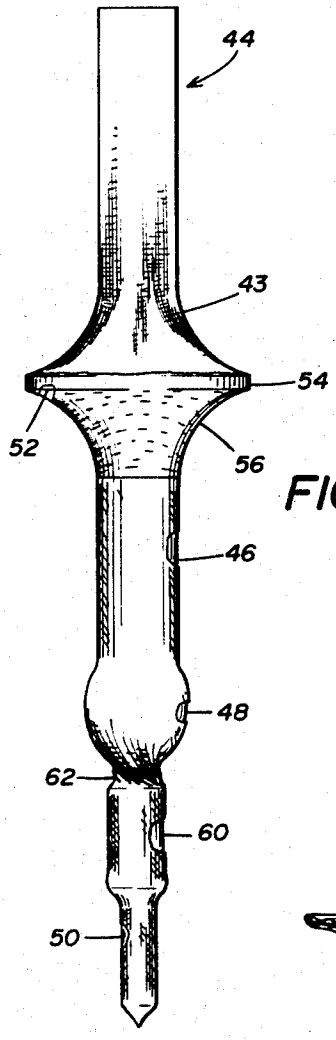


FIG. 7

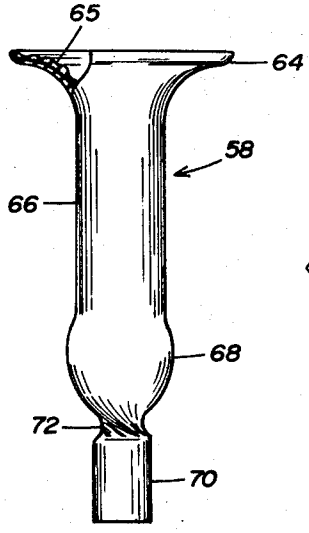


FIG. 8

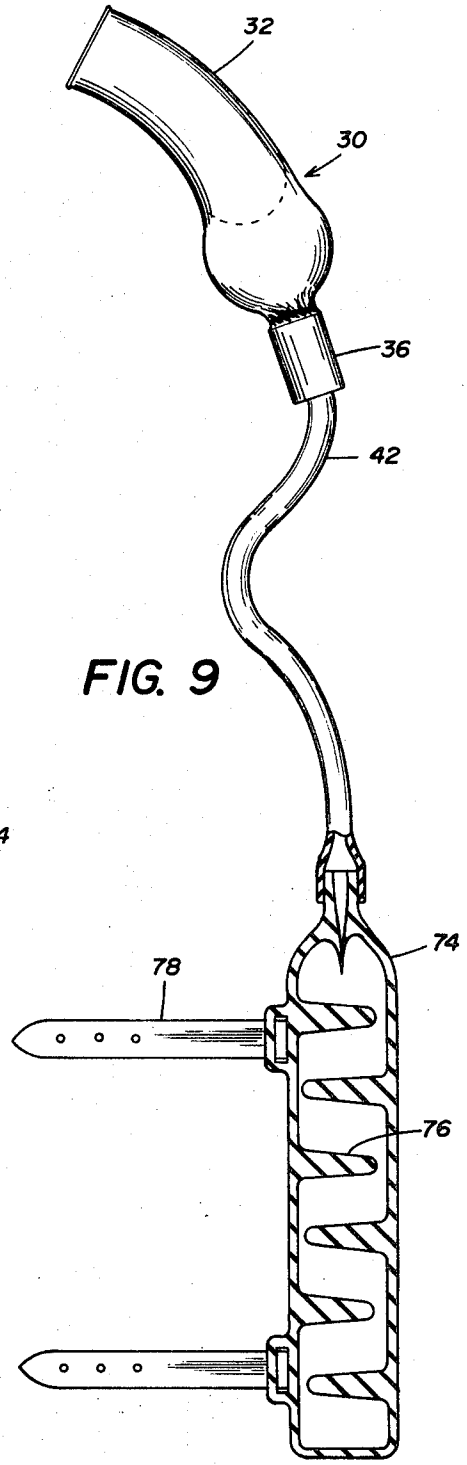


FIG. 9

MALE URINAL DEVICE

This invention is a continuation-in-part application of copending patent application, Ser. No. 8,819, filed Feb. 5, 1970 and now U.S. Pat. No. 3,608,552.

This invention relates to a male urinary evacuation device for use by individuals with partial or total urinary incontinence. In another aspect, this invention relates to a novel method of making a fiber-reinforced rubber impregnated tubular object having a constricted outlet which is pivotally flexible and adapted to allow liquid communication therethrough during flexure. In still another aspect, this invention relates to a novel method of making a male urinary evacuation device. In a further aspect, this invention relates to a novel method of providing for partial or total urinary incontinence of a male individual by bonding a silicone rubber urinal sheath directly to the skin with a silicone resin adhesive.

Prior art male urinal devices have had many disadvantages which have mitigated against their acceptance by the medical profession. Among these disadvantages are discomfort, lack of fluid tightness, bulk, and lack of flexibility. Prior art devices are also not satisfactory where, with some individuals, such as small boys, the penis periodically retracts and goes completely internal. Upon reemergence, the penis would not properly enter the prior art device, thereby causing the person great discomfort and embarrassment. Furthermore, when a device of this sort is worn by a person who moves around, there is a tendency for the device to twist at the area of connection with the smaller drain tube, and in some instances, for the collection container to be squeezed and accidentally force the collected urine back up the collection tube. Normally, backflow is prevented by a check valve in the bag inlet. However, on occasion that valve sticks or becomes inoperative, permitting excessive hydrostatic pressure to force the tubing to separate from the bag or device.

In addition, many such prior art devices comprise a relatively thick sheath member which must be held in place by an adjustable strap. Many times the strap is too tightly applied and causes edema as the result of constriction. Furthermore, because the sheath is relatively non-stretchable because of its thickness, it is uncomfortable to the wearer and will not accommodate both the flaccid and turgid state of the male organ.

Recently, the improved male urinary device has been developed which includes a fabric base, tubular, expansive, liquid conveying sheath adapted to receive the penis and be affixed thereto in fluid-tight relation and thereby overcomes many of the disadvantages of prior art devices. This device is disclosed in my copending patent application Ser. No. 8,819, filed Feb. 6, 1970.

One object of this invention is to provide an improved flexible fluid connection for rubber articles such as a male urinal device and a method for making the same.

Another object of this invention is to provide an improved male urinal device.

A further object of this invention is to provide a method for producing a fiber-reinforced expansible male urinal device having at the downstream end thereof a pivotally flexible outlet connection which allows liquid communication therethrough during flexure.

A further object of this invention is to provide a method for controlling urinary incontinence by applying a flexible silicone rubber sheath to a male and bonding it to the skin with silicone resin adhesive.

According to one embodiment of this invention, a novel method of producing a constricted, pivotally flexible fluid coupling for a tubular article such as a male urinal device is provided, comprising forming a layer of rubber, such as silicone rubber on a form for the device, placing an expansible fiber tube over the rubber layer and twisting the tube at the point of constriction on the form to position the fiber tube transverse of the axis thereof, and thereafter encapsulating the expansible fibrous tube with rubber to form a unitary body.

According to another embodiment of this invention, an improved male urinal device is produced by the method of said one embodiment.

According to still a further embodiment of this invention, a method of applying a male urinal device made of a material comprising silicone rubber is provided which comprises encapsulating the penis in such device and securing the device to the skin with a silicone resin adhesive

This invention can be more easily understood from a study of the drawings in which:

FIG. 1 is an elevational view of a mold for the novel male urinary device of this invention;

FIG. 2 is a partial sectional view of the mold of FIG. 1 carrying a fluid-tight connection member and a thin layer of rubber thereon;

FIG. 3 is a plan view of the mold of FIG. 1 carrying a knitted fabric tube thereon;

FIG. 4 is a partial sectional view of the mold of FIG. 3, carrying a knitted fabric tube thereon;

FIG. 5 is a partial sectional view of the mold of FIG. 3 wherein the fabric tube is encapsulated with a rubber material;

FIG. 6 is an elevational view of the male urinal device of this invention with a suitable drain tube connection;

FIG. 7 is an elevational view of an alternate form of the subject invention for producing urinary devices for small boys, which carries a knitted fabric tube thereon;

FIG. 8 is a perspective view of the male urinal device produced with the form of FIG. 7; and

FIG. 9 is a schematic view of the urinary system including the urinary device of the subject invention, drain tube, and cutaway section of a collection container therefor.

Now referring to FIG. 1, a form for producing the novel urinal device of the subject invention is illustrated in detail. Form 10 comprises an elongated cylindrical body section 12, bulbous section 14, and cylindrical section 16 which is smaller in diameter than body section 12. Form 10 can be made of any suitable material such as Teflon (a trademark for tetrafluorethylene) coated glass, or a polymeric material such as polyethylene, or Teflon. Form 10 is illustrated in the drawings as a Teflon coated glass body.

When utilizing form 10 of the subject invention, tube 18 which is a short piece of flexible tubing, preferably surgical tubing made of silicone rubber, is initially inserted upon cylindrical section 16 to a position shortly spaced from bulbous section 14 of mold 10 (see FIGS. 2 and 3). After tube 18 is properly positioned upon cylindrical section 16 of form 10, form 10 is dipped into a liquid uncured rubber bath to obtain a coating thereon.

Any elastomeric compound which can be handled in the liquid uncured state can be used, including purified liquid latex commonly used for the manufacture of medical devices. By proper selection of rubber and curing agent, a combination can be obtained which gives good room temperature vulcanizing properties, can be easily dispersed in the uncured state, and can be rapidly cured. However, silicone rubbers have substantial advantages. These rubbers generally do not tend to absorb urine odors and are capable of withstanding repeated high temperature treatments, for example, by autoclaving. Furthermore, the use of a silicone rubber device in accordance with one embodiment of this invention has substantial advantages, as will be described in detail hereinbelow. Therefore, the forming method will be described in relation to the production of a fiber base silicone rubber impregnated male urinal device.

After form **10** carrying tube **18** is dipped within a vat of liquid uncured silicone rubber, it is removed from the vat, horizontally positioned and then rotated about its axis (see directional arrow **20** in FIG. 3). The horizontal spinning operation will assure that a layer **22** of substantially uniform thickness will form and cure on the outside of body section **12** and bulbous section **14** (FIG. 2). It is noted that rubber layer **22** has a substantially greater thickness within constriction **38** than on the remainder of the form.

After rubber layer **22** has cured on the outside of form **10**, an expansible fabric, preferably knitted tube **24** is stretched over rubber layer **22** on form **10**. The ends **24***a* and **24***b* of knitted tube **24** are secured by suitable means such as tying, clamping, and the like to assure it will remain stretched over form **10** during the molding operation. The natural contraction of the knitted tube **24** causes it to tenaceously adhere to all peripheral areas on form **10** except the constricted region between bulbous section **14** and tube **18**, which it will bridge. This bridging action is shown by broken line in FIG. **3**. However, in order to obtain a pivotally flexible joint between the resulting molded unitary urinal device and the outlet connection therefor which will assure that liquid flow will pass therethrough during flexure of the outlet, it is necessary to twist knitted tube **24** at the constriction between bulbous section **14** and tube **18**. This action will cause sidewall portions **26** of knitted tube **24** to extend transverse to the axis of mold **10**, as illustrated in FIG. **3**. Thus, the sidewalls of knitted tube **24** are generally positioned parallel to the axis of body section **12** and bulbous section **14** of form **10**. However, sidewall portions **26** of knitted tube **24** are twisted in the constriction between bulbous section **14** and tube **18**. The position of knitted tube **24** upon rubber layer **22** carried by form **10** is illustrated in FIG. **4**.

Next, form **10** carrying knitted tube **24** is again dipped into the vat of uncured liquid silicone rubber. After the dipping operation, form **10** is placed in a horizontal plane and rotated about its axis as illustrated by directional arrow **20** in FIG. **3**. This operation will cause the thorough impregnation of knitted tube **24** by rubber layer **28** so that it is encapsulated within a resulting wall of silicone rubber formed by layers **22** and **28**, as illustrated in FIG. **5**. The resulting molded body has a sufficient strength for most applications. However, the thickness of the rubber layer on form **10** can be increased as desired by subsequent dipping and curing operations, as described above. In addition, a fiber-reinforced rubber roll ring can be formed on the proximal end of the device by severing the rubber layers and knitted tube with a circumferential cut around the proximal end of form **10**, rolling the formed tube at least one turn (generally one to three turns) toward the distal end therof and thereafter coating the roll with rubber such as by dipping the entire body in the uncured rubber.

Any fibers can be used to form knitted tube **24**, including cotton, polyester, spandex, polypropylene, nylon and others, or mixtures of such fibers. The main advantage to be gained by the use of the knitted tube is to give strength to the soft, pliable rubber portion of the device, while at the same time permitting necessary substantial expansion and contraction.

Once the sufficient thickness of the silicone rubber is acquired on form **10**, the last rubber layer is dusted with a powder, such as talcum powder, and the resulting male urinal device is removed from form **10** by rolling the resulting fiber-reinforced rubber tube from the proximal end of form **10** toward bulbous section **14** until the roll reaches bulbous section **14**. Next, the outlet section of the male urinal device formed by the coated surgical tubing **18** is engaged and removed from cylindrical section **16**, thereby carrying the entire urinal device **30** from the mold. The tubular end portion adjacent the downstream end of tube **18** is severed from the device to yield the male urinal device **30**, as illustrated in FIG. **6**.

As shown in FIG. **6**, male urinal device **30** comprises a unitary, expansible, silicone rubber-impregnated, liquid-impervious tubular fabric sleeve **32** (shown in the rolled position), surge chamber **34**, and an outlet section **36**. It is noted that the thickness of the sidewalls within constriction **38** is substantially greater (at least about twofold) than the thickness of the sidewalls of sleeve **32** and surge chamber **34**. Outlet section **36** is pivotally flexible at constriction **38** relative to surge chamber **34**, because of the thickly reinforced sidewall portions **26** of knitted tube **24** which are twisted transversely of the axis of urinal device **30** to yield an aperture at the downstream end of surge chamber **34**. The pivotal action of outlet section **36** with respect to the remainder of male urinal device **30** causes a slight deformation of surge chamber **34** adjacent constriction **38**; however, the aperture within constriction **38** will always remain open during complete flexure of outlet section **36** relative to surge chamber **34**. The flexible tube **18** which is contained within the major portion of outlet section **36**, serves as a fluid-tight female connection member and operatively functions with a serrated fluid-tight connection member **40** carried by outlet tube **42**, as illustrated in FIG. **6**.

Now referring to FIG. **7**, a suitable form for making a male urinal device for a small boy, is illustrated in detail. Form **44** as illustrated, carries knitted tube **43**. As shown, form **44** is basically the same as form **10**, illustrated in FIG. **1** and comprises a body section **46**, a bulbous section **48**, and a small diameter cylindrical section **50**. In addition, flange form **52** is operatively connected to body section **46** of form **44**. Flange form **52** comprises an outwardly extending disc communicating with body section **46** via sloping sidewalls **56**. In addition, sloping sidewalls **56** preferably carry a series of annular protrusions illustrated by broken line in FIG. **7**. The recessed areas between the annular protrusions serve to form protrusions on the interior of the resulting flange of the urinal device made by form **44**.

Urinal device 58, as illustrated in FIG. 8 is made utilizing form 44 by the same procedure as that described in relation to the production of urinal device 30. Initially, tube 60 (a short piece of flexible surgical tubing) is inserted upon cylindrical section 50 to a point shortly spaced from bulbous portion 48, and the mold is dipped in an uncured silicone rubber bath and cured while being rotated in a horizontal position. Form 44 is dipped into the rubber vat to a depth such that the outside edges 54 of flange form 52 are immersed. Next, knitted tube 43 is positioned over the cured rubber layer on form 44, and twisted at constriction 62 so that portions of the sidewalls of knitted tube 42 extend transversely of the axis of form 44. The end of knitted tube 43 which passes over flange form 52 is retained adjacent the proximal end of form 44 by any suitable means, such as clamps, bands, and the like. Next, form 44 carrying the knitted tube 42 is again dipped into the silicone rubber bath and immersed to a depth such that the outside edges 54 of flange form 52 are immersed. The dipped article is then cured while spinning on its axis in a horizontal plane. The form can be dipped as many times as desired to form the desired thickness of rubber thereon, however, generally the initial layer coupled with a layer which impregnates the knitted tube 43 is usually sufficient for most purposes.

Next, knitted tube 43 is severed adjacent the top of flange form 52. In addition, the lower tubular portion adjacent the downstream end of tube 60 is severed, and the resulting male urinal device 58 as shown in FIG. 8 is removed from form 44. The male urinal device comprises an attachment flange 64 carrying a series of gripping protrusions 65, an expansible, silicone-impregnated, liquid-impervious, tubular fabric sleeve 66, surge chamber 68, and outlet section 70. Outlet section 70 is pivotally flexible relative to male urinal device 58. The flexure of outlet section 70 in a pivotal manner will cause slight deformation of surge chamber 68; however, the aperture through constriction 72 will always remain open to fluid communication due to the reinforcing action of the sidewalls of knitted tube 43 which extend transversely to the axis of male urinal device 58 around constriction 72.

Male urinal device 30 for adult males and male urinal device 58 for small boys can be connected to a suitable container such as illustrated in FIG. 9. FIG. 9 shows the hook-up for a male urinal device 30, but it is understood that male urinal device 58 can be connected to the container in the same manner.

Referring now to FIG. 3, the downstream end of the male urinal device 30 (outlet section 36) is affixed to drain tube 42 which in turn is connected to the upstream end of container 74. Container 74 can be formed of a knitted fabric and rubber such as that used for the formation of male urinal device 30, thus providing odor-resistance and autoclaving capabilities. The walls of the container can be formed in any one of many ways known to the art, including molding a sheet of rubber from which the container walls are cut and then welding the outer edges together to form the container. It will be noted in the cut-out portion of the container that a number of projections 76 may be built into the inside walls of the container so as to prevent the container from being compressed to an extent that the hydrostatic pressure ruptures the bag or, in the event the check valve fails or sticks open, prevents hydrostatic pressure from forcing the drain tube connections to separate.

In utilization of this system, container 74 is affixed to the leg of the user by means of straps 78, or other suitable fastener means. The sleeve 32 is preferably rolled from the upstream end as shown in FIG. 6 for ease of placing on the penis. The position of the distal end of the penis is illustrated in broken line in FIG. 9. A medically approved body cement, such as medical adhesive "B," distributed by Dow Corning Medical Products Division, is used to coat a substantial portion of the penis. The sheath is then placed on the penis and unrolled letting the adhesive affix it in place.

When utilizing urinal device 58 for a small boy, the medical adhesive is applied to the inside of flange 64, and sleeve 66 encapsulates the penis while flange 64 is affixed to the body skin surrounding the proximal end of the penis.

It has been found in accordance with one embodiment of this invention, that the use of the silicone rubber-impregnated sheath urinal device and a silicone resin (organosiloxane polymer) adhesive is unexpectedly superior to the use of any other rubber, such as a rubber latex together with a medically approved adhesive including silicone resin medically approved adhesives. The silicone resin can be liberally applied to the penile shaft, or to the area surrounding the penis (for a small boy), and the silicone rubber is bonded thereto as the sheath is applied in the above-described manner to form a very tenaceous bond therebetween which is non-irritating to the skin and, that will not become separated in normal usage. This particular combination can be applied to the penis and left in place for several days without causing any harmful effects whatsoever, which is quite surprising due to the irritation and other deleterious effects which are commonly caused when using other combinations. The use of this combination can prevent fatal infections that oftentimes occur with paraplegics and other bedridden patients.

Male urinal devices 30 and 58 can be removed from the patient by the application of a suitable solvent to the silicone resin as the device is being pulled away from the skin. The preferred solvent to be used in the scope of this invention is the medical solvent disclosed and claimed in my copending patent application Ser. No. 163,498 filed July 16, 1971, and includes a combination of liquid aliphatic hydrocarbons and a silicone fluid.

While this invention has been described in relation to its preferred embodiments, it is to be understood that various modifications thereof will be apparent to one skilled in the art upon reading this specification and it is intented to cover such modifications as fall within the scope of the appended claims.

I claim:

1. A male urinal device comprising a unitary, expansible, rubber impregnated, liquid-impervious, tubular fabric sleeve, having a constricted downstream tubular end section which is pivotally flexible at the point of constriction thereof and which carries a fluid-tight coupling member therein, and an enlarged surge chamber adjacent the downstream end of said constriction.

2. The male urinal device of claim 1 wherein the fabric is of a knit construction, and wherein said sleeve is twisted at said point of constriction between said surge chamber and said fluid-tight coupling member.

3. The male urinal device of claim 2 wherein said rubber is silicone rubber.

4. The male urinal device of claim 2 wherein the upstream end portion is provided with an outwardly flaring flexible flange adapted to be adhesively joined in fluid-tight engagement to the human body.

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