

[54] DRAINAGE TUBE

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[51] Int. Cl. A61m 27/00

[58] Field of Search 128/2 R, 349 R, 350, 275

[56] References Cited

UNITED STATES PATENTS

3,220,960 11/1965 Wichterle et al. 128/2 R

3,566,874 3/1971 Shepherd 128/349
3,583,401 6/1971 Vaillancourt 128/275

Primary Examiner—Aldrich F. Medbery
Attorney, Agent, or Firm—Cushman, Darby &
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[57] ABSTRACT

Means are provided for eliminating negative pressure problem, e.g. in a closed urinary system comprising a catheter, a downwardly extending tube and a collection bag. The tube has an internal coating of a hydrophilic polymer, preferably a 2-hydroxyethyl methacrylate polymer, or can be made completely of the hydrophilic polymer.

9 Claims, 9 Drawing Figures

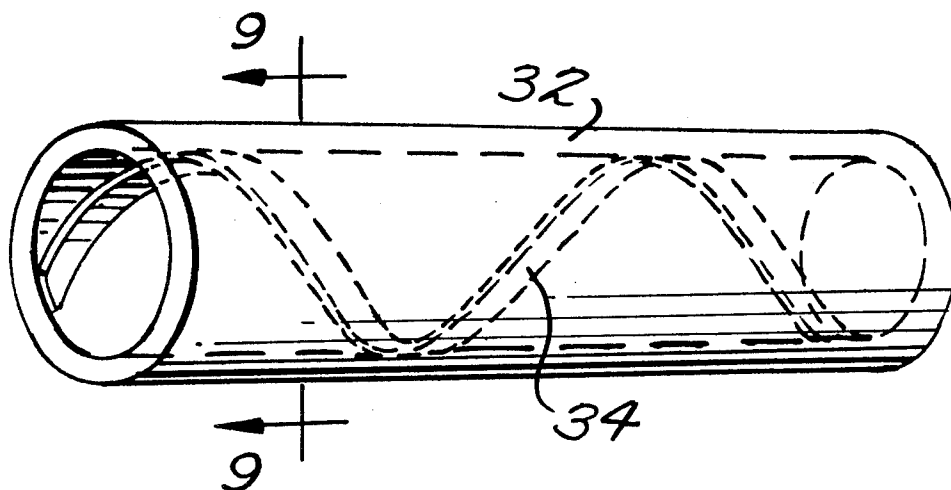


Fig. 1.

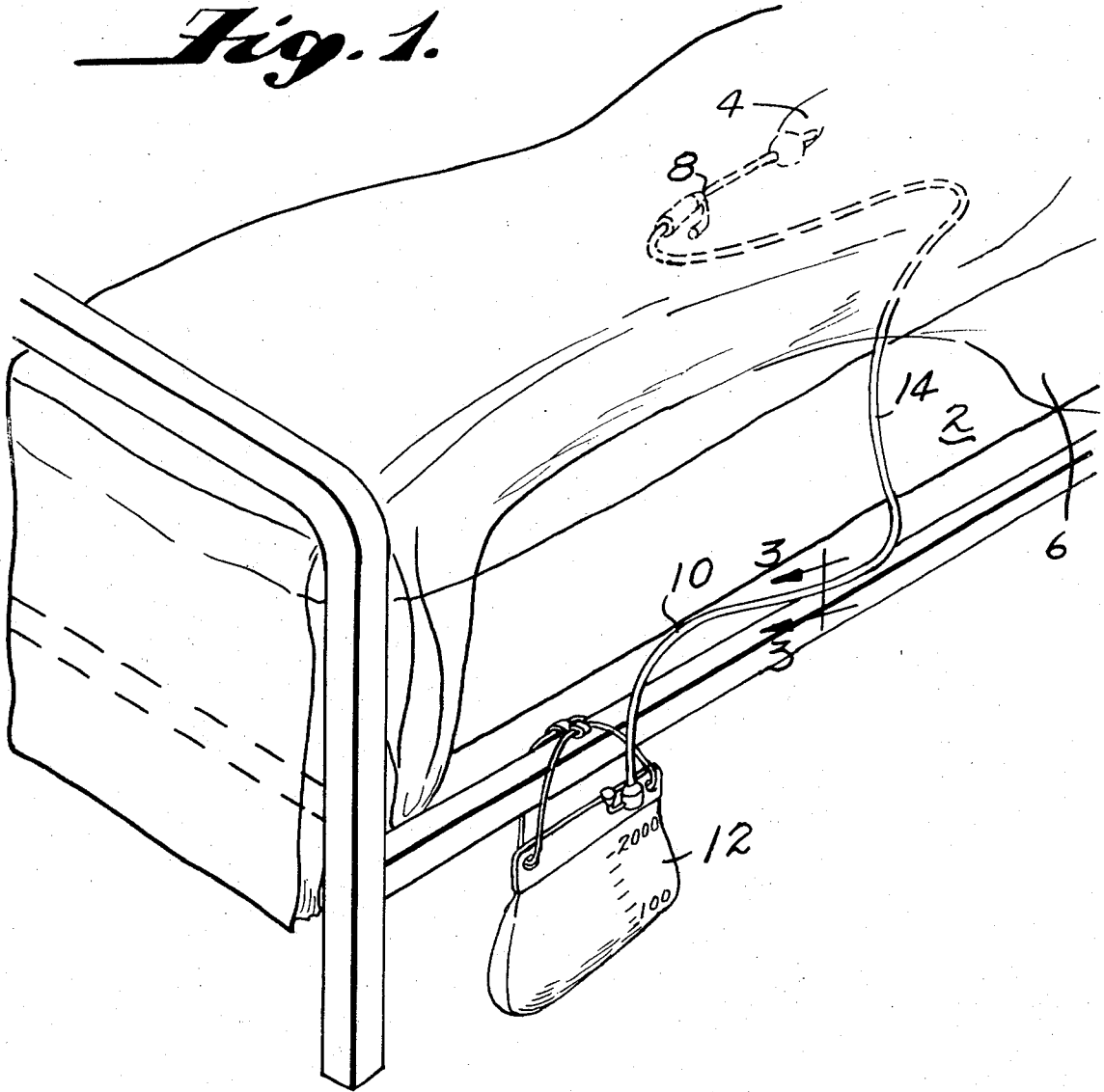


Fig. 2.

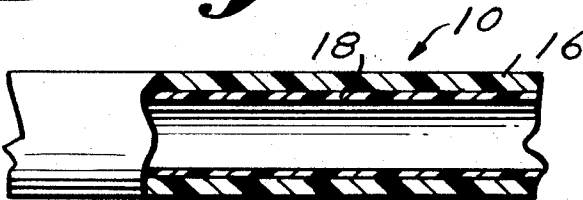


Fig. 3.

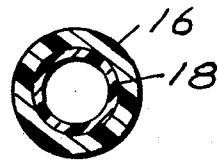


Fig. 4.

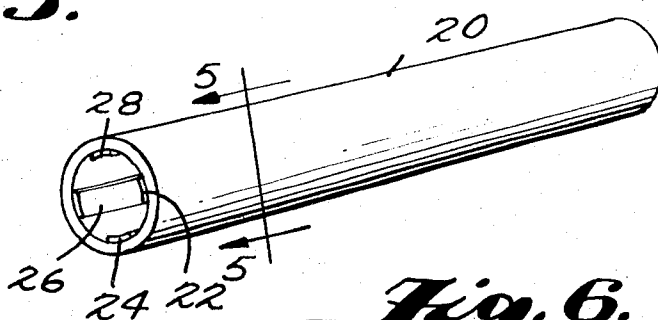


Fig. 6.

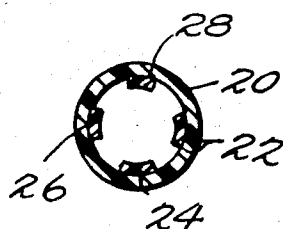


Fig. 7.

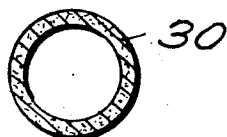
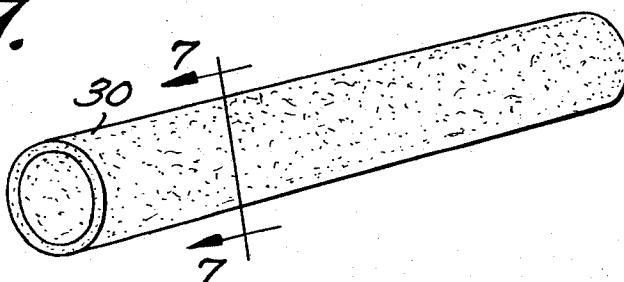


Fig. 8.

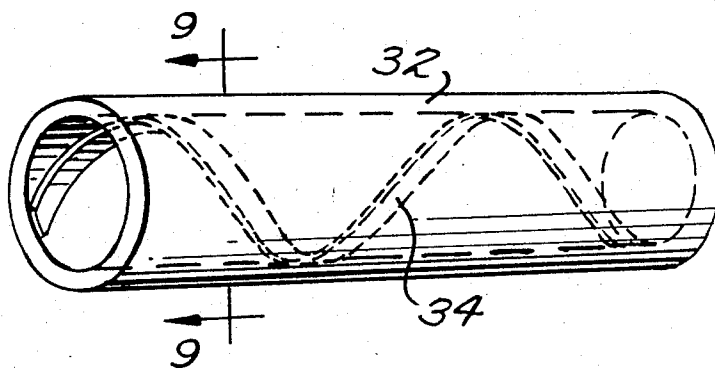
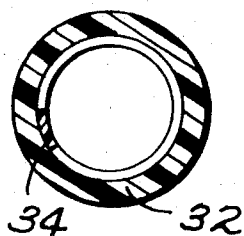


Fig. 9.



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DRAINAGE TUBE

This invention is concerned with a method for eliminating negative pressure and negative pressure build-up in the in-vivo and in-vitro drainage systems, more specifically for use in patients being catheterized and/or using shunts, hydro cephalic valves, etc. One current drainage system consists of a catheter to which is affixed a drainage tube and a collection bag for sampling. This system is normally totally closed, with a bacterial filter vent placed in the bag. A major problem with these systems is build-up of negative pressures in the bladder for example, due to the build-up of the fluids columns in the various cannulae (lumens), e.g. see Vaillancourt U.S. Pat. No. 3,583,401.

This build-up is due to a combination of: a) closed system- which precludes the influence of atmospheric pressures which would break this column, and b) the surface tension of the tubing which acts to hold or retain the fluid in the tube.

Methods currently used to overcome this problem include: large bore drain tubing and the placing of a vent in the catheter connector. The former solution suffers from the limitation that the product is bulky and difficult to work with, whereas the latter has been demonstrated to only work for a very short period of time before the filter element gets clogged due to infestations, and/or hydrostatic pressures. This disclosure is concerned with a novel method which allows for the use of smaller bore tubing, as well as functioning over the life of the drainage system.

Briefly, this invention is concerned with using a hydrophilic tubing having an internal diameter of at least 0.2 inch to prevent capillary action as the connecting member (drainage tube) between the cannulae and collector. It has been found that a hydrophilic tube (having water-wetting properties) will not support a column of fluid even though a vacuum may be applied at one end.

The entire connecting member can be made of a water insoluble hydrophilic polymer or alternatively the hydrophilicity can be imparted to a hydrophobic tubing by coating the inside (lumen) surface of a hydrophobic plastic polymer tube with a hydrophilic polymer. This form of the invention has the advantage over the use of an all hydrophilic polymer of being more economical and also of being able to take advantage of the strength, flexibility and other properties of the hydrophobic plastic.

As the hydrophilic polymer there are preferably employed polymers made from a hydrophilic monomer which are a hydroxy lower alkyl acrylate or methacrylate, or hydroxy lower alkoxy lower alkyl acrylate or methacrylate, e.g., 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, diethylene glycol monoacrylate, diethylene glycol monomethacrylate, 2-hydroxypropyl acrylate, 2-hydroxypropyl methacrylate, 3-hydroxypropyl acrylate, 3-hydroxypropyl methacrylate and dipropylene glycol monomethacrylate. The preferred monomers are hydroxyalkyl acrylates and methacrylates having 2-3 carbon atoms in the hydroxyalkyl group, most preferably 2-hydroxyethyl methacrylate as stated above. The polymers employed can be organic solvent soluble, e.g., alcohol soluble, but are water insoluble. The organic solvent soluble polymers can be prepared, for example, as shown in Shepherd U.S. Pat. No. 3,618,213 e.g., example 36 a, b and c or

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Chromacek U.S. Pat. No. 3,575,946. The entire disclosure of the Shepherd and Chromacek patents is hereby incorporated by reference.

The hydroxyalkyl acrylate or methacrylate less preferably can also be replaced in whole or in part by vinyl pyrrolidone, acrylamide, methacrylamide, N-propyl acrylamide, N-isopropyl methacrylamide, N-methylacrylamide, N-methylmethacrylamide, N-methylol acrylamide and N-methylol methacrylamide, N-2-hydroxyethyl acrylamide, N-2-hydroxyethyl methacrylamide. Since these monomers usually form water soluble homopolymers they require the presence of sufficient cross-linking agent or copolymerization with a sufficient amount of the hydroxyalkyl acrylates and methacrylates or other material to render the copolymers water insoluble. When such monomers are employed they are usually used in an amount of 1-60 percent, preferably 1-25 percent, of the total monomers by weight.

Other enthylenically unsaturated monomers can be used in conjunction with the above monomers to prepare the hydrophilic polymers. These include neutral monomers such as acrylonitrile, methacrylonitrile, vinyl acetate, alkyl acrylates and methacrylates, alkoxyalkyl acrylates and methacrylates.

Examples of alkyl acrylates and methacrylates include methyl acrylate, ethyl acrylate, butyl acrylate, 2-ethylhexyl acrylate, methyl methacrylate and butyl methacrylates. Examples of suitable alkoxyalkyl acrylates and methacrylates are methoxyethyl acrylate, methoxyethyl methacrylate, ethoxyethyl acrylate, ethoxyethyl methacrylate, propoxyethyl acrylate, butoxyethyl methacrylate, methoxypropyl acrylate, ethoxypropyl methacrylate. These comonomers when used in an amount preferably not higher than 50 percent (and usually between 0.5 and 20 percent) of the monomeric mixture contribute to the mechanical properties of the final gel. They should not be used in an amount to impair the hydrophilic nature of the polymer. Other vinyl monomers bearing ionizable functional groups can be copolymerized with the hydroxyalkyl acrylates or methacrylates. They include acidic type monomers such as acrylic acid, methacrylic acid, maleic acid, fumaric acid, itaconic acid, aconitic acid, cinnamic acid, crotonic acid, carboxylic acid, propionic acid, citraconic acid, vinyl sulfonic acid, p-vinylbenzenesulfonic acid, partial esters such as mono-2-hydroxyethyl itaconate, mono-2-hydroxypropyl citraconate, mono-2-hydroxyethyl maleate, mono-2-hydroxypropyl fumarate, monomethyl itaconate, monoethyl itaconate, monomethyl cellosolve itaconate (Methyl Cellosolve is the monoethyl ether of diethylene glycol), monomethyl Cellosolve maleate, mono-2-hydroxyethyl aconitate.

They also include basic type monomers such as aminoethyl methacrylate, dimethyl aminoethyl methacrylate, monomethylaminoethyl methacrylate, t-butylaminoethyl methacrylate, p-aminostyrene, o-aminostyrene, 2-amino-4-vinyltoluene, diethylaminoethyl acrylate, dimethylaminoethyl acrylate, t-butylaminoethyl acrylate, piperidinoethyl acrylate, piperidinoethyl methacrylate, morpholinoethyl acrylate, morpholinoethyl methacrylate, 2-vinyl pyridine, 3-vinyl pyridine, 4-vinyl pyridine, 2-ethyl-5-vinyl pyridine, dimethylaminopropyl acrylate, dimethylamino propyl methacrylate, dipropylaminoethyl acrylate, dimethylaminoethyl vinyl ether, dimethylaminoethyl vinyl sulfide, diethylaminoethyl vinyl ether, aminoethyl

vinyl ether, 2-pyrrolidinoethyl methacrylate 3-(dimethylaminoethyl)-hydroxypropyl acrylate, 3-(dimethylaminoethyl)-2-hydroxypropyl methacrylate, 2-aminoethyl acrylate, 2-aminoethyl methacrylate. The alkylaminoethyl acrylates and methacrylates are preferred in this group. In particular cases there can be used multipolymers prepared from a mixture of 3, 4 or more of the above monomers. These monomers are usually used in an amount of 0.1 – 20 percent, preferably 1 to 15 percent of the total monomers.

To make the final product insoluble in water (if it is not already insoluble therein) and organic solvents, it is eventually cross-linked. This is done by sparingly cross-linking the polymer. Preferably, the cross-linking agent is added in an amount of 1 to 10 percent most preferably, not over 2.0 percent, and still more preferably between 0.1 and 1 percent, although from 0.05 to 15 percent or even 20 percent of cross-linking agents can be used. Cross-linking renders the otherwise solvent soluble polymers insoluble, although it does not impair the hydrophilic properties.

Typical examples of cross-linking agents include ethylene glycol diacrylate, ethylene glycol dimethacrylate, 1,4-butylene dimethacrylate, diethylene glycol dimethacrylate, propylene glycol dimethacrylate, diethylene glycol dimethacrylate, dipropylene glycol dimethacrylate, diethylene glycol diacrylate, dipropylene glycol diacrylate, divinyl benzene, divinyl toluene, diallyl tartrate, allyl pyruvate, allyl malate, divinyl tartrate, triallyl melamine, N,N'-methylene diacrylamide, diallyl maleate, divinyl ether, diallyl monoethylene glycol citrate, ethylene glycol vinyl allyl citrate, allyl vinyl maleate, diallyl itaconate, ethylene glycol diester of itaconic acid, divinyl sulfone, hexahydro-1, 3, 5-triacryltriazine, triallyl phosphite, diallyl ether of benzene phosphonic acid, polyester of maleic anhydride with triethylene glycol, diallyl aconitrate, divinyl citraconate, diallyl fumarate, ammonium dichromate. Of course toxic cross-linking agents should not be used in therapeutic applications. Cross-linking can also be accomplished with dichromates, e.g., sodium, potassium and ammonium dichromate.

As catalysts for carrying out the polymerization there is employed a free radical catalyst in the range of 0.05 to 1 percent of the polymerizable hydroxyalkyl ester or the like. The preferred amount of catalyst is 0.1 to 0.2 percent of the monomer. Usually only a portion of the catalyst, e.g. 10–20 percent is added initially to the monomer and the balance is added to the casting syrup after partial polymerization. Typical catalysts include t-butyl peroctoate, benzoyl peroxide, isopropyl percarbonate, methyl ethyl ketone peroxide, cumene hydroperoxide, and dicumyl peroxide. Irradiation, e.g., by ultra violet light or gamma rays, also can be employed to catalyze the polymerization. Polymerization can be done at 20° to 150°C., usually 40° to 90°C.

The solvent soluble polymers can be applied as internal coatings to tubes made of a hydrophobic polymer, and the solvent evaporated. If a cross-linking agent is present the solvent soluble polymer can then be rendered insoluble, e.g., by heating.

If the entire tube is made of a hydrophilic polymer this can be accomplished conveniently by casting a syrup of cross-linkable partial polymer, e.g., using a casting syrup from 100 parts of 2-hydroxyethyl methacrylate and 0.2 parts of ethylene glycol dimethacrylate in the presence of a catalyst, e.g., t-butyl peroctoate,

such as the casting syrup in Shepherd U.S. Pat. No. 3,618,213, example 12 *b* and then curing to form a hydrophilic, water insoluble tube.

Alternatively instead of using hydrophilic polymer tubing the hydrophilicity can be obtained by internally coating a hydrophobic plastic cannula such as polytetrafluoroethylene, tetrafluoroethylene-hexafluoropropylene copolymer, polyurethane (either of the polyester or polyether type), polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-propylene-non conjugated polyene terpolymer, natural rubber, butadiene-styrene rubber, butadiene-acrylonitrile rubber, polyethylene terephthalate, polystyrene, polymethyl methacrylate, vinylidene chloride-acrylonitrile copolymer. The preferred hydrophobic tubing is made from a vinyl chloride polymer such as polyvinyl chloride and copolymers of vinyl chloride with vinylidene chloride, chlorostyrene, vinyl esters of carboxylic acids, e.g., vinyl acetate, vinyl propionate, vinyl butyrate and vinyl benzoate, esters of unsaturated acids, e.g., alkyl and alkenyl acrylates such as methyl acrylate, ethyl acrylate, propyl acrylate, butyl acrylate and allyl acrylate as well as the corresponding methacrylates, e.g., methyl methacrylate and butyl methacrylate, vinyl aromatic compounds, e.g., styrene, p-ethyl styrene, divinyl benzene, vinyl naphthalene, α -methyl styrene, p-methyl styrene, dienes such as butadiene and isoprene, unsaturated amides such as acrylamide, methacrylamide and acrylanilide and the esters of α , β -unsaturated carboxylic acids, e.g., the methyl, ethyl, propyl, butyl, amyl, hexyl, heptyl, octyl, allyl, methylallyl and phenyl esters of maleic, crotonic, itaconic and fumaric acids and the like. Specific examples of such esters are diethyl maleate, dibutyl maleate and dibutyl fumarate.

The copolymers in which at least 50 percent of the copolymers is made from vinyl chloride are preferably employed in the invention as is polyvinyl chloride.

Typical examples of copolymers include vinyl chloride-vinyl acetate (95:5 weight ratio), vinyl chloride-vinyl acetate (87:13 weight ratio), vinyl chloride-vinyl acetate-maleic anhydride (86:13:1 weight ratio), vinyl chloride-vinylidene chloride (95:5 weight ratio), vinyl chloride-diethyl fumarate (95:5 weight ratio), vinyl chloride-trichloroethylene (95:5 weight ratio).

The resin employed in the tubing, e.g., polyvinyl chloride, can either be plasticized or unplasticized. As the plasticizer there can be employed conventional materials such as dioctyl phthalate, octyl decyl phthalate, tricresyl phosphate, 2-ethylhexyl diphenyl phosphate, dodecyl dicresyl phosphate, tributyl acetyl citrate, dioctyl sebacate, dibutyl sebacate, etc. The plasticizer is used in conventional amount, e.g., 10 to 100 parts for each 100 parts of the vinyl chloride containing resin.

When a tubing such as polyvinyl chloride is coated with the hydrophilic polymer, this can be accomplished in any convenient fashion. Thus the polyvinyl chloride tubing can be dipped in a casting syrup of the hydrophilic polymer and the polymer cured, e.g., there can be used a casting syrup from 98.5 percent of 2-hydroxyethyl methacrylate and 1.5 percent of ethylene glycol dimethacrylate in the manner shown in Shepherd U.S. Pat. No. 3,556,874 col. 3, lines 5–12 and in example 16. If it is not desired to coat the outside of the tube, then it can be suitably protected in the dipping process, e.g., with a removable (e.g., prelabel) covering.

Any conventional coating process can be employed such as by spray coating or dip coating. There likewise can be used coextrusion so that the hydrophilic polymer is extruded as an integral inner concentric tubular liner for the polyvinyl chloride or other hydrophobic polymer. Spiral tubing can be prepared from the hydrophilic polymer either as the entire tubing or as an inner liner for polyvinyl chloride, etc., by winding on a mandrel. A film of the hydrophilic polymer can be joined to one of polyvinyl chloride on a mandrel.

The catheter employed can be a conventional catheter, e.g., of the Foley type but preferably is a catheter of the type set forth in Shepherd U.S. Pat. No. 3,566,874 which has an external coating, an internal coating or both an external and internal coating of hydrophilic polymer, e.g., as set forth in examples 19 and 22 of that patent. The entire disclosure of Shepherd U.S. Pat. No. 3,566,874 is hereby incorporated by reference.

The catheter can be made of natural rubber, synthetic rubber, e.g., poly cis isoprene, butadiene styrene copolymer, silicon rubber, neoprene, polyvinyl chloride, etc.

The invention will be understood best in connection with the drawings wherein:

FIG. 1 is a plan view showing the overall apparatus of the invention;

FIG. 2 is a fragmentary view partially in section of the drainage tube used in FIG. 1;

FIG. 3 is a view along the line 3—3 of FIG. 1;

FIG. 4 is a plan view of an alternative form of drainage tube;

FIG. 5 is a sectional view taken along the line 5—5 of FIG. 4;

FIG. 6 is a plan view of another form of drainage tube;

FIG. 7 is a view taken along the line 7—7 of FIG. 6;

FIG. 8 is a view of yet another form of drainage tube; and

FIG. 9 is a view taken along the line 9—9 of FIG. 8.

Referring more specifically to FIG. 1 of the drawings there is shown a conventional hospital bed 2 with a patient 4, covered by sheet 6. In the bladder of the patient there is inserted a Foley catheter 8. The Foley catheter can be of conventional rubber construction but preferably the rubber has external and internal coatings of a copolymer of 2-hydroxyethyl methacrylate and ethylene glycol dimethacrylate (e.g., 99.8:0.2). The catheter can be connected by a conventional adapter (not shown) to the drainage tube 10 which extends downwardly over the side of the bed and is connected to the drainage bag or receptacle 12. The area of urine hold up is designated at 14.

As shown in FIGS. 2 and 3 the drainage tube 10 is made of polyvinyl chloride 16 and there is provided an

overall internal coating 18 of hydrophilic cross-linked 2-hydroxyethyl methacrylate-ethylene glycol dimethacrylate copolymer (99.7:0.3).

As shown in FIGS. 4 and 5 there is provided a drainage tube 20 of polyvinyl chloride having internal strips 22, 24, 26, 28 running throughout its length of hydrophilic polymerized 2-hydroxyethyl methacrylate.

FIGS. 6 and 7 show a drainage tube 30 which is made entirely of a copolymer of 2-hydroxyethyl methacrylate and ethylene glycol dimethacrylate (99.8:0.2).

FIGS. 8 and 9 show a polyvinyl chloride drainage tube 32 having a helical inner liner strip 34 of a 2-hydroxyethyl acrylate-ethylene glycol diacrylate copolymer (99.8:0.2).

It is also possible to employ a tube extruded from a mixture of hydrophobic plastic, e.g., polyvinyl chloride and hydrophilic plastic, e.g., polymerized 2-hydroxyethyl methacrylate.

While the invention has been illustrated by an urinary drainage system, the invention is also useful in draining other human and animal cavities, for example, the thoracic suprapubic and cephalic regions.

What is claimed is:

1. A means for eliminating negative pressure and negative pressure build-up in a drainage tube in a system for the drainage of liquid from a body cavity comprising a tube of said system having an internal diameter of at least 0.2 inch, said means further including a coating extending the length of the tube and on at least a part of the inner peripheral surface of the drainage tube, wherein said coating is comprised, at least in part of a hydrophilic, water-insoluble plastic.

2. The means of claim 1 wherein the inner surface of the drainage tube is composed of said hydrophilic plastic.

3. The system of claim 2 wherein the entire drainage tube is made of said hydrophilic plastic.

4. The means of claim 2 wherein the drainage tube is made of a hydrophobic material and has a lumen and the lumen is coated at least in part by a geometrical arrangement of said hydrophilic plastic.

5. The means of claim 4 wherein the lumen is completely coated by said hydrophilic plastic.

6. The means of claim 4 wherein the hydrophobic material is a vinyl chloride polymer.

7. The means according to claim 6 wherein the lumen is completely coated by said hydrophilic plastic.

8. The means according to claim 7 wherein the hydrophilic plastic is a hydroxy lower alkyl acrylate or a hydroxy lower alkyl methacrylate polymer.

9. The means according to claim 8 wherein the hydrophilic plastic is a 2-hydroxyethyl methacrylate polymer.

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