PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 3 :
A61F 5/44; A61L 2/00
A61M 25/00; B01J 8/00

A1

(11) International Publication Number: WO 84/ 04036

(43) International Publication Date: 25 October 1984 (25.10.84)

(21) International Application Number: PCT/US84/00200

(22) International Filing Date: 13 February 1984 (13.02.84)

(31) Priority Application Number: 485,681

(32) Priority Date: 18 April 1983 (18.04.83)

(33) Priority Country: US

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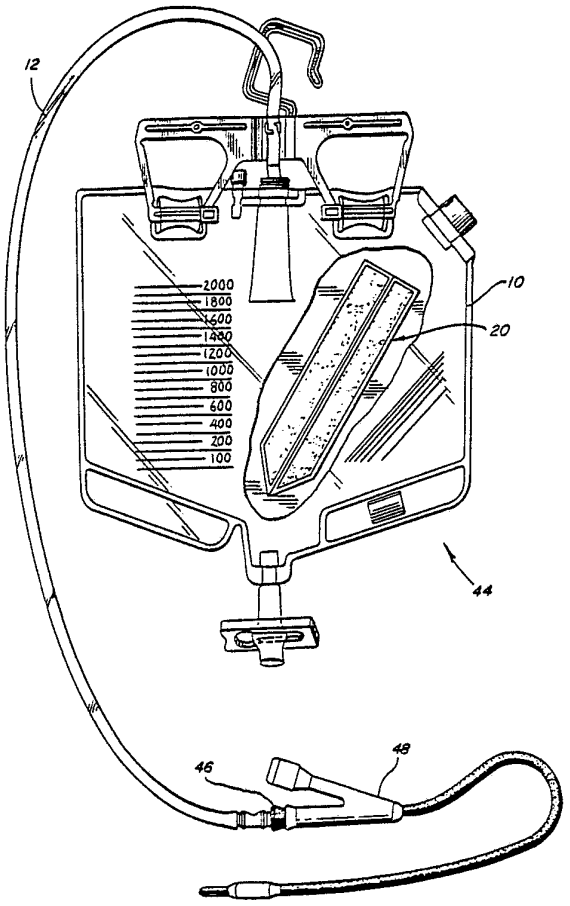
(81) Designated States: AU, BE (European patent), DE (European patent), FR (European patent), GB (European patent), JP.

Published
With international search report.

(54) Title: ARTICLES AND COMPOSITIONS PROVIDING ANTIMICROBIAL EFFECT DURING URINARY DRAINAGE

(57) Abstract

Compositions and an article of manufacture (20) intended for introduction into a urinary drainage bag (10) to provide antimicrobial effect to the interior of the urinary drainage bag (10) and the urine contained therein. The composition can be placed directly into the urinary drainage bag (10) and may be used as part of a urinary drainage system having a urinary drainage bag (10), a urinary catheter (48), and a catheter adapter (46) on the end of catheter tubing (12) providing flow communication from catheter (48) to bag (10). The article of manufacture (20) also can be used as part of a similar system. Antimicrobial effect is provided to the interior of the urinary drainage bag (10), and the catheter (48) and catheter adapter (46) provide levels of antimicrobial effect as well.



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ARTICLES AND COMPOSITIONS PROVIDING ANTIMICROBIAL EFFECT DURING URINARY DRAINAGE

Field of the Invention

Compositions and methods useful in providing antimicrobial effect to medical devices are numerous. This invention generally relates to articles of manufacture providing antimicrobial effect to urinary drainage systems. The specific province of this invention resides in compositions and an article of manufacture, generally for insertion into a urinary drainage bag, which provide antimicrobial effect to the interior of the urinary drainage bag and the urine contained therein. The article can be used as part of a urinary drainage system having a urinary drainage bag, a urinary catheter, and a catheter adapter on the end of catheter tubing providing flow communication from catheter to bag. When placed directly in the urinary drainage bag, the compositions also can be used as part of a similar system. The article, catheter and catheter adapter of the system all would provide levels of antimicrobial effect.

Background of the Invention

Indwelling urethral catheterization is performed in approximately 10 to 15 percent of hospitalized patients. About 25 percent of these patients contract bacterial infections of the urinary tract. Two studies of note are, Garibaldi, R. A.; Burke, J. P.; Dickman, M. L.; and Smith, C. B., "Factors Predisposing to Bacteriuria During Indwelling Urethral Catheterization". New England Journal of Medicine, 291:215, 1974, and Kunin, C. M. and McCormack, R. C., "Prevention of Catheter-Induced Urinary-Tract Infections by Sterile Closed Drainage". New England Journal of Medicine, 274:1155, 1966.

The incidence of catheter-induced urinary tract infections still remains a problem despite various prophylactic measures that have been tried. Attempts to reduce the incidence of urinary tract infections have included the application of antibiotic ointments or other bacteriocidal agents to the surface of the catheters, frequent bladder irrigation with concommitant prophylactic administration of antibiotics, or inhibition of the growth of bacteria in urine drainage containers. See, Akiyama, H. and Okamoto, S., "Prophylaxis of Indwelling Urethral Catheter Infection: Clinical Experience with a Modified Foley Catheter and Drainage System". The Journal of Urology, 121:40, 1979.

Urinary drainage bags have been cited as one of the contamination routes through which a patient may obtain a urinary tract infection when catheterized. Two other predominant sites susceptible to contamination which can contribute to urinary tract infections are the catheter adapter at the end of a catheter drainage tube which connects the urinary drainage bag with a catheter and the catheter itself. Microorganisms which have been introduced into the urinary drainage bag through the drainage conduit when the bag is emptied can colonize in the bag and migrate up the catheter drainage tubing and catheter and thereafter into a patient's bladder. Furthermore, microorganisms from an infected patient may proliferate in the urinary drainage bag and, when emptied, can lead to cross-contamination of other areas of the body, other patients, or both.

The patent literature is illustrative of attempts to eliminate the urinary drainage bag as a source of contamination leading to urinary tract infection. U.S. Patent 4,193,403, Patient-Care Apparatus Housing Device for Controlling Presence of Pathogens, to Langston, et al. and U.S. Patent 4,241,733, Patient-Care Apparatus With Device for Dispensing Anti-pathogenic Agent, to Langston, et al. describe a urinary drainage bag system where an antimicrobial agent is continuously released into the catheter drainage tubing

and the urinary drainage bag. The mode of release of the antimicrobial agent involves the depolymerization of paraformaldehyde into formaldehyde in the presence of moisture. Formaldehyde is not a preferred antimicrobial agent because it is believed to be a mutagen and a carcinogen.

Introducing 3 percent U.S.P. hydrogen peroxide solution into a urinary drainage bag prior to each period of urine collection significantly reduces the risk of urinary tract infection. This discovery is the subject of U.S. Patent 4,233,263, Method of Maintaining Bacterial Sterility in Urine Drainage Bags, to Schaeffer [hereinafter cited as Schaeffer]. The key to the effectiveness of the Schaeffer method is user compliance. Each time urine is drained from the urinary drainage bag, hydrogen peroxide must be reintroduced. Practical experience teaches that the hydrogen peroxide of the Schaeffer system must be actively mixed or agitated to disperse throughout the urine in the bag. Also, several urinary tract infection organisms are resistent to hydrogen peroxide.

U.S. Patent 3,312,221, Urinary Drainage Apparatus, to Overment describes a urinary drainage bag having a porous plastic pouch containing an antimicrobial agent. The pouch is suspended so that incoming urine cascades over and through the pouch so that the antimicrobial agent will dissolve in the urine. Adequate dwell time of antimicrobial agent in the urine is not always assured, however. Undersaturation of the urine is a possibility when there is a high flow rate of urine. Also, potential exists for restricting the flow of urine into the bag by the placement of the pouch in the urine flow path. This situation may become critical especially when there is high flow of urine or when a patient drains bloody or viscous urine.

It would be advantageous to have an article of manufacture for a urinary drainage bag which releases antimicrobial agent only when wet or humidified and not necessarily on a continuous basis.

Such selective release of antimicrobial agent would insure effectiveness for longer periods of time without excessively high concentrations or pressures of antimicrobial vapors.

A desirable antimicrobial agent would be less toxic than formaldehyde. The agent desirably would have high enough solubility in urine to exert antimicrobial effect, and it desirably would provide antimicrobial effect to those portions of the interior of the urinary drainage bag not contacting the urine.

Good dispersion qualities of the antimicrobial agent and an adequate dwell time in urine would be desirable. Undersaturation of the urine in high flow rate conditions would be obviated.

Also, it would be expedient to have a system which did not require introduction of antimicrobial agent into the urinary drainage bag each time after a bag is emptied. Placement of the antimicrobial agent desirably would be away from urine flow to avoid restricting urine flow.

Description of the Invention

An antimicrobial urinary drainage system and an article of manufacture having antimicrobial effect constitute this invention. A method of this invention comprises introducing a halogenating agent into a urinary drainage bag in order to provide antimicrobial effect to the urinary drainage bag interior and to urine in the bag. The article of manufacture comprises an antimicrobial gas-generating agent, for example, trichloroisocyanuric acid (TCCA), contained within a gas permeable material. The general configuration may be that of a pouch, a coated solid, a solid mixture or the like. A preferred embodiment is a pouch which may be segmented into compartments. The article also may be variously shaped as sheets, rods, tubes or the like. When the article, for example the pouch, is placed in a urinary drainage bag, it is exposed to humidity or wetness when urine is present. Water vapor diffuses through the material forming the pouch walls to activate the anti-microbial gas-generating agent. Chlorine gas or other vapor having antimicrobial effect is thus released through the pouch walls into the urine which contacts the pouch and is thus released into the drainage bag.

The material forming the pouch walls is permeable to at least water vapor and chlorine gas. Preferably it is a hydrophobic material permeable to gases but impermeable to fluids such as urine. When urine is drained from the urinary drainage bag, the pouch containing the antimicrobial agent remains in the bag. Chlorine gas or other vapor having antimicrobial effect is again released into the urine and drainage bag when fresh urine enters the bag. By pouch we also contemplate an agent coated by a gas permeable material and a solid mixture of antimicrobial agent and gas permeable material.

Solid, halogenating agents providing antimicrobial effect and suitable for direct introduction into the urinary drainage bag as a step in the method of this invention include, but are not limited to, the classes of N-halo-amines, N-halo-amides, N-halo-sulfonamides and hypochlorites, such as the following:

trichloroisocyanuric acid (TCCA), dichloroisocyanuric acid (DCCA) and alkali metal salts thereof, such as [(monotrichloro)-tetra-(monopotassium dichloro)] penta-isocyanurate, sodium dichloro-isocyanurate, sodium dichloroisocyanurate dihydrate and potassium dichloroisocyanurate; N-chlorinated-hydantoins, N-brominated-hydantoins and N-chlorinated-N-brominated-hydantoins, such as 1,3-dichloro-5, 5-dimenthyl hydantoin; chlorinated melamine, brominated melamine, and chlorobromomelamines, such as tri-chloromelamine, dichloromelamine and monochloromelamine; N, N'-dichloroazodicarbonamidine; sodium p-toluenesulfonchloramide; p-toluenesulfondichloramides; sodium benzenesulfonchloramide; succinchlorimide; p-sulfondichloramidobenzoid acid; calcium hypochlorite; chlorinated trisodium phosphate. Quantities of these agents, not contained within a gas permeable material, are introduced into a urinary drainage bag before each period of urine collection in the method of this invention.

Liquid antimicrobial halogenating agents suitable for direct introduction into the urinary drainage bag as a step in the method of this invention are aqueous solutions of hypochlorous acid, sodium hypochlorite, calcium hypochlorite or the agents listed in the paragraph above. Also, these liquid agents may be contained in non-porous, gas permeable containers made from, for example, polyethylenevinylacetate or silicone rubber.

One embodiment of the urinary drainage system of the present invention comprises a urinary drainage bag, catheter drainage tubing connected to the urinary drainage bag and terminating at one end in a catheter adapter, a catheter connected to the catheter adapter, and an antimicrobial agent contained by material to form a pouch or the like. The pouch easily can provide antimicrobial effect to the urinary drainage bag interior and urine collected therein. Portions of the catheter adapter, urinary catheter, or both are coated with

the antimicrobial composition of U.S. Patent Application Serial No. 439,506, Antimicrobial Compositions, to Laurin and Stupar, filed November 5, 1982 [hereinafter cited as the '506 application], commonly owned with this application by Baxter Travenol Laboratories, Inc., which material included therein is incorporated by reference.

Another embodiment of the urinary drainage system of the present invention is similar to the embodiment just described except that quantities of the solid halogenating agents or liquid halogenating agents, not contained within a material, are directly introduced into the urinary drainage bag before each period of urine collection.

The material forming the article, for example the pouch, of the present invention preferably is a hydrophobic, gas permeable material. The pouch is closed so that an antimicrobial agent contained therein is prevented from spilling out. TYVEK® non-woven, spun wound, microporous polyolefin fabric (TYVEK® is a registered trademark of E. I. du Pont de Nemours and Company), a hydrophobic, polyolefin paper material or the like, may be used as the material for the pouch or the like. Also, the material for containing the agent may be polyethylenevinylacetate or silicone rubber. Indeed, useful hydrophilic gas permeable materials may be used for containing the antimicrobial agent, for example, cellophane and polyvinylalcohol. Antimicrobial agent may be contained directly between layers of the material to form a closed pouch or the like. The agent may be contained in elongated gas barrier capsules in the pouch which protect the agent during storage and which can be broken later to expose the antimicrobial agent during urine collection use.

The antimicrobial agent also may be coated by the material or formed into a solid mixture with the material. The solid mixture then can be formed into configurations desired.

Alternatively, the urinary drainage bag may be manufactured with a polyolefin paper material window or other gas permeable material. An antimicrobial agent-containing pouch then may be attached

at the window area. This embodiment pouch preferably would have one side covered with metal foil or other gas impermeable material while the edges of the opposite face would contain an adhesive. This layered pouch then would seal in face-to-face engagement with the window on the urinary drainage bag.

An antimicrobial agent which preferably is contained in a TYVEK® material pouch is trichloroisocyanuric acid (TCCA). The other solid halogenating agents listed hereinabove also can be contained in the TYVEK® pouch. Gaseous chlorinating compounds from the TCCA or halogen gases from the other antimicrobial agent, would be released only in the presence of humidity or wetness. A sufficient quantity of agent to release antimicrobial gas for 10 to 14 days could be contained in the pouch.

One benefit of the present invention is that halogenating gases, such as chlorine, and hypochlorous acid, as the antimicrobial agent, are released only in the presence of humidity or wetness and not necessarily continuously released. It is contemplated that gaseous chlorinating compounds released in this way are less toxic than other antimicrobial agents introduced into urine.

Another benefit achieved by the present invention is that the solubility of the antimicrobial agent in urine is high enough to render the urine antimicrobial. Gas generated can render interior surfaces, not in contact with urine, antimicrobial as well. Impediments to urine flow from the catheter drainage tube are not present because the pouch or article does not reside in the urine flow path. Flow of urine is not restricted, and urine need not contact the pouch to render it antimicrobial.

An additional benefit of the present invention is that a pouch or article containing the antimicrobial agent need be introduced into the urine drainage bag only once. Treatment with additional antimicrobial agent after every emptying of the bag is not necessary with the pouch embodiment.

Brief Description of the Drawings

For a more complete understanding of this invention, reference should now be had to the embodiments illustrated in greater detail in the accompanying drawings.

In the drawings:

Figure 1 is a plan view of a urinary drainage bag, partially broken away, showing the antimicrobial agent-containing article in the form of a pouch inside the drainage bag.

Figure 2 is a partial plan view illustrating the pouch of the present invention being inserted into a urinary drainage bag.

Figure 3 is a plan view showing a urinary drainage bag with a gas permeable window and antimicrobial agent-containing pouch being affixed thereto.

Figure 4 illustrates, in perspective, an embodiment of the antimicrobial agent-containing pouch.

Figure 5 is a plan view of another embodiment of an antimicrobial agent-containing pouch having breakable, gas-impermeable ampules therein for containing the antimicrobial agent prior to use.

Figure 6 is a cross-section taken at 6--6 of Figure 5, showing the breakable ampules contained in the pouch.

Figure 7 illustrates, in a plan view, the urinary drainage system of this invention comprising a urinary drainage bag containing an antimicrobial agent-containing pouch, a catheter drain tube, a catheter adapter coated with an antimicrobial compound and a catheter coated with an antimicrobial compound.

Detailed Description of the Drawings

Turning now to the drawings, Figure 1 illustrates urinary drainage bag 10 of generally conventional configuration. Catheter drainage tubing 12 drains urine from an indwelling catheter to drainage bag 10. Drainage conduit 14, residing in the bottom of drainage bag 10, allows urine periodically to be emptied from bag 10. Port 16 is provided for insertion of an article, a pouch or the like comprised of material which contains an antimicrobial agent. Port 16 can be capped at its end 18 by a cap of appropriate configuration.

Pouch 20, containing an antimicrobial agent, is shown in the interior of urinary drainage bag 10. Pouch 20 is generally of rectangular configuration tapering to a pointed end 22. Pouch 20 is comprised of opposing layers of a gas permeable, urine impermeable, material. The material forming the layers is permeable to at least water vapor and chlorine gas. Preferably, pouch 20 is constructed of a hydrophobic material permeable to gases but impermeable to fluids such as urine. A preferred material for the layers is a non-woven, spun wound, microporous polyolefin material such as TYVEK® fabric. Pouch 20 is shown having two separate compartments 24, 26 each containing an antimicrobial, gas-generating agent, preferably trichloroisocyanuric acid (TCCA).

Other materials, both hydrophobic and hydrophilic, can be used to contain antimicrobial, gas-generating agents. These materials include polyethylenevinylacetate, silicone rubber, cellophane and polyvinylalcohol. Solid halogenating agents also can be coated by or mixed with these materials.

Other antimicrobial agents which release gases having antimicrobial effect at the bag interior can be contained within pouch 20 or coated or mixed with the gas permeable, urine impermeable materials. For example, the solid halogenating agents earlier identified can be used.

Urine from a patient drains through catheter drainage tubing 12 into urinary drainage bag 10. In the presence of humidity or wetness, a gas having antimicrobial effect at the bag interior is released. When TCCA is contained in pouch 20, chlorine gas and vaporous hypochlorous acid are released.

As earlier mentioned, pouch 20 may be made from a microporous, hydrophobic, polyolefin paper material such as TYVEK® fabric or nonporous highly gas permeable material such as polyethylene-vinylacetate or silicone rubber. Pouch 20 may be closed using conventional heat sealing techniques to form seal 28 at its periphery and to form seal 30 which separates pouch 20 into compartments 24, 26.

Pouch 20 is inserted into urinary drainage bag 10 as shown in Figure 2. Opposing layers of material 27, 29 comprise pouch 20. Pouch 20 conveniently can be folded along sealing line 30. Angled front portion 22 of pouch 20 allows its easy insertion through port 16. Pouch 20 can be packaged in aluminum or other metal foil, polymers of vinylidene chloride or the like to provide a vapor barrier for pouch 20 prior to use. Also, pouch 20 can be coated with a dissolvable material functioning as a vapor barrier; gelatins, polyvinylalcohol, inorganic salts or the like which dissolve in urine would be preferable.

Figure 5 illustrates another embodiment of the present invention. Urinary drainage bag 10a is substantially similar to urinary drainage bag 10 except as herein noted. The back 11 of urinary drainage bag 10a is illustrated in Figure 3. Window portion 32, of generally rectangular configuration, has been removed from back 11 of bag 10a. The bag material has been replaced by panel 34 generally made from a gas permeable, hydrophobic material such as a polyolefin paper, TYVEK® fabric or the like. Panel 34 is sealed along line 36 to the bag material.

Figure 4 illustrates an antimicrobial agent-containing pouch 20a substantially similar to pouch 20 except as hereinafter noted. Pouch 20a can be made from the same layers of opposing material

as pouch 20 with the exception that side 38 is backed with a gas and water impermeable material such as a metal foil, polyvinylidene chloride or the like. Also, pouch 20a can be made from one layer of gas permeable, hydrophobic material and an opposing layer of gas and water impermeable material. Pouch 20a is of generally rectangular configuration and is shown with two compartments 24a, 26a. Compartments 24a, 26a are filled with an antimicrobial agent such as TCCA or the like which can release an antimicrobial gas such as chlorine gas into the interior of bag 10a through gas permeable panel 34.

Still another embodiment of the antimicrobial agent-containing pouch 20b is illustrated in Figure 5. Pouch 20b is substantially similar to pouch 20 except as hereinafter noted. Compartments 24b, 26b of pouch 20b are shown separated by sealing line 30b. Elongated, breakable gas-impermeable ampules 40 are contained in compartments 24b, 26b. Ampules 40 contain an antimicrobial agent such as TCCA, or the like. When ready for use, ampules 40 in pouch 20b can be broken thereby providing the intended antimicrobial effect. Figure 6 illustrates a cross-section taken at 6--6 in Figure 5 showing ampules 40 containing antimicrobial agent 42. Ampules 40 can be made of glass, polymers of acrylonitrile or vinylidene chloride, other brittle plastics or metal foil-plastic laminates.

A particular advantage in using the embodiment of pouch 20b resides in its ease of storage. When antimicrobial agent 42 is TCCA or another chlorine gas releasing agent which functions in the presence of humidity or wetness, the agent 42 can be stored indefinitely. Chlorine gas will be released only when the ampules are shattered thereby exposing the antimicrobial agent to the atmosphere. Furthermore, pouch 20b conveniently may be placed in a urinary drainage bag at a manufacturing facility, prior to sterilization of the urinary drainage bag. Insertion of an antimicrobial agent-containing pouch into the urinary drainage bag

at a hospital by a nurse or other trained individual is obviated. All that needs to be done is the shattering of ampules 40.

Similarly, other problems are obviated by containing TCCA in ampules in pouch 20 before use. Chlorine gas released from TCCA reacts with polyvinyl chloride in urinary drainage bags causing yellowing in 7 to 10 days and a more severe tackiness over a period of months. Ethylene oxide sterilization of the urinary drainage bag could involve a vigorous reaction with TCCA and the production of toxic ethylene chlorohydrin. Encapsulated TCCA in a pouch would overcome these disadvantages thereby allowing pouches to be inserted as a manufacturing step.

Antimicrobial urinary drainage System 44 is illustrated in Figure 7. System 44 comprises urinary drainage bag 10, antimicrobial agent-containing pouch 20, catheter drainage tubing 12, catheter adapter 46 and urinary catheter 48. Urinary catheter 48 communicates with catheter adapter 46 which communicates with urinary drainage bag 10 through urinary drainage tube 12. Catheter 48 and catheter adapter 46 are shown having surfaces coated with a composition having antimicrobial effect. The antimicrobial composition preferably is chosen from among the compositions disclosed in our prior patent application, the '506 patent application. In System 44, either catheter adapter 46, catheter 48 or both may have surfaces coated with an antimicrobial composition.

A method of this invention involves directly introducing an uncoated solid or aqueous halogenating agent into the urinary drainage bag. Referring again to Figure 1, instead of introducing a pouch into the interior of urinary drainage bag 10, a halogenating agent is introduced into bag 10 through port 16 prior to each period of urine collection. For example, the solid and liquid antimicrobial agents earlier identified can

be used. Antimicrobial effect is provided to urine contained therein and to interior portions of bag 10 not directly contacting urine.

The examples below are offered for illustrative purposes only and are not intended to limit the scope of the invention of this application, which is defined in the claims below.

EXAMPLE 1

A urinary drainage bag of conventional configuration was opened and a pouch made from TYVEK® polyolefin fabric material was placed thereinto. The pouch measured 8-1/2 inches by 4 inches and was segmented into 12 equally sized compartments. Each of the 12 compartments contain approximately 1 gram of powdered trichloroisocyanuric acid. The drainage was sealed closed. Over an 8-hour period, 500 milliliters of urine containing 10^5-10^6 E.Coli per milliliter was infused into the bag. Urine drained from the bag was filtered, and the filter was cultured for bacterial growth. No organisms grew on the filter after 16 of the 8-hour challenges described above.

EXAMPLE 2

A TYVEK® polyolefin fabric material pouch measuring approximately 8 inches by 3 inches and divided into two compartments containing a total of 20 grams of TCCA was inserted into a urinary drainage bag. 500 milliliters of urine containing 10^5-10^6 E.Coli per milliliter was then infused into the bag over an 8-hour period. Urine drained from the bag was filtered and cultured for bacterial growth. No bacteria grew on the filters after six such challenges.

EXAMPLE 3

A tablet, approximately 1 inch diameter and 1 1/2 inch thick,

made from one part powdered TCCA (less than 100 mesh size particals) and one part silicone rubber (alkoxy-cured RTV) was placed into a urinary drainage bag. One ml. of urine challenge containing 10^5 organisms (E.Coli or candida albicans) was added through the drainage port at the bottom of the bag. Urine was added to the bag at a rate of 500 ml. per 8 hours. After 8 hours of collection, urine was drained and filtered. The filters were cultured. No growth of bacteria occurred on the filters after 14 of these challenges and bag fillings.

EXAMPLE 4

Quantities of various halogen-releasing agents were added to 50 ml. of urine. Prior to the addition of the agents, the urine was sterilized by microporous filtration. Samples were left at room temperature for more than 8 hours. The samples then were contaminated with microorganisms to the level of 10^4 organisms per milliliter. Periodically, urine from the samples was streaked on agar plates and incubated to detect the amount of surviving organisms compared to urine with no antimicrobial agents added thereto. Separate populations of microorganisms introduced into the samples were E.Coli, Candida albicans, Pseudomonas aeruginosa, and Staphylococcus aureus. Results of the separate challenges were generally identical and are tabulated in Table 1 below. As used below, cidal means no surviving organisms detectable, and static means no organisms multiplied in the treated urine.

TABLE 1

Agent	Concentration in Urine (wt%)	Appearance Initially	Activity Against all Organisms	Appearance After 1-2 days
TCCA	0.02	Clear	30 min. - Cidal	Clear
Br_3Cl-dimenthyl hydantoin	1.0	Slightly turbid	Less than 1 hr. - Cidal	Slightly turbid
Chloramine -T	1.0	Slightly turbid	Less than 1 hr. - Cidal	Slightly turbid
Trichloro-melamine	0.2	Clear, sl. orange	30 min. - Cidal	Clear, sl. orange
$Ca(OCl)_2$	0.04	Clear	24 hr. - static	Clear (no growth)

WHAT IS CLAIMED IS:

1. An article of manufacture for use with a urinary drainage bag comprising:

a closed, urine-impermeable, gas permeable pouch means; and,

an agent contained in said pouch means for generating gas having antimicrobial effect upon activation by proximity to urine.

2. The article of manufacture of Claim 1 wherein said pouch means is made from hydrophobic material.

3. The article of manufacture of Claim 2 wherein said closed, gas permeable, hydrophobic pouch means is made from opposing layers of gas permeable, hydrophobic material, said pouch means having at least two separate compartments.

4. The article of manufacture of Claim 2 wherein said closed, gas permeable, hydrophobic pouch means is made from opposing layers of polyolefin paper material.

5. The article of manufacture of Claim 3 wherein said closed, gas permeable, hydrophobic pouch means is a polyolefin paper material.

6. The article of manufacture of Claim 1 wherein said agent generates a gaseous halogen compound.

7. The article of manufacture of Claim 2 wherein said agent generates a gaseous halogen compound.

8. The article of manufacture of Claim 3 wherein said agent generates a gaseous halogen compound.

9. An article of manufacture for use with a urinary drainage bag and providing antimicrobial effect to the bag interior, comprising:

a closed pouch made from opposing layers of gas permeable, hydrophobic material, said pouch having at least two separate segments, wherein said hydrophobic material is a polyolefin paper material; and,

trichloroisocyanuric acid contained in said pouch for generating chlorine gas and hypochlorous acid vapors when humidity is present.

10. A urinary drainage system comprising:

a urinary drainage bag; and,

a closed pouch made from opposing layers of a gas permeable, hydrophobic material, said pouch containing an agent for generating a gaseous halogen compound.

11. The urinary drainage system of Claim 10 further comprising a urinary catheter communicating with said urinary drainage bag, said urinary catheter having surfaces coated with a composition having antimicrobial effect.

12. The urinary drainage system of Claim 10 further comprising a urinary catheter adapter communicating with said urinary drainage bag and intended for communication with a urinary catheter, said catheter adapter having surfaces coated with a composition having antimicrobial effect.

13. A urinary drainage system comprising:

a urinary drainage bag;

a closed pouch made from a gas permeable, hydrophobic polyolefin paper material and containing an agent for generating chlorine gas;

a urinary catheter adapter communicating through a catheter drainage tube with said urinary drainage bag, said catheter adapter having a surface coated with a composition having antimicrobial effect; and,

a urinary catheter communicating with said catheter adapter and having a surface coated with a composition having antimicrobial effect.

14. The urinary drainage system of Claim 13 wherein said agent for generating chlorine gas is trichloroisocyanauric acid, said urinary catheter adapter and said urinary catheter being coated with an antimicrobial composition comprising 30 to 85 percent by weight of a binder consisting essentially of a material selected from the group consisting of acrylonitrile-butadiene-styrene copolymers, polyvinyl chloride, mixtures thereof, polyesters, polyurethanes, styrene-containing block copolymers,

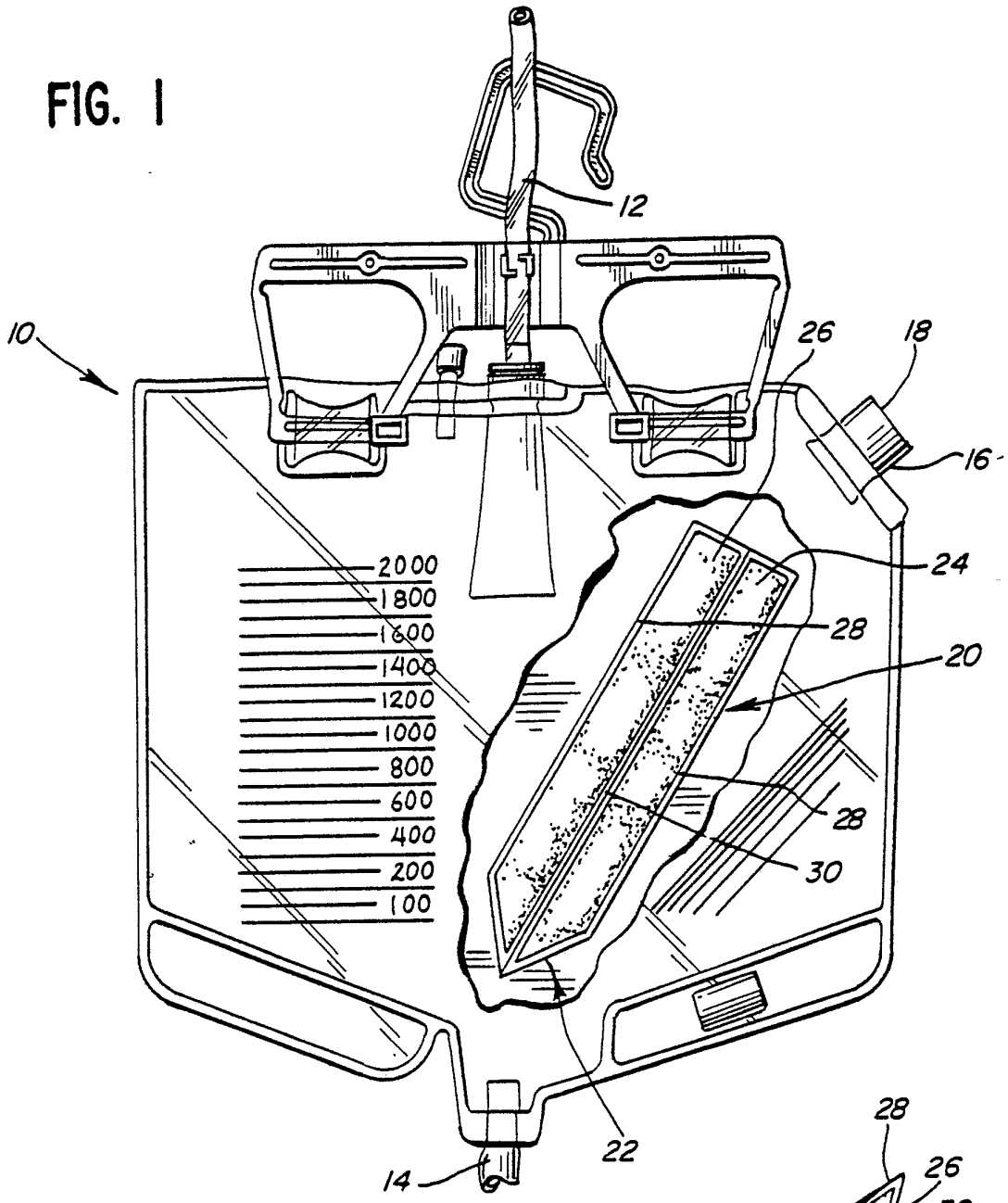
natural and synthetic rubbers, polycarbonates, nylon and silicone rubber; and 15 to 70 percent by weight of an antimicrobial agent selected from the group consisting of compounds of physiologically acceptable, antimicrobial metals and mixtures thereof.

15. A method of providing antimicrobial effect in a urinary drainage bag wherein urine is collected in said bag for a period of time and then emptied therefrom, consisting essentially of introducing into said bag for each period of urine collection a halogen compound-releasing agent.

16. The method of Claim 15 wherein said agent is selected from the group consisting of N-Halo-Amines, N-Halo-Amides, N-Halo-Sulfonamides and hypochlorites.

17. The method of Claim 15 wherein said agent is trichloro-isocyanuric acid.

FIG. 1



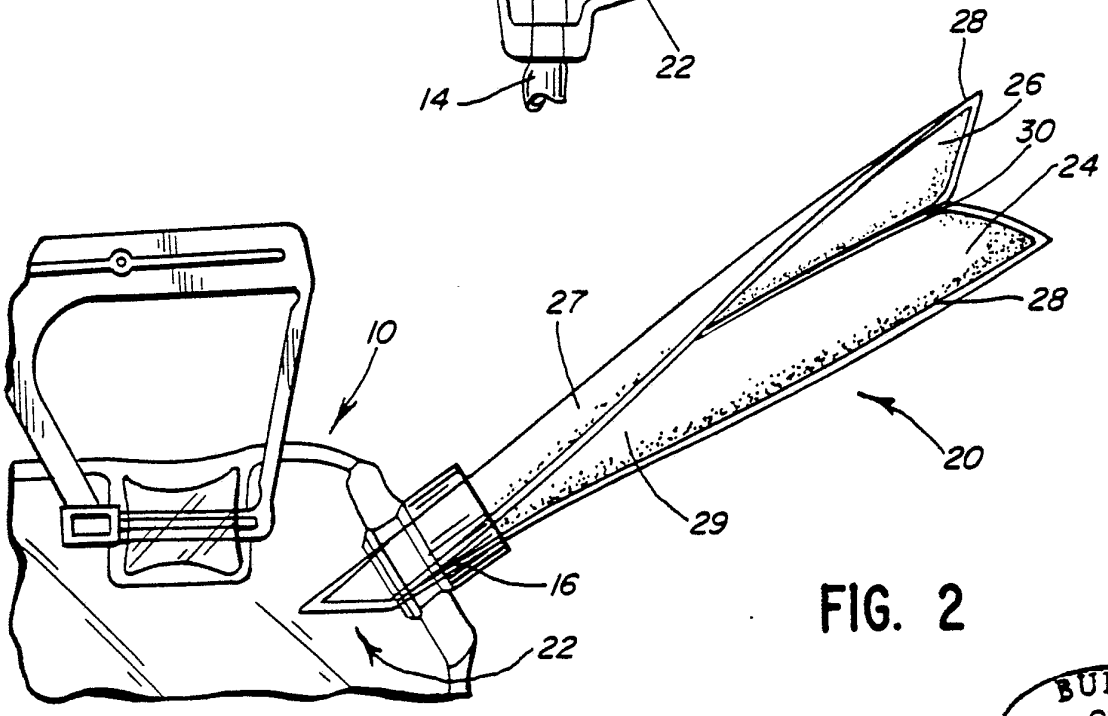


FIG. 2

FIG. 3

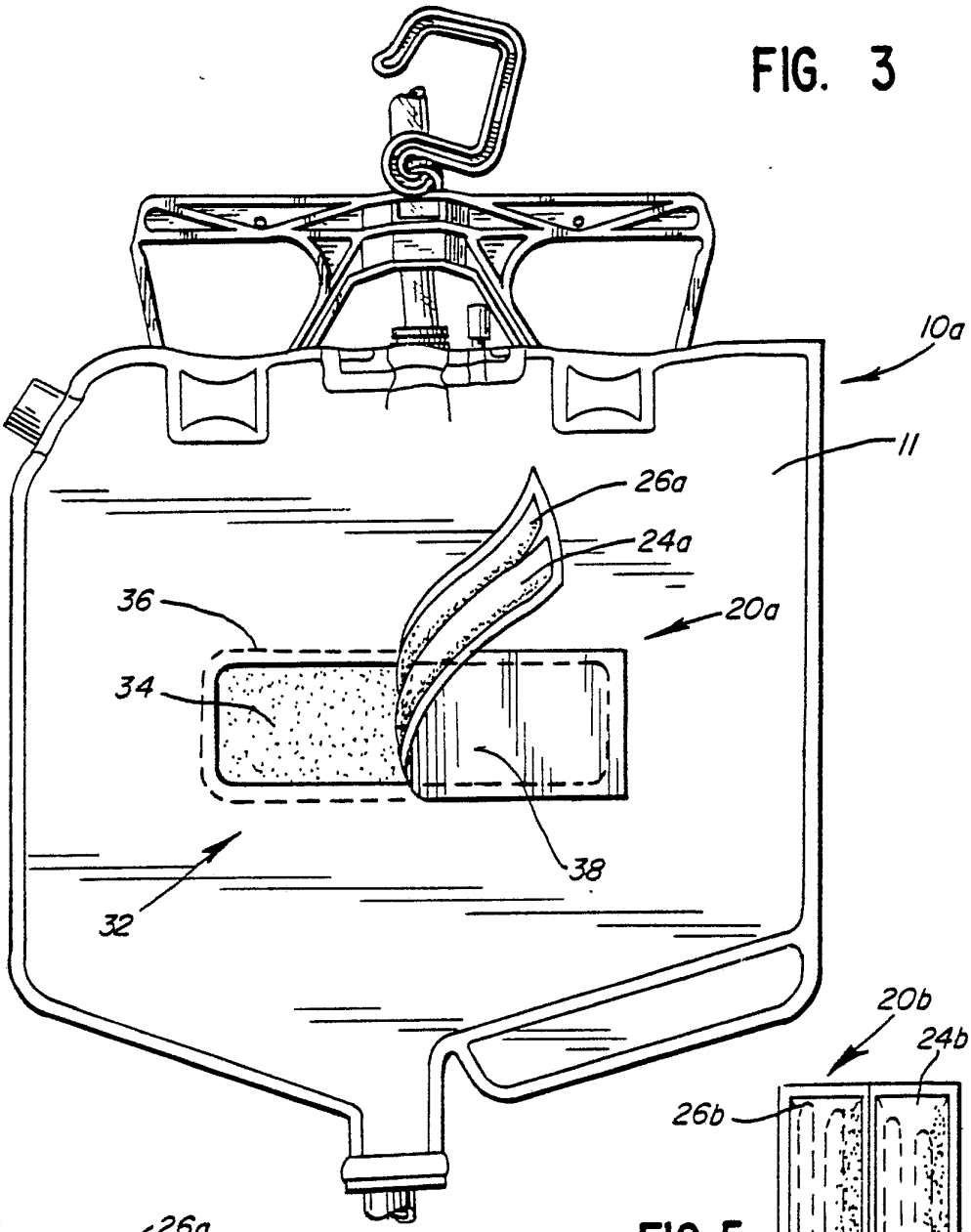


FIG. 4

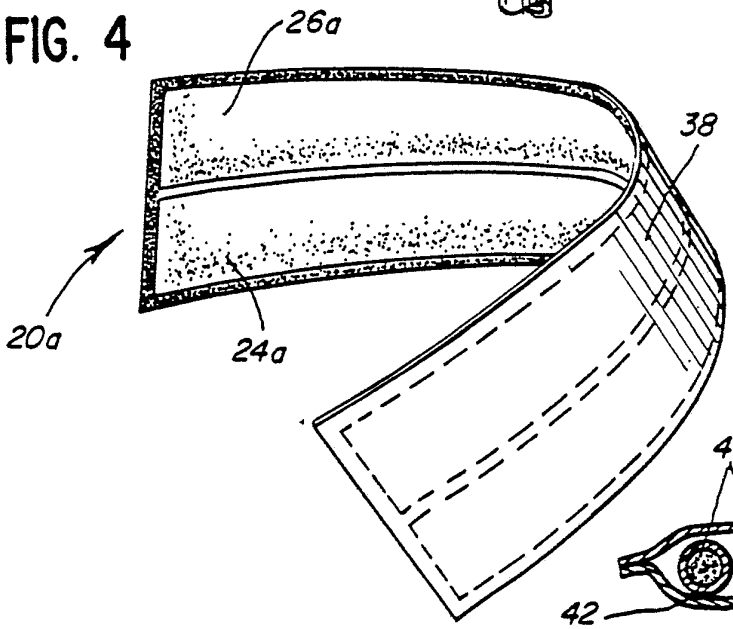
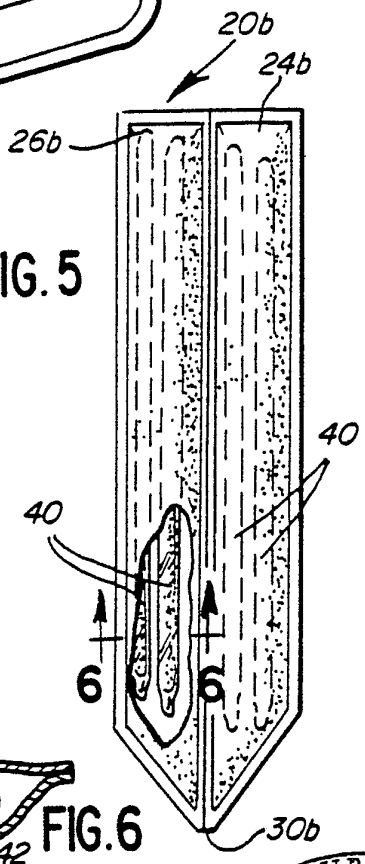


FIG. 5



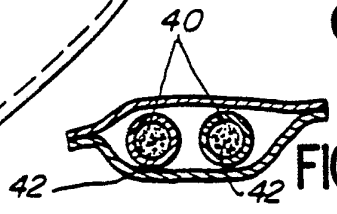
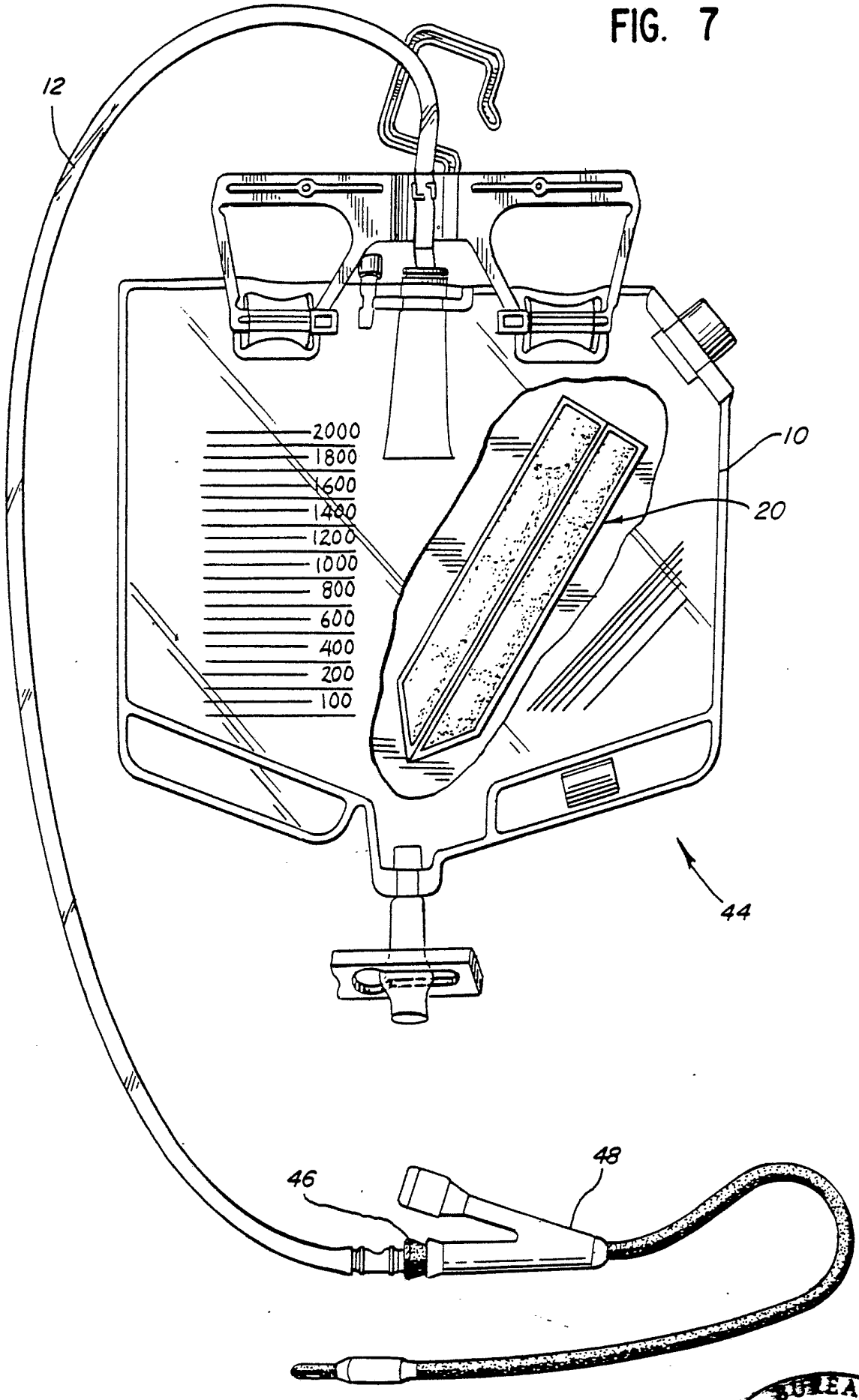


FIG. 6

FIG. 7



INTERNATIONAL SEARCH REPORT

International Applicat. No PCT/US84/00200

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

U.S. CL. 422/37,239 604/265,317

INT. CL. 3A61F 5/44,A61L 2/00,A61M 25/00,B01J 8/00

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	422/28,37,239,294,305 604/265,317,322,333,416 128/DIG 24

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
A	US,A, 2,572,669, PUBLISHED 23 OCTOBER 1951 SARGE ET AL.	
A	US,A, 2,913,460 PUBLISHED 17 NOVEMBER 1959 BROWN ET AL.	
A	US,A, 3,096,148 PUBLISHED 02 JULY 1963 WALKER	
A	US,A, 3,183,057 PUBLISHED 11 MAY 1965 MARKS ET AL.	
A	US,A, 3,312,221 PUBLISHED 04 APRIL 1967 OVERMENT	
A	US,A, 3,342,674 PUBLISHED 19 SEPTEMBER 1967 KOWALSKI	
A	US,A, 3,396,727 PUBLISHED 13 AUGUST 1968 MOUNT	
A	US,A, 3,476,506 PUBLISHED 04 NOVEMBER 1969 ANDERSEN ET AL.	
Y	US,A, 3,598,127 PUBLISHED 10 AUGUST 1971 WEPSIE	11,13-14
A	US,A, 3,705,938 PUBLISHED 12 DECEMBER 1972 HYMAN ET AL.	
Y	US,A, 3,716,961 PUBLISHED 20 FEBRUARY 1973 COPE ET AL.	3-5, 8
A	US,A, 3,848,603 PUBLISHED 19 NOVEMBER 1974 THRONER	
Y	US,A, 4,054,139 PUBLISHED 18 OCTOBER 1977 CROSSLEY	11,13-14

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
30 APRIL 1984	16 MAY 1984
International Searching Authority [1]	**Signature of Authorized Officer** [20]
ISA/US	Brian P. Kinney

Form PCT/ISA/210 (second sheet) (October 1981)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No [18]
A	US,A, 4,054,998 PUBLISHED 25 OCTOBER 1977 HESSELGREN	
A	US,A, 4,193,403 PUBLISHED 18 MARCH 1980 LANGSTON, ET AL.	
A	US,A, 4,203,445 PUBLISHED 20 MAY 1980 JESSUP ET AL.	
A	US,A, 4,232,677 PUBLISHED 11 NOVEMBER 1980 LEIBINSOHN	
A	US,A, 4,233,263 PUBLISHED 11 NOVEMBER 1980 SCHAEFFER	
A	US,A, 4,248,971 PUBLISHED 03 FEBRUARY 1981 YOUSSEF	
A	US,A, 4,284,444 PUBLISHED 18 AUGUST 1981 BERNSTEIN ET AL.	
Y	US,A, 4,289,815 PUBLISHED 15 SEPTEMBER 1981 LEE	9
Y	US,A, 4,306,029 PUBLISHED 15 DECEMBER 1981 CARPENTER	10-14
A	US,A, 4,318,406 PUBLISHED 09 MARCH 1982 MCLEOD	
A	US,A, 4,333,480 PUBLISHED 08 JUNE 1982 VILLARI ET AL.	
Y	US,A, 4,340,052 PUBLISHED 20 JULY 1982 DENNEHET ET AL.	12
X	US,A, 4,370,305 PUBLISHED 25 JAN. 1983 AFFONSO	1,2,6,7
Y,P	US,A, 4,381,380 PUBLISHED 26 APRIL 1983 LEVEEN ET AL.	11,13-14
A,P,	US,A, 4,417,891 PUBLISHED 29 NOVEMBER 1983 CIANCI	
A,P,	US,A, 4,417,892 PUBLISHED 29 NOVEMBER 1983 MEISCH	
A,P,	US,A, 4,427,425 PUBLISHED 24 JANUARY 1984 BRIGGS ET AL.	

FURTHER INFORMATIO ONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

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

1. ☐ Claim numbers ....., because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

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

Claims 1-14 refer to a device for sterilizing urine. Claims 15-17 refer to a method for sterilizing urine. The device recited in claims 1-14 can be used to sterilize fluids other than urine.

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

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

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

Claims 1-14

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.