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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 April 2009 (09.04.2009)

PCT

(10) International Publication Number
WO 2009/045874 A1

(51) International Patent Classification:
A61M 25/00 (2006.01)

(21) International Application Number:
PCT/US2008/077796

(22) International Filing Date:
26 September 2008 (26.09.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/976,214 28 September 2007 (28.09.2007) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT,

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(54) Title: MULTI-LAYER ODOR BARRIER TUBE, AND COMBINATION ODOR BARRIER TUBE AND ODOR BARRIER COLLECTION BAG

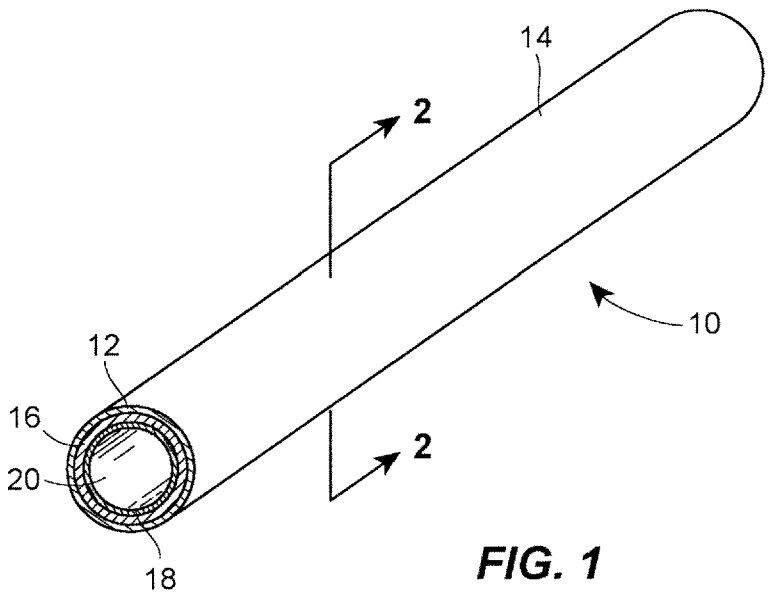


FIG. 1

(57) Abstract: A multi-layer odor barrier catheter tube (10) for a fecal drainage catheter. The external surface (14) has a low coefficient of friction, as does the internal surface (20). The layers of the catheter tube may be co-extruded, or formed as a heat-laminated film rolled into a cylindrical shape and heat-welded. A flexible scrim (42) may be included intermediate the first (12) and third layers (18). One or more tie layers may be included between at least one of the first and second layers (16), or the second and third layers. A combination of a multi-layer odor barrier catheter tube with an odor barrier collection bag (44) is also described.

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RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

MULTI-LAYER ODOR BARRIER TUBE, AND COMBINATION ODOR BARRIER TUBE AND ODOR BARRIER COLLECTION BAG

Reference to Related Applications

[0001] This application claims the benefit of the filing date of United States Provisional Application No. 60/976,214, filed September 28, 2007.

Field of the Disclosure

[0002] This disclosure is generally directed to medical tubing and, more specifically, to multi-layered tubing having odor barrier properties suitable for use as catheter tubing for fecal drainage systems, and a combination odor barrier tube and odor barrier collection bag.

Background

[0003] Catheter tubes for fecal drainage systems are designed to facilitate flow of fecal matter, with the fecal matter typically draining into a collection bag. A catheter tube can include a lubricious coating on an interior to facilitate movement of fecal matter. While various materials have been used to form the walls of a catheter tube, no catheter tubes for fecal drainage systems are known that include integral odor barrier properties. One reason for the lack of catheter tubes having odor barrier properties is that odor barrier materials are understood to be too stiff and not suitable for catheter tubing applications. By providing a multi-layer catheter tube with at least one odor barrier layer, the catheter tube can reduce or eliminate exposure of the patient, caregivers, and other persons in the vicinity of the patient to unpleasant odors.

[0004] Fecal drainage systems are frequently employed in combination with enema, lavage, or other irrigation techniques to loosen stool in the rectum of a patient. As a result, water or other liquid is likely to travel through the catheter tube with fecal matter.

Summary of the Disclosure

[0005] In preferred embodiments of the present disclosure, the catheter tubing for a fecal drainage system is made of at least two layers of different materials. The layers are preferably co-extruded, or one layer may be extruded and one or more subsequent layers may subsequently be applied by extrusion over the first layer, but alternately, the layers may be formed as a generally flat laminate sheet that is rolled into a tubular shape, then sealed along a seam, for example using sealing technology, such as heat sealing or RF sealing, using adhesive sealing, or ultrasonic welding. In order to increase durability, at least one of the layers of the flat laminate sheet that is then rolled into a cylinder can be a semi-rigid mesh or scrim material.

[0006] Another desirable feature of a catheter tube for a fecal drainage system is minimal wall thickness. The multi-layer odor barrier catheter tube of the present disclosure can be manufactured with a total wall thickness in the range of about 10 mil to about 60 mil.

[0007] The odor barrier layer may be a resin, preferably a polyamide, and most preferably nylon 666. The odor barrier layer may include an additive in the form of a modifier for reduced modulus, preferably ethylene-ethylacrylate-maleic anhydride terpolymer (commercially available as Lotader® 4720, from Arkema, Inc. of Philadelphia, Pennsylvania). The odor barrier layer is preferably the outermost layer, or outer skin, of the catheter tube.

[0008] The odor barrier layer of the catheter tube preferably has a thickness of 3 mil or less, and the thickness of the odor barrier is preferably less than 30% of the total tube wall thickness. The odor barrier layer preferably has a kinetic coefficient of friction less than 0.5.

[0009] A second layer of the catheter tube may be a resin or resin blend, preferably having a modulus of elasticity less than 100,000 psi (2% secant) when measured according to ASTM D882.

[0010] A third layer forming the innermost layer or inner skin of the catheter tube may also be employed. The third or innermost layer preferably has a low kinetic coefficient of friction, preferably less than 0.5. The low kinetic coefficient of friction may be an inherent property of a dry material of which the third layer is formed. Lubricity is a beneficial feature of the innermost layer of the catheter tube to promote or facilitate flow of fecal matter through the catheter tube. In order to achieve the desired lubricity of the innermost surface of the catheter tube, the inner layer of the multi-layer odor barrier tube of the present disclosure may be made of a copolymer of ethylene, preferably an ethylene vinylacetate copolymer (EVA) with an added slip agent concentrate, such as 10090 Slip PE MB, having a concentration of 5% Erucamide, available from Ampacet of Tarrytown, New York, to lower the coefficient of friction. Preferably, the slip agent concentrate is only about 2% of the overall composition of the innermost layer of the catheter tube, so the effective concentration of the Erucamide is about 0.1%.

[0011] In light of the likely presence of water or other liquid traveling through the catheter tube with the fecal matter, as an alternative to an EVA copolymer, a hydrophilic polymer that becomes lubricious in contact with water, preferably polyethyleneoxide or polyvinylalcohol, may be used as the inner layer of the multi-layer odor barrier catheter tube.

[0012] If the collection bag into which the catheter tube drains lacks odor barrier properties, unpleasant odors can escape the collection bag, thereby negating the odor barrier benefits achieved by the odor barrier catheter tube. It is therefore desirable for the odor barrier tube to drain into a collection bag that itself has odor barrier walls.

Brief Description Of The Several Views Of The Drawing

[0013] FIG. 1 is a perspective view of a first embodiment of a multi-layer odor barrier catheter tube of the present disclosure;

[0014] FIG. 2 is an axial cross-sectional view, taken along lines 2-2 of FIG. 1;

[0015] FIG. 3 is an axial cross-sectional view, similar to FIG. 2, of a second embodiment of a multi-layer odor barrier catheter tube of the present disclosure, wherein tie layers are provided between the first and second layers, and between the third and fourth layers;

[0016] FIG. 4 is a perspective view of a heat-laminated film employed in a method of manufacture of a multi-layer odor barrier catheter tube of the present disclosure;

[0017] FIG. 5 is a perspective view of the heat-laminated film of FIG. 4, rolled into a cylindrical shape and sealed along a seam;

[0018] FIG. 6 is a perspective view of a heat-laminated film similar to that of FIG. 4, and including a flexible scrim layer;

[0019] FIG. 7 is a perspective view of the heat-laminated film of FIG. 6, rolled into a cylindrical shape and sealed along a seam;

[0020] FIG. 8 is a front view of a combination of a multi-layer odor barrier catheter tube of the present disclosure in combination with a drainable collection bag having odor barrier walls;

[0021] FIG. 9 is a front perspective view of a combination of a multi-layer odor barrier catheter tube of the present disclosure in combination with a closed, single-use collection bag having odor barrier walls; and

[0022] FIG. 10 is a front perspective view of a multi-layer odor barrier catheter tube of the present disclosure having only two layers.

Detailed Description of the Preferred Embodiments

[0023] With reference to the drawings, in a first embodiment of a multi-layer odor barrier catheter tube 10 of the present disclosure connectable at a first end to a patient-proximal internal section, and/or a trans-anal section of a rectal catheter (not shown), and at a second end, connectable to a waste collection bag or to a disposal receptacle (e.g., a bedpan or toilet (not

shown)) is provided. At least one of the layers of the multi-layer catheter tube 10 is constructed of materials resistant to transmission of fecal and flatus gasses.

[0024] A first layer 12 of the catheter tube 10 defines the external surface 14 of the catheter tube 10. The first layer 12 is preferably comprised of one or more materials that possess a relatively low coefficient of friction, most preferably less than 0.5, so as to reduce drag of the catheter tube 10 against a patient's skin, and against items surrounding the patient, including a hospital gown, bed sheets, chair or other objects in the patient's immediate vicinity. The low coefficient of friction of the external surface 14 of the catheter tube 10 also facilitates "milking" the fecal matter down the length of the catheter tube 10. The material or materials defining the first layer 12 of the catheter tube 10 include an odor barrier resin. In other embodiments within the scope of the present disclosure, the odor barrier resin may be employed as a layer of the catheter tube 10 other than the first layer 12 defining the outside surface 14.

[0025] A suitable material for the first layer 12 of the catheter tube 10 of the present disclosure is a polyamide, most preferably nylon 666. A modifier may be added to achieve a reduced modulus, preferably ethylene-ethylacrylate-maleic anhydride terpolymer, commercially available as Lotader® 4720 from Arkema, Inc. The external surface 14 of the first layer 12 is preferably a surface that will receive inks such as permanent or semi-permanent markers, and retain such markings thereon without smudging or wiping off, to facilitate receiving instructions, patient data, collection bag change data, dates of indwell or intended removal of the catheter tube, and the like.

[0026] An intermediate layer 16 of the multi-layer catheter tube 10 preferably comprises a resin or resin blend having a modulus of elasticity less than 100,000 psi (2% secant) when measured according to ASTM D882. The resin used as the material forming the intermediate layer 16 is

preferably a thermoplastic elastomer, most preferably polyurethane or a polyurethane blended with another thermoplastic elastomer, having a preferred modulus less than 40,000 psi (2% secant). As described in more detail below, more than one layer of material may be provided intermediate the first layer 12 defining the external surface 14 of the catheter tube 10 and a third layer 18 defining an internal surface 20 of the catheter tube 10. If only a first layer 12 and a low modulus layer are provided, the layer referenced herein as the intermediate layer 16 may instead be the inner-most layer of the catheter tube 10, as shown in FIG. 10.

[0027] Depending on the compatibility of the materials of adjacent layers of the multi-layered catheter tube 10, as shown in FIG. 3, a tie layer 22, such as a Bynel® tie material available from DuPont, may be employed between adjacent layers to improve adhesion of the adjacent layers to one another.

[0028] Another layer 18 of the multi-layer catheter tube 10, defining the internal surface 20 of the catheter tube 10, is preferably made of one or more materials that possess a relatively low coefficient of friction, preferably less than 0.5, to allow stool and bowel discharge to flow easily along the internal length of the catheter tube 10 for collection and/or disposal. A suitable material for the layer 18 is a copolymer of ethylene, most preferably an ethylene – vinylacetate copolymer (EVA) with an added slip agent (such as 10090 Slip PE MB, having a concentration of 5% Erucamide, available from Ampacet of Tarrytown, New York), wax, PTFE, or other friction-reducing additive to achieve a low coefficient of friction. Such additives may also be used to lower the coefficient of friction of the first layer 12 defining the external surface 14 of the catheter tube 10. As an alternate to the material or materials defining the layer 18 of the catheter tube 10 inherently possessing a low coefficient of friction, a hydrophilic polymer that becomes lubricious in contact with water, preferably polyethyleneoxide or polyvinylalcohol, may

be used as the innermost layer of the multi-layer odor barrier catheter tube 10. This may be accomplished by the layer 18 having a capability of anchoring hydrophilic materials thereto, and then supplying an additional hydrophilic layer, such as by co-extrusion, internally of the layer 18. As a further alternate, the layer 18 may itself be formed entirely of a hydrophilic polymer, and anchored directly to intermediate layer 16, provided that there is adequate adhesion between the hydrophilic layer 18 and the intermediate layer 16.

[0029] The multi-layer catheter tube 10 of the first embodiment of the present disclosure may be manufactured by co-extrusion. In order to maximize tube softness and flexibility, it is desirable for the odor barrier layer of the catheter tube 10 to be thin, preferably in a range of less than about 2 to about 3 microns. However, it is not possible with conventional co-extrusion processes to co-extrude a sufficient length of catheter tubing having such a thin odor barrier layer.

[0030] As an alternative to co-extrusion, as shown in FIGS. 4-5, the layers of the catheter tube 10 may be formed into a flat or substantially flat heat-laminated film 24, having two parallel edges 26, 28 that are rolled toward one another, brought into register with one another, and sealed to one another, such as by heat sealing, RF sealing, adhesive sealing, or ultrasonic welding, to form a cylinder, with the first layer 12 of the film 24 defining an external surface 14 of the cylinder and the third layer 18 defining an internal surface 20 of the cylinder. A leading end 30 and a trailing end 32 of the heat-laminated film 24 are left open, forming first and second ends 34, 36 of the catheter tube 10. Optionally, tie layers (represented by broken lines in FIG. 4) may be provided to enhance bonding between the first and second layers, and/or between the second and third layers 16, 18. The first, second and third layers 12, 16, 18 of the catheter tube 10 are preferably clear or translucent. The sealed edge or seam 38 may be visible, and can

advantageously provide a medical caregiver with a visible indicator of any kinking or twisting of the catheter tube.

[0031] The total cumulative wall thickness of the multi-layer catheter tube 10 is preferably in the range of about 10 mil to about 40 mil, and more preferably in a range of about 25 mil to about 35 mil, with the thickness of the odor barrier layer (e.g., the first layer 12) making up less than about 30% of the total wall thickness of the catheter tube 10.

[0032] Adjustments may be made to process conditions under which the layers of the multi-layer catheter tube of the present disclosure are co-extruded or heat laminated to reduce the coefficient of friction of one or more of the layers.

[0033] In another embodiment, shown in FIGS. 6-7, in order to provide reinforcement and avoid kinking or twisting of a catheter tube 40, a mesh or flexible scrim layer 42 may be included as an additional layer intermediate the first layer 12 and third layer 18 of the multi-layer catheter tube 40. The scrim layer 42 also provides the catheter tube 40 with shape memory, permitting the catheter tube 40 to collapse and recover to its cylindrical shape without any permanent deformation. Materials other than a scrim layer 42 may be utilized instead of or in addition to the scrim layer 42 to enhance structural integrity of the catheter tube 40, such as polymeric materials.

[0034] The material(s) forming the internal and/or external surfaces of the multi-layer catheter tube of the present disclosure preferably facilitate attachment and assembly of the catheter tube to peripheral components of fecal drainage and management systems, such as the Bowel Management System available from Hollister Incorporated of Libertyville, Illinois, the assignee of the present disclosure. As such systems are intended for long-duration use, on the order of about twenty-nine days, it is advantageous to employ materials that will easily form a reliable

bond, by adhesive and/or heat, between the catheter tube and the peripheral components, such as internal or external silicone balloons, catheter connections, such as to a collection bag or to a catheter tube extension, or plastic or metal ports, such as ports for providing endoscope access or for sampling fecal matter directly from the catheter tube, for the entire duration of use of the catheter.

[0035] As noted above, the advantages achieved by the odor barrier properties of the catheter tubes of the present disclosure would be negated, or significantly diminished, if fecal or flatus gasses could be transmitted through one or more walls of a collection bag 44 (see FIG. 8) to which the catheter tube 10 is connected. It is therefore desirable to use the multi-layer odor barrier catheter tube 10 in combination with a collection bag 44 having odor barrier walls. For example, each of the walls of the collection bag may include a barrier layer film such as the one disclosed in U.S. Patent No. 7,270,860.

[0036] The odor barrier collection bag may be a drainable collection bag 44, having a drainage tube 46 with a drainage tube stopper 48 and a cap 50 for capping a catheter tube connection port 52, as shown in FIG. 8. Alternately, the odor barrier collection bag may be a so-called "closed" collection bag 54, as illustrated in FIG. 9. A closed collection bag 54 is intended for single use, and preferably includes an integral vent 56 with a deodorizing filter 58.

[0037] While certain embodiments of multi-layer odor barrier catheter tubes, combinations of multi-layer odor barrier catheter tubes and odor barrier collection bags, and methods of manufacturing multi-layer odor barrier catheter tubes are disclosed herein, the appended claims are not intended to be limited thereto. Variations can be made to the disclosed embodiments that are still within the scope of the appended claims, literally or under the doctrine of equivalents.

Claims

We claim:

1. A catheter tube for a fecal drainage system comprising:

at least two layers of material wherein at least one of the layers of the catheter tube includes an odor barrier material.

2. The catheter tube of claim 1, wherein a first of the layers defines an external surface of the catheter tube and is relatively thinner than a second of the layers, the first layer having a coefficient of friction less than about 0.5.

3. The catheter tube of claim 1, wherein a first of the layers defines an external surface of the catheter tube and is the layer including the odor barrier material, the first layer having a thickness in a range of less than about 2 mil to about 3 mil.

4. The catheter tube of claim 3, wherein a second layer adjacent to the first layer is thicker than the first layer and has a modulus of elasticity less than 100,000 psi when measured according to ASTM D882.

5. The catheter tube of claim 4, further comprising a third layer defining an inner surface of the catheter tube, the third layer having a coefficient of friction less than about 0.5.

6. The catheter tube of claim 4, further comprising a third layer capable of anchoring a hydrophilic coating layer, the hydrophilic coating layer defining an inner surface of the catheter tube.

7. The catheter tube of claim 1, wherein an overall wall thickness of the catheter tube is in a range of about 10 mil to about 40 mil.

8. The catheter tube of claim 1, wherein an overall wall thickness of the catheter tube is in a range of about 25 mil to about 35 mil.

9. The catheter tube of claim 1, wherein at least one layer of the catheter tube includes a flexible scrim layer.

10. The catheter tube of claim 1, further comprising at least one tie layer between at least two layers of the catheter tube.

11. The catheter tube of claim 1, wherein the layer including the odor barrier material has a thickness less than 30% of a total wall thickness of the catheter tube.

12. The catheter tube of claim 1, in combination with a collection bag having odor barrier walls.

13. A catheter tube for a fecal drainage system comprising:

a first layer defining an external surface of the catheter tube, the first layer including polyamide with odor barrier properties; and

a second layer.

14. The catheter tube of claim 13, wherein the second layer includes a hydrophilic material that becomes lubricious when exposed to liquid.

15. The catheter tube of claim 13, the first layer including a modulus-reducing modifier.

16. The catheter tube of claim 13, in combination with a collection bag having odor barrier walls.

17. A method for manufacturing a catheter tube for a fecal drainage system comprising: coextruding a first layer including a polyamide with odor barrier properties, the first layer defining an external surface of the catheter tube, with a second layer including a resin.

18. The method for manufacturing a catheter tube for a fecal drainage system of claim 17, further including coextruding a third layer with the first and second layers, the third layer being capable of anchoring a hydrophilic coating.

19. The method of claim 18, wherein coextruding the first layer with the second and third layers includes coextruding a tie layer between at least one of the first and second layer or the second and third layer.

20. A method of manufacturing a catheter tube for a fecal drainage system comprising:

forming a laminate sheet including a first layer including a polyamide with odor barrier properties, a second layer including a resin, the laminate sheet having a leading edge, a trailing edge, and two parallel sides;

rolling the laminate sheet into a tubular shape with the two parallel sides of the laminate sheet in register with one another; and

heat-sealing the two parallel sides of the laminate sheet to one another forming a cylinder, with the first layer defining an external surface of the cylinder.

21. The method of claim 20, wherein in forming the laminate sheet, the laminate sheet includes a tie layer intermediate at least one pair of layers of the laminate sheet.

22. The method of claim 20, wherein in forming the laminate sheet, the laminate sheet includes a layer of flexible scrim material.

23. The method of claim 20, wherein in forming the laminate sheet, the laminate sheet includes a third layer that defines an internal surface of the cylinder, and applying a hydrophilic coating to the third layer.

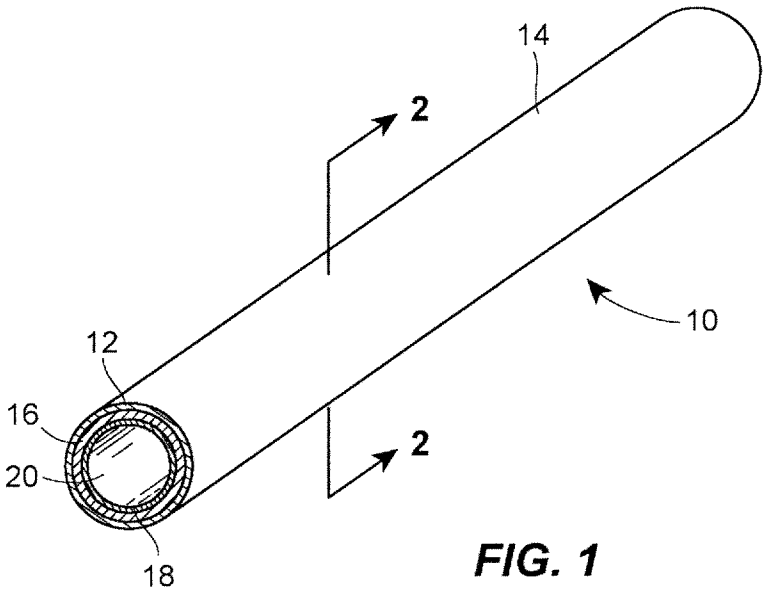


FIG. 1

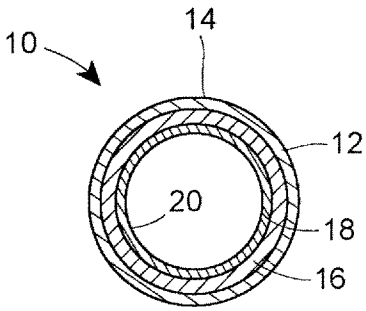


FIG. 2

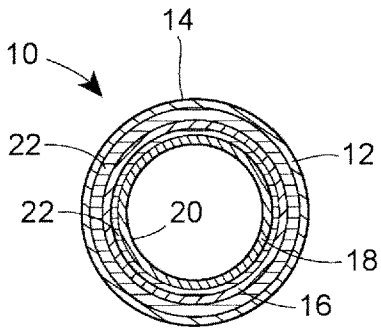


FIG. 3

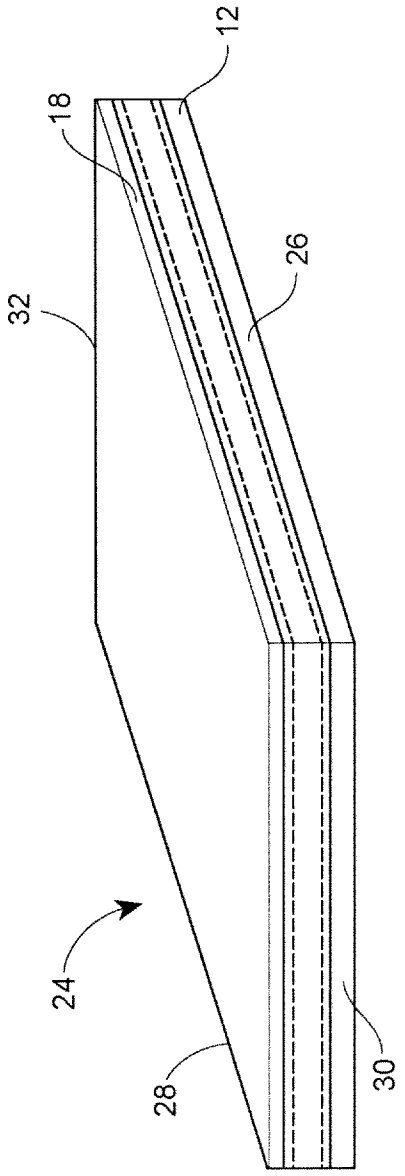


FIG. 4

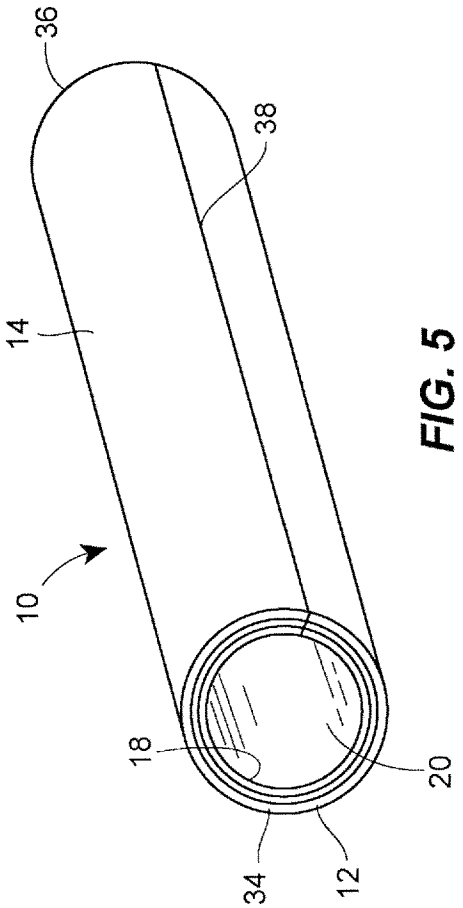


FIG. 5

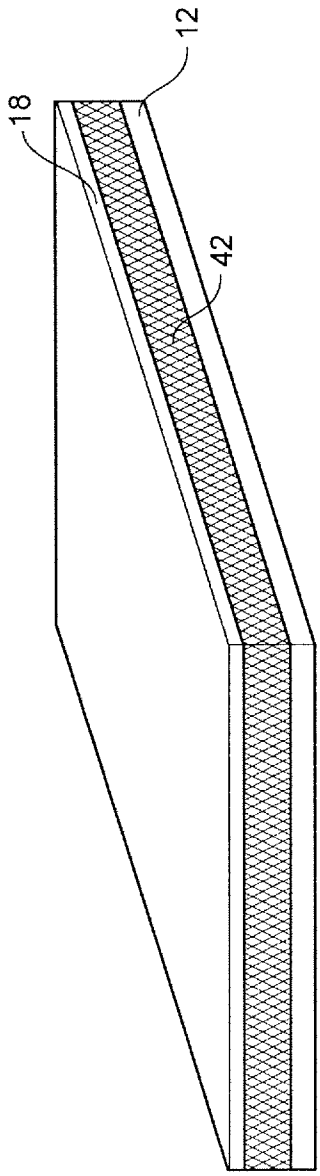


FIG. 6

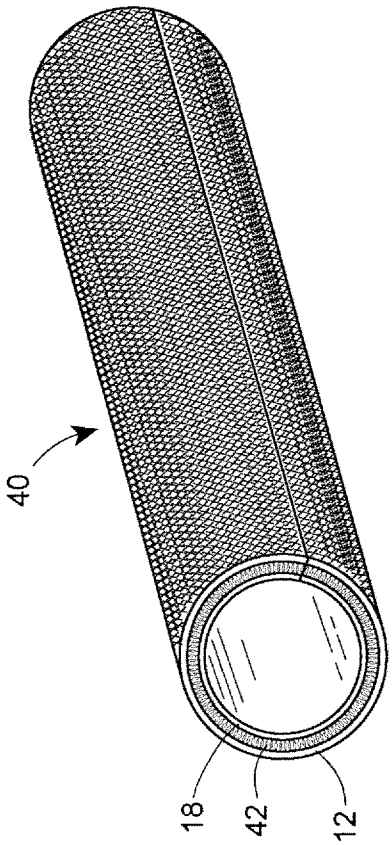


FIG. 7

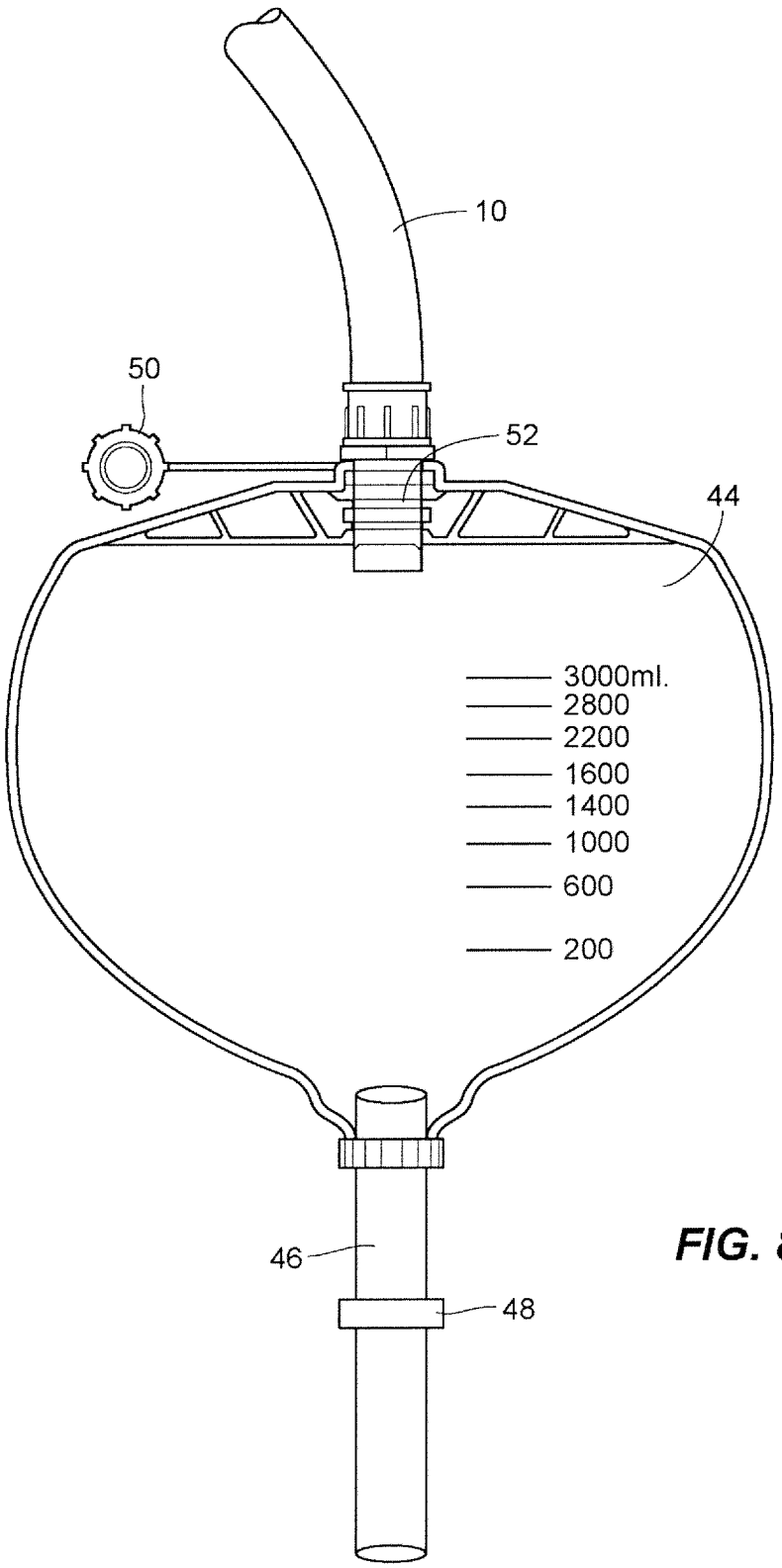


FIG. 8

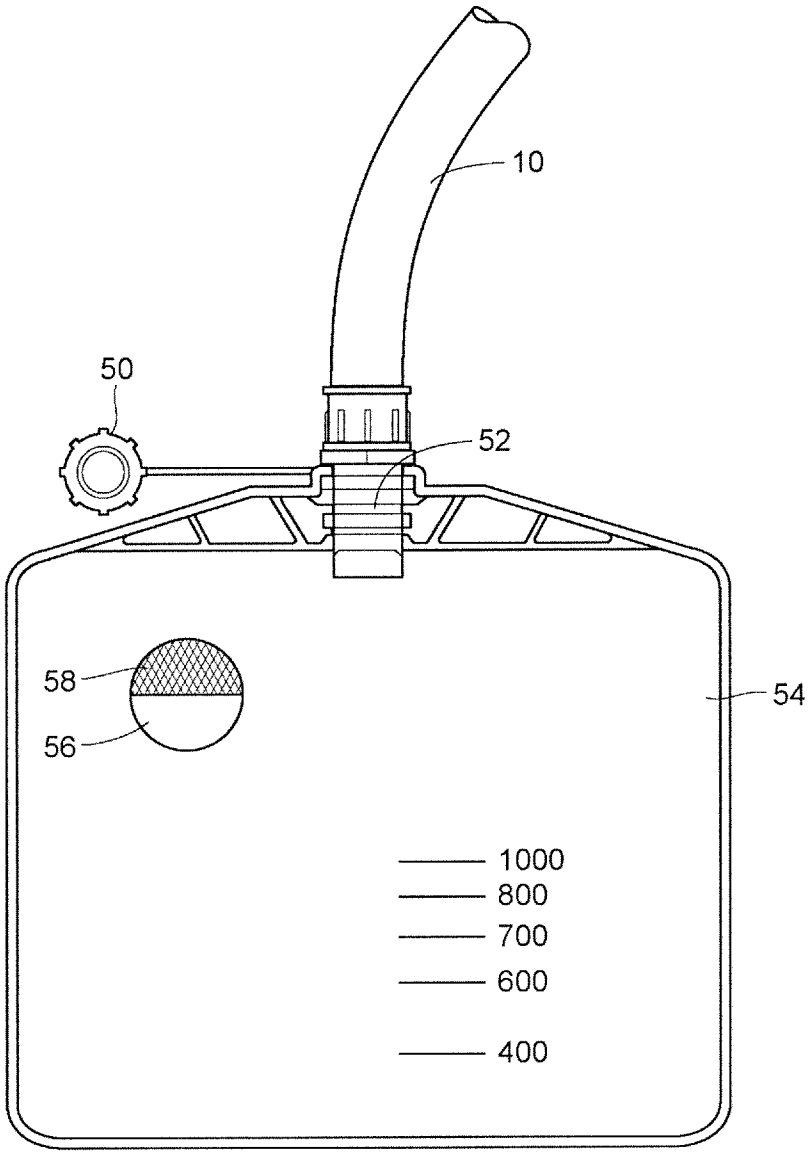


FIG. 9

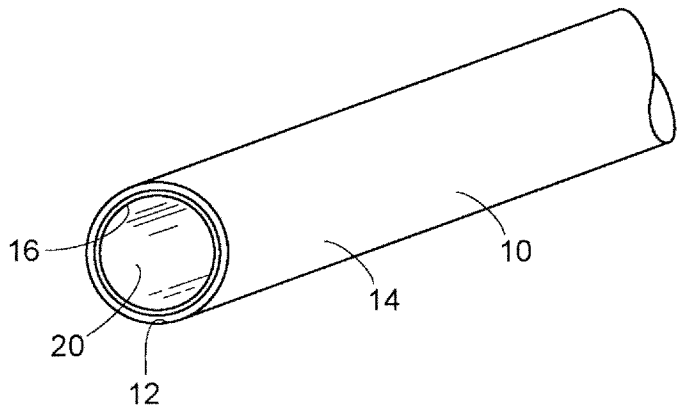


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/077796

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00

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)
A61M A61L A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 643 375 A (WILFONG DEBRA L [US] ET AL) 1 July 1997 (1997-07-01) claims 1-13; figures 1,2; tables 3,5,7,9-11,22 column 1, line 15 - line 25 column 4, line 30 - column 6, line 12 column 9, line 50 - column 39, line 48	1-23
X A	EP 1 514 572 A (SQUIBB BRISTOL MYERS CO [US]) 16 March 2005 (2005-03-16) paragraphs [0002], [0051] - [0088]	1 2-23
P,X	WO 2008/052018 A (SQUIBB BRISTOL MYERS CO [US]; TSAI MINGLIANG LAWRENCE [US]; GREGORY CH) 2 May 2008 (2008-05-02) page 1, line 5 - line 10 page 2, line 21 - page 13, line 13	1,3,6-8, 10-13, 16-21

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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Date of the actual completion of the international search	Date of mailing of the international search report
15 December 2008	23/12/2008

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/077796

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/038374 A1 (WILLIAMS ROBERT C [US] ET AL WILLIAMS ROBERT C [US] ET AL) 17 February 2005 (2005-02-17) the whole document	1-23

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2008/077796

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A multi-layer odor barrier catheter tube (10) for a fecal drainage catheter. The external surface (14) has a low coefficient of friction, as does the internal surface (20). The layers of the catheter tube may be co-extruded, or formed as a heat-laminated film rolled into a cylindrical shape and heat-welded. A flexible scrim (42) may be included intermediate the first (12) and third layers (18). One or more tie layers may be included between at least one of the first and second layers (16), or the second and third layers. A combination of a multi-layer odor barrier catheter tube with an odor barrier collection bag (44) is also described.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/077796

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