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FEE TRANSMITTAL

Complete if known	
Application Number	
Filing Date	
First Named Inventor	Jennifer Tomes
Examiner Name	
Art Unit	
Practitioner Docket No.	10055UCIP2D1C1C1C1C1

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

TOTAL AMOUNT OF PAYMENT ($)

METHOD OF PAYMENT (check all that apply)

☐ Check ■ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

■ Deposit Account Deposit Account Number: 503608 Deposit Account Name: Burrus Intellectual Prop…

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☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

	FILING FEES			SEARCH FEES			EXAMINATION FEES			
Application Type	**U ($)**	**S ($)**	**M ($)**	**U ($)**	**S ($)**	**M ($)**	**U ($)**	**S ($)**	**M ($)**	**Fees Paid ($)**
Utility	300	150*	75	660	330	165	760	380	190	1720
Design	200	100	50	160	80	40	600	300	150	
Plant	200	100	50	420	210	105	620	310	155	
Reissue	300	150	75	660	330	165	2,200	1,100	550	
Provisional	280	140	70	0	0	0	0	0	0	

* The $150 small entity status filing fee for a utility application is further reduced to $75 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	**Undiscounted Fee ($)**	**Small Entity Fee ($)**	**Micro Entity Fee ($)**
Each claim over 20 (including Reissues)	100	50	25
Each independent claim over 3 (including Reissues)	460	230	115
Multiple dependent claims	820	410	205

Total Claims		**Extra Claims**		**Fee ($)**		**Fee Paid ($)**
_____	-20 or HP =	_____	x	_____	=	_____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		**Extra Claims**		**Fee ($)**		**Fee Paid ($)**
_____	-3 or HP =	_____	x	_____	=	_____

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Multiple Dependent Claims	
Fee ($)	**Fee Paid ($)**
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $400 ($200 for small entity) ($100 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**		**Fee ($)**		**Fee Paid ($)**
_____	- 100 =	_____	/ 50 =	_____ (round **up** to a whole number)	x	_____	=	_____

4. OTHER FEE(S) **Fees Paid ($)**

Non-English specification, $130 fee (no small or micro entity discount) _____

Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, $400 fee ($200 small or micro entity) _____

Other (e.g., late filing surcharge): _____ _____

SUBMITTED BY

Signature	/Philip H. Burrus, IV/	Registration No. (Attorney/Agent) 45432	Telephone 4047978111
Name (Print/Type)	Philip H. Burrus, IV		Date 2020-03-27

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

CROSS REFERENCE TO PRIOR APPLICATIONS

[001] This application is a continuation application claiming priority to Ser. No. 15/684,787, filed August 23, 2017, which is a continuation application claiming priority to Ser. No. 14/793,455, filed July 7, 2015, which is a continuation application claiming priority to Ser. No. 13/860,902, filed April 11, 2013, which is a divisional application from Ser. No. 13/155,026, filed June 7, 2011, which claims priority and benefit under 35 U.S.C. §119(e) from U.S. Provisional Applications: Ser. No. 61/352,140, filed June 7, 2010; Ser. No. 61/352,155, filed June 7, 2010; Ser. No. 61/428,944, filed December 31, 2010; and Ser. No. 61/437,796, filed January 31, 2011, each of which is incorporated herein by reference. Moreover, Ser. No. 13/155,026 is further a continuation in part of: Ser. No. 12/495,148, filed June 30, 2009, which claims priority and bent under 35 U.S.C. §119(e) from U.S. Provisional Application: Ser. No. 61/183,629, filed June 3, 2009; Ser. No. 12/647,515, filed December 27, 2009; Ser. No. 13/153,265, filed June 3, 2011; and Ser. No. 13/153,300, filed June 3, 2011, each of which is incorporated herein by reference. As the present application claims priority to Ser. No. 13/155,026 through Ser. No. 14/793,455 and Ser. No. 13/860,902, the present application also, by law, claims priority to each of Ser. No. 12/495,148, Ser. No. 12/647,515, Ser. No. 13/153,265, and Ser. No. 13/153,300 through its priority claim to Ser. No. 13/155,026.

[002] This application is related to commonly assigned US Pat. No. 7,624,869 to Primer, which is incorporated herein by reference. This application is related to commonly assigned US Patent Application No. 12/004,796, filed December 21, 2007, which is incorporated herein by reference.

Bard Exhibit 1004.0004

BACKGROUND

TECHNICAL FIELD

[003] This invention relates generally to storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices, as well as an instruction manual included therewith.

BACKGROUND ART

[004] Medical devices, including surgical instruments, supplies, and so forth, are generally shipped from manufacturer to medical services provider in sterile packaging. For example, a scalpel may be shipped to a surgeon in a plastic, vacuum-sealed, sterile package. Similarly, bandages may be shipped in paper, plastic, or paper composite sterile wrappers. When the medical services provider is ready to use the medical supply, the sterile package is removed. The medical services provider then uses the object in accordance with the procedure being performed.

[005] While conventional packaging works well for objects having a generally unchanging form factor, special considerations have to be taken into consideration for some medical supplies. By way of example, catheter assemblies and other flexible equipment is generally shipped in a coiled configuration. Once the sterile packaging is removed, the catheter must be uncoiled prior to use. Care must be taken in shipping, unwrapping, and using the catheter. For instance, if a catheter is inadvertently bent, kinked, or otherwise damaged, it may no longer be suitable for use. Compounding this issue, catheters are available in a variety of lengths ranging from 100 centimeters to over 250 centimeters.

[006] Traditional catheters are packaged, for example, in individual packaging. The catheter and card are then sealed in a sterile plastic wrap. These catheters are prone to damage in shipment, storage, and when being unpacked, as the card and wrap provide little physical protection.

[007] Some manufacturers have started shipping catheters and other similar devices in flat plastic trays. For example, US Pat. No. 6,068,121 to McGlinch teaches one such tray. The tray has several

specifically contoured loops such that one universal tray will accommodate several different sized catheters. Such packaging presents a problem, however, in that large amounts of storage space are taken with a universal tray, especially when a relatively short catheter is shipped therein. Additionally, when in use, these trays occupy large amounts of a medical service provider's sterile workspace or table, leaving little room for related components, such as lubricants, fluid bags, and so forth.

[008] There is thus a need for an improved container for flexible medical devices or catheters that facilitates more effective and simpler deployment of the device during a procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

[009] The accompanying figures, where like reference numerals refer to identical or functionally similar elements throughout the separate views and which together with the detailed description below are incorporated in and form part of the specification, serve to further illustrate various embodiments and to explain various principles and advantages all in accordance with the present invention.

[010] FIG. 1 illustrates a top, front, right perspective view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

[011] FIG. 2 illustrates a top, front, left perspective view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

[012] FIG. 3 illustrates a top plan view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

[013] FIG. 4 illustrates a front elevation view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

[014] FIG. 5 illustrates a cut-away, left elevation view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

[015] FIG. 6 illustrates a bottom plan view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

[016] FIG. 7 illustrates a top, front, right perspective view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

[017] FIG. 8 illustrates a top plan view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

[018] FIG. 9 illustrates a transparent, front elevation view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

[019] FIG. 10 illustrates a perspective view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, along with instructions and packaging, in accordance with embodiments of the invention.

[020] FIG. 11 illustrates a method of manufacturing one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

[021] FIG 12 illustrates one embodiment of printed instructions in accordance with embodiments of the invention.

[022] FIG. 13 illustrates one embodiment of printed instructions in accordance with embodiments of the invention.

[023] FIGS. 14-19 illustrate exemplary panels of printed instructions in accordance with embodiments of the invention.

[024] FIG. 20 illustrates a physical configuration of printed instructions in accordance with one embodiment of the invention.

[025] FIG. 21 illustrates a method in accordance with embodiments of the invention.

[026] FIGS. 22-30 illustrate various stages of a method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

[027] FIGS. 31-33 illustrate various stages of a method of deploying a medical procedure kit configured in accordance with embodiments of the invention.

[028] FIGS. 34-37 illustrate various stages of an alternative method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

[029] FIGS. 38-39 illustrate various stages of an alternative method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

[030] FIG. 40 illustrates an alternate health care services provider portion of printed materials configured as an adhesive label with an opening flap in accordance with one embodiment of the invention.

[031] FIG. 41 illustrates an alternative patient portion of printed instructions configured as a greeting card and having patient information therein, in accordance with one embodiment of the invention.

[032] Skilled artisans will appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[033] Embodiments of the invention are now described in detail. Referring to the drawings, like numbers indicate like parts throughout the views. As used in the description herein and throughout the claims, the following terms take the meanings explicitly associated herein, unless the context clearly dictates otherwise: the meaning of "a," "an," and "the" includes plural reference, the meaning of "in" includes "in" and "on." Relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another

entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. Also, reference designators shown herein in parenthesis indicate components shown in a figure other than the one in discussion. For example, talking about a device (10) while discussing figure A would refer to an element, 10, shown in figure other than figure A.

[034] Embodiments of the present invention provide a medical procedure kit that includes medical products for performing a medical procedure. In one embodiment, the medical procedure kit is configured for a catheterization procedure. Such an embodiment will be used herein for illustration purposes. However, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments of the invention are not so limited. Other medical procedure kits for performing other procedures could be substituted for the illustrative catheterization tray disclosed herein by substituting other medical implements for the catheterization implements. In the illustrative embodiment, a tray is configured to accommodate a medical device or assembly. In an illustrative embodiment, the medical device is a coiled device, such as a catheter or catheter assembly. In addition to accommodating the coiled medical device, embodiments of the present invention are also configured to contain devices and materials intended for use with the coiled medical device.

[035] Using a catheter assembly as an example, when a catheter assembly is inserted into a patient, sterile water may be used to inflate the catheter. Additionally, the catheter may be coated in a lubricating jelly prior to insertion into the patient. Fluids and other samples may then be monitored and obtained from the patient via the catheter. Embodiments of the present invention provide a single container configured to accommodate not only the catheter assembly and fluid bag, but also syringes containing sterile water or lubricants. Further, the tray can accommodate a sterile specimen jar for capturing samples taken from the patient via the catheter.

[036] In addition to simply accommodating these corresponding medical devices, in one embodiment the tray is configured to provide the medical services provider with mnemonic devices instructing

them in which order to use each device. For example, a compartment containing syringes, in one embodiment, includes an inclined, stair-stepped bottom member to present the plungers of each syringe at an easy to reach angle and at different heights based upon order of use.

[037] Another advantage of embodiments of the present invention is that compartments have multi-purpose functionality. For example, in one embodiment, a container configured to accommodate a syringe having lubricating jelly disposed therein is also configured to be used as a lubricating jelly applicator. A medical services provider first dispenses the lubricating jelly into the syringe compartment. The medical services provider then passes the catheter from another compartment through an opening in a barrier separating the compartments into the lubricating jelly. As such, the tray not only serves as a shipping and storage container for an assembly of devices used with a catheter procedure, but also as an application device to assist a medical services provider in using those products together.

[038] Turning now to FIGS. 1-6, illustrated therein are views of one embodiment of a tray 100 configured to accommodate a catheter assembly in accordance with embodiments of the invention. FIG. 1 illustrates a top, front right perspective view of the tray 100. FIG. 2 illustrates a top, front, left perspective view of the tray 100. FIG. 3 illustrates a top plan view of the tray 100. FIG. 4 illustrates a front elevation view of the tray 100. FIG. 5 illustrates a cut-away, left elevation view of one embodiment of a tray 100. Likewise, FIG. 6 illustrates a bottom plan view of the tray 100. For simplicity of discussion, these figures will be referred to collectively with like reference numerals referring to identical or functionally similar elements throughout the separate views.

[039] The tray 100, in one embodiment, is formed by a contoured surface 104 that defines the various features and compartments of the tray 100. The contoured surface 104 of the tray 100 can be manufactured in various ways. For example, in one embodiment, the tray 100 can be thermally formed on a mold from a soft thermoplastic, such as styrene or polystyrene. In another embodiment, the tray 100 can be injection molded. In another embodiment, the tray can be

poured on a mold using a quick setting plastic, epoxy, or resin. Other methods of manufacture will be obvious to those of ordinary skill in the art having the benefit of this disclosure.

[040] Exemplary dimensions for one embodiment of the tray 100 are as follows: The length 112 can be between nine and twelve inches, such as ten inches. One illustrative length 112 may be 10.380 inches. Similarly, the width 113 can be between eight and eleven inches, such as nine inches. One illustrative width 113 is 9.250 inches. The height 114 can be between one and three inches. One illustrative height 114 is 1.750 inches.

[041] In one embodiment, the tray 100 includes three main compartments: a first compartment 101, a second compartment 102, and a third compartment 103. The first compartment 101 is separated from the second compartment 102 by a first barrier 105. The second compartment 102 is separated from the third compartment 103 by a second barrier 106.

[042] In one embodiment, the compartments are open from the top of the tray 100 – the top being opposite the base members of the tray 100 – and are bounded on the bottom by a first base member 107, a second base member 108, and a third base member 109. The compartments are bounded on the sides by a perimeter wall 110. In the illustrative "open top" embodiment of FIG. 1, the perimeter wall 110 ends in a horizontal flange 111 extending substantially orthogonally from the perimeter wall 110. It will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments other than that shown in FIG. 1 are possible without departing from the spirit and scope of the invention. For instance, the top of the tray 100 could have a hinged or snap-coupled lid that is opened or removed to reveal the compartments there beneath.

[043] In one illustrative embodiment, the tray 100 is configured to hold or otherwise accommodate all of the necessary devices and materials to perform a catheter-based procedure on a patient. Said differently, the tray 100 is configured to hold not only the catheter assembly, but the medical devices corresponding to catheter use as well. Using one illustrative procedure as an example, the

following devices will be used: a syringe holding sterile water, a syringe holding lubricating jelly or another equivalent lubricant, a catheter assembly, skin cleansing or preparation materials, and a specimen jar. The various compartments and features of the tray 100 shown in FIGS. 1-6 will be described for use with these devices. As will be described in more detail below, additional objects can be included with the tray, such as one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, swab sticks, a securement device, a Foley insert tag, a printed instruction pamphlet, and so forth. The syringe holding sterile water, syringe holding lubricating jelly, catheter assembly, and specimen jar are used for illustration purposes only, as it will be clear that other objects may be added to or substituted for these objects. Further, subsets of these objects may be used.

[044] In one embodiment suitable for procedures using the syringe holding sterile water, syringe holding lubricating jelly, catheter assembly, and specimen jar, in one embodiment, the tray 100 is configured such that these objects are ordered in accordance with their use during the procedure. For example, in one embodiment the tray 100 includes a first compartment 101 for accommodating one or more syringes, a second compartment 102 for accommodating the catheter assembly, and a third compartment 103 for accommodating the specimen jar. These devices stowed in the various compartments will be illustrated and described with respect to FIGS. 7-10 below. The discussion of FIGS. 1-6 will include the features of the tray 100 that make the tray100 suitable for accommodating these devices.

[045] For example, in one embodiment the first compartment base member 107 includes a stair-stepped contour 115 suitable for accommodating a plurality of syringes at different heights. For example, a first step portion 116 of the stair-stepped contour 115 may be at a different height within the tray 100 than a second step portion 117 of the stair-stepped contour. In the illustrative embodiment of FIGS. 1-6, the first step portion 116 – which is disposed farther from the first barrier 105 than the second step portion 117 – is shallower than the second step portion 117. Said

differently, the second step portion 117 is disposed at a greater depth within the tray 100 than the first step portion 116.

[046] The stair-stepped contour 115 can be used as mnemonic device when multiple syringes are stored within the first compartment 101. For example, it may be intuitive that a syringe placed on a higher step portion may need to be used first. This intuition is further enforced when the higher step portion is disposed farther to the left in a left-to-right usage configuration. Thus, a user receives a mnemonic reminder to use a syringe disposed on the first step portion 116 prior to a syringe disposed on the second step portion 117, as it is both higher and farther to the left.

[047] Where syringes are stowed in the first compartment 101, the first compartment base member 107 can further be configured for syringe ease of use. For example, in one embodiment the first compartment base member 107 is inclined relative to other compartment base members. In the illustrative embodiment of FIGS. 1-6, the second compartment base member 108 and third compartment base member 109 are substantially coplanar with each other. Further, the second compartment base member 108 and third compartment base member 109 are generally flat in these views, although it will be clear to those of ordinary skill in the art having the benefit of this disclosure that contours could be incorporated into one or both of these base members.

[048] In this illustrative embodiment, however, the first compartment base member 107 is configured to be inclined relative to one or both of the second compartment base member 108 and third compartment base member 109. As such, the stair-stepped contour 115 forms a ramp upon which syringes may be placed so that the plunger of each syringe is predisposed to project upward and out of the tray 100. Said differently, the stair-stepped contour 115 is configured such that the first step portion 116 and the second step portion 117 are disposed in a non-parallel orientation relative to the second compartment base member 108. This configuration makes it easier for a medical services provider to grasp the syringes and remove them from the tray 100.

[049] The first compartment base member 107 may include other features suitable for accommodating one or more syringes as well. In one embodiment, one or both of the first step portion 116 and second step portion 117 include recesses 118,119 for accommodating a syringe flange. These recesses 118,119 generally function to prevent the syringes from sliding lengthwise within the first compartment 101. Similarly, in one embodiment one or both of the first step portion 116 and the second step portion 117 include protrusions 120 that help to prevent the syringes from sliding laterally within the first compartment 101.

[050] In one embodiment, one or both of the first barrier 105 and the second barrier 106 include openings disposed therein. In the illustrative embodiment shown in FIGS. 1-6, the first barrier 105 includes a first opening 121 between the first compartment 101 and the second compartment 102. Similarly, the second barrier 106 includes a second opening 122 between the second compartment 102 and the third compartment 103. Each of these openings has an opening depth associated therewith. Similarly, each opening has an opening width associated therewith. In the illustrative embodiment of FIGS. 1-6, the first opening 121 is bounded by a first opening base member 129 and two inclined first opening side members 127,128, while the second opening 122 is bounded by a second opening base member 131, an inclined second opening side member 130, and the perimeter wall 110.

[051] While the opening depths can be the same, in one embodiment the opening depths are different. For example, in the illustrative embodiments of FIGS. 1-6, the first opening 121 has a first opening depth 123 that is less than the second opening depth 124 of the second opening 122. Similarly, in one embodiment the opening widths are different. For example, in the illustrative embodiments of FIGS. 1-6, the first opening 121 has a first opening width 125 that is less than the second opening width 126 of the second opening 122. Such a disparity in opening depths and widths, as well as the inclusion of inclined opening side members, provides an advantage in some applications.

[052] For instance, in many catheter procedures a pair of syringes – such as syringes having a one-half inch diameter – fits easily into the first compartment 101 when the tray 100 is made with the illustrative dimensions set forth above. However, some procedures require one or more of the syringes to be larger. For example, some syringes are larger in diameter. These larger syringes are capable of nesting within the first opening 121 and second opening 122. The inclined opening side members prevent the syringe from moving lengthwise, while the disparate opening heights present the plunger of the syringe to the medical services provider for easy removal from the tray 100.

[053] The stair-stepped contour 115, working in tandem with the first opening 121, gives the tray additional advantages over prior art catheter containers. For instance, when the first compartment 101 has a first compartment base member 107 configured with a stair-stepped contour 115, the first compartment 101 can be used as a lubricant applicator for the catheter.

[054] Specifically, the medical services provider may dispense the lubricating jelly along the second step portion 117. As the second step portion 117 is lower in the tray 100 than the first step portion 116, the second step portion 117 serves as a channel in which the lubricating jelly may spread. A medical services provider may then pass the catheter through the first opening 121, through the channel formed by the second step portion 117, i.e., along the second step portion 117 through the dispensed lubricating jelly, and out the top of the tray 100 to the patient. This feature of the tray 100 greatly eases the application of lubricating jelly to the catheter when compared to prior art solutions. In one embodiment, the tray 100 is packaged with printed instructions showing the medical services provider how to apply lubricating jelly in this manner. The printed instructions will be described in more detail below with respect to FIGS. 12-23.

[055] It will be clear to those of ordinary skill in the art having the benefit of this disclosure that alternative methods may be used to apply the lubricating jelly as well. For example, in another embodiment, the lubricating jelly is dispensed directly onto the catheter tubing while the tubing is

in or above the first compartment 101. Excess lubricant falling from the catheter tubing can then collect, and be retained, in the second step portion 117.

[056] This particular feature highlights another advantage of the "compartmentalized" structure of various embodiments of the invention. As the tray 100 includes multiple compartments, various tasks associated with a catheterization procedure can be completed while keeping the catheter within the tray 100. The ability to keep the catheter in the tray 100 reduces the risk that the catheter or corresponding devices will be contaminated with bacteria or microbes on other objects within the procedure room. For example, when the first compartment 101 is used to apply lubricating jelly to the catheter, the lubricating jelly can be applied while the catheter is contained within the tray 100, thereby reducing the risk that the catheter will become contaminated. This correspondingly reduces the risk of infection for the patient receiving the catheter.

[057] Prior art systems, for example such as those in which the catheterization procedure components are shipped in separate containers, may contribute to substandard techniques in that the catheter can become contaminated when moving it from its shipping container. Consequently, the patient can be at an elevated risk of infection as the catheter is moved from one tray to another. Embodiments of the present invention solve this problem by providing a single level tray 100 with compartments. Further, in one embodiment the first compartment 101 includes the first opening 121 so the catheter can stay in place during and after lubrication. By having easy access to the components disposed in the single level tray 100, the medical services provider can more easily prepare and use the components within the tray 100. This helps to minimize the risk of contaminating the patient or the sterile field during the procedure.

[058] In one embodiment, the second step portion 117 is configured to be inclined at a shallower angle than the first step portion 116 in at least a portion opposite the recess 119 from the first opening 121. When configured in such a fashion, the second step portion 117 includes a "cutdown" so that the catheter can stay within the channel both during and after lubrication.

[059] Additionally, the catheter can be placed in both the first opening 121 and second opening 122 during lubrication. When positioned in this configuration, the second opening 122 helps to align the catheter with the first opening for easy passage through the lubrication channel formed by the second step portion 117.

[060] The tray 100 of FIGS. 1-6 includes additional advantages over prior art catheter packaging as well. For example, in one embodiment, instructions 132 or other graphical indicia can be printed, placed upon, or molded into the horizontal flange 111. In one embodiment, compartment designations can be placed above each compartment to ensure the medical services provider uses the correct device or material at the correct time. In another embodiment, expiratory dates for materials or devices disposed within the tray 100 may be placed on the horizontal flange 111. It will be obvious to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. Any number of various text or picture combinations can be printed on, placed upon, or molded into various parts of the tray. For instance, graphical indicia can be applied to the compartment base members in addition to the horizontal flange 111. Note that the horizontal flanges, in one embodiment, can terminate in downwardly protruding vertical flanges for increased stability during the printing process.

[061] Another advantage of the tray 100 is that its compartmentalized configuration helps to reduce the risk of contaminating a patient or compromising the sterile nature of the components stored in the tray 100. Since both the catheter assembly and medical devices corresponding to catheter use are stored within the same tray 100, the risk of cross-contamination between sterile work areas and non-sterile spaces is minimized. Further, by having the catheter assembly and the devices corresponding to catheter use stowed in a one-level tray rather than a multi-level, stacked configuration, the medical services provider can more easily prepare and use the catheter and corresponding devices disposed within the tray 100.

[062] Turning now to FIGS. 7-9, illustrated therein is a tray having a catheter assembly 700, syringes 701,702, and a specimen container 703 stored therein as a catheter packaging system in accordance with one embodiment of the invention. As with FIGS. 1-6, FIGS. 7-9 will be referred to collectively with like reference numerals referring to identical or functionally similar elements throughout the separate views. FIG. 7 illustrates a top, front, right perspective view of the catheter packaging system, while FIG. 8 illustrates a top plan view of the catheter packaging system. FIG. 9 illustrates a transparent, front elevation view of the catheter packaging system.

[063] The illustrative catheter packaging system of FIGS. 7-9 includes a tray 100 having a first compartment 101, a second compartment 102, and a third compartment 103. In this illustrative embodiment, the first compartment 101 is configured to accommodate syringes 701,702. The second compartment 102 is configured to accommodate a coiled medical device, such as catheter assembly 700. The third compartment 103 is configured to accommodate the specimen container 703. The third compartment 103 can accommodate other materials as well, including skin sanitizers and cleansing liquids, solutions, or gels. As mentioned above, additional devices corresponding to catheter use, including towels, drapes, rubber gloves, and so forth, can be disposed in the tray 100 as well. As an illustration of this flexibility, a towel 704 is disposed beneath the catheter assembly 700.

[064] As noted above, in one embodiment the flange 111 can include instructions 770 or other graphical indicia. As also noted above, the implements disposed in the various compartments 101,102,103 can have implements therein arranged in accordance with use. In one embodiment, shown illustratively in FIG. 7, the instructions 770 can be coordinated with this arrangement, indicating that components disposed in the first compartment 101 should be used first, components disposed in the second compartment 102 should be used next, and so forth. To assist the user in understanding workflow, arrows 771 or other directional elements can be included on the flange 111 as well.

[065] As illustrated in FIGS. 1-6, each compartment of the tray 100 includes a compartment base member. Further, each compartment is separated by a barrier having an opening therein. A first barrier 105 having a first opening 121 therein separates the first compartment 101 from the second compartment 102. Similarly, a second barrier 106 having a second opening 122 therein separates the second compartment 102 from the third compartment.

[066] Syringes 701,702 are disposed in the first compartment, with one syringe 701 being supported at a different elevation within the tray than the other syringe 702. The different elevations can be relative to each syringe 701,702, or to other components of the tray 100, such as the second compartment base member 108. Said differently, one syringe 701 is supported by the first compartment base member 107 at a shallower depth within the tray 100 than the depth of the second compartment base member 108. Further, where the first compartment base member 107 is inclined relative to other base members, one or both syringes 701,702 will be supported in a non-parallel configuration relative to the second compartment base member 108. This is most readily seen in FIG. 9.

[067] As noted above, some medical procedures will call for more materials than can be accommodated by a syringe capable of fitting within the first compartment 101. For such procedures, the tray 100 can be packed with larger syringes. A large syringe (not shown) can be supported laterally within the tray 100 when it is placed across the tray 100 such that it lies within both the first opening 121 of the first barrier 105 and the second opening 122 of the second barrier 106. Such a syringe will pass across the top of the catheter assembly 700, but will be held in place by the side members of each opening.

[068] Turning now to FIG. 10, illustrated therein is an exploded view of the tray 100 having the catheter assembly 700, a pair of syringes 701,702, and a specimen container 703 disposed therein. While only a specimen container 703 is shown as being disposed in the third compartment, note that additional items could also be included within the third compartment, including swab sticks.

Other devices could also be inserted into the tray 100 in various compartments as well. For example, in one embodiment, a catheter securement device, and a Foley insertion tag, which is a dated and/or time stamped label that is secured to the catheter tubing once the catheter is inserted, can be inserted into the second compartment 102. Also, note that the pair of syringes 701,702 can be configured as shown in FIG. 10, or alternatively can be both inserted in the first compartment, as described above. In the configuration of FIG. 10, rather than having both syringes 701,702 disposed within the first compartment 101, one syringe 702 is disposed laterally in the first opening 121 and the second opening 122 of the first barrier 105 and second barrier 106, respectively. This configuration is illustrative only.

[069] Once the necessary components are disposed within the tray 100, the tray can be sealed with a wrap 1000 to keep the internal components sterile. The wrap 1000 can be any of a number of types of material. In one embodiment, the wrap 1000 comprises a Central Sterile Reprocessing (CSR) wrap that is used widely by medical professionals in hospitals, ambulatory surgical centers, and the like during medical procedures. While a CSR wrap is one example of a wrap that can be used, it will be clear to those of ordinary skill in the art that other wraps, such as plastic, cotton, linen, paper, or combinations thereof, can be substituted without departing from the spirit and scope of the invention.

[070] Using a CSR wrap as an illustrative example, in one embodiment as indicated in FIG. 10, the CSR wrap 1000 is folded about the tray 100 for sealing, and can be correspondingly unfolded to reveal the tray 100. Once unfolded, the CSR wrap 1000 can then be used in the catheter insertion process. For example, an unfolded CSR wrap 1000 can be used to provide a sterile field in which the tray 100 sits for unloading and subsequent use. This process will be explained in more detail in the discussion of FIGS. 22-30 below.

[071] Printed instructions 1001 can then be attached to, disposed upon, or disposed within the tray 100. In one embodiment, the printed instructions 1001 include a health care services portion and a patient portion, as will be shown in FIGS. 12-13 below. The health care services portion can

include instructions telling the health care services provider, for example, how to set up a sterile or otherwise clean work environment, how to prepare the catheter assembly 700 disposed within the tray, how to use the other devices within the tray, how to insert the catheter, how to secure the drainage bag to the catheter, how to empty the drainage bag, how to obtain a urine sample, and so forth. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

[072] The patient portion can include helpful suggestions or instructions for the patient. The patient portion can be detachably coupled to the health care services portion, such as by a perforated line that is easily torn to separate the patient portion from the health care services portion. Examples of suggestions or instructions that may be included in the patient portion include information on what a catheter is, what the patient should understand about the catheter, how to reduce the chance of getting an infection, information about infections commonly associated with catheters, symptoms of infections commonly associated with catheters, and suggestions for home use of the catheter assembly 700. In one embodiment, the health care services portion may include an instruction for the health care services provider to detach the patient portion from the health care services portion and instructions to discuss the patient portion with the patient.

[073] The health care services portion can tell the medical services provider how to perform a standard catheterization procedure. For instance, in one embodiment, the tray 100 is equipped with an adhesive label that can be used to identify the patient or specimen in the specimen container 703. Further, a label can be included to mark or otherwise identify the material in the fluid bag attached to the catheter. Such labels can include pre-printed fields, such as date, time and name. Further the printed instructions 1001 can notify the medical services provider that the devices disposed within the tray 100 are ordered corresponding to use during the catheterization procedure.

[074] In another embodiment, the printed instructions 1001 can inform the medical services provider of special instructions. For instance, in one embodiment the printed instructions 1001 can inform the

medical services provider not to leave a catheter in a patient for more than forty-eight hours without a physician's approval. Where the printed instructions 1001 include such information, the labels included in the tray 100 may have pre-printed fields for the time of insertion that can be filled in by the medical services provider performing the catheterization procedure.

[075] Once the printed instructions 1001 have been affixed to, or placed with, within, or atop the tray 100, the assembly can be sealed in a sterile wrap 1002 such as a thermally sealed bag. The thermally sealed bag can optionally include a preformed opening. For example, in one embodiment, the opening can include one or more tabs that a health care services provider is instructed to pull to open the bag. Inclusion of a sterile wrap 1002 not only keeps the contents within the bag sterile, but also allows the instructions to be included with the tray assembly, yet outside the CSR wrap 1000.

[076] In one embodiment the printed instructions 1001 are disposed atop the CSR wrap 1000 such that the health care services portion of the printed instructions 1001 is disposed on the top of the printed instructions 1001, with the patient portion being disposed adjacent to the CSR wrap 1000, such as when the printed instructions 1001 are configured as an accordion-style folded instruction pamphlet. While the printed instructions 1001 of one embodiment are configured as a folded, printed, separate article disposed atop the CSR wrap 1000, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. For example, in one embodiment the sterile wrap 1002 can be optional. In one embodiment, rather than including separate printed instructions 1001, the instructions for use can be printed on the CSR wrap 1000 as well.

[077] Additional instruction materials may be included with the completed assembly as well. For example, in one embodiment an adhesive instruction tag 1003 can be affixed to the sterile wrap 1002. In another embodiment the instruction tag may be adhered to an outer packaging, that encloses the tray, the sterile wrap material or both. For example, in one embodiment the instruction tag 1003 can include information regarding whether a catheter procedure is needed.

Text 1004 such as "Is there a valid clinical reason?" may be included under an instruction to "Stop" that includes the following information:

[078] Before inserting the Foley catheter, at least one of the following conditions should exist:

[079] Acute urinary retention or obstruction

[080] Precise measurement of urinary output needed

[081] Select surgical procedures

[082] Open sacral or perineal wounds in incontinent patient

[083] Prolonged immobilization

[084] End of life care

[085] Further, checklist text 1005 may be included, such as "Checklist for Foley Catheter Insertion" included under the word "Check" that includes the following information:

[086] Check Each Box Upon Completion:

[087] Obtain order from physician/provider

[088] Document clinical reason for insertion

[089] Explain procedure to patient

[090] Use smallest catheter possible

[091] Perform hand hygiene

[092] Follow aseptic technique

[093] Additional information may also be included, such as a fillable form 1006 that provides fields for the date and time of insertion of the catheter to be recorded, the name of the health care services provider, and the signature of the health care services provider. The above text 1004 for the instruction tag 1003 is illustrative only, and may be customized as desired by the manufacturer.

[094] Turning now to FIG. 11, illustrated therein is a method 1100 for manufacturing a packaged catheter assembly in accordance with embodiments of the invention. At step 1101, the

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manufacturer provides a tray (100) having at least a first compartment (101) for accommodating one or more syringes (701,702) and a second compartment (102) for accommodating a flexible medical device, such as a catheter assembly (700). As noted above, in one embodiment the first compartment (101) will have a first compartment base member (107) having an inclined, stair-stepped contour (115). The first compartment (101) and second compartment (102) can be separated by a first barrier (105) having an opening (121) therein.

[095] Once the tray (100) is procured, the manufacturer can dispose at least one syringe (701) in the first compartment (101) at step 1102. Optionally, at step 1103, the manufacturer may include additional components with the tray (100). For example, a catheter securement device, a Foley insert tag, or other complementary components may be included at this step 1103.

[096] In one embodiment, as determined at decision 1105, a second syringe (702) will be disposed in the first compartment (101) at step 1106. In another embodiment, the second syringe (702) will be disposed laterally within the first opening (121) and, where present, a second opening (122) at step 1107.

[097] At step 1104, the manufacturer will place the catheter assembly (700) in the second compartment (102). Other components may be disposed in the tray (100) as well, including a specimen container (703) that is disposed in a third compartment (103) at step 1108. Further, other devices may be included, such as towels, drapes, printed instructions, one or more antiseptic packets, and so forth. These other devices can be disposed in various compartments within the tray (100).

[098] At step 1109, the tray (100) is sealed. This can be accomplished by folding a CSR wrap about the tray (100). In such an embodiment, the CSR wrap can be used during the catheter insertion procedure as well. At optional step 1110, the manufacturer can enclose printed instructions (1001). In one embodiment, the printed instructions (1001) will direct a user to discharge contents of at least one syringe into the first compartment (101) and to pass at least a portion of the catheter assembly (700) through the opening and into the contents to lubricate the catheter.

[099] At step 1111, the manufacturer can place a sterile wrap about the tray (100) and the printed instructions (1001), where included. A sticker or other sealing device can be applied that indicates the contents to be sterile as well. At step 1112, the completed assembly can be shipped to a medical services provider.

[0100] Turning now to FIGS. 22-30, illustrated therein is a method of packaging a catheter assembly and corresponding tray in accordance with embodiments of the invention. FIGS. 22-30 illustrate one exemplary method graphically, which each figure representing one or more steps of the method, as the illustrations serve to better explain these steps than would a flow chart or other diagram. While FIGS. 22-30 illustrate one method of packaging a tray and catheter assembly, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that other methods can be used as well. Further, in creating this article of manufacture, i.e., the packaged catheter assembly, the steps of FIGS. 22-30 may be either manual or automated. A person can execute the steps to create the article of manufacture in one embodiment. Alternatively, industrial machinery, equipment, and robotics can be designed and programmed to execute the steps with the assistance of one or more processors and executable instructions stored in memory.

[0101] Beginning with FIG. 22, in this step, a tray 100 is provided. The tray includes at least one compartment, such as the first compartment 101 that is configured for receiving the catheter assembly 700. As described above, the tray 100 can include additional compartments as well, such as those for receiving syringes, specimen jars, and so forth.

[0102] At this step, the catheter assembly 700 is placed within the first compartment 101 as previously described. The tray is then placed upon one or more layers of wrap material 2200. In one embodiment, the wrap material 2200 can be CSR wrap. For example, in the illustrative embodiment of FIG. 22, the wrap material 2200 comprises a white layer of CSR wrap measuring 24 inches square. As previously noted, other materials can be used as well, including plastic

materials, cotton materials, paper materials, synthetic materials and so forth. The wrap material 2200 can be of different shapes and sizes as well.

[0103] While the tray 100 can be sealed with a simple layer of plastic adhered to the top of the tray 100, providing the wrap material 2200 can be advantageous in many applications. For example, as will be explained below with respect to FIGS. 31-33, when the wrap material 2200 is a medically usable material, such as CSR wrap, a medical services provider may unfold the wrap about the tray 100 to create a sterile field for the catheterization procedure. For this reason, one or more layers of wrap material 2200 are simply folded about the tray 100 in this illustrative embodiment.

[0104] Note that for reference and ease of explanation, the tray 100 will be described as having four sides: a first side 2201, a second side 2202, a third side 2203, and a fourth side 2204. As these sides will not be visible in every view, due to the folding of the wrap material 2200 about the tray 100, they are initially noted here. Note that four sides are used because the illustrative tray 100 is rectangular in shape. Were the tray a triangle, there would be three sides. Were the tray ovular or circular, there would be an infinite number of sides.

[0105] Turning now to FIG. 22, at this step a first portion 2301 of the one or more layers of wrap material 2200 is folded about a first side (2201) of the tray 100. In this illustrative embodiment, the tray 100 is oriented at a rotation of approximately forty-five degrees relative to the one or more layers of wrap material 2200, with both the wrap material 2200 and the tray 100 being rectangular in shape. As such, the first portion 2301 comprises a first corner of the wrap material 2200. It will be clear to those of ordinary skill in the art having the benefit of this disclosure, however, that embodiments of the invention are not so limited. For example, the wrap material 2200 can be configured as a circle or oval. Executing the step shown in FIG. 22, a first portion of that material could be folded about a first side of the tray 100 in similar fashion.

[0106] Turning to FIG. 23, illustrated therein is an optional step that can be included in the method of packaging the catheter assembly. As noted above, in one embodiment the one or more layers of

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wrap material 2200 can be unfolded to create a sterile field about the tray 100. A patient can be placed atop this sterile field for the catheterization procedure. Even if the surface below the wrap material 2200 is also sterile, the use of the wrap material 2200 as a foundation for the procedure further ensures that the sterile field will not be breached.

[0107] Turning now to FIG. 24, to help ensure that the health care provider does not inadvertently breach the sterile field, in one embodiment a package of liquid hand sanitizer 2401 or other cleanser and/or a package of rubber gloves 2402 may be included. Alternatively, other medical implements such as alcohol wipes or other materials could be enclosed as well. In such an embodiment, upon opening the packaged catheter assembly, the health care services provider may – before ever touching the catheter assembly or tray contents – apply the liquid hand sanitizer 2401 to their hands and dawn rubber gloves. The inclusion of these accessories in the packaging eliminates the need for the health care services provider to have to leave the sterile field to wash their hands, obtain gloves, and so forth.

[0108] In the illustrative embodiment of FIG. 23, the package of liquid hand sanitizer 2401 and package of rubber gloves 2402 are simply placed atop the first portion 2301 of the one or more layers of wrap material 2200. As will be shown below, they will be held in place by other portions of the one or more layers of wrap material 2200 by way of subsequent folding steps. Other methods of holding them in place, including light adhesives or the design of pockets in the one or more layers of wrap material 2200 may also be used. The sanitizer 2401 and gloves 2402 are shown placed atop the first portion 2301, but may be alternatively placed atop, and therefore outside of the sterile field, other layers of the wrap as well, (for example, 2501, 2601, 2801 or the like).

[0109] Turning now to FIG. 25, at this step a second portion 2501 of the one or more layers of wrap material 2200 is folded about a second side (2202) of the tray 100. Where the optional package of liquid hand sanitizer 2401 and package of rubber gloves 2402 are included, the second portion 2501 of the one or more layers of wrap material 2200 may be folded so as to cover or partially cover these items.

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[0110] Turning now to FIG. 26, at this step of the method a third portion 2601 of the one or more layers of wrap material 2200 is folded about a second side (2203) of the tray 100. Where the optional package of liquid hand sanitizer 2401 and package of rubber gloves 2402 are included, the third portion 2601 of the one or more layers of wrap material 2200 may be folded so as to cover or partially cover these items.

[0111] Turning now to FIG. 27, illustrated therein is another optional step of the method of packaging the catheter assembly and tray. In many catheterization procedures, a first layer of material will be placed under the patient, while a second layer of material is placed atop the patient. For such applications, the packaged catheter assembly can include an additional layer of wrap material 2701. In the illustrative embodiment of FIG. 25, the additional layer of wrap material 2701 comprises a folded layer of CSR wrap measuring 17 by 17.5 inches. The additional layer of wrap material 2701 in this illustrative embodiment is folded as a 4 by 2 matrix.

[0112] The one or more layers of wrap material 2200 and the additional layer of wrap material 2701 can be the same type of material. Alternatively, the one or more layers of wrap material 2200 and the additional layer of wrap material 2701 can be different. In one embodiment, for example, the additional layer of wrap material 2701 can be a fenestrated wrap with one or more pre-formed openings suited to the catheterization procedure.

[0113] In one embodiment, the additional layer of wrap material 2701 is configured to be visibly distinguishable from the one or more layers of wrap material 2200. For example, in one embodiment, the additional layer of wrap material 2701 is a different color than the one or more layers of wrap material 2200. The one or more layers of wrap material 2200 can be white, for instance, while the additional layer of wrap material 2701 can be light blue or light green. Other color combinations can equally be used.

[0114] As with the package of liquid hand sanitizer 2401 and package of rubber gloves 2402, in one embodiment the additional layer of wrap material 2701 can be placed atop portions of the one or

more layers of wrap material 2200. In such an embodiment, the additional layer of wrap material 2701 can be held in place by way of subsequent folding steps, as the additional layer of wrap material 2701 is disposed along other folded portions of the one or more layers of wrap material 2200 prior to folding a fourth portion of the one or more layers of wrap material about the fourth side (2204) of the tray (100).

[0115] As will be shown below, medical procedure kits configured in accordance with embodiments of the invention can include printed instructions. The printed instructions can include a patient portion and a health care services provider portion. The health care services provider portion can include information such as how to use the medical procedure kit, what is included therein, checklists, and so forth. The patient portion can include helpful information for the patient, such as information about the procedure, questions to ask, and post procedure care suggestions. These two portions can be detachably coupled together. Alternatively, they can be separate.

[0116] In one embodiment of the invention where the health care services portion of the printed instructions are physically separated from the patient portion, it can be advantageous to stage the various portions at different locations within the assembled medical procedure kit. One advantage offered by embodiments of the invention is that the medical devices and implements can be staged within the kit in accordance with an order of use. Accordingly, the health care services provider can draw out each device in order of use.

[0117] Turning now briefly to FIG. 34, illustrated therein is an alternate embodiment of the stage shown in FIG. 27. The embodiment of FIG. 34 is well suited to situations in which the health care services portion is physically separated from the patient portion.

[0118] In FIG. 34, another optional step corresponding to a method of packaging a medical procedure kit is shown. As with FIG. 27, the medical procedure kit of FIG. 34 illustrates a packaged catheter assembly. Also as with FIG. 27, the packaged catheter assembly can include an additional layer of material 2701, which may be a patient drape, under-buttocks drape, or a combination thereof

disposed within one or more layers of wrap material 2200. As noted above, the additional layer of material 2701 can be configured to be visibly distinguishable from the one or more layers of wrap material 2200. For example, in one embodiment, the additional layer of material 2701 is a different color than the one or more layers of wrap material 2200.

[0119] The package of liquid hand sanitizer 2401 and package of rubber gloves 2402, optionally the additional layer of material 2701, and the separated health care services portion 3401 of the printed instructions can be placed atop portions of the one or more layers of wrap material 2200. In such an embodiment, the package of liquid hand sanitizer 2401, the rubber gloves 2402, the additional layer of material 2701, and the separated health care services portion 3401 can be held in place by way of subsequent folding steps, as they are disposed along other folded portions of the one or more layers of wrap material 2200 prior to folding a fourth portion of the one or more layers of wrap material about the fourth side (2204) of the tray (100). Accordingly, the health care services provider will be readily able to access these devices after unfolding a single fold of the one or more layers of wrap material 2200.

[0120] Turning now to FIG. 28, the tray (100) is enclosed in the one or more layers of wrap material 2200 by folding a fourth portion 2801 of the one or more layers of wrap material 2200 about a fourth side (2204) of the tray (100) and then tucking at least one of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the one or more layers of wrap material 2200 beneath at least another of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the layer of wrap material 2200. In the illustrative embodiment of FIG. 28, a part of the fourth portion 2801 is tucked beneath parts of each of the (2301), the second portion (2501), and the third portion (2601). This step of tucking encloses both the additional layer of wrap material 2701 and the package of liquid hand sanitizer (2401) and the package of gloves (2402) within the one or more layers of wrap material 2200.

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[0121] Turning briefly to FIG. 35, illustrated therein is a variation of FIG. 28 in which the printed instructions include a health care services portion and a patient portion, wherein these portions are separate. In FIG. 35, as with FIG. 28, the tray (100) is enclosed in the one or more layers of wrap material 2200 by folding a fourth portion 2801 of the one or more layers of wrap material 2200 about a fourth side (2204) of the tray (100) and then tucking at least one of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the one or more layers of wrap material 2200 beneath at least another of the first portion (2301), the second portion (2501), the third portion (2601), or the fourth portion 2801 of the layer of wrap material 2200. The separated health care services portion 3401 of the printed instructions is thus tucked within the fourth portion 2801.

[0122] The separated patient portion 3501 is then placed atop the fourth portion 2801. The health care services provider is therefore able to access the separated patient portion 3501 and deliver it to, and possibly discuss it with, a patient prior to unfolding the fourth portion 2801. The step of tucking shown in FIG. 34 encloses each of the additional layer of wrap material 2701, the separated health care services portion 3401, the package of liquid hand sanitizer (2401) and the package of gloves (2402) within the one or more layers of wrap material 2200, while leaving the patient portion 3501 outside the various folds of the one or more layers of wrap material 2200.

[0123] Turning now to FIG. 29, the packaged catheter assembly 2901 can be sealed in a bag 2902 as was described in FIG. 10. Prior to depositing the packaged catheter assembly 2901 into the bag 2902, optional printed instructions 1001 can be attached to or disposed upon the packaged catheter assembly 2901 as well. As with FIG. 10, the printed instructions 1001 can include a health care services portion and a patient portion as shown in FIGS. 12-13. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

[0124] Turning briefly to FIG. 36, illustrated therein is an alternative to FIG. 29, which is used when printed instructions including a health care services provider portion and a patient portion, each

physically separate from the other, is included. In FIG. 36, the packaged catheter assembly 2901 having the tucked-in, separated health care services portion 3401 of the printed instructions is sealed in a packaging material. The packaging material of FIG. 36 is illustratively shown as a bag 2902.

[0125] Prior to depositing the packaged catheter assembly 2901 into the bag 2902, the separated patient portion 3501 of the optional printed instructions can be attached to or disposed upon the packaged catheter assembly 2901 as described in FIG. 35.

[0126] Once the printed instructions 1001 have been affixed to, or placed with or atop the packaged catheter assembly 2901, as in either FIG. 29 or 36, the assembly can be sealed in a sterile wrap such as a bag 2902, which may be thermally or otherwise sealed. The completed assembly 3001 is shown in FIGS. 30 and 37, where an outer packaging material is shown. In FIGS. 30 and 37, the outer packaging material is a thermally sealed bag 2902. It will be understood that this outer packaging is but one embodiment of the various packaging materials that can be used in accordance with embodiments of the invention. In FIGS. 30 and 37, the thermally sealed bag 2902 optionally includes a preformed opening 3002. For example, in one embodiment, the preformed opening 3002 can include one or more tabs that a health care services provider is instructed to pull to open the bag 2902. Inclusion of a sterile wrap not only keeps the contents within the bag sterile, but also allows the printed instructions 1001 to be included with the tray assembly, yet outside the one or more layers of wrap material (2200).

[0127] Turning back to FIG. 29, in one embodiment the printed instructions 1001 are disposed atop the one or more layers of wrap material 2200 such that the health care services portion of the printed instructions 1001 is disposed on the top of the printed instructions 1001, with the patient portion being disposed adjacent to the one or more layers of wrap material 2200. As with FIG. 10, additional instruction materials may be included with the completed assembly as well. For example, in one embodiment an adhesive instruction tag 1003 can be affixed to the bag 2902.

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[0128] Turning now to FIGS. 38 and 39, illustrated therein are steps of method of assembling yet another embodiment of medical procedure kit in accordance with embodiments of the invention. In FIGS. 38 and 39, the printed instructions are physically separated into a patient portion 3801 and a health care services provider portion 3802, as was the case in FIGS. 34-37. However, unlike FIGS. 34-37, the embodiment of FIGS. 38 and 39 has the health care services provider portion 3802 configured as an adhesive label with the checklist 1003 forming an extension thereof. Further, as will be shown in more detail in FIG. 40, the health care services provider portion 3802 has a picture of the contents of the medical procedure kit on the top, and has a peelable flap 3803 that may be opened to reveal instructions and other indicia therein.

[0129] Another difference in the embodiment of FIGS. 38 and 39 involves the patient portion 3801. While some embodiments provide a patient portion that is very straight-forward, informational, and clinical in nature, in the embodiment of FIGS. 38 and 39, the patient portion 3801 is configured as a greeting card. Experimental testing has shown that when the patient portion is configured as an instruction or informational sheet, it is less likely that the patient portion will be delivered to the patient. However, by configuring the patient portion 3801 as a greeting card, such as with a pleasant picture of flowers or similar objects on the front and stylized text providing the information therein, it is more likely to be given to the patient. The patient portion 3801 will be described in more detail below.

[0130] Beginning with FIG. 38, illustrated therein is an exploded view of a tray 100 suitable for use in a medical procedure kit. The tray 100 has the catheter assembly 700, a pair of syringes 701,702, and a specimen container 703 disposed therein. While only a specimen container 703 is shown as being disposed in the third compartment, note that additional items could also be included within the third compartment, including swab sticks. Other devices could also be inserted into the tray 100 in various compartments as well. For example, in one embodiment, a catheter securement device, and a Foley insertion tag can be inserted into the second compartment 102. Also, note that the pair of syringes 701,702 can be configured as shown in FIG. 38, or alternatively can be both

inserted in the first compartment, as described above. In the configuration of FIG. 38, rather than having both syringes 701,702 disposed within the first compartment 101, one syringe 702 is disposed laterally in the first opening 121 and the second opening 122 of the first barrier 105 and second barrier 106, respectively. This configuration is illustrative only.

[0131] Once the necessary components are disposed within the tray 100, the tray can be enclosed with a wrap 1000. The wrap 1000 can be one or more layers in number, and further can be any of a number of types of material. In one embodiment, the wrap 1000 comprises a CSR wrap.

[0132] Using a CSR wrap as an illustrative example, in one embodiment as indicated in FIG. 38, the CSR wrap 1000 is folded about the tray 100 for sealing, and can be correspondingly unfolded to reveal the tray 100 and other implements. Once unfolded, the CSR wrap 1000 can then be used in the catheter insertion process. For example, an unfolded CSR wrap 1000 can be used to provide a sterile field in which the tray 100 sits for unloading and subsequent use. This process is explained in more detail in the discussion of FIGS. 22-30.

[0133] Printed instructions can then be attached to, disposed upon, or disposed within the tray 100. In the illustrative embodiment of FIG. 38, the printed instructions are configured as a physically separate health care services portion 3802 and a patient portion 3801, as will be shown in more detail in FIGS. 40-41 below. The health care services portion 3802 can include instructions telling the health care services provider, for example, how to set up a sterile or otherwise clean work environment, how to prepare the catheter assembly 700 disposed within the tray, how to use the other devices within the tray, how to insert the catheter, how to secure the drainage bag to the catheter, how to empty the drainage bag, how to obtain a urine sample, and so forth. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

[0134] In the embodiment of FIG. 38, the health care services portion 3802 is configured with a checklist 1003 extending therefrom. Further, the health care services portion 3802 includes, in one

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embodiment, a photograph of the contents disposed within the medical procedure kit. When viewing the health care services portion 3802 from the top, the health care services provider is able to easily inventory what contents are disposed therein.

[0135] In one embodiment, the health care services portion 3802 includes a peelable flap 3803. By pulling back the peelable flap 3803, the health care services portion 3802 opens to reveal instructions and other information therein. For example, in one embodiment, the interior of the health care services portion 3802 can include one or more of the panels shown in FIGS. 15-19. In one embodiment, the health care services portion 3802 may include an instruction for the health care services provider to give the patient portion 3801 to the patient, and in one embodiment, insructions to discuss the patient portion 3801 with the patient.

[0136] The patient portion 3801 can include helpful suggestions or instructions for the patient. The patient portion 3801 can be configured as a greeting card to make the information more pleasantly received by a patient. Examples of suggestions or instructions that may be included in the patient portion include information on what a catheter is, what the patient should understand about the catheter, how to reduce the chance of getting an infection, information about infections commonly associated with catheters, symptoms of infections commonly associated with catheters, and suggestions for home use of the catheter assembly 700.

[0137] In the embodiment of FIG. 38, the patient portion 3801 is disposed within the packaging 3804, while the health care provider portion 3803 is affixed to the outside of the packaging 3804. As with FIG. 34, the medical procedure kit of FIG. 38 can include an additional layer of wrap material 2701 disposed within one or more layers of wrap material 2200. As noted above, the additional layer of wrap material 2701 can be configured to be visibly distinguishable from the one or more layers of wrap material 2200. For example, in one embodiment, the additional layer of wrap material 2701 is a different color than the one or more layers of wrap material 2200.

[0138] The package of liquid hand sanitizer and package of rubber gloves described above (not shown in FIG. 38 for simplicity) can then be placed under the additional layer of wrap material 2701. The patient portion 3801 can be placed atop the additional layer of wrap material 2701. In such an embodiment, the package of liquid hand sanitizer (where used), the rubber gloves (where used), the additional layer of wrap material 2701, and the patient portion 3801 can be held in place by way of a final folding step 3805. Accordingly, they will be held in place by a folded portion 3806. The health care services provider will be readily able to access these implements after unfolding the folded portion 3806 shown in FIG. 38.

[0139] The health care services portion 3802 can be affixed to the packaging 3804. The packaging 3804 can optionally include a preformed opening. For example, in one embodiment, the opening can include one or more tabs that a health care services provider is instructed to pull to open the packaging 3804.

[0140] Turning now to FIG. 39, illustrated therein is the medical procedure kit 3901 of FIG. 38 having the patient portion 3802 tucked-into the one or more layers of wrap 2200. The health care services portion 3802 is affixed to the packaging 3804. The packaging 3804 of FIG. 39 is illustratively shown as a thermally or adhesively sealed bag.

[0141] Turning now to FIGS 12-13, illustrated therein is one embodiment of the printed instructions 1001 in accordance with embodiments of the invention. The printed instructions 1001 can be configured as an instruction manual suitable for inclusion with a tray (100) as described above. FIG. 12 illustrates a view of a first side of the instruction manual, while FIG. 13 illustrates a view of a second side of the instruction manual.

[0142] In one embodiment, the printed instructions 1001 are configured as a two-portion instruction manual having a health care services portion 1201 and a patient portion 1202. In the illustrative embodiment of FIGS. 12-13, the patient portion 1202 is detachably coupled to the health care services portion 1201, and is thus separated from the health care services portion 1201, by a

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perforation 1203. For example, where the printed instructions 1001 are configured as a printed material on a paper-based stock, the perforation 1203 can be a perforated line running along a dimension of the printed instructions 1001 such that the printed instructions 1001 can be easily torn along the perforation 1203 to separate the patient portion 1202 from the health care services portion 1201. Note that the embodiment of FIGS. 12 and 13 is but one illustrative embodiment of the invention. The patient portion 1202 need not be detachably coupled to the health care services portion 1201. As will be shown in FIGS. 27-34 below, the patient portion 1202 may be physically separate from the health care services portion 1201 as well. In the separated configuration, the health care services portion 1201 and patient portion 1202 can be disposed at different locations within a medical procedure kit.

[0143] In one embodiment, the printed instructions 1001 are configured as a plurality of panels 1204,1205,1206,1301,1302,1303. As will be shown in FIG. 20, in one embodiment the printed instructions 1001 can be configured as an instruction manual that is formed with an accordion-style fold, with each of the panels 1204,1205,1206,1301,1302,1303 forming a page of the instruction manual. In the illustrative embodiment of FIGS. 12-13, panels 1204,1205 and panels 1301,1302 form the health care services portion 1201, while panels 1206,1303 form the patient portion. Panels 1206,1303 are separated from panels 1204,1205 and panels 1301,1302 by the perforation 1203 such that the patient portion 1202 is tearably separable from the health care services portion 1201.

[0144] In one embodiment, the health care services portion 1201 includes instructions 1304 for using the catheter assembly and other corresponding medical devices disposed within the accompanying tray. The instructions 1304 can include text and/or figures or illustrations showing how to use the catheter assembly and corresponding medical devices on the patient, as well as instructions on preparation, taking samples, preventing infection, and so forth. The instructions 1304, in one embodiment, also include an instruction to detach the patient portion 1202, give the patient

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portion 1202 to the patient, as well as an instruction to discuss the information disposed on the patient portion 1202 with the patient.

[0145] Similarly, the patient portion 1202 may also include instructions 1305 and/or helpful suggestions for the patient who is undergoing the catheterization procedure. For instance, this information can include any one or more of the following: a description of what a catheter is, what the patient should know about the catheter, how to reduce the chance of getting an infection from the catheterization procedure, what infections commonly associated with catheterization procedures typically are, the symptoms associated with infections commonly associated with catheterization procedures, and information about using the catheter at home. Additionally, the patient portion 1202 may include custom information as well. For example, in one embodiment the patient portion 1202 includes an informational section configured such that the health care service provider's name and contact information can be written thereon. It will be clear to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. For example, additional types of health care service instructions or patient instructions or suggestions can also be included.

[0146] Turning now to FIGS. 14-19, illustrated therein are exemplary panels 1204,1205,1206,1301,1302,1303. These panels 1204,1205,1206,1301,1302,1303 are intended to illustrate exemplary instructions for the health care services portion (1201) and patient portion (1202) of an illustrative instruction manual for a catheter assembly and corresponding medical devices included with an accompanying tray (100). It will be clear that these panels 1204,1205,1206,1301,1302,1303 and the information printed thereon can be varied in any number of ways without departing from the spirit and scope of the invention as described herein and recited in the following claims. For example, the number of panels can be varied. Additionally, the information printed thereon can be condensed, expanded, or altered without departing from the spirit and scope of the invention. Also, the exemplary information may be moved from the panels shown to other panels, as a particular application may warrant.

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[0147] Beginning with FIG. 14, illustrated therein is one exemplary panel 1204. In one embodiment, panel 1204 will be configured such that when the catheter package assembly within which the instruction manual is disposed is initially opened, panel 1204 will be readily viewable. For example, where the catheter package assembly is assembled as shown in FIG. 10 above, once the sterile wrap (1002) is removed, the panel 1204 will be viewable prior to removal of the CSR wrap (1000).

[0148] Panel 1204 can include general information about the catheter assembly and corresponding medical devices disposed within the tray. For example, this information can include part number information 1401, trade name information 1402, and manufacturer information 1403. A diagram 1404 of the contents of the package assembly may be included as well. The illustrative diagram 1404 of FIG. 14 illustrates a tray 100 having a catheter assembly 700 and corresponding medical devices disposed therein. The corresponding medical devices of this illustrative embodiment include a pair of syringes 701,702 and a specimen container 703. Additionally swab sticks 1408, a catheter securement deice 1409, a Foley insert tag 1410, vinyl gloves 1411, a fenestrated drape 1412, an underbuttocks drape 1413, and a hand sanitizer 1414 solution or wipe are disposed within the tray 100.

[0149] In addition to a diagram 1404, panel 1204 can also include a written description 1407 of the elements included in the tray 100. Further, sterility information 1407 can be included. Panel 1204 can even include instructional material 1406 on how to use the instruction manual as well.

[0150] Turning now to FIG. 15, illustrated therein is one embodiment of panel 1301. As will be described below with respect to FIG. 20, in one embodiment the printed instructions (1001) are configured as an accordion-style folded instruction manual. In such a configuration, panel 1301 can be disposed on the back of panel 1204. Panel 1301 will therefore be visible upon a health care services provider opening the instruction manual.

[0151] Panel 1301 can include instructions for using the catheter assembly and the corresponding medical devices. As can be seen from this illustrative embodiment, panel 1301 can include instructions for setting up a clean work area. The instructions can include text, pictures, illustrations, or combinations of these.

[0152] In one embodiment, the instructions for setting up a clean work area include a hygiene performance step 1501, which may include instructions to wash hands, optionally put on gloves (which at this step can be non-sterile gloves), and so froth. The instructions may then include information on opening the remainder of the catheter package assembly. For instance, in FIG. 15 step 1502 indicates that the health care provider should remove the CSR wrap (1000), which in this case is folded about the tray (100). Note that in this illustrative embodiment, as the CSR wrap (1000) is folded about the tray (100), removal of the CSR wrap (1000) by unfolding creates a sterile field about the tray (100).

[0153] Step 1503 then instructs the health care provide to pick up the underbuttocks of the patient and to place the underbuttocks wrap beneath the patient. Step 1504 then instructs the health care provider to use the hand sanitizing solution provided with the catheter package assembly.

[0154] As with other panels shown in FIGS. 14-19, the various panels may include suggestions 1505 for preventing a catheter associated urinary tract infection. Some of this information is illustratively shown in FIG. 15. It will be understood that this information can be placed on one or more panels.

[0155] In addition to information for setting up a clean work area, in one embodiment panel 1301 includes instructions for preparing the catheter assembly (700) as well. For example, step 1506 instructs the health care services provider to don sterile gloves, as the hands were sanitized at step 1504. Step 1507 tells the health care services provider to place the fenestrated drape with a shiny side down on the patient without contaminating the sterile gloves donned at step 1506. Step 1508 instructs the health care services provider to test the balloon of the catheter assembly with the

water-filled syringe stored in the first compartment. Step 1508 also instructs the health care services provider to leave the syringe connected to the catheter assembly.

[0156] Step 1509 then provides instructions on using the first compartment of the tray as a lubricant application chamber as described above. Specifically, in this illustrative embodiment, step 1509 instructs the health care services provider to inject the lubricating jelly found in the second syringe of the first compartment into the first compartment. Step 1509 also instructs the health care services provider to pass the tip of the catheter through the first opening in the wall separating the first compartment and second compartment into the lubricating jelly, thereby lubricating the tip of the catheter.

[0157] Turning now to FIG. 16, illustrated therein is an exemplary embodiment of panel 1302. The instructions printed thereon continue to provide the health care services provider with information regarding use of the catheter assembly. For example, in one embodiment, this information includes instructions on inserting the catheter.

[0158] At step 1601, the instructions direct the health care services provider to tear open the swab stick package and to use the swab sticks to clean the patient from the top down. The instruction also notes that each swab stick is intended for one use only to properly maintain the sterile field. Step 1602 directs the health care services provider to initiate the catheterization process by inserting the catheter assembly into the patient. Steps 1603 and 1604 continue this process as shown in FIG. 16.

[0159] Step 1605 directs the health care services provider to secure the drainage bag to the catheter assembly. Step 1606 directs the health care services provider to clean up upon completion of the catheterization process. Step 1607 provides instructions on completing the label on the Foley insertion tag included with the catheter package assembly and attaching it to the tubing or drain bag attached to the catheter assembly.

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[0160] At step 1608, the health care services provider is instructed to detach the patient portion (1202) from the health care services portion (1201) by tearing the two apart along the perforation (1203). Step 1609 further instructs the health care services provider to discuss the patient information printed upon the patient portion (1202) with the patient. Step 1609 instructs that documentation of the entire procedure should be completed.

[0161] Turning now to FIG. 17, illustrate therein is one embodiment of panel 1303, which represents a first side of the patient portion (1202). This panel 1303 includes information 1701 describing what a catheter is and why a catheter might be used. The panel 1303 also includes information 1702 describing what the patient should know regarding catheters and catheter use. For example, this information 1702 might notify the patient that the health care services provider should wash hands prior to inserting the catheter, and that it is acceptable to ask them to do so if they have not done so before the patient.

[0162] The panel 1303 also includes information 1703 regarding how the patient can reduce the chances of getting an infection. This information 1703 can include a statement that the patient should wash their hands prior to touching the catheter assembly. The information 1703 may also include a statement that the drainage bag should always be kept at a level beneath the patient's navel, and that the patient should inform a helper when the bag is more than half full.

[0163] Turning to FIG. 18, illustrated therein is one embodiment of panel 1206. In this illustrative embodiment, panel 1206 forms the second side of the patient portion (1202) of the instruction manual, and accordingly, includes additional information that a patient may wish to know when using a catheter assembly.

[0164] By way of example, information 1801 informs the patient as to what common infections associated with catheter use are and how they are contracted. Information 1802 provides symptoms of these common infections, such as fever, blood in the urine, burning or painful

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urination, or frequent or more urgent urination after catheter removal. Information 1803 informs the patient of what they should know prior to going home after a catheter procedure.

[0165] Information 1804 comprises an informational section configured such that a health care provider's name and contact information may be written thereon. This is helpful to the patient in the event that the symptoms recited in information 1802 should arise after the procedure, in that the patient has readily available access to the information required to contact a physician or other health care provider. An advantage of having this information 1804 on the patient portion (1202) when the patient portion (1202) is detachable is that the patient can take it with them upon completion of the procedure.

[0166] Turning now to FIG. 19, which is a portion of the health care services portion (1201), illustrated therein is one embodiment of panel 1205 that provides additional health services information. For example, information 1901 for emptying the drain bag and information 1902 describing how to obtain a urine sample can be included.

[0167] Turning now to FIG. 20, illustrated therein is one physical configuration in which the printed instructions 1001 can be delivered along with the catheter package assembly in accordance with embodiments of the invention. FIG. 20 is but one of many configurations, and embodiments of the invention are not to be limited in this respect, as FIG. 20 is illustrative only.

[0168] In FIG. 20, the printed instructions 1001 are configured as a tri-section, accordion style bi-folded panel. Three sections 2000,2001,2002 are folded in an accordion style, with two folds 2003,2004 existing between the sections 2000,2001,2002. When the printed instructions 1001 are configured as shown in FIGS. 12-13, folding the printed instructions 1001 in this manner allows the health care services portion 1201 to be disposed atop the patient portion 1202. Further, when the printed instructions are disposed atop a CSR wrap (1000) as shown in FIG. 10, by disposing the patient portion 1202 adjacent to the CSR wrap (1000), the health care services provider removing the

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sterile wrap (1002) off of the catheter package assembly will be assured of seeing the health care services portion 1201 first.

[0169] Turning now to FIG. 40, illustrated therein is an alternate embodiment of printed instructions 4000 configured in accordance with embodiments of the invention. The printed instructions 4000 of FIG. 40 are suitable for use as the health care services portion (3802) of FIGS. 38-39, in that it can be configured as an adhesive label with a peelable flap 4001. Further, the illustrative embodiment includes a checklist 4002 as described above in FIG. 38.

[0170] In the embodiment of FIG. 40, the top cover of the printed instructions 4000 include a picture 4003 of the contents of the medical procedure kit. In one embodiment, the picture 4003 is a color photograph set on a black background to make visibility simple. Above the picture is a title bar 4004. In one embodiment, the title bar 4004 tells a health care services provider what type of medical procedure kit is disposed therein, and is white text on a blue background.

[0171] A flap indicator 4005 indicates that more information is located within the printed instructions 4000. The additional information, which can be one or more of the panels shown in FIGS. 15-19 above, can be accessed by the peelable flap 4001. In one embodiment, the flap indicator is configured with black text on a yellow background.

[0172] The checklist 4002 can be configured as described above. In the embodiment of FIG. 40, a red warning bar 4006 having white text thereon is disposed above a checklist section 4007 that is yellow, having black text and white check boxes in this illustrative embodiment.

[0173] Turning now to FIG. 41, illustrated therein is one embodiment of a patient portion 3801 configured as a greeting card as was described with FIGS. 38-39. The patient portion 3801 in this illustrative embodiment includes an inspirational phrase 4103 on the front cover, along with an aesthetically pleasing image 4101. The aesthetically pleasing image 4101 of FIG. 41 is a vase of flowers, although it will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments of the invention are not so limited. Other aesthetically pleasing

images include puppies, sunsets, mountain streams, and so forth. The bottom of the patient portion 3801 includes in identifier 4103 that tells the patient the purpose of the patient portion 3801.

[0174] The interior of the patient portion 3801 can include text. For example, in one embodiment where the patient portion 3801 is to be included with a catheter assembly, the interior includes the following illustrative text:

[0175] Here is some simple information about foley catheterization:

[0176] 1. What is a Urinary Catheter?

[0177] A thin flexible tube that drains urine from the bladder into a collection bag. The catheter helps:

[0178] When you can't urinate.

[0179] To measure how much urine you're producing.

[0180] During and after some surgeries or tests.

[0181] 2. What should you know about your catheter?

[0182] Only a trained technician inserts a catheter when necessary, and it is removed as soon as possible.

[0183] Caregivers must wash hands with soap or use alcohol-based rubs before and after touching your catheter.

[0184] If your caregivers don't clean their hands, politely ask them to.

[0185] Do not disconnect the catheter yourself.

[0186] Inquire every day whether you still need the catheter.

[0187] 3. What is 'catheter-associated' urinary tract infection (CAUTI)?

[0188] If a catheter introduces 'outside' germs into your urinary tract, they can cause an invention. If a UTI is acquired, you may experience:

[0189] Sudden fever and/or bloody urine.

[0190] Burning or painful urination, or pain below the stomach.

[0191] Frequent, or more urgent, urinating after catheter is removed.

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[0192] Tell your provider right away. An antibiotic may be needed.

[0193] 4. Can you reduce your chances of an infection? Absolutely!

[0194] Wash your hands before and after touching your catheter.

[0195] Make sure the tube is secured to your leg. Never twist, or tug on it.

[0196] Always keep the collection bag below the level of your belly button.

[0197] Do not disconnect the catheter yourself.

[0198] Ask your doctor every day whether you still nee the catheter.

[0199] The above information on the patient portion 3801 can be printed in multiple languages, such as in Spanish or in English. Where two languages are used, the back portion may be the same as the image shown in FIG. 41, but with the inspirational phrase 4102 and identifier 4103 set forth in a different language. Further, alternatives and variations of the information can be substituted for the example set forth above.

[0200] Turning now to FIG. 21, illustrated therein is a method 2100 of using the printed instructions (1001) as described herein. At step 2101, a health care services provider removes the sterile wrap (1002) disposed about the catheter package assembly. Where the catheter package assembly is configured as shown in FIG. 10, removal of the sterile wrap (1002) will reveal the printed instructions (1001). Where the printed instructions (1001) are configured as described in FIG. 20, with the patient portion (1202) disposed adjacent to the CSR wrap (1000), the health care services provider will see the health care services portion (1201) first.

[0201] At step 2102, the health care services provider accesses the printed instructions (1001) and begins to read the panels, which in one embodiment are panels configured in accordance with those described in FIGS. 14-19 above.

[0202] At step 2103, the health care services provider unfolds the outer CSR wrap (1000), which in one embodiment is then used to create a sterile field about the tray (100). At step 2104, the health care services provider prepares the workspace, which in one embodiment may be in accordance with

steps (1501,1502,1503,1504) of panel (1301) in FIG. 15. For example, this may include donning non-sterile gloves, as shown at step (1501) of FIG. 15. This may further include picking up the underbuttocks drape, included with the tray (100), by the edge without contaminating the contents and placing the shiny side down under the area of the patient to be prepped as shown at step (1503) of FIG. 15. This may further include using the hand sanitizer as shown at step (1504 of FIG. 15.

[0203] At step 2105, the health care services provider prepares the catheter, which in one embodiment may be in accordance with steps (1506,1507,1508,1509) of panel (1301) as described in FIG. 15. For example, this can include donning sterile gloves as shown at step (1506) of FIG. 15. This may include placing a fenestrated drape, included with the tray (100), with the shiny side down on the patient without contaminating the sterile gloves, as shown at step (1507) of FIG. 15. This may include filling a test balloon of the catheter assembly with water as shown at step (1508) of FIG. 15, and injecting lubricating jelly from a syringe into the first compartment of the tray (100) as shown at step 1509 of FIG. 15.

[0204] At step 2106, the health care services provider inserts the catheter. In one embodiment, this can be in accordance with steps (1601,1602,1603,1604) of panel (1302) as described in FIG. 16. At step 2107, the health care provider secures the drain bag to the catheter assembly, which can be in accordance with steps (1605,1606,1607) described with respect to FIG. 16.

[0205] At step 2108, the health care services provider detaches the patient portion (1202) of the printed instructions (1001) from the health care services portion (1201). In one embodiment, this occurs by tearing the patient portion (1202) from the health care services portion (1201) along the perforation (1203), thereby transforming the printed instructions (1001) or instruction manual from a singular or unitary object into a two-piece object consisting of the patient portion (1202) and the health care services portion (1201). As described, above, the health care services provider may then discuss the patient portion (1202) with the patient and further give the patient portion (1202) to the patient to take home after the procedure.

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[0206] Turning now to FIGS. 31, 32, and 33, illustrated therein is one embodiment of a method of using the packaged catheter assembly 2901 of FIG. 29. At FIG. 31, a health care services provider 3101 opens the outer bag 2902 that is disposed about the tray 100 and removes the bag 2902 to reveal the packaged catheter assembly 2901 therein. The health care services provider 3101 can then access the instruction manual 1001 that is disposed atop the packaged catheter assembly 2901 in this illustrative embodiment.

[0207] The health care services provider 3101 can then unfold the one or more layers of wrap material 2200. Where an additional layer of wrap material 2701 is included, this unfolding step reveals and makes accessible the additional layer of wrap material 2701. Note that portions of the additional layer of wrap material 2701 may be visible, as shown in FIG. 29, prior to the steps of unfolding.

[0208] As noted above, in one embodiment the one or more layers of wrap material 2200 can be unfolded to form a sterile field. Turning now to FIG. 32, illustrated therein is a step of the method that utilizes this sterile field. Specifically, in FIG. 32 the health care services provider 3101 places the one or more layers of wrap material 2200 beneath the patient 3201, thereby transforming the area beneath the patient from a non-sterile field to a sterile field. Said differently, by placing the patient 3201 atop the one or more layers of wrap material 2200, the patient is effectively moved from a location that may have not been a sterile field to the sterile field atop the one or more layers of wrap material 2200.

[0209] Turning now to FIG. 33, illustrated therein is a step of the method that may be used when an additional layer of wrap material 2701 is included with the packaged catheter assembly 2901. In FIG. 33, the health care services provider 3101 is placing the additional layer of wrap material 2701 atop the patient 3201. Note that in the illustrative embodiment of FIG. 33, the additional layer of wrap material 2701 is fenestrated, in that it includes a perforated opening 3301 suitable for performing a catheterization procedure.

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[0210] In the foregoing specification, specific embodiments of the present invention have been described. However, one of ordinary skill in the art appreciates that various modifications and changes can be made without departing from the scope of the present invention as set forth in the claims below. Thus, while preferred embodiments of the invention have been illustrated and described, it is clear that the invention is not so limited. Numerous modifications, changes, variations, substitutions, and equivalents will occur to those skilled in the art without departing from the spirit and scope of the present invention as defined by the following claims. Accordingly, the specification and figures are to be regarded in an illustrative rather than a restrictive sense, and all such modifications are intended to be included within the scope of present invention. The benefits, advantages, solutions to problems, and any element(s) that may cause any benefit, advantage, or solution to occur or become more pronounced are not to be construed as a critical, required, or essential features or elements of any or all the claims.

What is claimed is:

1. A medical procedure kit, comprising:

    a single layer tray comprising a compartment separated by a wall from a lubricating jelly application chamber;

    a container of lubricating jelly disposed within the single layer tray; and

    a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the compartment;

    wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly.

2. The medical procedure kit of claim 1, further comprising one or more swabsticks disposed within the single layer tray.

3. The medical procedure kit of claim 1, further comprising a syringe containing water disposed within the single layer tray, wherein the syringe is at least partially disposed in the compartment with the Foley catheter.

4. The medical procedure kit of claim 1, the wall comprising an opening defined by an opening depth.

5. The medical procedure kit of claim 1, the container of lubricating jelly comprising a syringe containing the lubricating jelly.

6. The medical procedure kit of claim 5, the syringe situated within the lubricating jelly application chamber.

7. The medical procedure kit of claim 6, further comprising a second syringe disposed within the single layer tray.

8. The medical procedure kit of claim 7, the second syringe at least partially situated in the compartment.

9. The medical procedure kit of claim 7, the second syringe containing water.

10. The medical procedure kit of claim 9, wherein the water comprises sterile water.

11. The medical procedure kit of claim 7, wherein the syringe and the second syringe are arranged in the single layer tray in accordance with their order of use during a Foley catheterization procedure.

12. The medical procedure kit of claim 11, the lubricating jelly application chamber comprising one or more contours for accommodating flanges of one or more of the syringe or the second syringe.

13. A medical procedure kit, comprising:

a single layer tray comprising a container of lubricating jelly, a container of water, and a coiled tubing coupling a Foley catheter to a drain bag, wherein each of the container of lubricating jelly, the container of water, the coiled tubing, the Foley catheter, and the drain bag are positioned within the single layer tray; and

a lubricating jelly application chamber defined by contours of the single layer tray, wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter when the lubricating jelly is in the lubricating jelly application chamber.

14. The medical procedure kit of claim 13, wherein the container of lubricating jelly and the container of water are situated within the single layer tray in accordance with their order of use during a Foley catheterization procedure.

15. The medical procedure kit of claim 14, wherein the container of water comprises a syringe of water.

16. The medical procedure kit of claim 15, wherein the container of lubricating jelly comprises a syringe of lubricating jelly.

17. The medical procedure kit of claim 16, wherein the lubricating jelly application chamber

comprising one or more contours for accommodating flanges of one or more of the syringe of water or the syringe of lubricating jelly.

18. A medical procedure kit, comprising:

a single layer tray defining a wall separating a compartment from a lubricating jelly application chamber;

a container of lubricating jelly situated in the lubricating jelly application chamber; and

a coiled tubing coupled between a Foley catheter and a drain bag situated within the compartment;

wherein the lubricating jelly application chamber is configured to receive at least some lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the at least some lubricating jelly when the at least some lubricating jelly is in the lubricating jelly application chamber.

19. The medical procedure kit of claim 18, further comprising one or more of one or more swabsticks, or a specimen container, or a container of water, or combinations thereof, disposed within the single layer tray.

20. The medical procedure kit of claim 19, the wall defining an opening situated between the compartment and the lubricating jelly application chamber.

ABSTRACT

A tray (100) for accommodating a coiled medical device, such as a catheter assembly (700), includes a first compartment (101), a second compartment (102), and a third compartment (103). The catheter assembly (700) and devices associated with a catheterization procedure, such as syringes (701,702) containing sterile water and lubricating jelly and a specimen container (703) can be disposed within the tray. Printed instructions (1001) can be included with the tray (100). One or more layers of wrap material (2200) can be folded about the tray (100) to enclose the tray (100) and other items, such as an additional layer of wrap material (2701), packaged liquid hand sanitizer (2401), and packaged gloves (2402). When a health care services provider (3101) unfolds the wrap material, the same can be used to create a sterile field beneath a patient (3201).

Bard Exhibit 1004.0053

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Filer:	Philip Henry Burrus/Kayla Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1720**

Electronic Acknowledgement Receipt

EFS ID:	38997600
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	28-MAR-2020
Filing Date:	
Time Stamp:	18:06:39
Application Type:	Utility under 35 USC 111(a)

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Payment Type	CARD
Payment was successfully received in RAM	$1720
RAM confirmation Number	E20203RI07073800
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	10055U_P2_D1_C1_USA_2017-7-7_Declarations_Filed.pdf	6289078 d59371cdd402ebf161595bc7321b97837e866ee4	no	8
Warnings:					
Information:					
2	Drawings-only black and white line drawings	10055U_CIP2D1C1C1C1C1_FIGS_All.pdf	7668118 0e3e4624f02a6789523a37e094b7e85da13991f8	no	35
Warnings:					
Information:					
3	Application Data Sheet	10055U_CIP2_D1_C1C1C1C1_USA_2020-3-27_ADS.pdf	1824484 6b264ef0ff9923e403b1f4635c6f6f13169c6fe7	no	12
Warnings:					
Information:					
4	Transmittal of New Application	10055UCIP2D1C1C1C1C1_USA_2020-3-27_FeeTrans.pdf	182995 9da91282fc5c190cd444bf04514c28379e25938f	no	2
Warnings:					
Information:					
5		10055UCIP2D1C1C1C1C1_USA_2020-3-28_Spec.pdf	327686 f1145216138b75451a23c735dab12f6ae87ebe8	yes	50

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	46
Claims	47	49
Abstract	50	50

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	35155 e8e79968fd0210375110af854cb5d412ef1460ea	no	2
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National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

As the below named inventor, I hereby declare that:

This declaration is directed to:

☒ The attached application, or

☐ United States application or PCT international application number _____

filed on _____

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I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: Jennifer E. Tomes Date (Optional): 1/5/2015

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Sarah Dickinson Date (Optional): 4/8/13

Signature: Sarah Dickinson

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As the below named inventor, I hereby declare that:

This declaration is directed to:

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LEGAL NAME OF INVENTOR

Inventor: Deborah Adler Date (Optional): July 22, 2015

Signature: Deborah Adler

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LEGAL NAME OF INVENTOR

Inventor: John Kutsch Date (Optional) 6/29/15

Signature: John Kutsch

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LEGAL NAME OF INVENTOR

Inventor: Jack Maze Date (Optional): 6/24/15

Signature: Jack E Maze

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Kenneth Chua Date (Optional): 7/16/15

Signature: Kenneth Chua

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LEGAL NAME OF INVENTOR

Inventor: Alberto Savage Date (Optional): 07/19/15

Signature: [signature]

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

■ United States application or PCT international application number 13/860,902 filed on April 11, 2013.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Earl Wilson Date (Optional) :

Signature: Earl D. Wilson

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

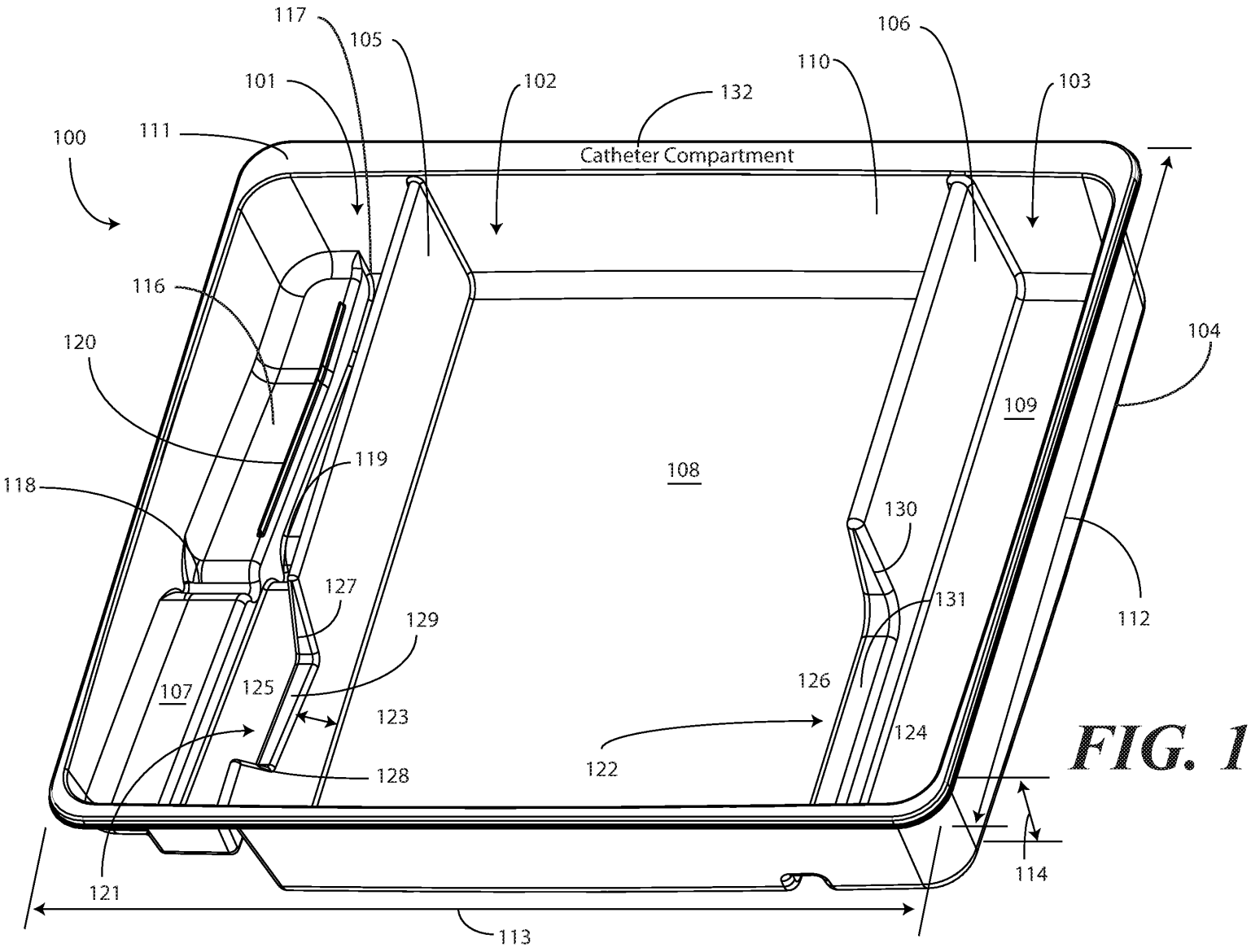
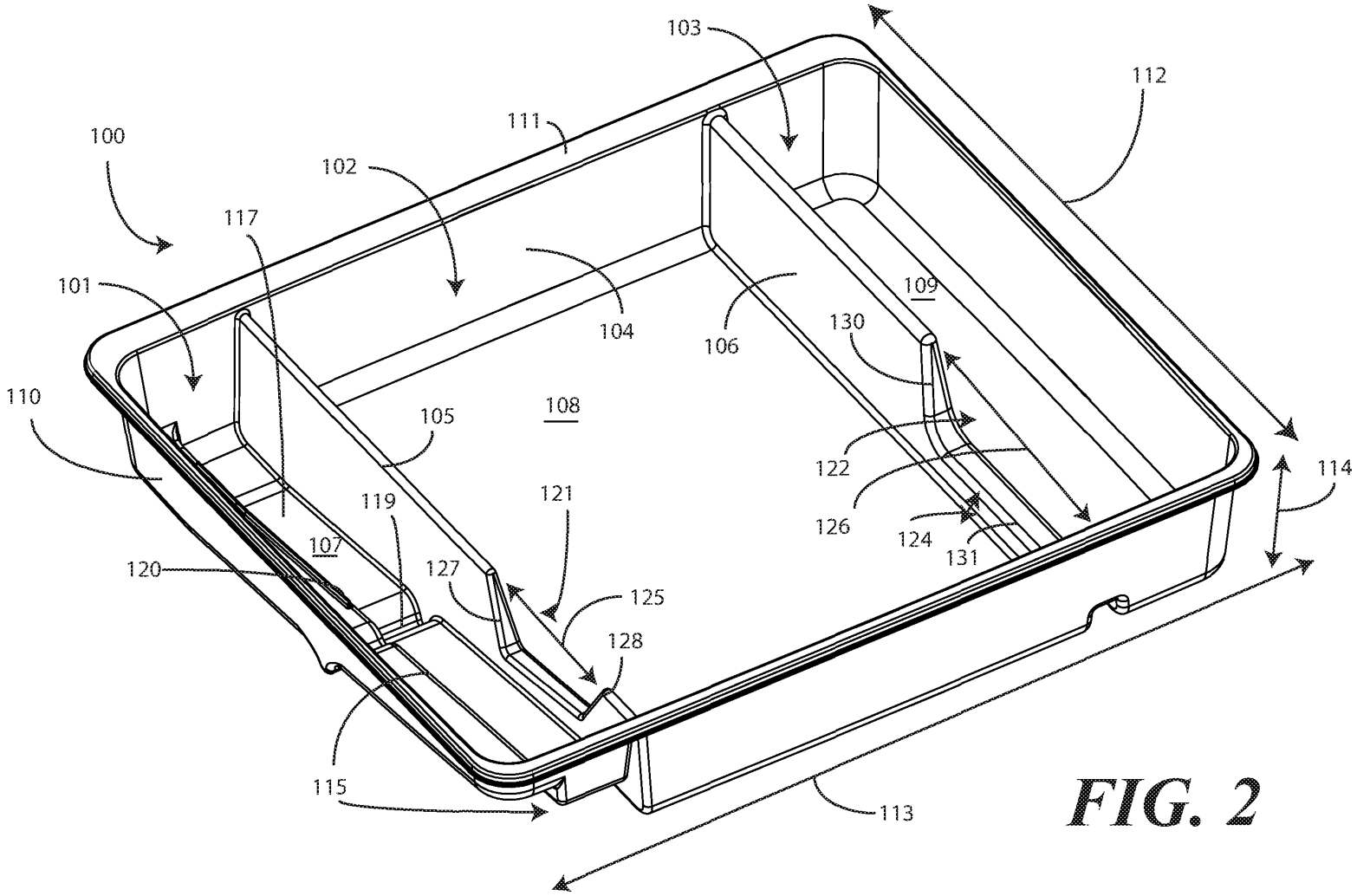

117
105
101
102
132
106
110
103
100
111
Catheter Compartment
116
120
104
109
119
118
108
130
127
131
112
129
107
125
123
126
124
122
128
121
114
113

FIG. 1


103
112
111
100
102
117
101
104
106
109
130
110
105
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122
114
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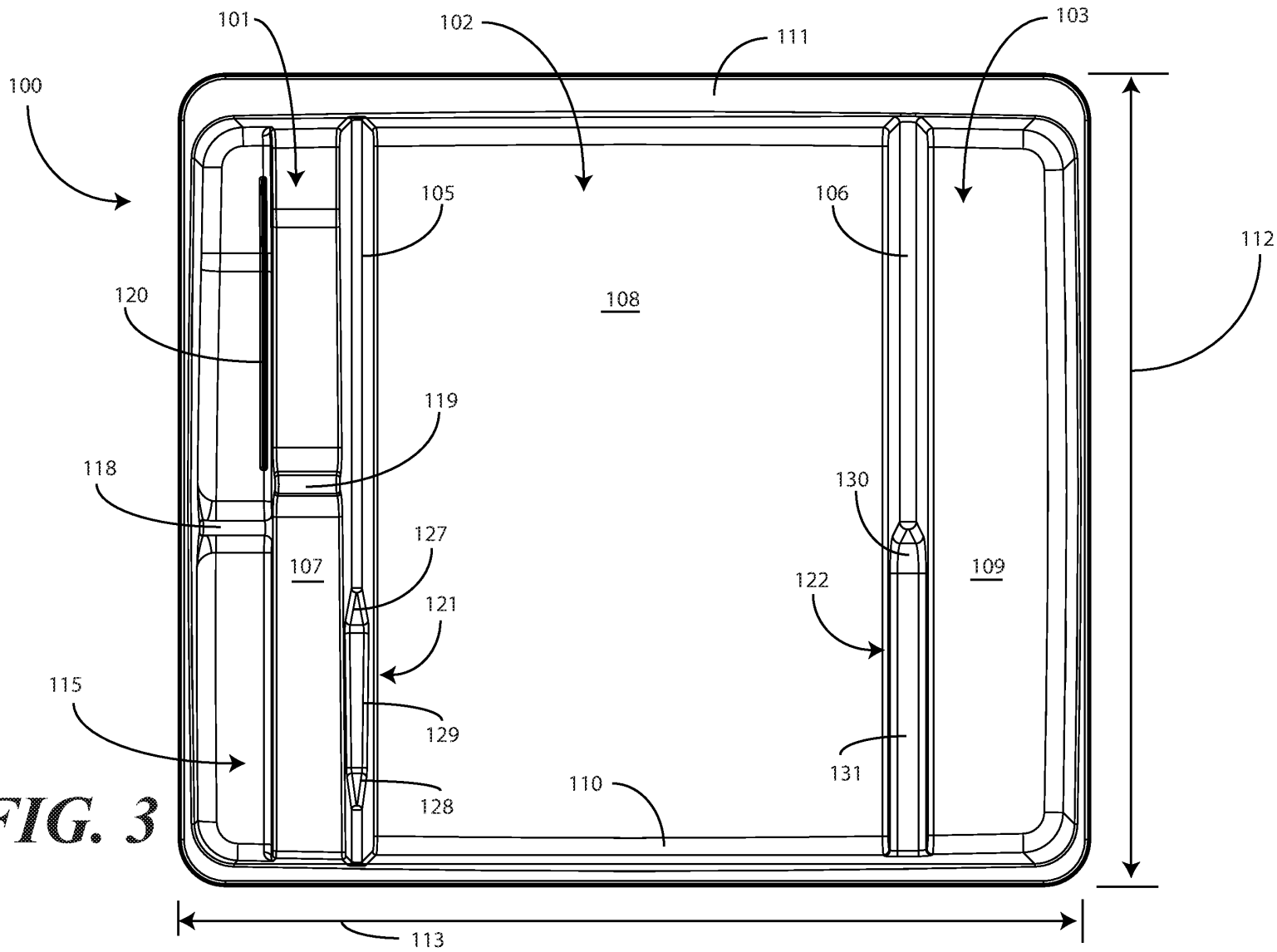
124
131
107
120
127
125
128
115
113

FIG. 2


100
101
102
103
105
106
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112
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118
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131
107
109
110
115

FIG. 3

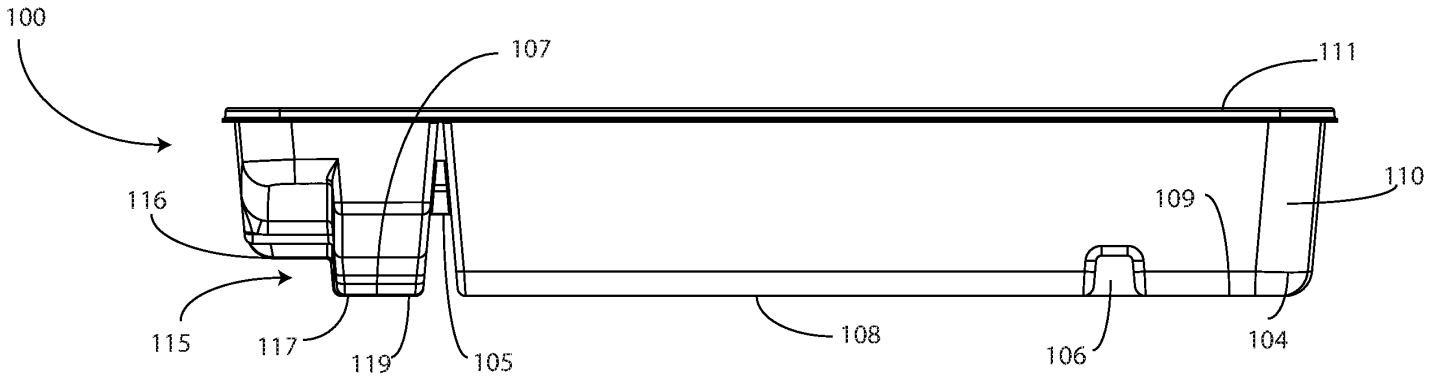
100
107
111
116
109
110
115
117
119
105
108
106
104

FIG. 4

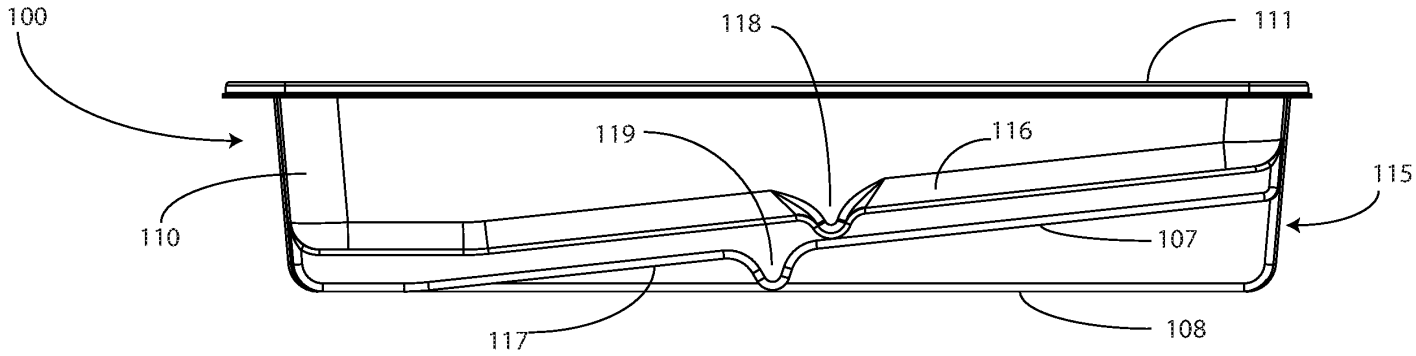
100
118
111
119
116
115
110
107
117
108

FIG. 5

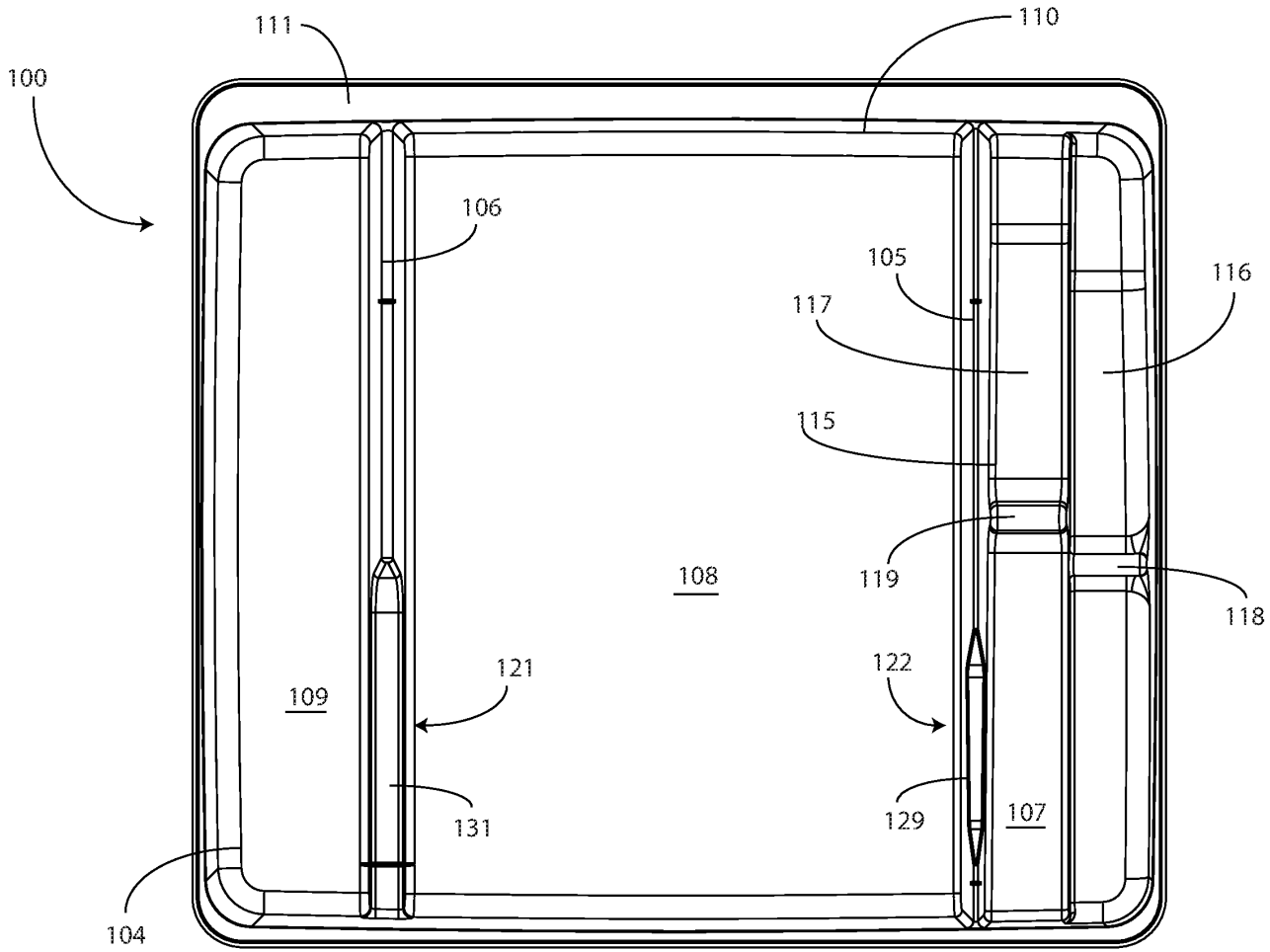
111
110
100
106
105
116
117
115
119
108
118
121
122
109
131
129
107
104

FIG. 6

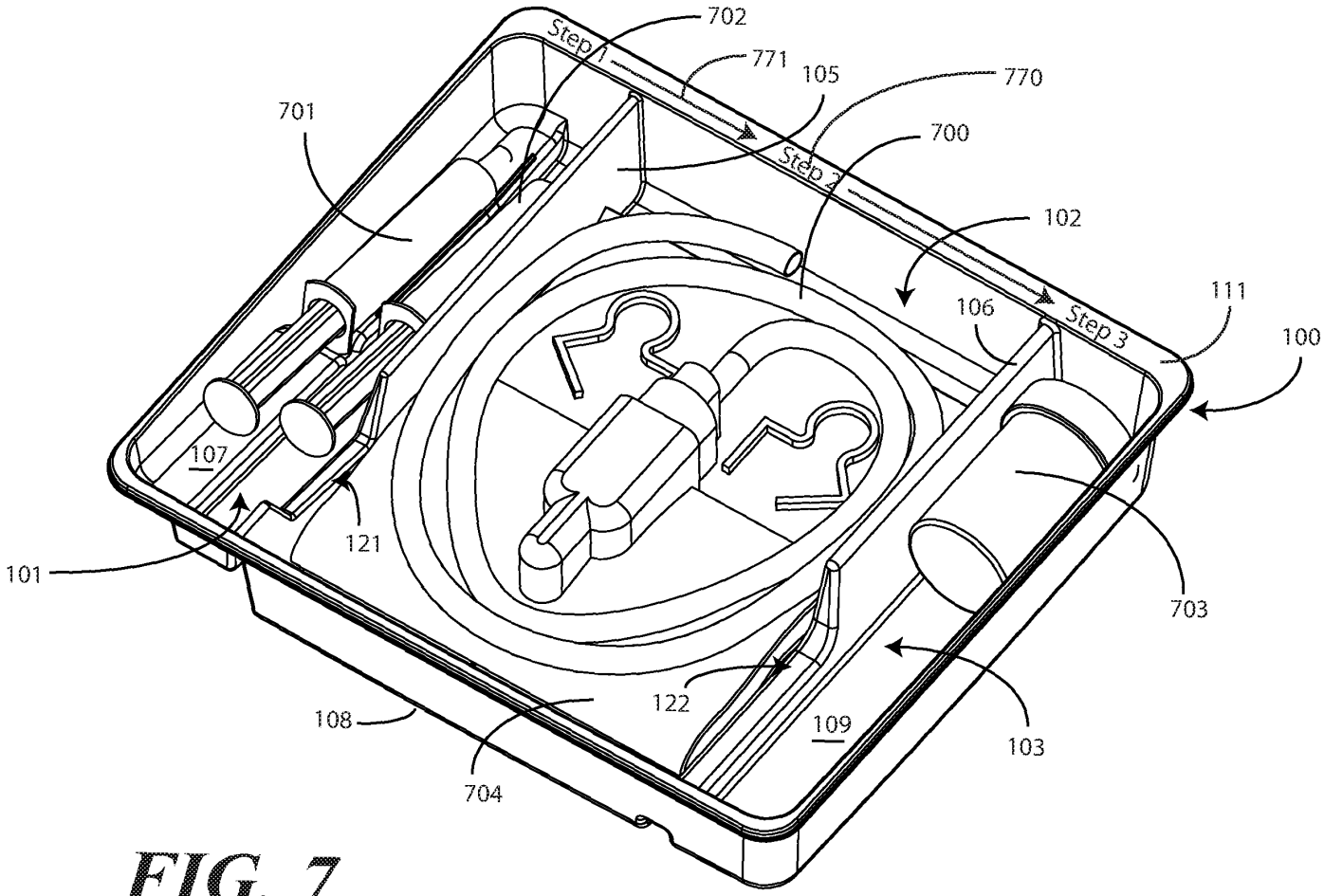
Step 1
Step 2
Step 3
702
771
105
770
701
700
102
111
106
100
107
121
101
703
122
109
103
108
704

FIG. 7

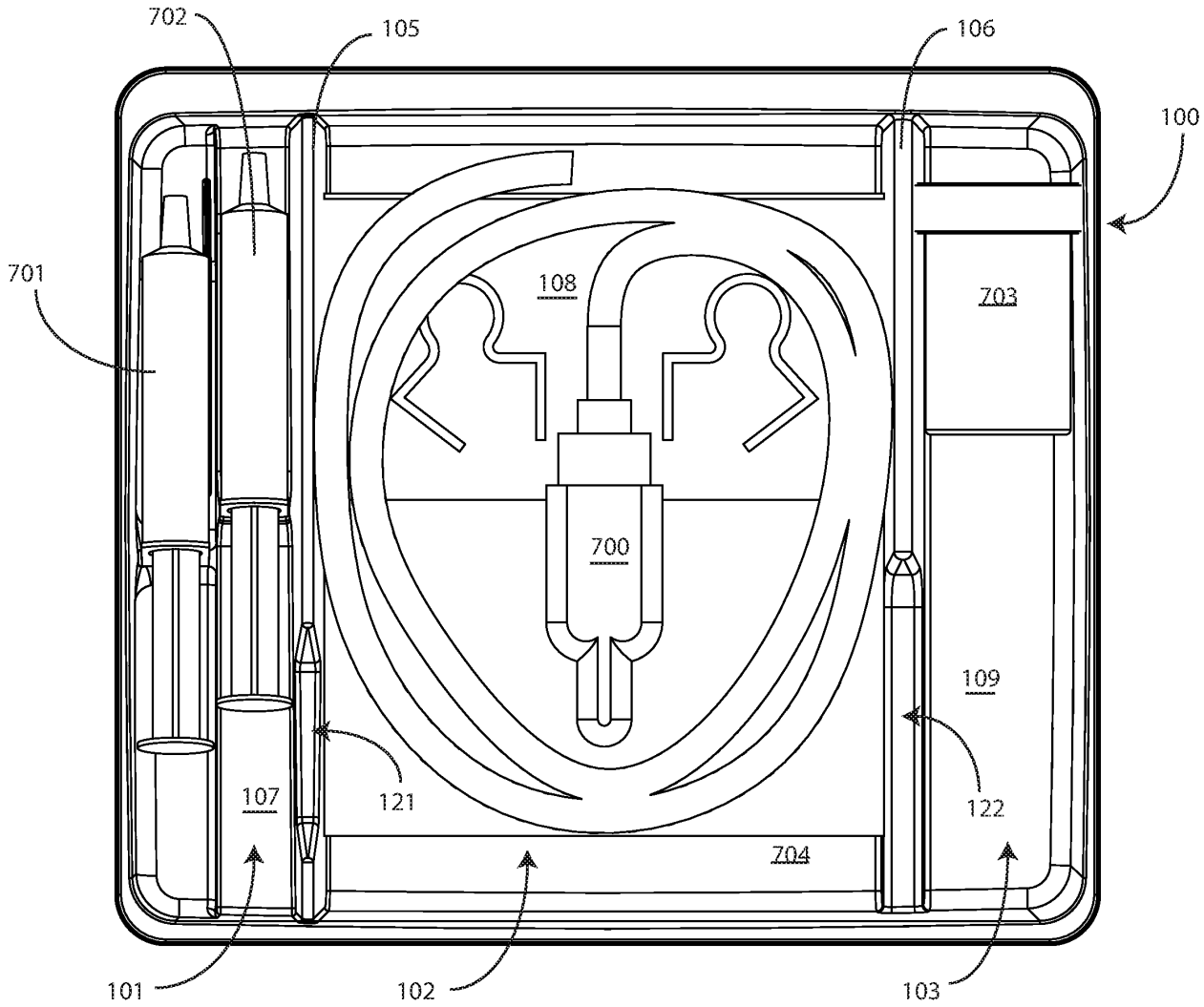

FIG. 8

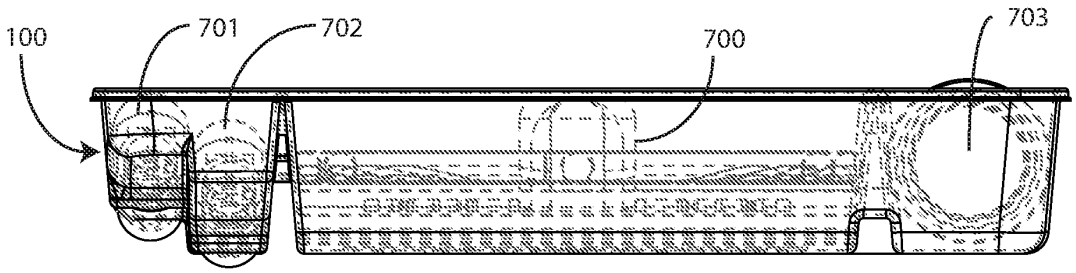
100
701
702
700
703

FIG. 9

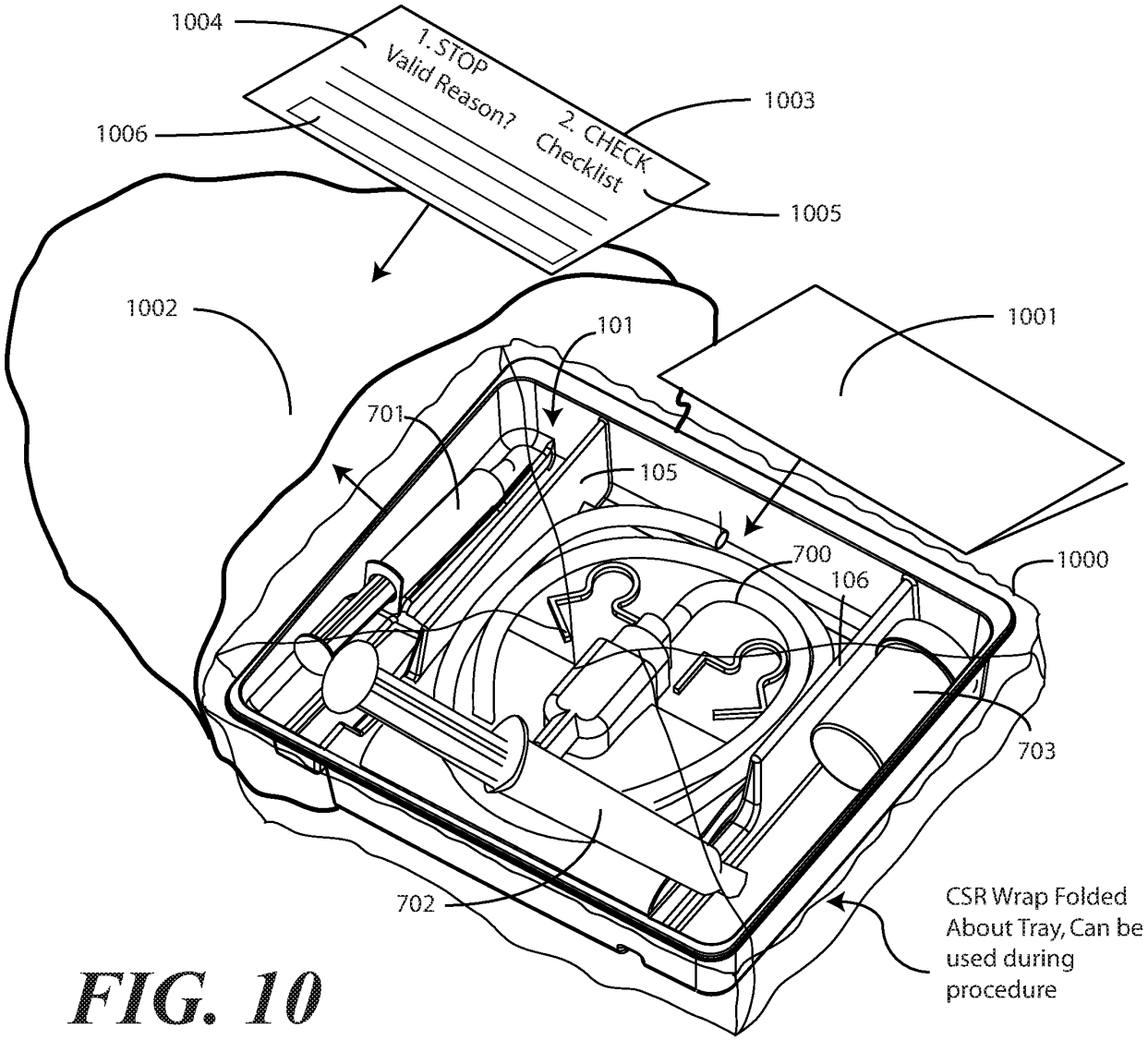
1004
1. STOP
Valid Reason?
2. CHECK
Checklist
1003
1006
1005
1002
101
1001
701
105
700
106
1000
703
702
CSR Wrap Folded
About Tray, Can be
used during
procedure

FIG. 10

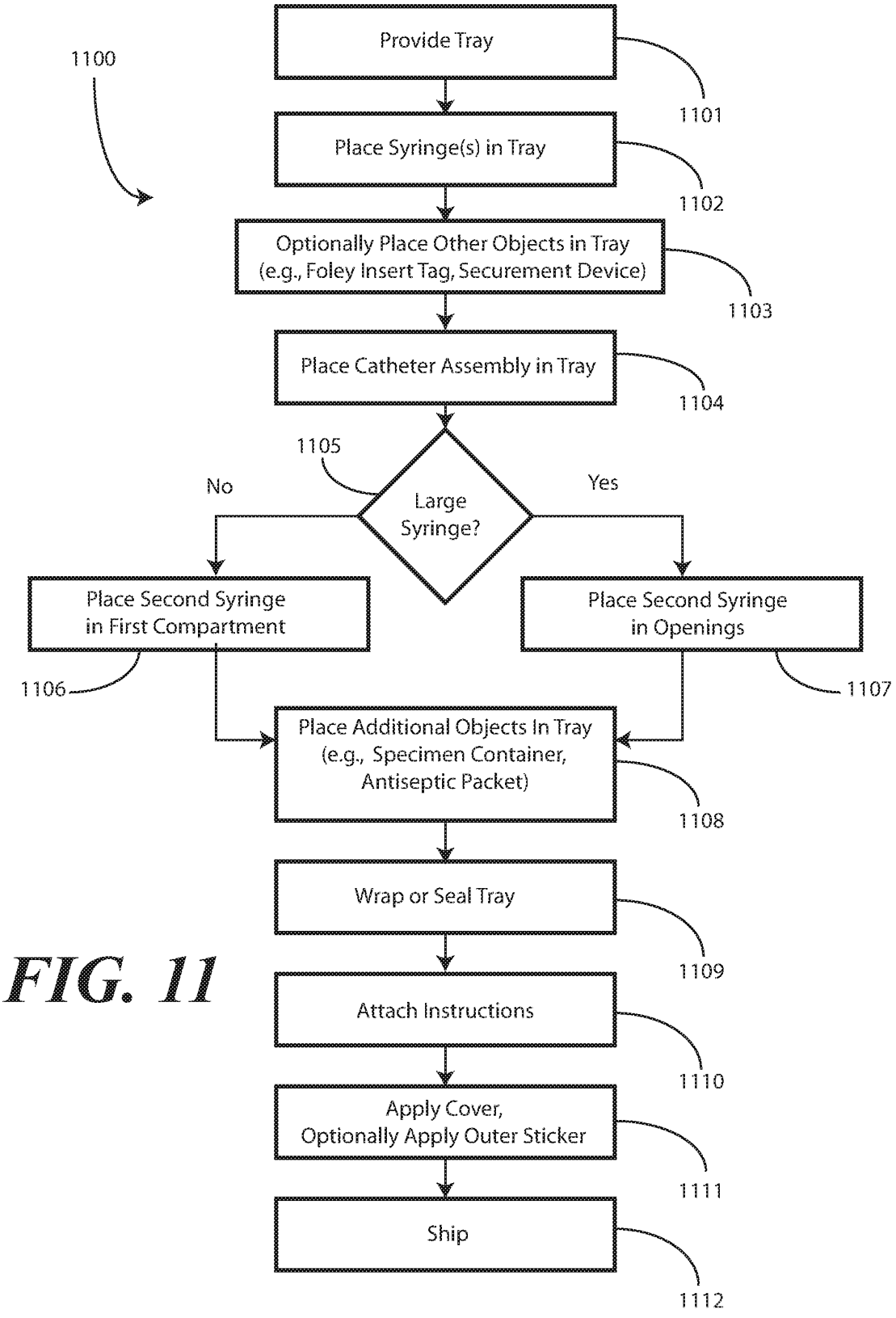
1100
Provide Tray
1101
Place Syringe(s) in Tray
1102
Optionally Place Other Objects in Tray
(e.g., Foley Insert Tag, Securement Device)
1103
Place Catheter Assembly in Tray
1104
1105
Large Syringe?
No
Yes
Place Second Syringe in First Compartment
1106
Place Second Syringe in Openings
1107
Place Additional Objects In Tray
(e.g., Specimen Container, Antiseptic Packet)
1108
Wrap or Seal Tray
1109
Attach Instructions
1110
Apply Cover,
Optionally Apply Outer Sticker
1111
Ship
1112

FIG. 11

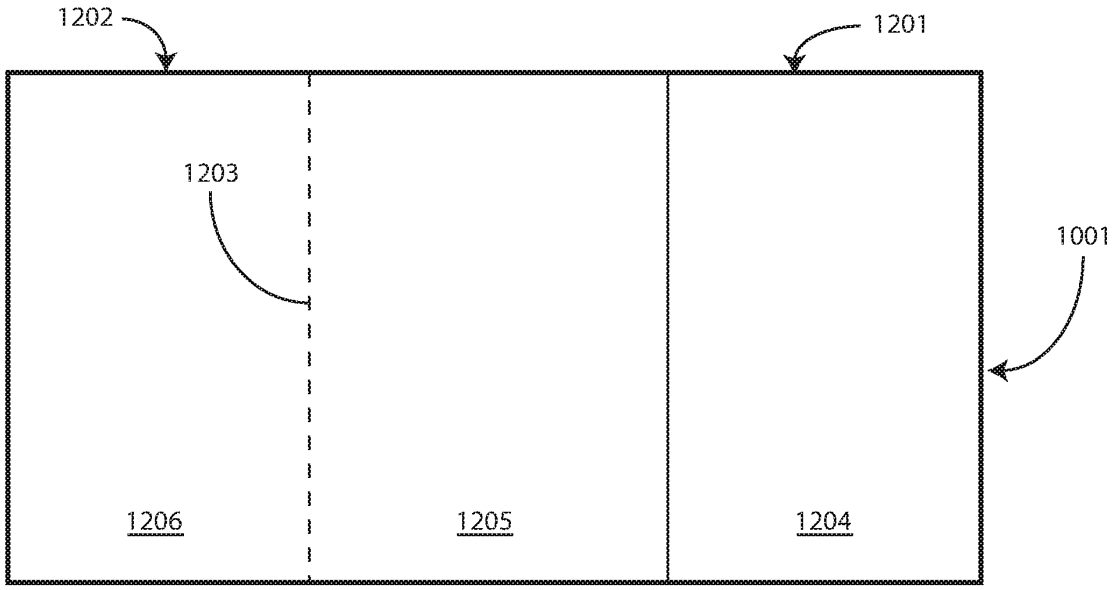
1202
1201
1203
1001
1206
1205
1204

FIG. 12

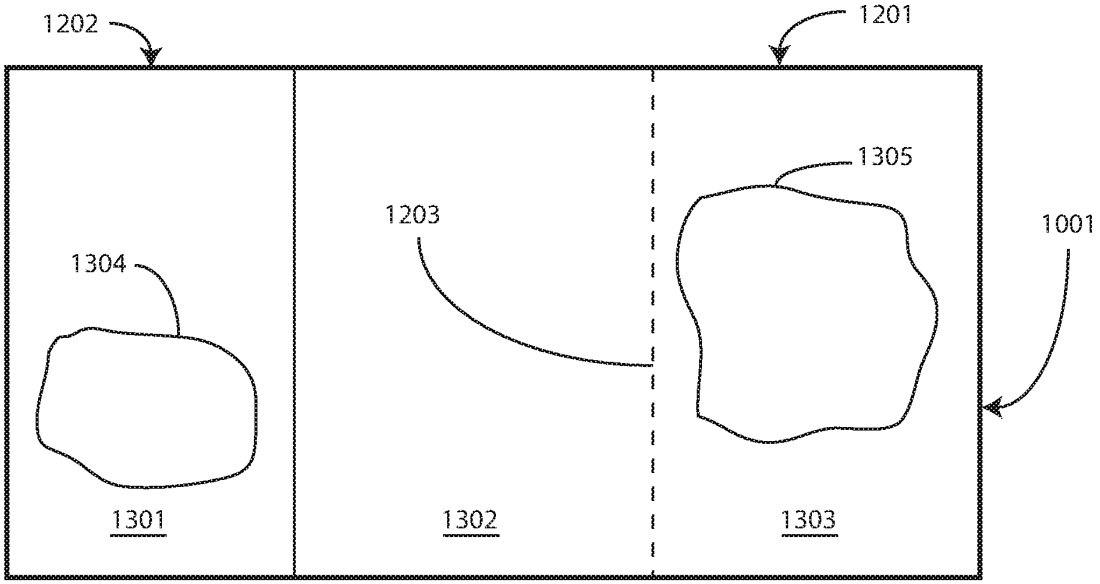
1202
1201
1305
1203
1001
1304
1301
1302
1303

FIG. 13

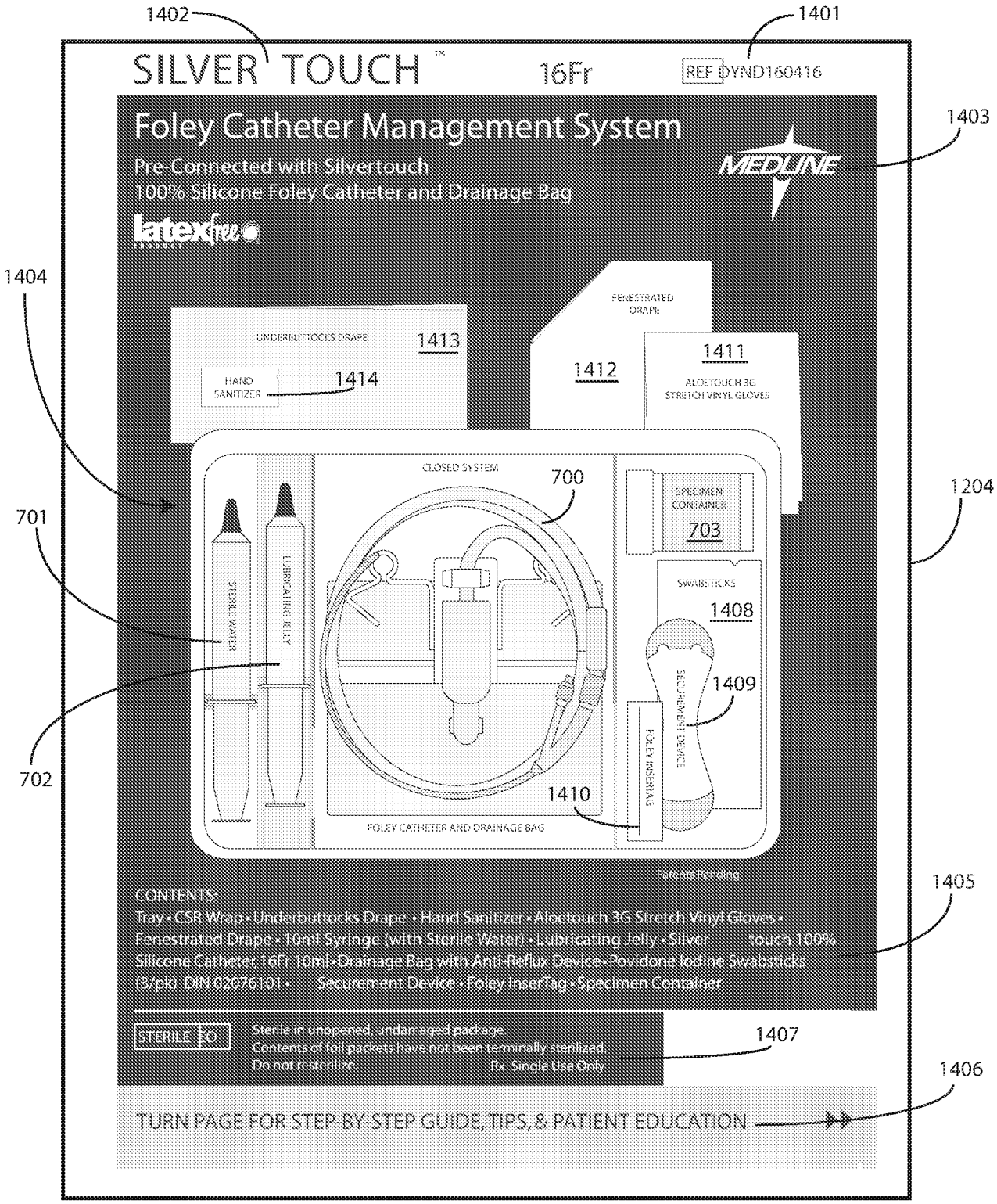
1402
1401
SILVER TOUCH™
16Fr
REF DYND160416
Foley Catheter Management System
Pre-Connected with Silvertouch
100% Silicone Foley Catheter and Drainage Bag
MEDLINE
1403
latexfree
1404
UNDERBUTTOCKS DRAPE
1413
HAND SANITIZER
1414
FENESTRATED DRAPE
1412
1411
ALOETOUCH 3G STRETCH VINYL GLOVES
CLOSED SYSTEM
700
SPECIMEN CONTAINER
703
1204
701
SWABSTICKS
1408
1409
702
1410
FOLEY CATHETER AND DRAINAGE BAG
Patents Pending
1405
CONTENTS:
Tray • CSR Wrap • Underbuttocks Drape • Hand Sanitizer • Aloetouch 3G Stretch Vinyl Gloves • Fenestrated Drape • 10ml Syringe (with Sterile Water) • Lubricating Jelly • Silver touch 100% Silicone Catheter 16Fr 10ml • Drainage Bag with Anti-Reflux Device • Povidone Iodine Swabsticks (3/pk) DIN 02076101 • Securement Device • Foley InserTag • Specimen Container
STERILE EO
Sterile if unopened, undamaged package
Contents of foil packets have not been terminally sterilized.
Do not resterilize
Rx Single Use Only
1407
1406
TURN PAGE FOR STEP-BY-STEP GUIDE, TIPS, & PATIENT EDUCATION

FIG. 14

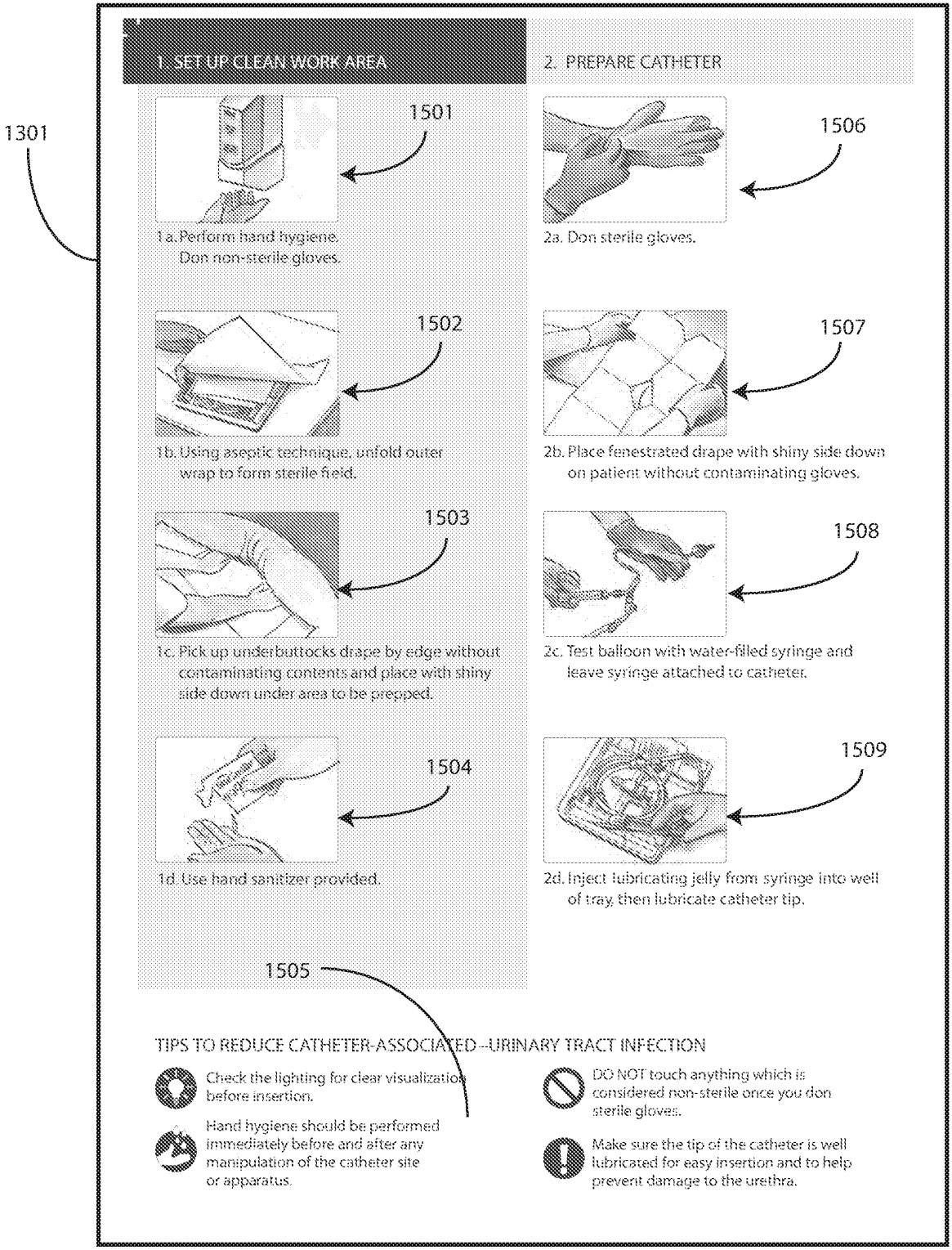
1301
1. SET UP CLEAN WORK AREA
2. PREPARE CATHETER
1501
1a. Perform hand hygiene. Don non-sterile gloves.
1502
1b. Using aseptic technique, unfold outer wrap to form sterile field.
1503
1c. Pick up underbuttocks drape by edge without contaminating contents and place with shiny side down under area to be prepped.
1504
1d. Use hand sanitizer provided.
1506
2a. Don sterile gloves.
1507
2b. Place fenestrated drape with shiny side down on patient without contaminating gloves.
1508
2c. Test balloon with water-filled syringe and leave syringe attached to catheter.
1509
2d. Inject lubricating jelly from syringe into well of tray, then lubricate catheter tip.
1505
TIPS TO REDUCE CATHETER-ASSOCIATED--URINARY TRACT INFECTION
Check the lighting for clear visualization before insertion.
Hand hygiene should be performed immediately before and after any manipulation of the catheter site or apparatus.
DO NOT touch anything which is considered non-sterile once you don sterile gloves.
Make sure the tip of the catheter is well lubricated for easy insertion and to help prevent damage to the urethra.

FIG. 15

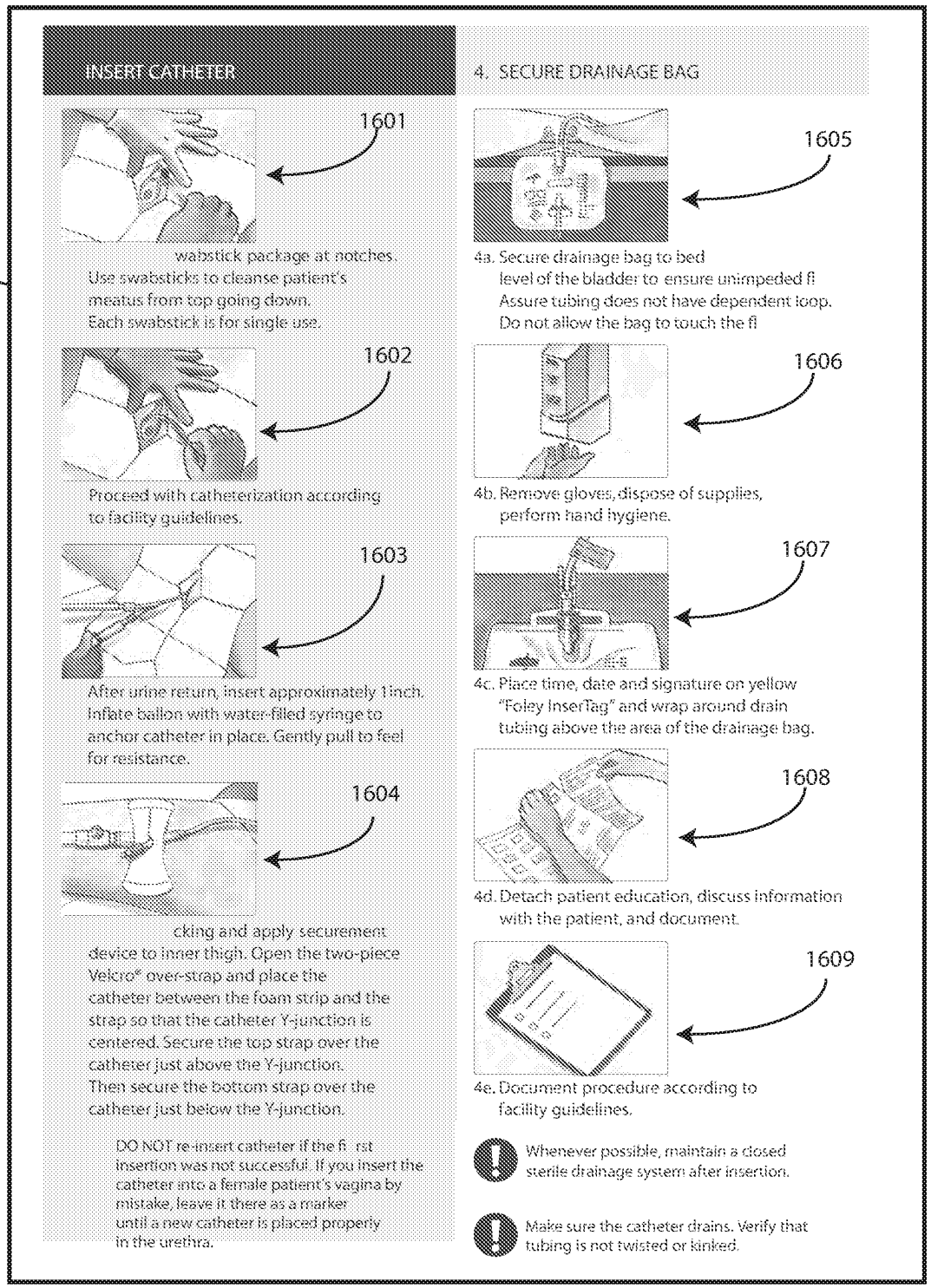
1302
INSERT CATHETER
1601
wabstick package at notches.
Use swabsticks to cleanse patient's
meatus from top going down.
Each swabstick is for single use.
1602
Proceed with catheterization according
to facility guidelines.
1603
After urine return, insert approximately 1 inch.
Inflate ballon with water-filled syringe to
anchor catheter in place. Gently pull to feel
for resistance.
1604
cking and apply securement
device to inner thigh. Open the two-piece
Velcro® over-strap and place the
catheter between the foam strip and the
strap so that the catheter Y-junction is
centered. Secure the top strap over the
catheter just above the Y-junction.
Then secure the bottom strap over the
catheter just below the Y-junction.
DO NOT re-insert catheter if the fi rst
insertion was not successful. If you insert the
catheter into a female patient's vagina by
mistake, leave it there as a marker
until a new catheter is placed properly
in the urethra.
4. SECURE DRAINAGE BAG
1605
4a. Secure drainage bag to bed
level of the bladder to ensure unimpeded fl
Assure tubing does not have dependent loop.
Do not allow the bag to touch the fl
1606
4b. Remove gloves, dispose of supplies,
perform hand hygiene.
1607
4c. Place time, date and signature on yellow
"Foley InserTag" and wrap around drain
tubing above the area of the drainage bag.
1608
4d. Detach patient education, discuss information
with the patient, and document.
1609
4e. Document procedure according to
facility guidelines.
Whenever possible, maintain a closed
sterile drainage system after insertion.
Make sure the catheter drains. Verify that
tubing is not twisted or kinked.

FIG. 16

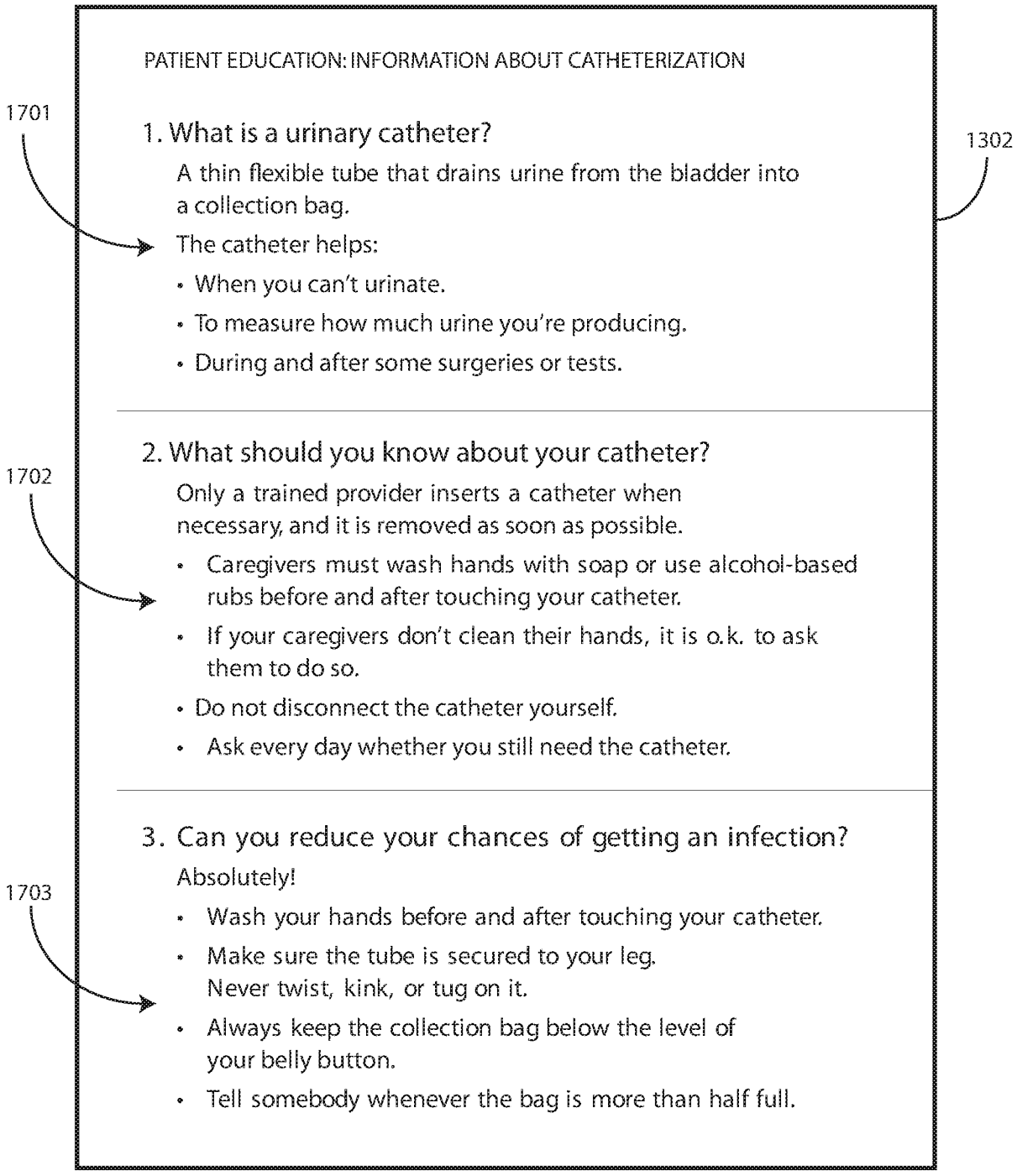
PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1701
1. What is a urinary catheter?
A thin flexible tube that drains urine from the bladder into a collection bag.
The catheter helps:
• When you can't urinate.
• To measure how much urine you're producing.
• During and after some surgeries or tests.
1302
2. What should you know about your catheter?
1702
Only a trained provider inserts a catheter when necessary, and it is removed as soon as possible.
• Caregivers must wash hands with soap or use alcohol-based rubs before and after touching your catheter.
• If your caregivers don't clean their hands, it is o.k. to ask them to do so.
• Do not disconnect the catheter yourself.
• Ask every day whether you still need the catheter.
3. Can you reduce your chances of getting an infection?
1703
Absolutely!
• Wash your hands before and after touching your catheter.
• Make sure the tube is secured to your leg. Never twist, kink, or tug on it.
• Always keep the collection bag below the level of your belly button.
• Tell somebody whenever the bag is more than half full.

FIG. 17

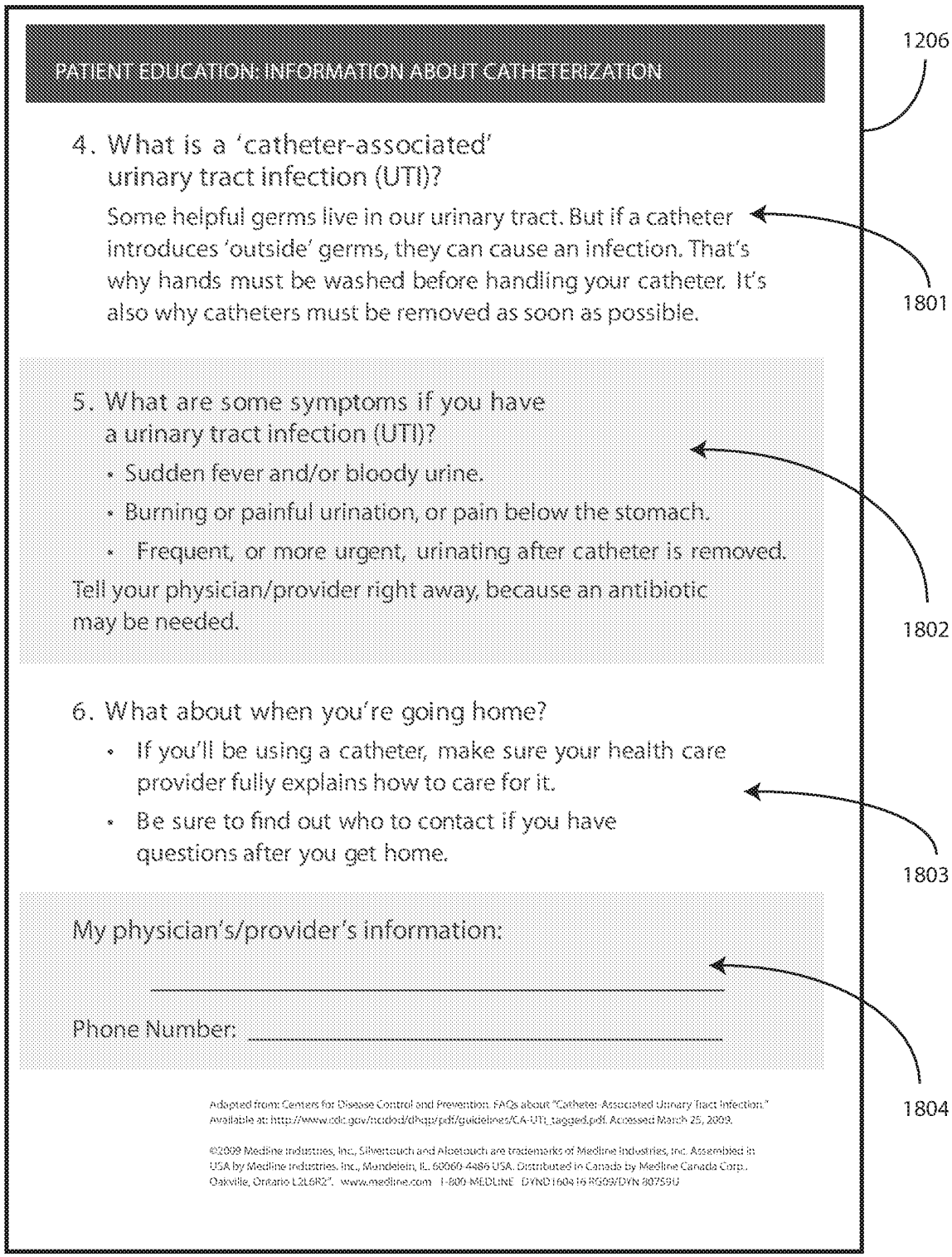
PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1206
4. What is a 'catheter-associated' urinary tract infection (UTI)?
Some helpful germs live in our urinary tract. But if a catheter introduces 'outside' germs, they can cause an infection. That's why hands must be washed before handling your catheter. It's also why catheters must be removed as soon as possible.
1801
5. What are some symptoms if you have a urinary tract infection (UTI)?
• Sudden fever and/or bloody urine.
• Burning or painful urination, or pain below the stomach.
• Frequent, or more urgent, urinating after catheter is removed.
Tell your physician/provider right away, because an antibiotic may be needed.
1802
6. What about when you're going home?
• If you'll be using a catheter, make sure your health care provider fully explains how to care for it.
• Be sure to find out who to contact if you have questions after you get home.
1803
My physician's/provider's information:
Phone Number:
1804
Adapted from: Centers for Disease Control and Prevention. FAQs about "Catheter-Associated Urinary Tract Infection." Available at: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/CA-UTI_tagged.pdf. Accessed March 25, 2009.
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FIG. 18

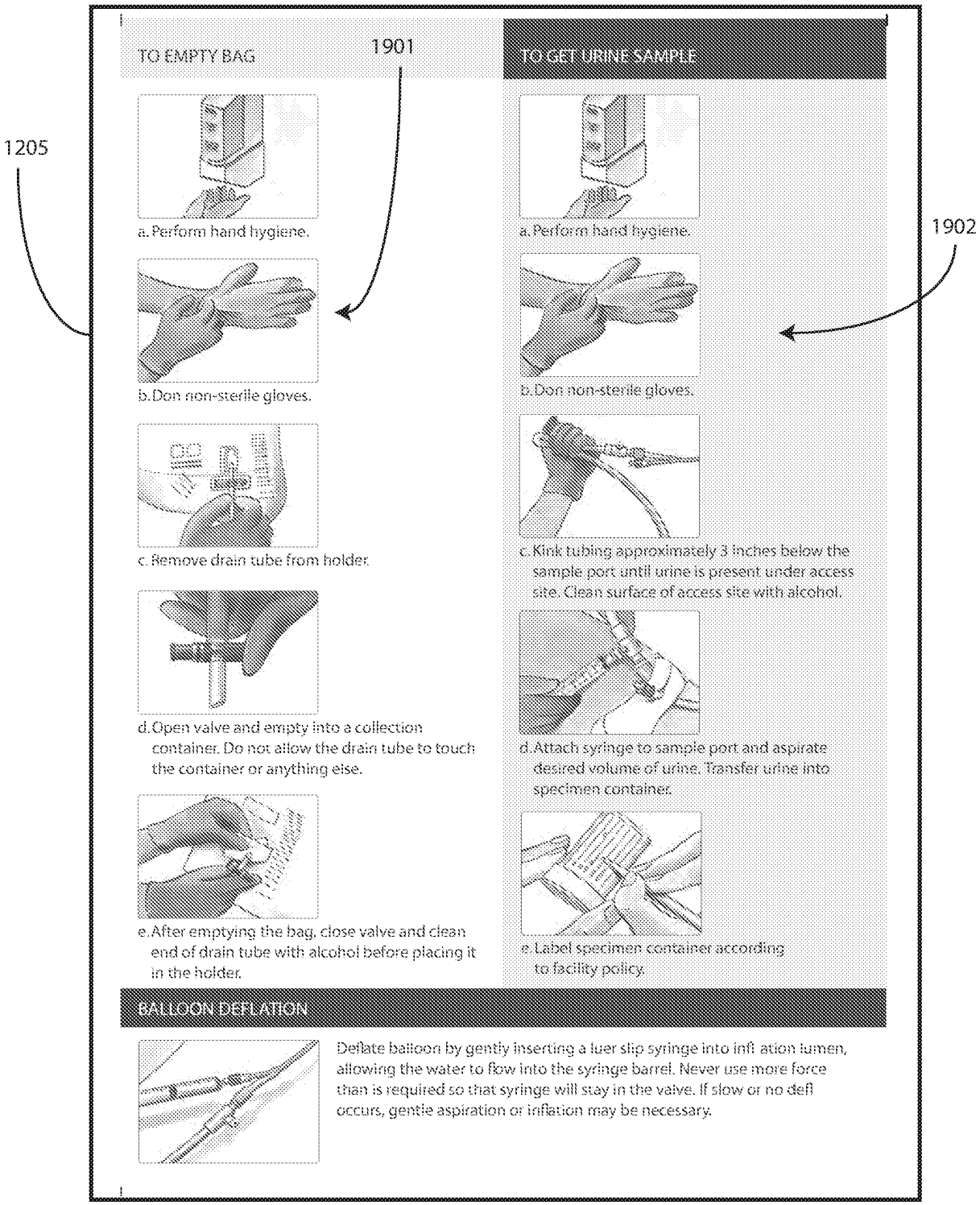
1205
1901
1902
TO EMPTY BAG
a. Perform hand hygiene.
b. Don non-sterile gloves.
c. Remove drain tube from holder.
d. Open valve and empty into a collection container. Do not allow the drain tube to touch the container or anything else.
e. After emptying the bag, close valve and clean end of drain tube with alcohol before placing it in the holder.
TO GET URINE SAMPLE
a. Perform hand hygiene.
b. Don non-sterile gloves.
c. Kink tubing approximately 3 inches below the sample port until urine is present under access site. Clean surface of access site with alcohol.
d. Attach syringe to sample port and aspirate desired volume of urine. Transfer urine into specimen container.
e. Label specimen container according to facility policy.
BALLOON DEFLATION
Deflate balloon by gently inserting a luer slip syringe into infl ation lumen, allowing the water to flow into the syringe barrel. Never use more force than is required so that syringe will stay in the valve. If slow or no defl occurs, gentle aspiration or inflation may be necessary.

FIG. 19

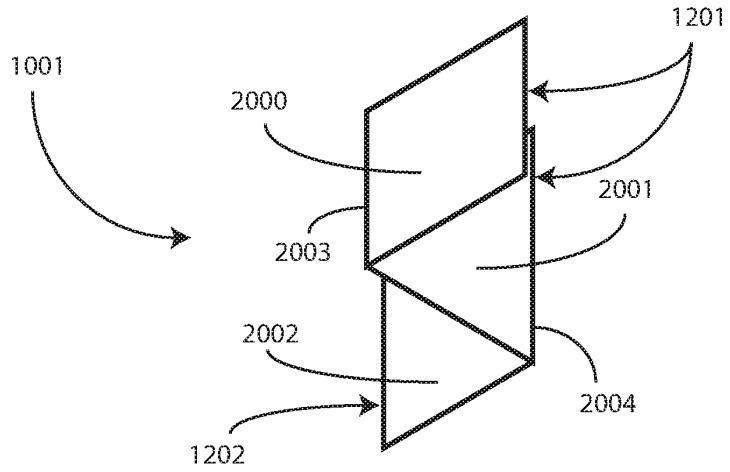
1001
1201
2000
2001
2003
2002
2004
1202

FIG. 20

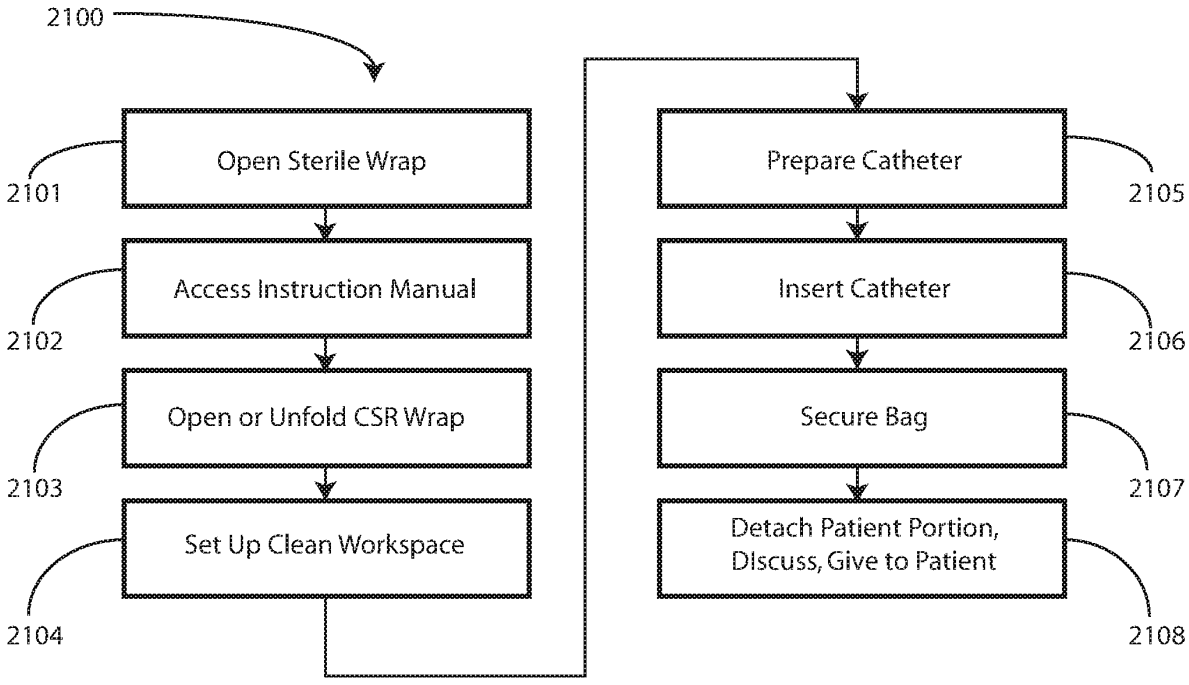
2100
Open Sterile Wrap
2101
Access Instruction Manual
2102
Open or Unfold CSR Wrap
2103
Set Up Clean Workspace
2104
Prepare Catheter
2105
Insert Catheter
2106
Secure Bag
2107
Detach Patient Portion, Discuss, Give to Patient
2108

FIG. 21

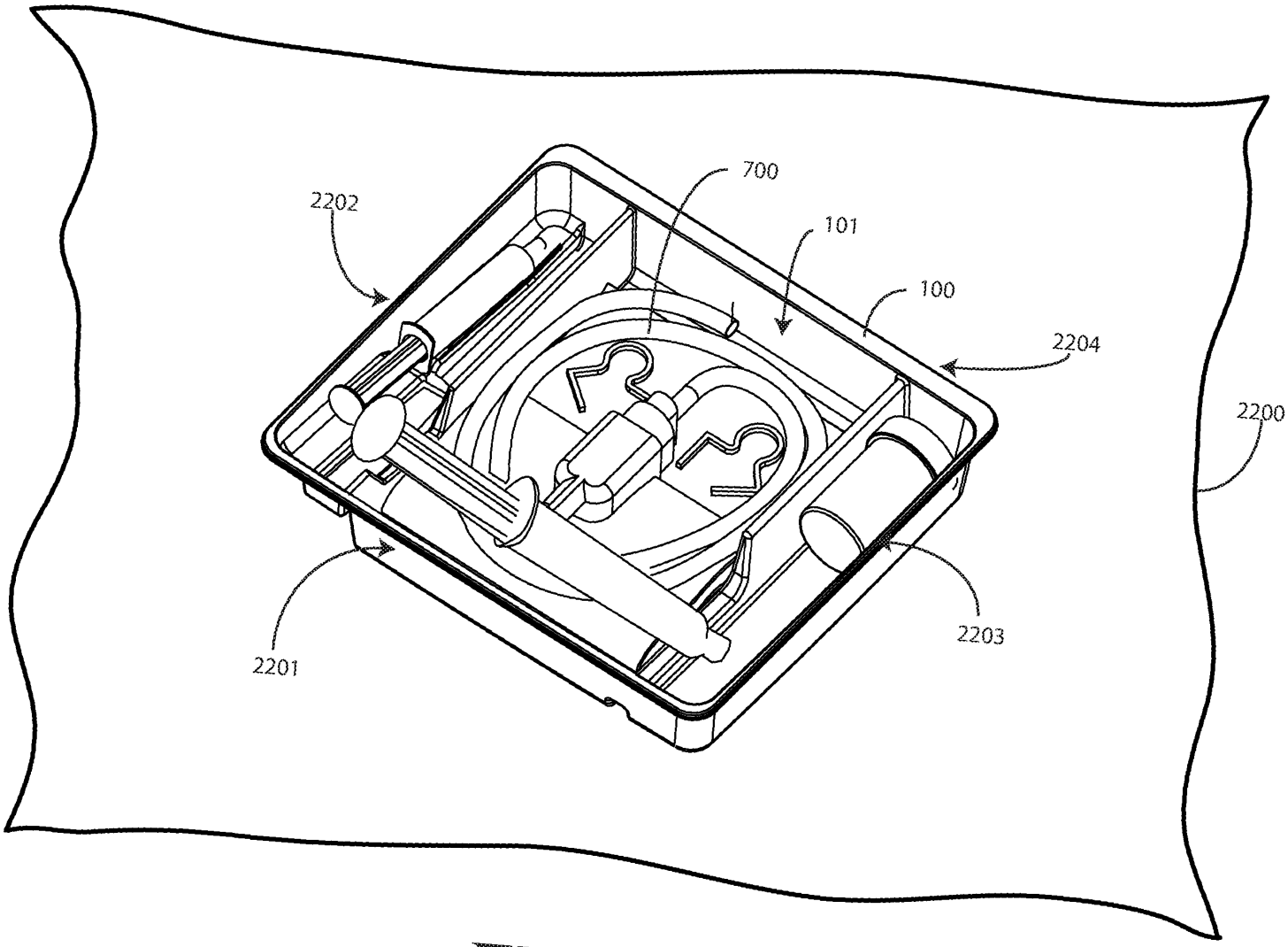

FIG. 22

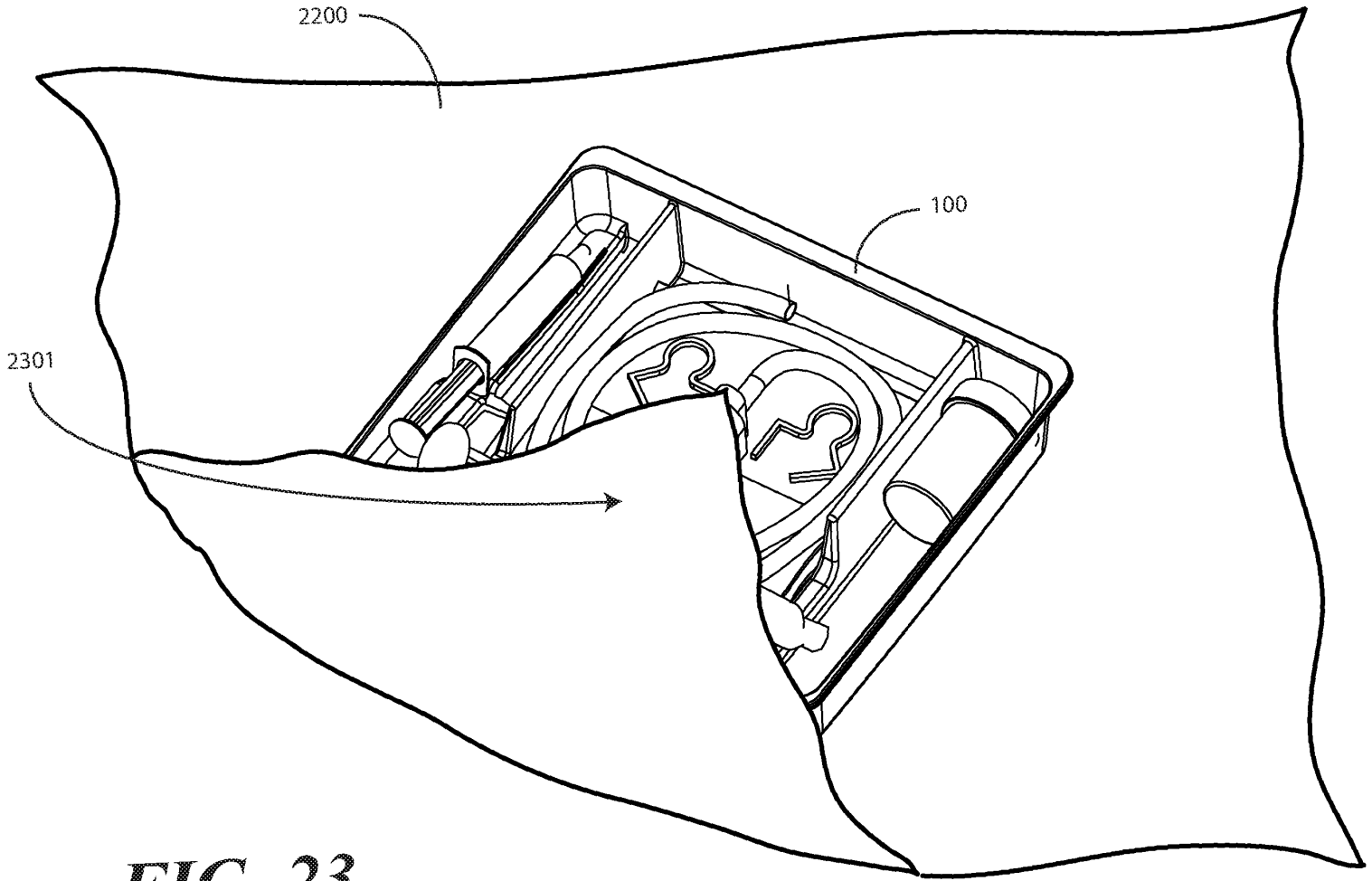

FIG. 23

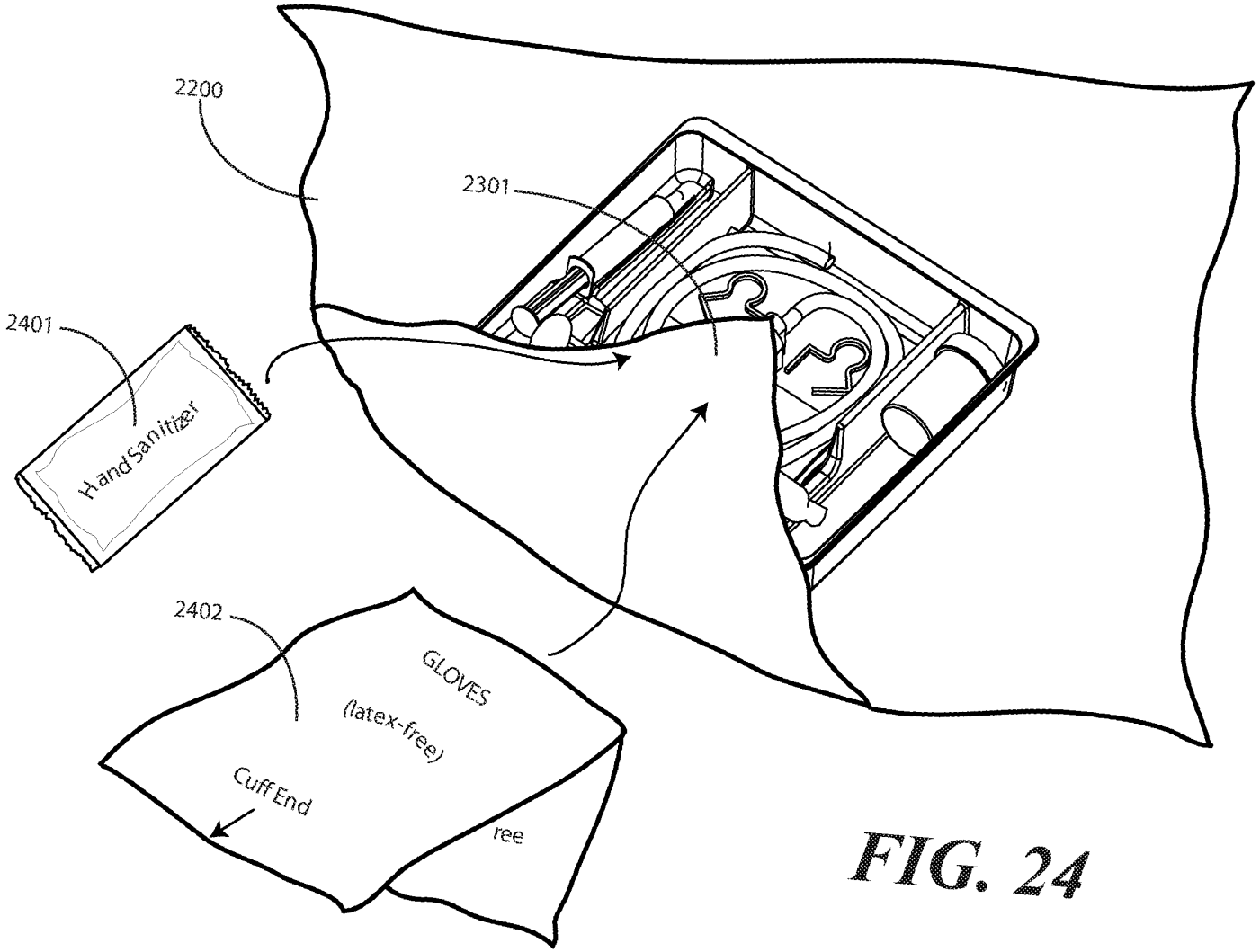
2200
2301
2401
Hand Sanitizer
2402
GLOVES
(latex-free)
Cuff End
ree

FIG. 24

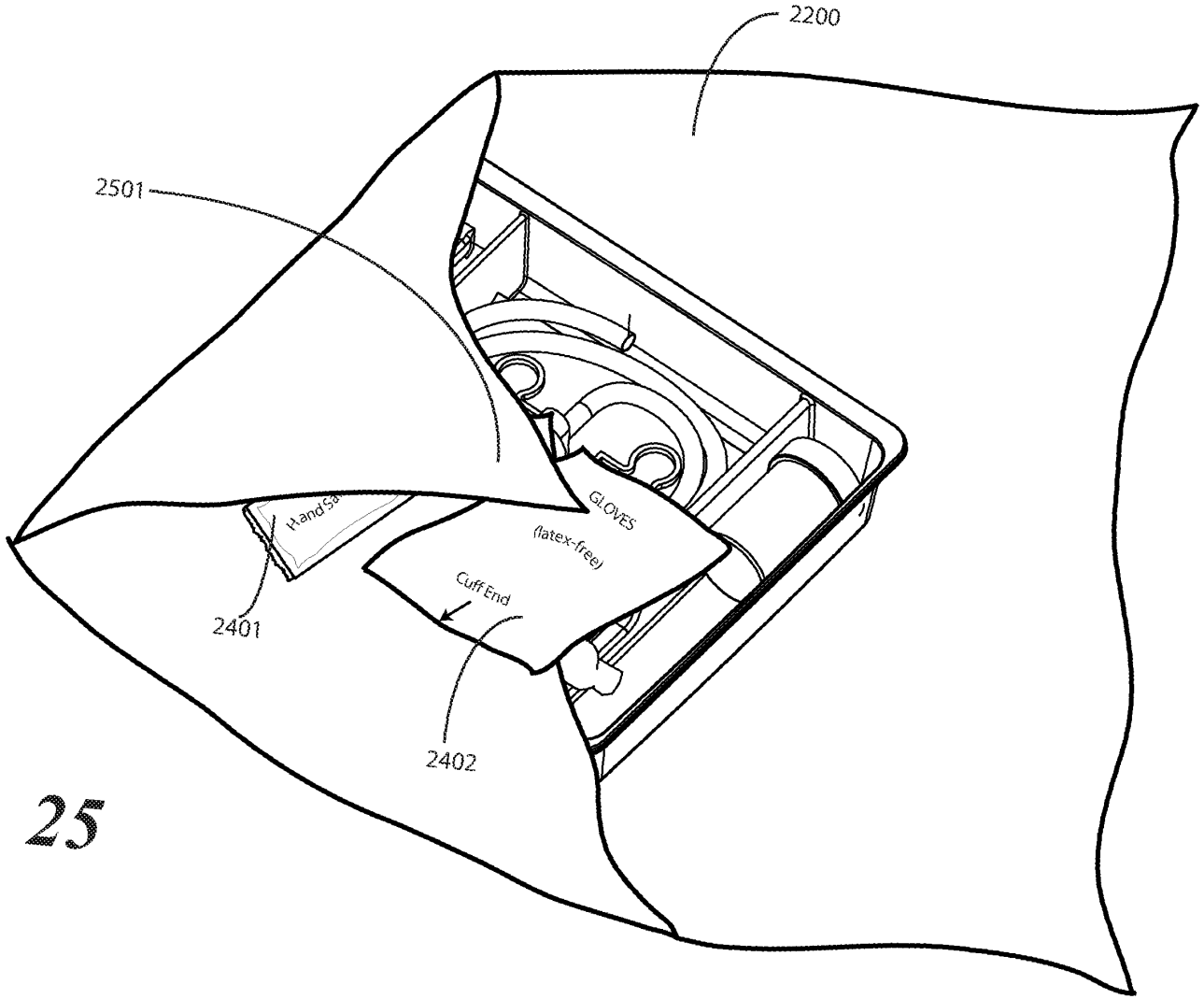

FIG. 25

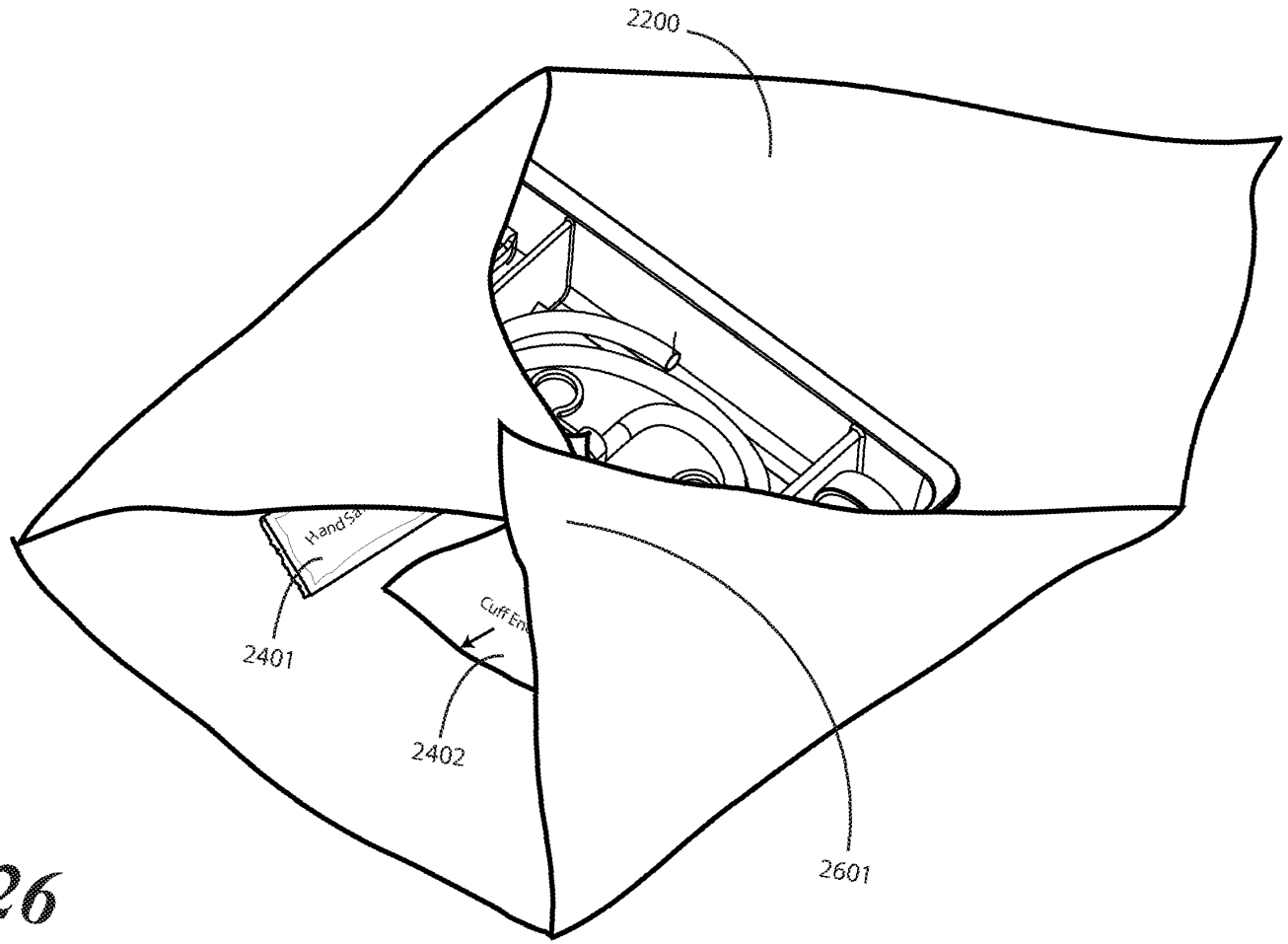

FIG. 26

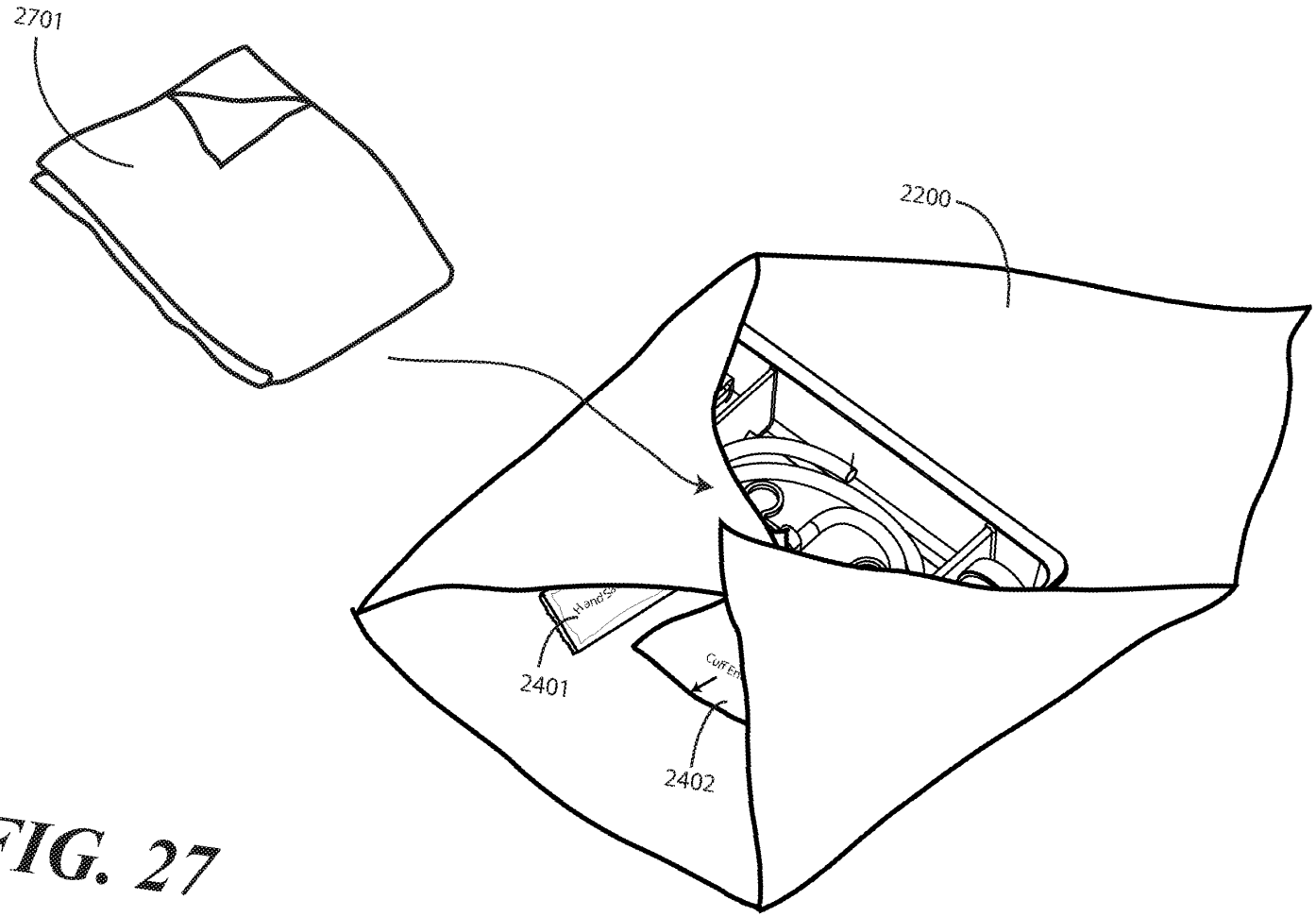

FIG. 27

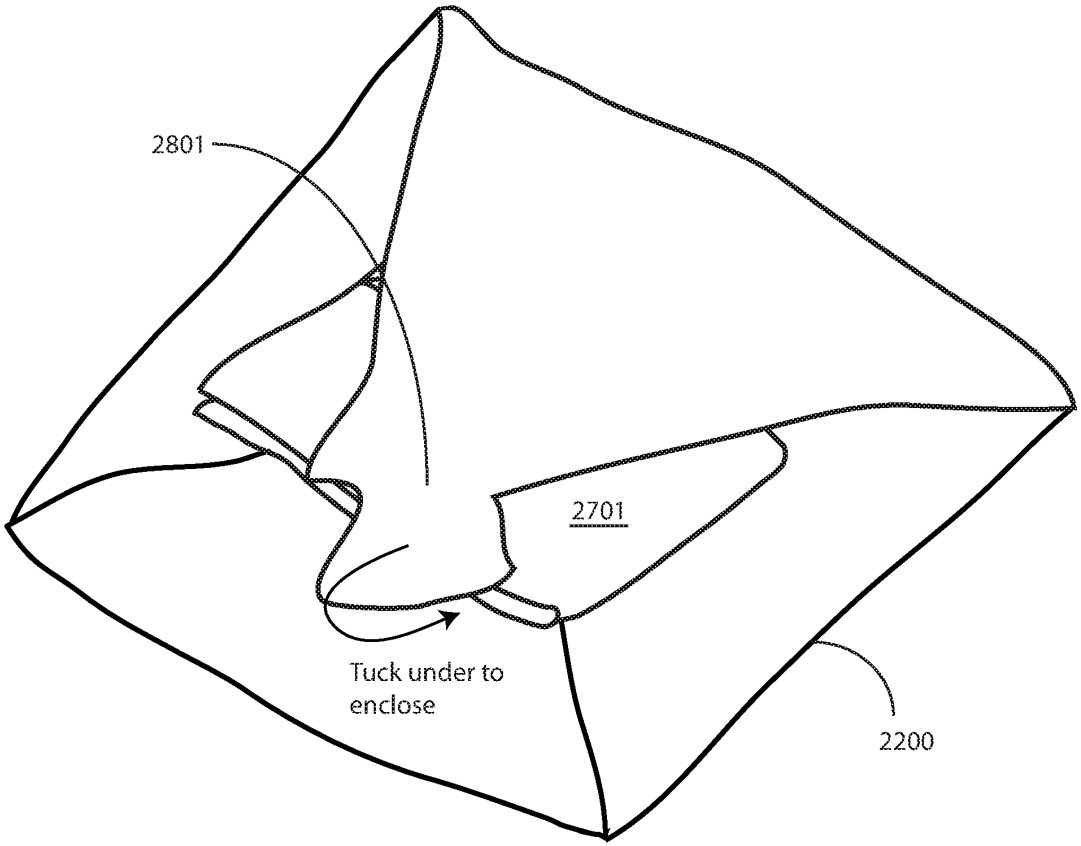

FIG. 28

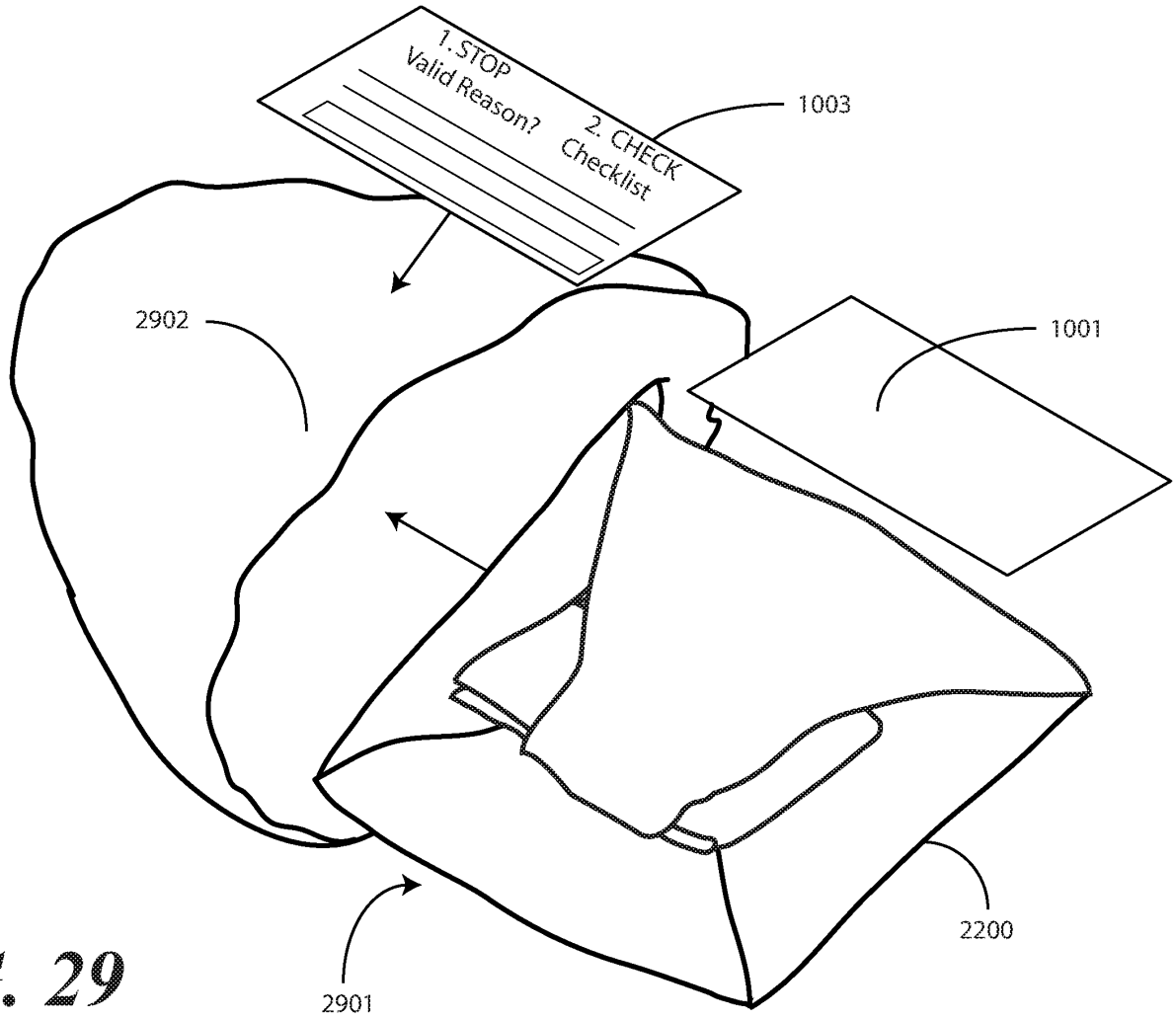
1. STOP
Valid Reason?
2. CHECK
Checklist
1003
2902
1001
2200
2901

FIG. 29

Bard Exhibit 1004.0092

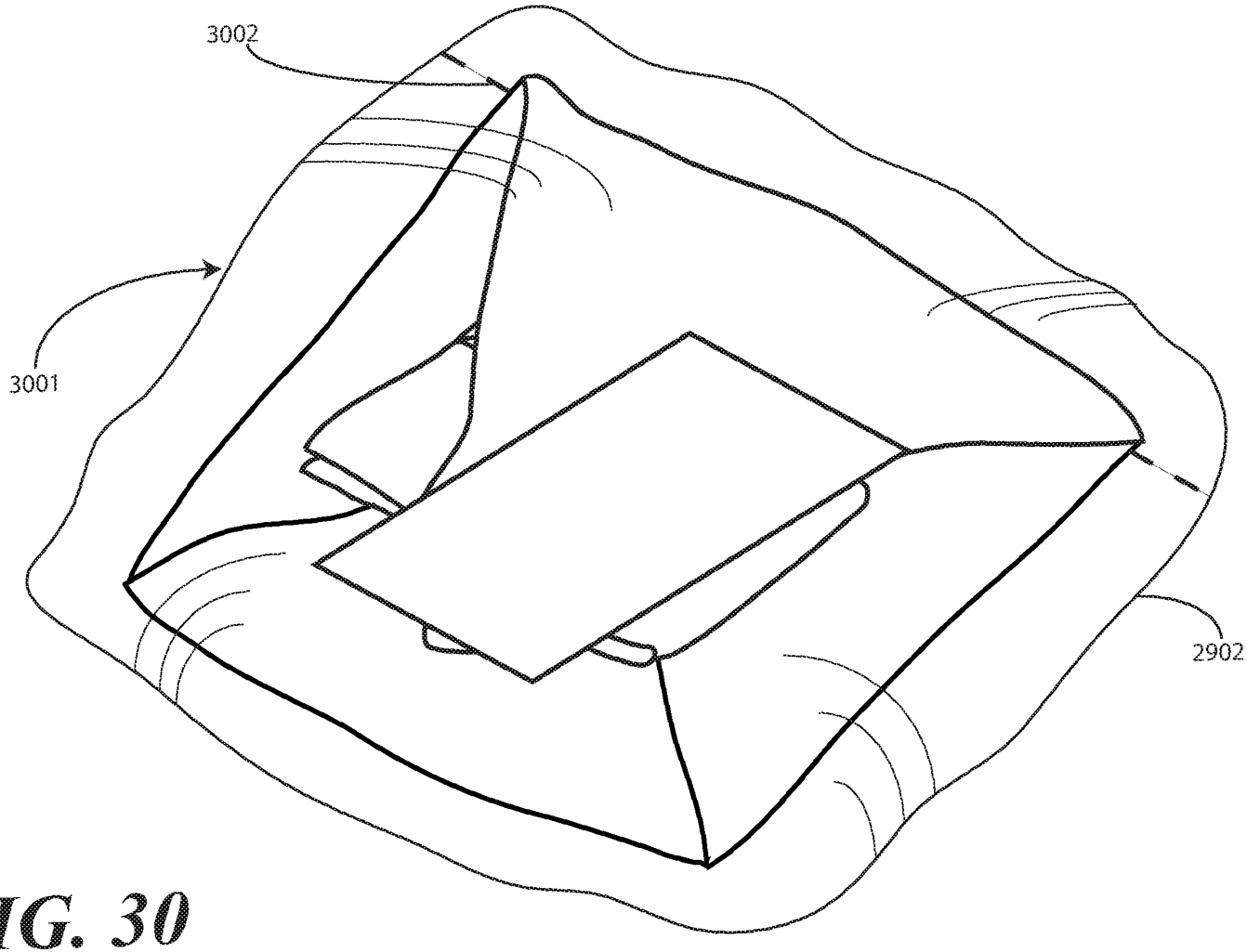

FIG. 30

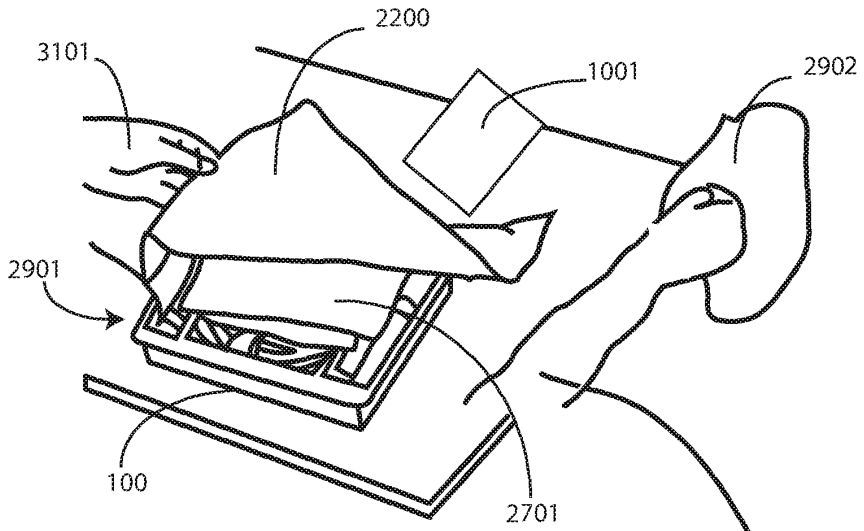

FIG. 31

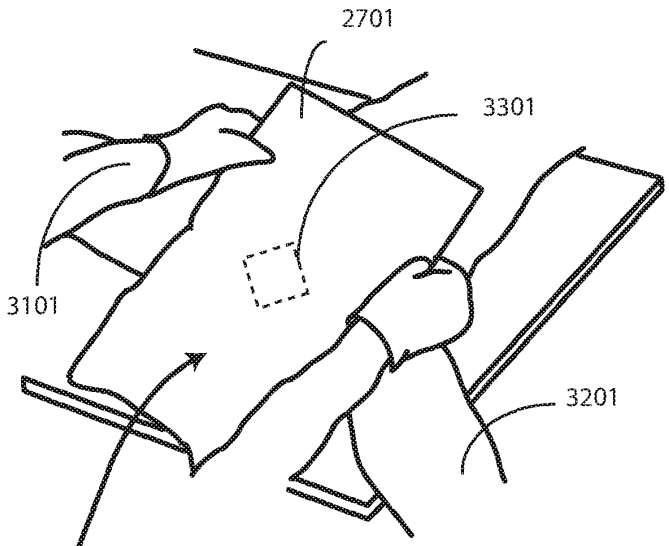

FIG. 33

FIG. 32

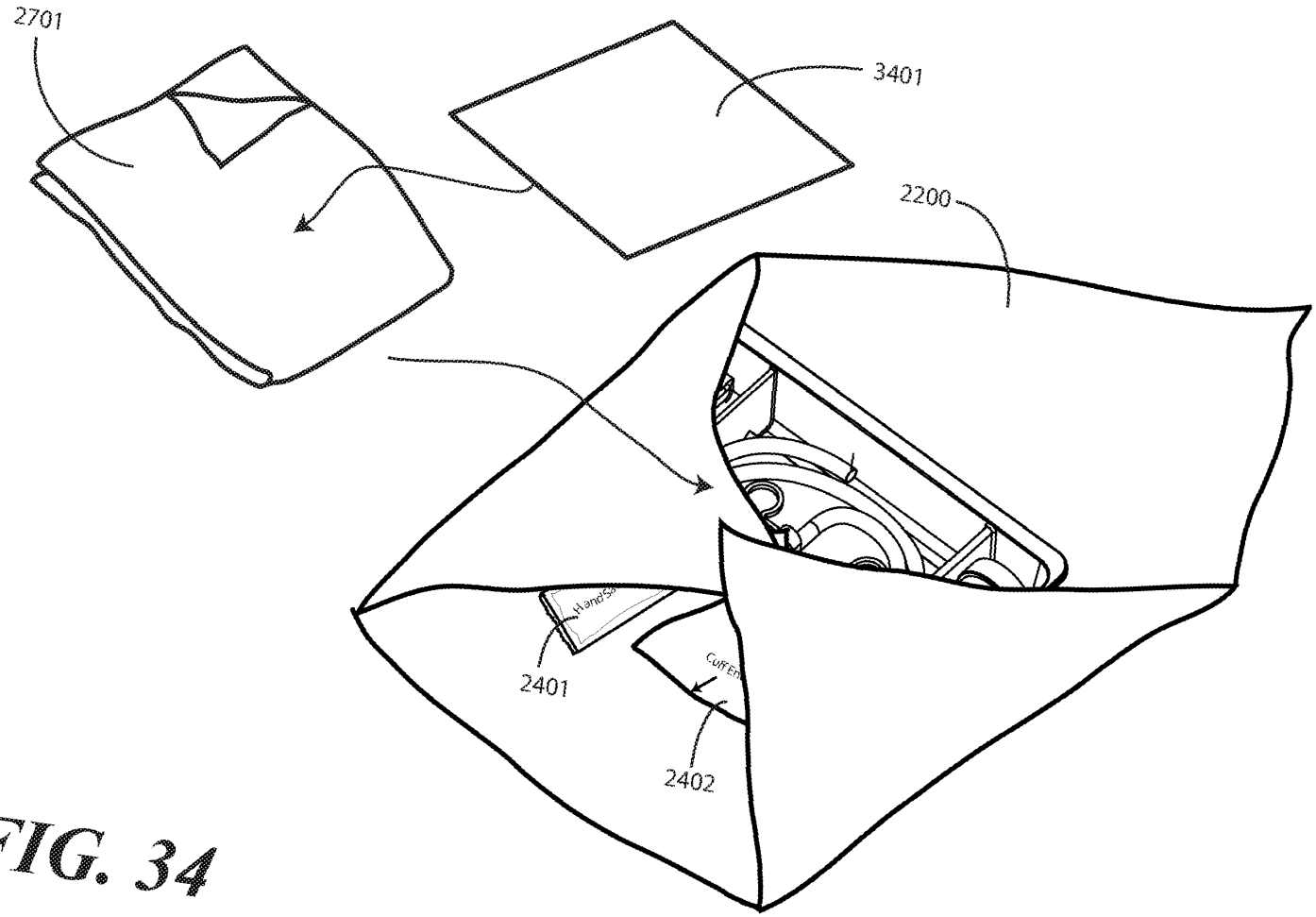

FIG. 34

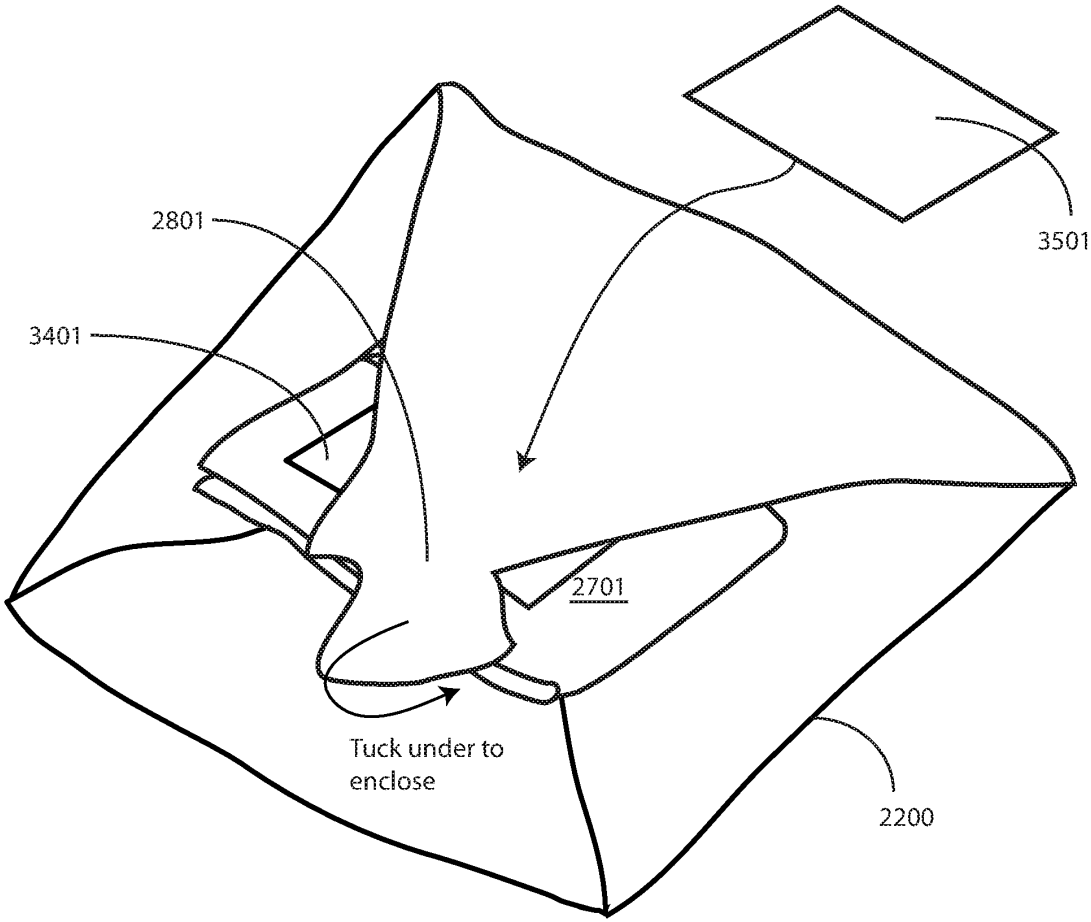

FIG. 35

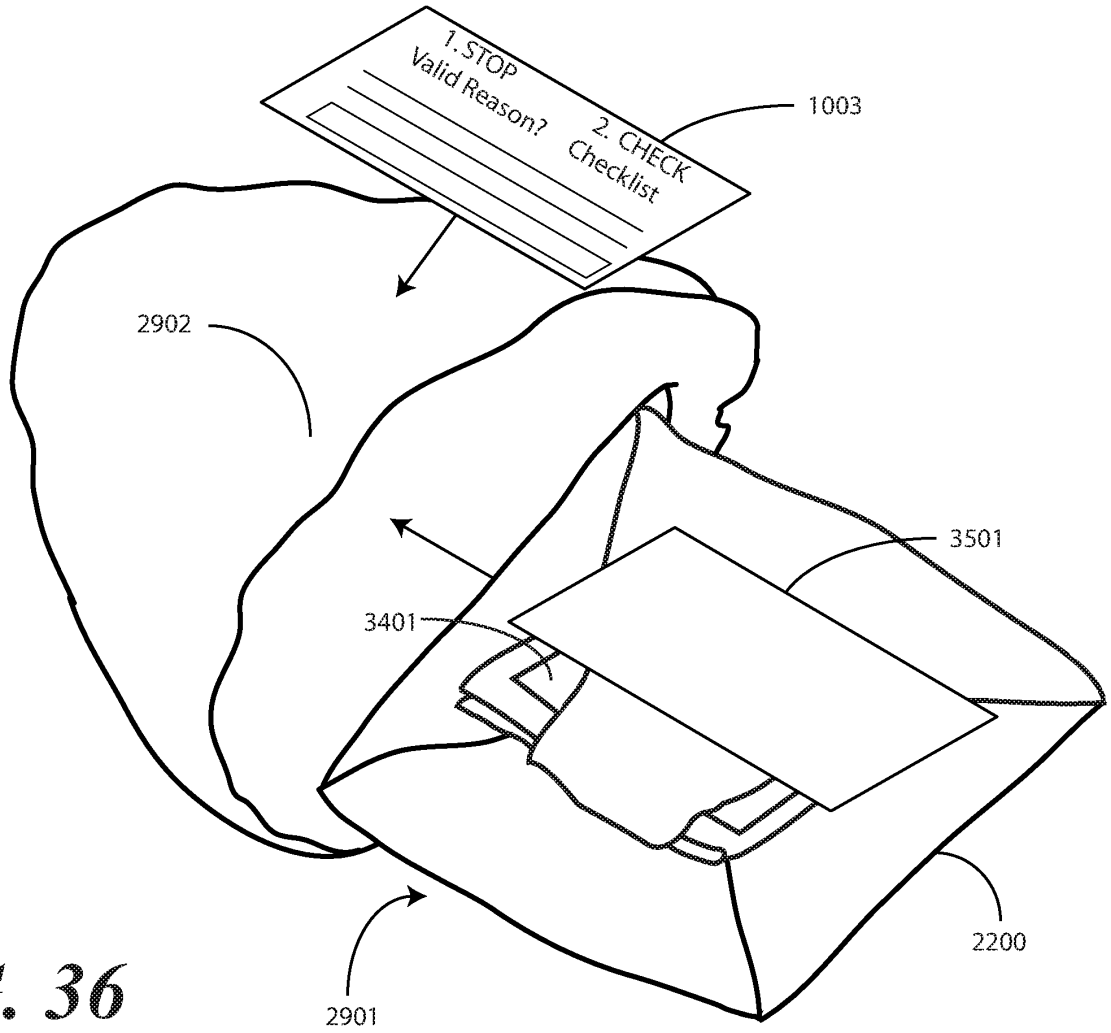
1. STOP
Valid Reason?
2. CHECK
Checklist
1003
2902
3501
3401
2200
2901

FIG. 36

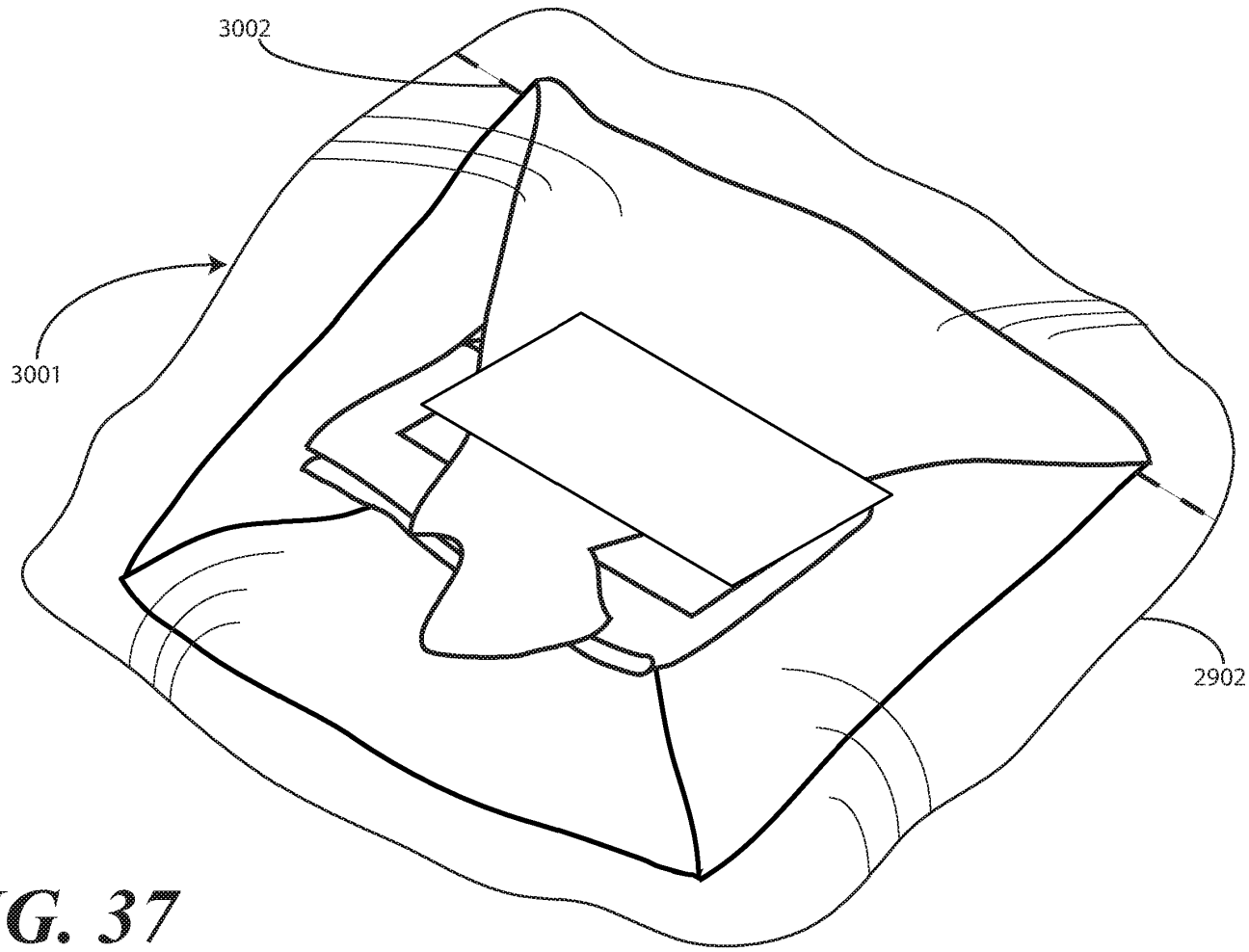

FIG. 37

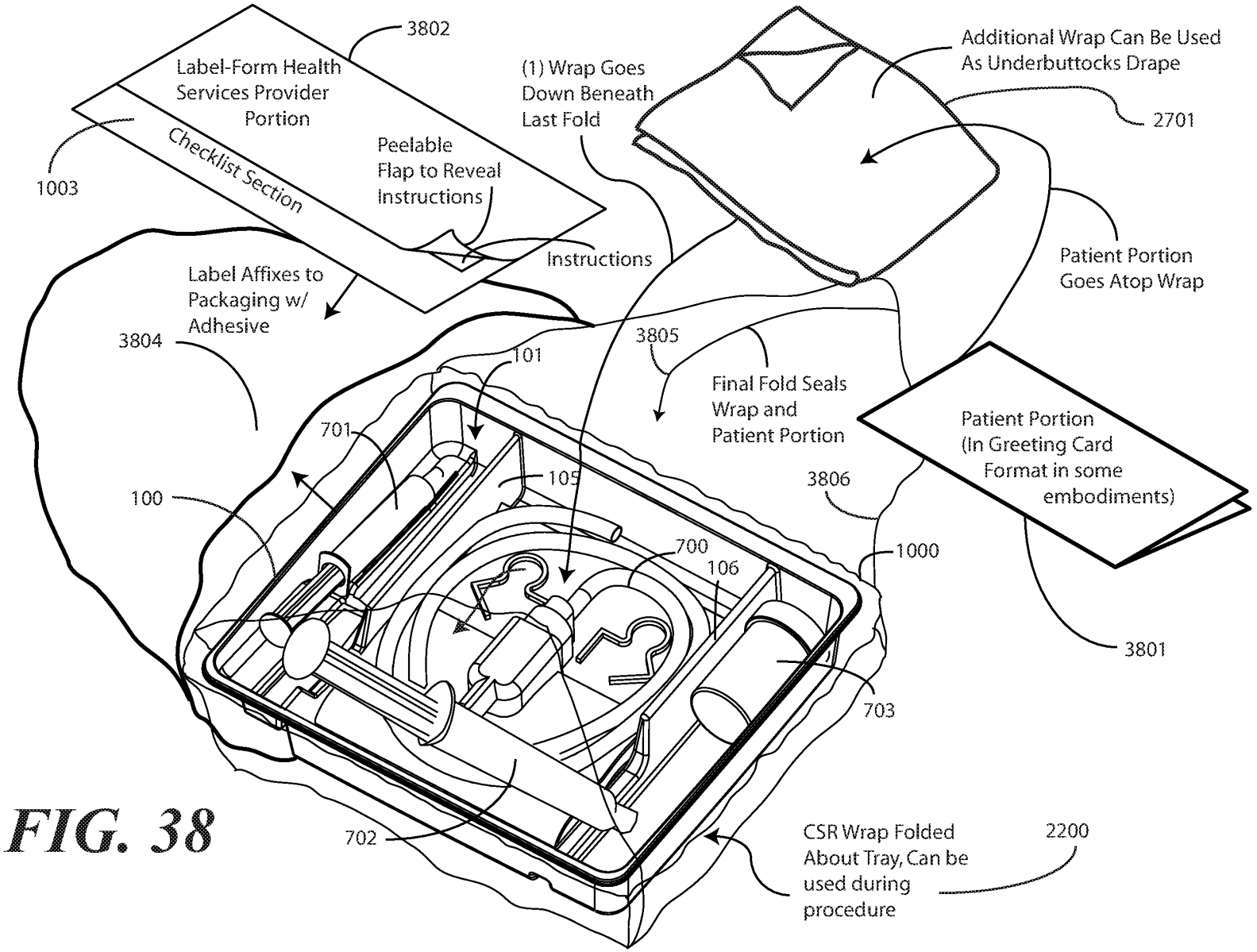
3802
Label-Form Health Services Provider Portion
Checklist Section
1003
Peelable Flap to Reveal Instructions
Instructions
(1) Wrap Goes Down Beneath Last Fold
Additional Wrap Can Be Used As Underbuttocks Drape
2701
Patient Portion Goes Atop Wrap
Label Affixes to Packaging w/ Adhesive
3804
3805
Final Fold Seals Wrap and Patient Portion
101
701
105
100
3806
Patient Portion (In Greeting Card Format in some embodiments)
700
106
1000
3801
703
702
CSR Wrap Folded About Tray, Can be used during procedure
2200

FIG. 38

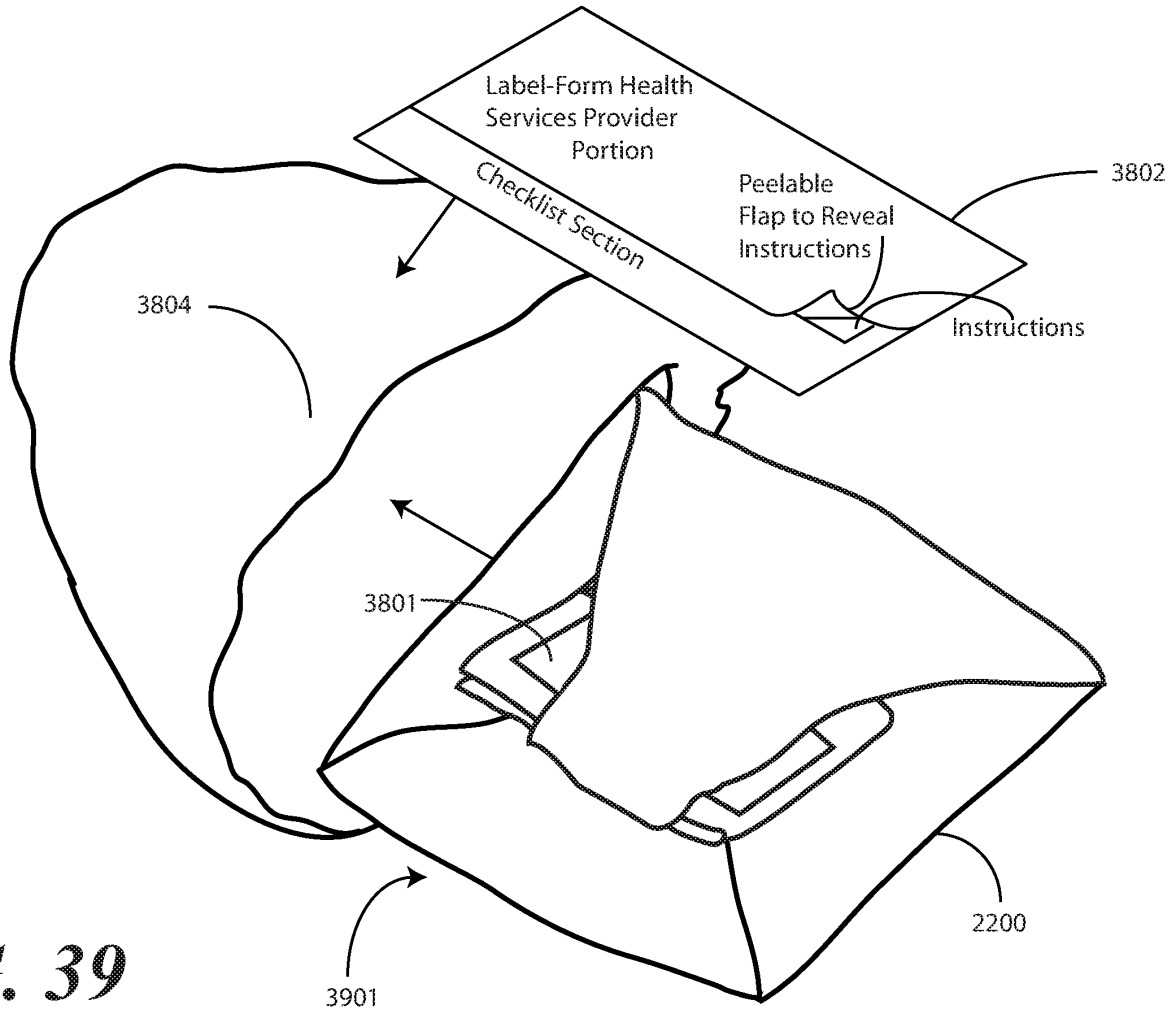
Label-Form Health Services Provider Portion
Checklist Section
Peelable Flap to Reveal Instructions
3802
Instructions
3804
3801
2200
3901

FIG. 39

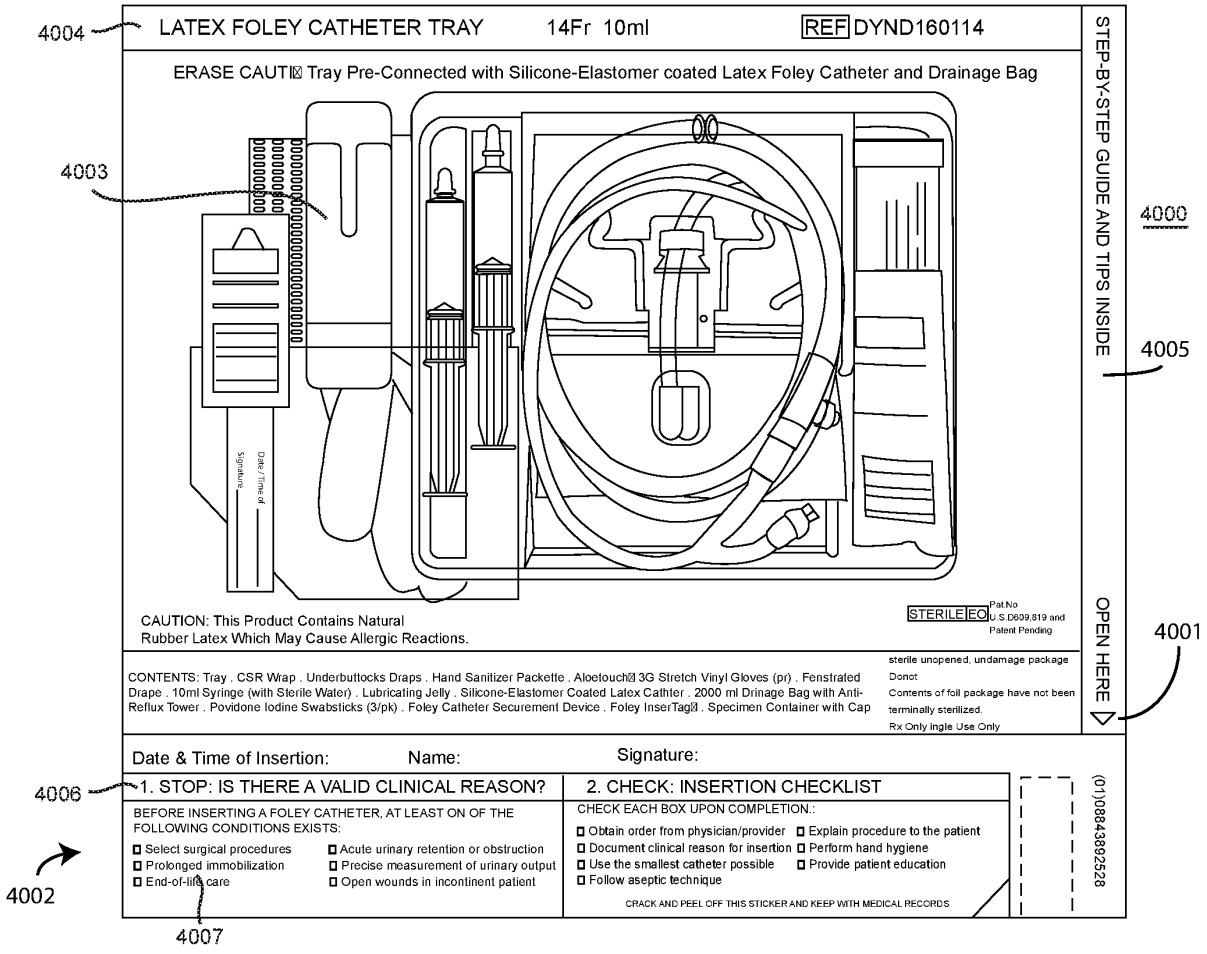
4004
LATEX FOLEY CATHETER TRAY
14Fr 10ml
REF DYND160114
ERASE CAUTI Tray Pre-Connected with Silicone-Elastomer coated Latex Foley Catheter and Drainage Bag
4003
Date / Time of Signature
CAUTION: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.
STERILE EO
Pat No U.S.D609,819 and Patent Pending
CONTENTS: Tray . CSR Wrap . Underbuttocks Draps . Hand Sanitizer Packette . Aloetouch 3G Stretch Vinyl Gloves (pr) . Fenstrated Drape . 10ml Syringe (with Sterile Water) . Lubricating Jelly . Silicone-Elastomer Coated Latex Cathter . 2000 ml Drinage Bag with Anti-Reflux Tower . Povidone Iodine Swabsticks (3/pk) . Foley Catheter Securement Device . Foley InserTag . Specimen Container with Cap
sterile unopened, undamage package
Donot
Contents of foil package have not been terminally sterilized.
Rx Only ingle Use Only
STEP-BY-STEP GUIDE AND TIPS INSIDE
4000
4005
OPEN HERE
4001
Date & Time of Insertion:
Name:
Signature:
4006
1. STOP: IS THERE A VALID CLINICAL REASON?
BEFORE INSERTING A FOLEY CATHETER, AT LEAST ON OF THE FOLLOWING CONDITIONS EXISTS:
Select surgical procedures
Prolonged immobilization
End-of-life care
Acute urinary retention or obstruction
Precise measurement of urinary output
Open wounds in incontinent patient
2. CHECK: INSERTION CHECKLIST
CHECK EACH BOX UPON COMPLETION.:
Obtain order from physician/provider
Document clinical reason for insertion
Use the smallest catheter possible
Follow aseptic technique
Explain procedure to the patient
Perform hand hygiene
Provide patient education
CRACK AND PEEL OFF THIS STICKER AND KEEP WITH MEDICAL RECORDS
(01)00884389252
4002
4007

FIG. 40

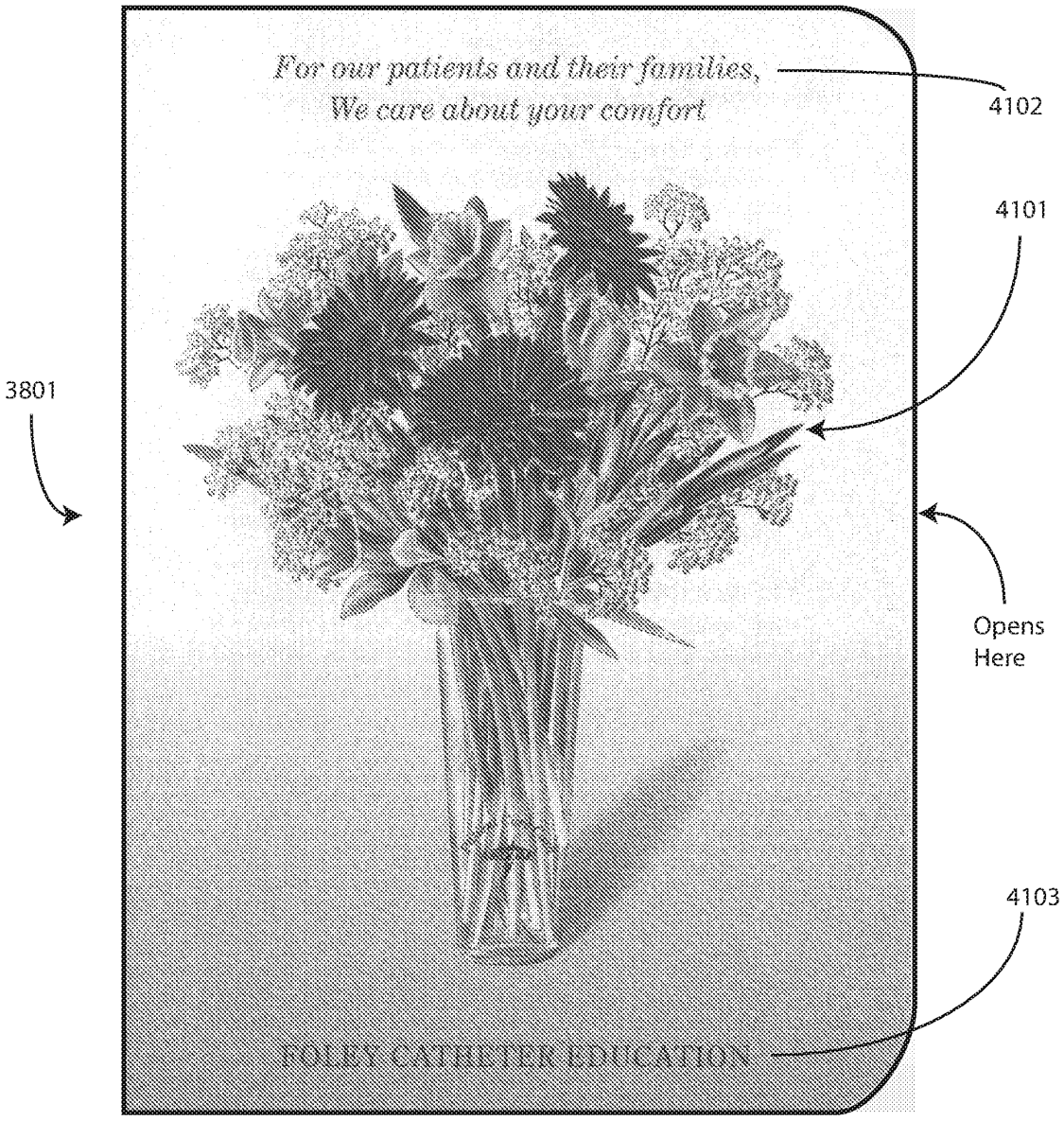
For our patients and their families,
We care about your comfort
4102
4101
3801
Opens
Here
4103
FOLEY CATHETER EDUCATION

FIG. 41

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jennifer	E.	Tomes	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	Mundelein	State/Province	IL	Country of Residence	US

Mailing Address of Inventor:

Address 1	P.O. Box 904		
Address 2			
City	Mundelein	State/Province	IL
Postal Code	60060	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Sarah		Dickinson	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	Chicago	State/Province	IL	Country of Residence	US

Mailing Address of Inventor:

Address 1	522 West Belden, Apartment L1		
Address 2			
City	Chicago	State/Province	IL
Postal Code	60614	Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Deborah		Adler	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

City	New York	State/Province	NY	Country of Residence	US

Mailing Address of Inventor:

Address 1	60 East 8th Street, Apt 5E		
Address 2			
City	New York	State/Province	NY
Postal Code	10003	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jack		Maze	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Long Grove	State/Province	IL	Country of Residence	US

Mailing Address of Inventor:

Address 1	5851 Teal Lane		
Address 2			
City	Long Grove	State/Province	IL
Postal Code	60047	Country	US

Inventor 5 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Alberto		Savage	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Buffalo Grove	State/Province	IL	Country of Residence	US

Mailing Address of Inventor:

Address 1	471 Arbor Gate Lane		
Address 2			
City	Buffalo Grove	State/Province	IL
Postal Code	60089	Country	US

Inventor 6 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kenneth		Chua	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Glenview	State/Province	IL	Country of Residence	US

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Mailing Address of Inventor:

Address 1	3904 Harvest Lane		
Address 2			
City	Glenview	**State/Province**	IL
Postal Code	60025	**Country**	US

Inventor 7 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Earl		Wilson	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Ingleside	**State/Province**	IL	**Country of Residence**	US

Mailing Address of Inventor:

Address 1	26075 West Rollins Road		
Address 2			
City	Ingleside	**State/Province**	IL
Postal Code	60041	**Country**	US

Inventor 8 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John		Kutsch	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Harvard	**State/Province**	IL	**Country of Residence**	US

Mailing Address of Inventor:

Address 1	107 West Front Street		
Address 2			
City	Harvard	**State/Province**	IL
Postal Code	60033	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	27939

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Email Address	pburrus@burrusiplaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
Attorney Docket Number	10055UCIP2D1C1C1C1C1	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	27939		

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
	Continuation of	15684787	2017-08-23	
Prior Application Status	Patented			Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15684787	Continuation of	14793455	2015-07-07	9745088	2017-08-29
Prior Application Status	Patented				Remove
14793455	Continuation of	13860902	2013-04-11	9522753	2016-12-20
Prior Application Status	Patented				Remove
13860902	Division of	13155026	2011-06-07	8448786	2013-05-28

Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
13155026	Claims benefit of provisional	61352140	2010-06-07	
Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
13155026	Claims benefit of provisional	61352155	2010-06-07	
Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
13155026	Claims benefit of provisional	61428944	2010-12-31	
Prior Application Status	Expired			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)	
13155026	Claims benefit of provisional	61437796	2011-01-31	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13155026	Continuation in part of	12495148	2009-06-30	8631935	2014-01-21
Prior Application Status	Abandoned				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
13155026	Continuation in part of	12647515	2009-12-27		
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13155026	Continuation in part of	13153265	2011-06-03	9795761	2017-10-24
Prior Application Status	Abandoned				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
13155026	Continuation in part of	13153300	2011-06-03		
Prior Application Status	Expired				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
12495148	Claims benefit of provisional	61183629	2009-06-03		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.					Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.			Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	10055UCIP2D1C1C1C1C1
	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Medline Industries, Inc		
Mailing Address Information For Applicant:			
Address 1	Three Lakes Drive		
Address 2			
City	Northfield	**State/Province**	IL
Country	US	Postal Code	60093
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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	Application Number	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Philip H. Burrus, IV/			Date (YYYY-MM-DD)	2020-03-27
First Name	Philip	Last Name	Burrus, IV	Registration Number	45432

Additional Signature may be generated within this form by selecting the Add button. Add

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This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Bard Exhibit 1004.0113

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		Medline Industries Inc. vs C.R Bard, Inc.; Exhibit E to Declaration of Kevin A. Lake; Civil Action No. 1:14-cv-03618, Judge John Z. Lee; Filed July 8.2016.,	
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		Medline Industries Inc. vs C.R Bard. Inc., Exhibit A to Declaration of Barbara Weintraub Regarding Claim Construction: Civil Action No. 1.14-cv-03618. Judge John Z. Lee; Filed July 8,2016.,	
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		Medline Industries Inc. vs C.R Bard. Inc.. Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John 2. Lee; Filed July 8.2016.,	
		Medline Industries Inc. vs C.R Bard. Inc.. Exhibit 11 to Declaration of Richard Meyst re Claim Construction: Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9,2016.,	
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		Medline Industries Inc. vs C.R Bard. Inc.; Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction Brief. Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 22,2017,	
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		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit 3 to Declaration of Peter Sauer in Support of Medline's Motion to Supplement Record; Civil Action No. 1:14-cv-03618: Judge John Z. Lee. Filed March 23.2017.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit 8 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit C to Declaration of Kevin A. Lake; Civil Action No. 1 14-cv-03618. Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit G to Declaration of Dylan J. Raife in Support of Bard Opening Claim Construction Brief, Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 17,2017.,	
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		Medline Industries Inc. vs C.R. Bard, Inc., Bard Response to Medline Surreply re Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed September 13.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit 2 to Declaration of Karl L. Lansing in Support of Bard's Rebuttal on Claim Construction: Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed August 15. 2016,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit B to Declaration of Kevin A. Lake. Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit D to Declaration of Nicole Smith in Support of Bard Reply to Claim Construction Brief; Civil Action No. 116-cv-03529; Judge Sharon Johnson Coleman. Filed January 12.2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit J to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529: Judge Sharon Johnson Coleman; Filed December 9.2016.,	

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		Medline Industries Inc. vs C.R. Bard, Inc.. Exhibit 1 to Declaration of Peter Sauer in Support of Medline's Motion to Supplement Record; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed March 23.2017,	
		Medline Industries Inc. vs C.R. Bard, Inc.. Exhibit 9 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8. 2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.. Exhibit L to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529: Judge Sharon Johnson Coleman: Filed December 9,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.. Medline Response to Bard Claim Construction Brief. Civil Action No. 1:14~cv-03618: Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.: Exhibit 2 to C.R. Bard's LPR 2.3 Contentions; Civil Action No. 117-CV-7216; Judge Sara L Eiiis; Filed January 16.2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Declaration of Barbara Weintraub re Claim Construction: Civil Action No. 1.16-cv-03529. Judge Sharon Johnson Coleman; Filed December 9,2016.,	
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		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 10 lo Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 2 to Declaration of Peter Sauer in Support of Medline's Motion to Supplement Record; Civil Action No. 1:14-cv-03618; Judge John Z. Lee. Filed March 23. 2017.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 5 to Declaration of Richard Meyst re Claim Construction: Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman, Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 6 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman. Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 7 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit C to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9,2016.,	
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		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit M to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9,2016.,	
		Medline Industries Inc. vs C.R. Bard. Inc., Exhibit 2 to Declaration of Richard Meyst Regarding Claim Construction: Civil Action No. 1:14-cv-03618; Judge John 2. Lee. Filed July 8.2016.,	
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		Medline Industries Inc. vs C.R Bard, Inc., Exhibit 11 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z Lee; Filed July 8.2016.,	
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		Medline Industries Inc. vs C R. Bard, Inc; C R. Bard's Opening Claim Construction Bnel; Civil Action No. 1:14-cv-03618; Judge John 2. Lee; Filed June 4, 2016.,	
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		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit N – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
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		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit P – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit Q – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit R – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	

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	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit S – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit T – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc; C.R. Bard's LPR 3.1 Contentions; Civil Action No. 1:16-cs-3529; Judge Sharon Johnson Coleman; Filed August 26, 2016,	
		Medline Industries Inc. vs C.R. Bard, Inc; Exhibit B to C R. Bard's LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed January 16.2018.,	
		Medline Industries vs. CR Bard, Inc; No 14-cv-3618; C.R. Bard's LPR 3.1 Contentions; Filed November 24, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Defendant C.R. Bards, Inc's Second Amended Answer to Second Amended Complaint; Filed September 25, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Medline Industries Inc's Opposition to C.R.Bard Inc's Motion For Leave to File Second Amended Answer to Add Counterclaim; Filed October 20, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Medline Industries, Inc.'s Response to C.R. Bard's Initial Invalidity Contentions; Exhibits A-H; Dated September 19, 2014,	

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		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Notice of Medline Industries Inc's Motion to Dismiss C.R. Bard Inc's Inequitable Conduct Counterclaim and to strike affirmative defense for the '786 Patent; Filed October 20, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Response to Medline Industries, Inc.'s First Set of Interrogatories; Dated September 26, 2014,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-3618; Responses to Medline Industries, Inc.'s First set of Requests for the Production of Documents; Dated September 26, 2014,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:17-cv-03618; Medline's Supplemental Responses to Bard's Interrogatory No. 1-24 (redacted), dated April 20, 2016; Filed as IPR Petition Exhibit 2013 in IPR2019-00035 and IPR2019-00036,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 1:17-cv-3539; Medline's Second Supplemental Responses to Bard's Interrogatory No. 11, 14, and 15 (redacted), dated October 26, 2017; Filed as IPR Petition Exhibit 2014 in IPR2019-00035 and IPR2019-00036,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 1:17-cv-7216; Medline's Objection and Response to Bard's First Set of Interrogatories (redacted), dated October 1, 2018; Filed as IPR Petition Exhibit 2012 in IPR2019-00035 and IPR2019-00036,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 14-cv-3618; C.R. Bard's LPR 2.3 Contentions - Initial Non-Infringement; Exhibits 1 and A-H; Dated September 5, 2014,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 14-cv-3618; Memorandum in Support of C.R. Bard's Motion for Leave to File Second Amended Answer to Add Counterclaim; Filed September 25, 2015,	

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		Medline Industries, Inc. vs. C.R. Bard, Inc.: Transcript of Proceedings - Claim Construction Hearing: Civil Action No. 1:14-cv-3618. Judge John Z. Lee; Dated January 11, 2017.	
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		Notice of Allowance; EP Application No. 10251025.2-1501; Reference P112645EP00; Attorney Docket No. BPMDL0005JT EP (10055U EP); Mailed February 18, 2016,	
		Inter Partes Review - Patent Owner's Prelim. Response; Patent 9,808,596; Inter Partes Review No. IPR2019-00223; Filed March 7, 2019,	
		Medline Industries Inc. vs. C.R Bard, Inc. Bard Opening Claim Construction Brief; Civil Action No 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 17, 2017.	
		Webster's Dictionary Definition of "Intend"; Webster's Third New International Dictionary of the English Language unabridged (1961); filed as IPR Petition Exhibit 2016 in IPR 2019-00035,	
		"Appeal Decision", USSN 12/785,064; Filed May 21, 2010; Attorney Docket No. BPMDL0018RL (10212U); Mailed May 18, 2016,	
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		"Australian First Exam Report", AU Patent Application No. 2011351971; Patent Examination Report No. 1; Mailed 25JL2015,	
		"Bard IPR Exhibit", "Inter Partes Review Petition", IPR Exhibit - Carrow Declaration for US Patent No. 8,631,935; Susan Carrow Declaration; Mailed December 30, 2014,	
		"Bard Medical Division Care & Catheterization Script", Care & Catheterization/Preventing UTI Script for education video; Preventing UTI: Care and Catheterization Techniques; Copyright 2006; AV0512-06 R12/05 XXX,	
		"Bard Publication", "A few important words about Catheter Care"; C.R. Bard, Inc.; Copyright 2001 C.R. Bard, Inc.,	
		"Bardex I.C. Complete Care StateLock Device 350 ml Urine Meter Foley Tray with Bacteriostatic Collection System", Bard Infection Control System; Bardex I.C. Complete Care Directions for Use; Copyright Dated September 2006,	
		"Bardex I.C. Infection Control 350ml Urine Meter Foley Tray", Bard Infection Control System; Bardex I.C. Urine Meter Foley Tray Directions for Use; Copyright Dated 2006,	
		"Bardex I.C. Infection Control Foley Tray", Bard Infection Control System; Bardex I.C. Directions for Use Infection Control Foley Tray; Copyright Dated 2006,	
		"Decision Instituting Inter Partes Review", IPR2019-00035; Patent No. 9,745,088; Mailed April 10, 2019,	

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		"Decision Instituting Inter Partes Review", IPR2019-00036; Patent No. 9,745,088; Mailed April 10, 2019,	
		"Decision Instituting IPR", IPR 2019-00208; Patent No. 9,808,400; Dated June 6, 2019,	
		"Decision Instituting Review", IPR 2019-00223; Patent No. 9,808,596; Dated June 6, 2019,	
		"DVD", Entitled "Preventing UTI: Care and Catheterization Techniques"; Publication Date unknown but believed to be prior to 2007,	
		"EPO Intent to Grant", EPO Application No. 10251024.5; Filed June 2, 2010; Attorney Docket No. P112645EP01 (BPMDL0005JT.P1.EPO); Mailed November 2, 2012,	
		"Examiner's Answer", USSN 13/153,265; Filed June 3, 2011; Attorney Docket No. BPMDL0005JT.P5 (10055U CIP5); Mailed December 17, 2013,	
		"Expert Report of Barbara Weintraub", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated June 14, 2019,	
		"Expert Report of Barbara Weintraub", Civil Action No. 1:16-cv-03529; Confidential Information Redacted Pursuant to Court Order; Dated August 1, 2019,	

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		"Expert Report of Dr. Edward Yun", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated June 13, 2019,	
		"Expert Report of Dr. Edward Yun", Civil Action No. 16-cv-3529; Confidential Information Redacted Pursuant to Court Order; Dated August 1, 2019,	
		"Expert Report of Dr. Edward Yun Related to Damages, Non-Infringement, and New Evidence of Alleged Secondary Considerations", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated July 23, 2019,	
		"Expert Report of Dr. John Abraham", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated June 14, 2019,	
		"Expert Report of Dr. John Abraham", Civil Action No. 1:16-cv-03529; Confidential Information Redacted Pursuant to Court Order; Dated August 1, 2019,	
		"Expert Report of Dr. Steven Brooks", Civil Action No. 14-cv-3618; Confidential Information Redacted Pursuant to Court Order; Dated July 25, 2019,	
		"Expert Report of Karl R Leinsing, MSME, PE Regarding Alleged Evidence of Secondary Considerations", Civil Action No. 1:14-cv-3618; Confidential Information Redacted Pursuant to Court Order; Dated June 14, 2019,	
		"Expert Validity Report of Dr. John Abraham", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated July 25, 2019,	

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		"Extended EPO Exam Report", EPO App No.: 10251025.2; Filed June 2, 2010; Attorney Docket No. BPMDL0005JT.EPO (10055U EP); Mailed December 17, 2013,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; Exhibit J to Declaration of Nicole M. Smith; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed June 4, 2016.	
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		"Intent to Grant", European Application No. 16177903.8-1501; Reference No. SJG/P112645EP02; Mailed September 18, 2017,	
		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent 8,631,935; Inter Partes Review No. IPR2015-00513; Filed April 21, 2015,	
		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent No. 8,448,786; IPR2015-00509; Filed April 22, 2015,	
		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent No. 8,631,935; Inter Partes Review No. IPR2015-00511; Filed April 22, 2015,	

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		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent No. 8,678,190; Inter Partes Review No.: IPR2015-00514; Filed April 21, 2015,	
		"Inter Partes Review - Patent Owner's Prelim Response", Patent 9,745,088; Inter Partes Review No. IPR2019-00035; Filed January 11, 2019,	
		"Inter Partes Review - Patent Owner's Prelim Response", Patent 9,745,088; Inter Partes Review No. IPR2019-00036; Filed January 11, 2019,	
		"Inter Partes Review No. IPR2019-00109", Petition for Review; Patent No. 9,795,761; Filed October 24, 2018,	
		"Inter Partes Review Petition", Exhibit - Amendment filed on April 3, 2013 for USSN 12/495,148; Attorney Docket No. BPMDL0005JT (10055U); Application Filed June 30, 2009,	
		"Inter Partes Review Petition", Exhibit - Bard DFU; Bardex Infection Control Foley Tray; Copyright 2006, publication date unknown,	
		"Inter Partes Review Petition", Exhibit - Bardex DFU; Directions for Use/Patient Education Information - Urology; Unknown Publication Date,	
		"Inter Partes Review Petition", Exhibit - Declaration of Susan Carrow for US Patent No. 8,631,935 claims 1-4 and 11-20; Mailed December 30, 2014,	

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	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		"Inter Partes Review Petition", Exhibit - Dorland's Definition of Bag; Dorland's Illustrated Medical Dictionary; 31st Edition; Publication Date Unknown,	
		"Inter Partes Review Petition", Exhibit - EC Guideline 1998; "A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use"; Published September 29, 1998 (29.09.98); Mailed December 30, 2014,	
		"Inter Partes Review Petition", Exhibit - Encyclopedia Dictionary of Medicine, Nursing and Allied Health; Miller Keane, Seventh Edition,	
		"Inter Partes Review Petition", Exhibit - FAQs "Catheter-Associated Urinary Tract Infection"; Unknown Publisher; Unknown Publication Date,	
		"Inter Partes Review Petition", Exhibit - FDA Article; "Guidance for the Content of Premarket Notifications fro Conventional and Antimicrobial Foley Catheters; http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080884.htm; Unknown Publication Date,	
		"Inter Partes Review Petition", Exhibit - Health Protection Scotland; CAUTI Maintenance Bundel; Version 2, February 2008,	
		"Inter Partes Review Petition", Exhibit - Infection Control Today Article; Medical Center Cuts Catheterizations by 21 Percent with Foley Catheter Management System; Published 2010,	
		"Inter Partes Review Petition", Exhibit - Kimmel Declaration for US Patent No. 8,631,935 claims 1-4 and 11-20; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	

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		"Inter Partes Review Petition", Exhibit - Medical News Today Article; "'Getting to Zero:' Medline's' Erase Cauti Program Helps Hospitals Reduce Catheter Use by 20 Percent; Article Date April 13, 2011,	
		"Inter Partes Review Petition", Exhibit - Medline Initial Infringement Contentions; Medline Industries vs. C.R. Bard; Dated August 22, 2014,	
		"Inter Partes Review Petition", Exhibit - Morning Start Article; "Floyd Medical Center Reduces Catheter-Associated Urinary Tract Infections 83 Percent and Catheter Use by 23 Percent"; Published January 2011,	
		"Inter Partes Review Petition", Exhibit - Mosby's Pocket Guide Excerpt; Mosby's Pocket Guide to Basic Skills and Procedures; Sixth Edition; Perry & Potter; "Urinary Catheter: Indwelling, Straight, Care and Removal"; Unknown Publication Date,	
		"Inter Partes Review Petition", Exhibit - Nursing Standard; Article in Learning Zone - Continue Professional Development; "Reducing the risks associated with urinary catheters"; Published March 25, 2009,	
		"Inter Partes Review Petition", Exhibit - RCE Filed November May 31, 2011 for USSN 12/495,148; Attorney Docket No. BPMDL0005JT (10055U); Application Filed June 30, 2009,	
		"Inter Partes Review Petition", Exhibit - Response to Office Action in USSN 12/495,148; Attorney Reference No. BPMDL0005JT (10055U); Application Filed June 30, 2009; Response Filed November 19, 2010,	
		"Inter Partes Review Petition", Exhibit - Soroka Glossary 'Bag'; Illustrated Glossary of Packaging Terminology, second edition; Walter Soroka; publication unknown,	

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		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration 8,448,786 Patent; Dr. Robert M. Kimmel Declaration; Received December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration for US Patent No. 8,631,935 claims 1-4 and 11-20; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration for US Patent No. 8,631,935 claims 7-8, 10, 21-23, 25, 27-28, and 30-34; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration for US Patent No. 8,768,190; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Susan Carrow Declaration 8,448,786 patent; mailed December 30, 2014,	
		"Inter Partes Review Petition for 8,448,786", US Patent No. 8,448,786; Filed December 30, 2014; Mailed December 30, 2014,	
		"Inter Partes Review Petition for 8,631,935", Inter Partes Review Petition for 8,631,935 for claims 1-4 and 11-20; Filed December 30, 2014,	
		"Inter Partes Review Petition for 8,631,935", Inter Partes Review Petition for 8,631,935 for Claims 7-8, 10, 21-23, 25, 27-28, and 30-34; Filed December 30, 2014,	

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		"Inter Partes Review Petition for 8,678,190", Inter Partes Review Petition for 8,678,190; Filed December 30, 2014,	
		"Inter Partes Review Petition for US Patent No. 9,745,088", IPR-0036; Filed October 4, 2018,	
		"Inter Partes Review Petition for US Patent No. 9,745,088", IPR2019-0035, filed October 4, 2018,	
		"IPR 2015-00514 - Patent Owner's Objection to Evidence", IPR 2015-00514 - Patent Owner's Objection to Evidence Submitted During a Preliminary Proceeding; Patent No. 8,678,190; Mailed July 13, 2015,	
		"IPR 2015-00514 - Patent Owner's Request for Adverse Judgment", Patent No. 8,678,190; Mailed July 23, 2015,	
		"IPR 2015-00514 - Request for Rehearing Denied", IPR2015-00514; Patent No. 8,678,190; Decision on Request for Rehearing - Denied; Mailed July 16, 2015,	
		"IPR 2015-00514 Petitioner's Request for Rehearing", IPR 2015-00514 Petitioner's Request for Rehearing; Patent 8678,190; Dated July 10, 2015,	
		"IPR 2019-00109", Exhibit 1031 - Declaration of Jennifer Tomes filed in USSN 12/647,515 dated December 7, 2012,	

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		"IPR 2019-00109", Patent No. 9,795,761; Filed October 24, 2018; Declaration of Dr. Edward Yun,	
		"IPR Decision Instituting Inter Partes Review", IPR2019-00109; Patent 9,795,761; Mailed May 6 2019,	
		"IPR Exhibit 1002", Declaration of Pliska; IPR2019-0035, Filed October 4, 2018,	
		"IPR Exhibit 1003", Declaration of Yun; IPR2019-0035; Filed October 4, 2018,	
		"IPR Exhibit 1022", Email from Medline counsel re claims constructions; IPR2019-0035; Filed October 4, 2018,	
		"IPR Petition Exhibit 1016", Excerpt from "The Design of Everyday Things"; IPR2019-0035; Filed October 4, 2018,	
		"IPR Petition Exhibit 1024", Email from Bard counsel re claims constructions; IPR2019-0035; Filed October 4, 2018,	
		"IPR0215-00513 Scheduling Order", Patent No. 8,631,935; Mailed July 15, 2015,	

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		"IPR2015-00509 Institution Decision", IPR2015-00509; Patent Number 8,448,786; Mailed July 15, 2015; Decision Denying Institution of Inter Partes Review,	
		"IPR2015-00511 Institution Decision", IPR2015-00511; Patent 8,631,935; Entered July 15, 2015; Decision Denying Institution of Inter Partes Review,	
		"IPR2015-00513 - Request for Adverse Judgment", IPR2015-00513 - Request for Adverse Judgment; Granted - Proceedings Terminated; Patent No. 8,631,935; Entered August 11, 2015,	
		"IPR2015-00513 - Patent Owner's Request for Adverse Judgment", Patent No. 8,631,935; Mailed July 23, 2015,	
		"IPR2015-00513 Institution Decision", IPR2015-00513 Institution Decision; Patent 8,631,935; Entered July 15, 2015; Decision Institution of Inter Partes Review,	
		"IPR2015-00514 - Scheduling Order", Patent No. 8,678,190; Mailed June 26, 2015,	
		"IPR2015-00514 Decision Institution of Inter Partes Review", IPR2015-00514; Patent 8,678,190; Mailed June 26, 2015; Decision Institution of Inter Partes Review,	
		"IPR2015-00514 Judgment - Termination of Proceeding", Patent No. 8,678,190; Mailed July 24, 2015,	

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		"IPR2019-00109", Exhibit 1026 - Bard's Opening Claim Construction Brief; Civil Action No. 1:17-cv-07216; Dated October 10, 2018; Filed October 24, 2018 as exhibit 1026,	
		"IPR2019-00109", Exhibit 1030 - Medline Industries, Inc.'s Final Infringement Contentions; Filed July 24, 2018 in Civil Action No. 1:17-cv-07216; Filed as exhibit October 24, 2018,	
		"IPR2019-00109", Patent No. 9,795,761; Filed October 24, 2018; Exhibit 1002 Declaration of Michael Plishka,	
		"Markman Decision", Medline Industries, Inc. vs. C.R. Bard, Inc.; Case No. 1:16-cv-03529\; Memorandum Opinion and Order; Judge Sharon Johnson Coleman Issued December 28, 2018,	
		"Markman Hearing", Medline Industries, Inc. vs. C.R. Bard, Inc.; Case No. 1:17-cv-07216; Memorandum Opinion and Order; Judge Sara L. Ellis; Issued January 28, 2019,	
		"Medline Catalog", Argyle Trocar Catheter Kits by Covidien; http://www.medline.com/sku/item/MDPSWD565028; Unknown Publication Date but believed to be prior to filing of present application,	
		"Medline Catalog", Argyle Turkel Safety Thoracentesis System by Covidien; 6"; http://www.medline.com/sku/item/MDPKDL5016; Unknown Publication Date but believed to be prior to filing of present application,	
		"Medline Catalog", Argyle Turkel Safety Thoracentesis System by Covidien; http://www.medline.com/sku/item/MDPKDL5014; Unknown Publication Date but believe to be prior to filing of present application,	

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		POON, ROBERT, "NonFinal Office Action", 15/703,514; Filed September 13, 2017; Attorney Docket No. BPMDL5JTP5C1 10055UCIP5C1; Mailed June 22, 2018,	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		POON, ROBERT, "NonFinal Office Action", USSN 15/804,520; Filed November 6, 2017; Attorney Docket No. 1037-001-02US; Mailed June 6, 2018,	
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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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	Application Number	16/833,575
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	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		POON, ROBERT, "Notice of Allowance", USSN 14/718,792; Filed May 21, 2015; Attorney Docket No. BPMDL0005JT.CIP.C1 (10055U CIP C1); Mailed February 2, 2016,	
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	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		POTHIER, ANDREW, "Office Action", Canadian Application No. 2,822,905; Attorney Docket No. 10055U CIP4 CA; Mailed June 13, 2019,	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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		VAN POELGEEST, A, "Examination Report", EP Application No. 11 854 003.8-1113; September 17, 2019,	
		VASAT, PETER, "NonFinal OA", USSN 12/785,064; Filed May 21, 2010; Attorney Docket No. BPMDL0018RL (10212U); Mailed February 9, 2018,	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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		POON, ROBERT , "NonFinal Office Action", USSN 15/703,514; Filed September 13, 2017; Attorney Docket No. 1037-002-09US; Mailed March 17, 2020,	
		POON, ROBERT , "Non-Final Office Action", USSN 15/803,383; Filed November 3, 2017; Attorney Docket No. 1037-002-08US; mailed March 16, 2020,	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Electronic Acknowledgement Receipt

EFS ID:	38998820
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	28-MAR-2020
Filing Date:	
Time Stamp:	18:50:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10055U_CIP2_D1_C1_C1_C1_C1_USA_2020-3-28_IDS.pdf	946606 bb86338ed5815e6ae68c956cf5e31f0fd0220bca	yes	83

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	2
	Information Disclosure Statement (IDS) Form (SB08)	3	83
Warnings:			
Information:			
	Total Files Size (in bytes):	946606	

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Medline Industries, Inc.	Group Art Unit:	Unknown
Application No.:	16/833,575	Examiner:	Unknown
Date Filed:	March 28, 2020		
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313

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I. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b)-(d): (check only one box)

- a. ☒ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; before the mailing date of a first Office Action on the merits; and/or before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114. No fee or statement is required.
- b. ☐ before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application. Petition fee set forth in §1.17(p) is required unless a statement under 37 C.F.R. §1.97(e) is provided.
- c. ☐ on or before payment of the issue fee. Petition fee set forth in §1.17(p) and a statement under 37 C.F.R. §1.97(e) are required.

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- c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

III. STATEMENT UNDER 37 C.F.R. §1.98

The undersigned hereby states that

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b. ☒ No copies of the publication listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. 14/793,455 to which the above-identified application claims priority under 35 U.S.C §120.

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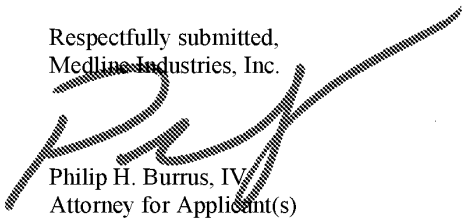
☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account **503608**, Burrus Intel. Prop. Law Group, Enclosed is a Fee Transmittal in duplicate.

☐ Two Copies of this paper are attached for Deposit Account charges and debits.

The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

Respectfully submitted,
Medline Industries, Inc.



Philip H. Burrus, IV
Attorney for Applicant(s)
Reg. No. 45,432
Tel. 404-797-8111

Burrus Intellectual Property Law Group
Customer Number 27939

Enclosures:
☒ Information Disclosure Statement by Applicant
☐ References
☐ Foreign Search Report
☐ Other:

Electronic Acknowledgement Receipt

EFS ID:	38998823
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus/Kayla Burrus
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Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	28-MAR-2020
Filing Date:	
Time Stamp:	18:53:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	10055U_CIP2_D1_C1_C1_C1_C1_USA_2020-3-28_IDSStatement.pdf	157965 2e57c12437cf273aaacb1f7ac51a77d56b136287	no	3

Warnings:

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National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application No.:	16/833,575	Examiner:	Unknown
Date Filed:	March 28, 2020		
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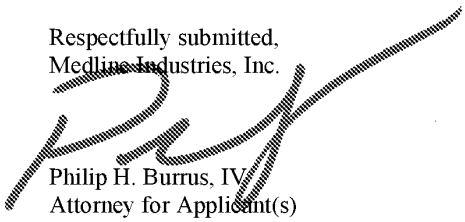
Respectfully submitted,
Medline Industries, Inc.



Philip H. Burrus, IV
Attorney for Applicant(s)
Reg. No. 45,432
Tel. 404-797-8111

Burrus Intellectual Property Law Group
Customer Number 27939

Enclosures:
☒ Information Disclosure Statement by Applicant
☐ References
☐ Foreign Search Report
☐ Other:

TRANSMITTAL FORM (to be used for all correspondence after initial filing)			
Total Number of Pages in this Submission		Application Number	13/153,265
		Filing Date	June 3, 2011
		First Named Inventor	Jennifer E. Tomes
		Group Art Unit	3788
		Examiner Name	Robert Poon
		Attorney Docket Number	BPMDL0005JT.P5 (10055U CIP5)

ENCLOSURES (check all that apply)

☐ Fee Transmittal Form	☐ Drawing(s)	☐ After Allowance Communication to Group
☐ Fee Attached	☐ Licensing-Related papers	☐ Appeal Communication to Board of Appeals and Interferences
☐ Amendment/Reply	☐ Petition	☐ Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/Declaration(s)	☐ Power of Attorney, Revocation, Change of Correspondence Address	☐ Status Letter with appropriate copies
☐ Extension of Time Request	☐ Terminal Disclaimer	☒ Other Enclosure(s) (please identify below): PCT Search Report, NPL Documents
☐ Express Abandonment Request	☐ Request for Refund	
☒ Information Disclosure Statement	☐ CD, Number of CDs ___	
☐ Certified Copy of Priority Documents		
☐ Response to Missing Parts/ Incomplete Application	Remarks	
☐ Response to Missing Parts Under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Philip H. Burrus, IV	Registration No.	45,432
Signature			
Date	April 25, 2012		

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Typed or printed name	Philip H. Burrus, IV		
Signature		Date	

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/833,575

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	660
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 460 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1720

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/833,575	03/28/2020	3736	1720	10055UCIP2D1C1C1C1C1	20	3

CONFIRMATION NO. 5069

FILING RECEIPT

27939
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

OC000000118049364

Date Mailed: 04/09/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Jennifer E. Tomes, Mundelein, IL;
Sarah Dickinson, Chicago, IL;
Deborah Adler, New York, NY;
Jack Maze, Long Grove, IL;
Alberto Savage, Buffalo Grove, IL;
Kenneth Chua, Glenview, IL;
Earl Wilson, Ingleside, IL;
John Kutsch, Harvard, IL;

Applicant(s)

Medline Industries, Inc, Northfield, IL;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/684,787 08/23/2017
which is a CON of 14/793,455 07/07/2015 PAT 9745088
which is a CON of 13/860,902 04/11/2013 PAT 9522753
which is a DIV of 13/155,026 06/07/2011 PAT 8448786
which claims benefit of 61/352,140 06/07/2010
and claims benefit of 61/352,155 06/07/2010
and claims benefit of 61/428,944 12/31/2010
and claims benefit of 61/437,796 01/31/2011
and is a CIP of 12/495,148 06/30/2009 PAT 8631935

and is a CIP of 12/647,515 12/27/2009 ABN
and is a CIP of 13/153,265 06/03/2011 PAT 9795761
and is a CIP of 13/153,300 06/03/2011 ABN
and said 12/495,148 06/30/2009
claims benefit of 61/183,629 06/03/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 04/07/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/833,575**

Projected Publication Date: 07/16/2020

Non-Publication Request: No

Early Publication Request: No
Title

Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

Preliminary Class

206

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Bard Exhibit 1004.0206

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed

from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		"Final Written Decision", IPR 2019-00035; Patent No. 9,745,008; Entered April 8, 2020; Docket No. 10055U CIP2 D1 C1,	
		"Final Written Decision", IPR 2019-00036; Patent No. 9,745,008; Entered April 8, 2020; Docket No. 10055U CIP2 D1 C1,	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

		"Final Written Decision", IPR 2019-00109; Mailed May 4, 2020; Patent No. 9,795,761,	
		"Final Written Decision", IPR 2019-00208; Patent No. 9,808,400; Entered June 3, 2020; Docket No. 10055U D1 C1,	
		"Final Written Decision", IPR 2019-00223; Patent No. 9,808,596; Entered June 3, 2020; 10055U CIP C1 C1,	
		POTHIER, ANDREW , "Office Action", Canadian Application No. 2,837,289; Mailed February 27, 2020,	
		POTHIER, ANDREW , "Office Action", Canadian Application No. 2822905; Mailed February 27, 2020,	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	**Application Number**	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2020-7-14
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	39995683
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	14-JUL-2020
Filing Date:	28-MAR-2020
Time Stamp:	14:58:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP2_D1_C1C1C1C1_USA_2020-7-14_IDS.pdf	138093 70c04f9111b4de6dc9ab6ed013b8facf06b2c3d1	no	4

Warnings:

Information:					
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2	Non Patent Literature	10055U_CIP4_CA_2020-2-27_OfficeAction.pdf	277829 ff1a0c773991e4d2f2275b1fd77aa4117199151d	no	4
Warnings:					
Information:					
3	Non Patent Literature	10055U_CIP5_CA_2020-2-27_FinalOA.pdf	275810 a1db37a3cdae09b4edf30ad65f9bdbaf2e7e39ab	no	4
Warnings:					
Information:					
4	Non Patent Literature	finalOrder400.pdf	1248572 64b0a061429830364e7b42e290678af0b96a2c01	no	36
Warnings:					
Information:					
5	Non Patent Literature	FinalOrder596.pdf	1654738 28e570efd66de2b62fb6c3dd5a4a0ce78f1bd631	no	37
Warnings:					
Information:					
6	Non Patent Literature	IPR2019-00109_FinalDecision.pdf	2099960 e862af7c719cc10b8b8177d08e65f9799ca63132	no	45
Warnings:					
Information:					
7	Non Patent Literature	PTAB-IPR2019-00035_Final_Decision.pdf	1962542 db4405a93309666027260b2ae79b0c4cef555d7a	no	31
Warnings:					
Information:					
8	Non Patent Literature	PTAB-IPR2019-00036-Final_Decision.pdf	985407 48475605694e7ca6ee88a6b0e015cfd1f81baf88	no	22
Warnings:					
Information:					

Total Files Size (in bytes):	8642951

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1

CONFIRMATION NO. 5069

27939
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

PUBLICATION NOTICE

Title: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

Publication No.US-2020-0223571-A1
Publication Date:07/16/2020

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Bard Exhibit 1004.0216

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/833,575	Filing Date 03/28/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/22/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CARMEN D WILLIAMS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/833,575	Filing Date 03/28/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/22/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
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☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
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APPLICATION AS AMENDED - PART II

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	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
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ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

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APPLICATION AS AMENDED - PART II

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/833,575
Examiner:	Unknown
Art Group:	3736
Reference No.:	BPMDL0005JT.D1.C1.C1.C1.C1 (10055U D1 C1 C1 C1 C1)
Appn. Filed:	March 28, 2020
Applicants:	Tomes, Jennifer et al.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

May 24, 2021

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Box: Amendment

This preliminary amendment is being filed prior to any Office Action being mailed in this matter. Entry of this paper into the file is respectfully requested.

Bard Exhibit 1004.0221

CLAIMS:

Listing of the claims:

1. (Currently Amended) A medical procedure kit, comprising:

   a ~~single layer~~ tray comprising a compartment separated by a wall from a lubricating jelly application chamber, and an opening allowing access to the lubricating jelly application chamber;

   a container of lubricating jelly disposed within the ~~single layer~~ tray; and

   a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the medical procedure kit ~~compartment~~;

   wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly.

2. (Currently Amended) The medical procedure kit of claim 1, further comprising one or more swabsticks disposed within the ~~single layer~~ tray.

3. (Currently Amended) The medical procedure kit of claim 1, further comprising a syringe containing water disposed within the ~~single layer~~ tray, wherein the syringe is at least partially disposed in the compartment with the Foley catheter.

4. (Currently Amended) The medical procedure kit of claim 1, the ~~wall comprising an~~ opening defined by an opening depth.

5. (Original) The medical procedure kit of claim 1, the container of lubricating jelly comprising a syringe containing the lubricating jelly.

6. (Original) The medical procedure kit of claim 5, the syringe situated within the lubricating jelly application chamber.

7. (Currently Amended) The medical procedure kit of claim 6, further comprising a second syringe disposed within the ~~single layer~~ tray.

8. (Original) The medical procedure kit of claim 7, the second syringe at least partially situated in the compartment.

9. (Original) The medical procedure kit of claim 7, the second syringe containing water.

10. (Original) The medical procedure kit of claim 9, wherein the water comprises sterile water.

11. (Currently Amended) The medical procedure kit of claim 7, wherein the syringe and the second syringe are arranged in the ~~single layer~~ tray in accordance with their order of use during a Foley catheterization procedure.

12. (Original) The medical procedure kit of claim 11, the lubricating jelly application chamber comprising one or more contours for accommodating flanges of one or more of the syringe or the second syringe.

13. (Currently Amended) A medical procedure kit, comprising:

a first syringe and a second syringe;

a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter;

a ~~single layer~~ tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly, and an opening allowing passage

of at least some of the medical assembly into a ~~container of~~ lubricating jelly application chamber~~, a container of water, and a coiled tubing coupling a Foley catheter to a drain bag, wherein each of the container of lubricating jelly, the container of water, the coiled tubing, the Foley catheter, and the drain bag are positioned within the single layer tray~~; and

an outer packaging disposed about the tray;

wherein:

one of the first syringe or the second syringe contains lubricating jelly;

another of the first syringe or the second syringe contains water;

the first syringe and the second syringe are ordered within the tray in accordance with their use during a Foley catheterization procedure; and

the first compartment defines one or more contours for accommodating one or more of the first syringe or the second syringe

~~a lubricating jelly application chamber defined by contours of the single layer tray, wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter when the lubricating jelly is in the lubricating jelly application chamber~~.

14. (Currently Amended) The medical procedure kit of claim 13, wherein the at least some of the medical assembly comprises at least some of the Foley catheter ~~container of lubricating jelly and the container of water are situated within the~~

~~single layer tray in accordance with their order of use during a Foley catheterization procedure~~.

15. (Currently Amended) The medical procedure kit of claim 14, wherein the tray comprises a third compartment containing one or more swabsticks ~~container of water comprises a syringe of water~~.

16. (Currently Amended) The medical procedure kit of claim 15, wherein the opening is defined by a boundary surface of the ~~container of~~ lubricating jelly application chamber ~~comprises a syringe of lubricating jelly~~.

17. (Currently Amended) The medical procedure kit of claim 16, wherein the opening allows passage of at least some of the coiled tubing into the lubricating jelly application chamber ~~comprising one or more contours for accommodating flanges of one or more of the syringe of water or the syringe of lubricating jelly~~.

18. (Currently Amended) A medical procedure kit, comprising:

a Foley catheter coupled to a fluid drain bag via a coiled tubing, a first syringe and a second syringe, one or more swabsticks, a specimen container, and a surface defining a tray having a lubricating jelly application chamber with the first syringe and the second syringe disposed within a single compartment and the one or more swabsticks disposed within another compartment;

~~a single layer tray defining a wall separating a compartment from a lubricating jelly application chamber;~~

~~a container of lubricating jelly situated in the lubricating jelly application chamber; and~~

~~a coiled tubing coupled between a Foley catheter and a drain bag situated within the compartment;~~

wherein:

the lubricating jelly application chamber is configured to receive at least some lubricating jelly from the first syringe ~~container of lubricating jelly~~ for lubricating at least a portion of the Foley catheter with the at least some lubricating jelly when the at least some lubricating jelly is in the lubricating jelly application chamber; and

the tray further defines an opening allowing passage of at least some of the coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of the Foley catheter.

19. (Currently Amended) The medical procedure kit of claim 18, wherein the ~~further comprising one or more of~~ one or more swabsticks~~, or a specimen container, or a container of water, or combinations thereof,~~ are disposed within the ~~single layer~~ tray.

20. (Currently Amended) The medical procedure kit of claim 19, further comprising a ~~the~~ wall ~~defining an opening~~ situated between the single compartment and the lubricating jelly application chamber.

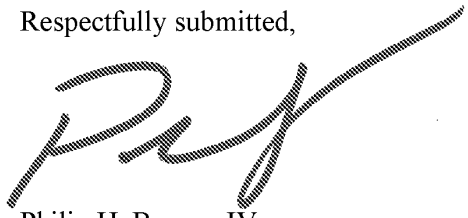
REMARKS – General

Voluntary amendments have been made above to more particularly set forth particular aspects of the claimed invention. It is respectfully submitted that support for each amendment above is found in the application as originally filed, with no new matter being added by way of amendment. Entry of this paper into the file is respectfully requested.

CONCLUSION

Applicant believes this application is now in condition for allowance, for which it respectfully submits.

Respectfully submitted,



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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code [1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5289919		1994-03-01	Fischer	
		10640243		2020- 05-05	Tomes et al.	

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code [1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20040031721		2004-02-19	Mann, David M.	
		20170202699		2017-07-20	Zani et al.	
		20170216558		2017-08-03	Hughett et al.	
		20170368302		2017-12-18	Brooks, Christopher	
		20190344044		2019-11-14	Dickinson et al.	

FOREIGN PATENT DOCUMENTS

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		"Summons to Attend Oral Proceedings", EP Application 11854003.8; Mailed December 22, 2020; 10055U CIP4 EP,	
		"Summons to Attend Oral Proceedings", EP Application 12792423.1; Mailed December 22, 2020; 10055U CIP6 EP,	
		"Summons to Attend Oral Proceedings", EP Application 12793939.5; Mailed December 23, 2020; 10055U CIP5 EP,	
		ARBLE, JESSICA , "Final OA", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed August 5, 2020,	
		ARBLE, JESSICA , "NonFinal Office Action", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed April 28, 2020,	

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	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

		ARBLE, JESSICA , "NonFinal Office Action", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed February 3, 2021,	
		ARBLE, JESSICA , "Notice of Allowance", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed August 17, 2021,	
		POON, ROBERT , "Final Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket No. 10055U D1 C2 C1; Mailed July 15, 2020,	
		POON, ROBERT , "NonFinal Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket NO. 10055U D1 C2 C1; Mailed March 31, 2021,	
		POON, ROBERT , "Notice of Allowance", USSN 15/703,514; Filed September 13, 2017; Attorney Docket No. 1037-002-09US; Mailed November 23, 2020,	
		POON, ROBERT , "Notice of Allowance", USSN 15/803,383; Filed November 3, 2017; Attorney Docket No. 1037-002-08US; Mailed November 27, 2020,	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2021-6-22
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16833575
Filing Date	March 28, 2020
First Named Inventor	Jennifer E. Tomes
Title	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
Art Unit	
Examiner Name	
Attorney Docket Number	10055UCIP2D1C1C1C1C1

SIGNATURE of Applicant or Patent Practitioner

Signature	/Philip H. Burrus, IV/	Date (Optional)	2021-6-22
Name	Philip H. Burrus, IV	Registration Number	45432
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA.
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 27939

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Medline Industries, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	David S. Noskowicz	Date (Optional)	17 MAR 2014
Name	David S. Noskowicz		
Title	Senior Patent Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	43059333
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	22-JUN-2021
Filing Date:	28-MAR-2020
Time Stamp:	19:35:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10055U_P2_D1_C1_C1_C1_C1_USA_2021-5-24_PreliminaryAmendment.pdf	118795 5df49e618b13449c2902c9de011dd2ca07df32d4	yes	8

	Multipart Description/PDF files in .zip description			
	Document Description	**Start**	**End**	
	Preliminary Amendment	1	1	
	Claims	2	6	
	Applicant Arguments/Remarks Made in an Amendment	7	8	

Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP2_D1_C1_C1_C1_C1_USA_2021-6-22_IDS.pdf	149489 d95d4eee492a87e62c0ea4ccfd9242e7956f3f86	no	5
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Non Patent Literature	1037-002-08US_2020-11-27_NoticeOfAllowance.pdf	634850 f336a631ec7ff1bfa0d5707ab1e4350faae25a4a	no	5
Warnings:					
Information:					
4	Non Patent Literature	1037-002-09US_2020-11-23_NoticeOfAllowance.pdf	726964 474a3dca54d55b64042654b179cd0c71307cb98c	no	7
Warnings:					
Information:					
5	Non Patent Literature	10055U_CIP4_EP_2020-12-22_SummonsToAttendOralHearing.pdf	554374 187eb65ddf60dd85caaaa8fe845141f2c818a92c	no	7
Warnings:					
Information:					
6	Non Patent Literature	10055U_CIP5_EP_2020-12-23_SummonsToAttendOralHearing.pdf	544992 b9e8a65a2d4c4a3d38dc28305066f96ed4561f09	no	7
Warnings:					
Information:					

7	Non Patent Literature	10055U_CIP6_EP_2020-12-22_SummonsToAttendOralHearing.pdf	430654 e087bbd5f9f79374227bd9d9b954fa80fe55542a	no	6
Warnings:					
Information:					
8	Non Patent Literature	10055U_D1_C2_C1_USA_2020-7-15_FinalOA.pdf	832390 499f75a793b2b3e7b7b4f6247053e8db47a159dd	no	11
Warnings:					
Information:					
9	Non Patent Literature	10055U_D1_C2_C1_USA_2021-3-31_NonFinalOA.pdf	858180 ad8823a560a8d8bce91ed17c8c918f5b9c12a444	no	12
Warnings:					
Information:					
10	Non Patent Literature	10055U_NP1_USA_2020-4-28_NonFinalOA.pdf	878960 18c5ea9155be1e99d7dd802e0014a9c5ce9e7222	no	11
Warnings:					
Information:					
11	Non Patent Literature	10055U_NP1_USA_2020-8-5_FinalOA.pdf	1137391 556f70c42b89f35a4ad78551325bb9fa0fe047bb	no	14
Warnings:					
Information:					
12	Non Patent Literature	10055U_NP1_USA_2021-2-3_NonFinalOA.pdf	1220354 23a8363845f84b709c5268b80f67aa45e08f10d3	no	16
Warnings:					
Information:					
13	Non Patent Literature	10055U_NP1_USA_2021-5-17_NoticeOfAllowance.pdf	979502 2231474f0623ba00e1042ed7ee06874c81f206bb	no	11
Warnings:					
Information:					

14	Power of Attorney	10055UCIP2D1C1C1C1C1_USA_2021-6-22_POA.pdf	601313 7ca40188e4e18b44bfb8c6c8397bd7fa160f5cbc	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	9668208	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/833,575	Filing Date 03/28/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/22/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CARMEN D WILLIAMS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/833,575	Filing Date 03/28/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/22/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CARMEN D WILLIAMS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1

CONFIRMATION NO. 5069

27939
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

POA ACCEPTANCE LETTER

OC000000126533837

Date Mailed: 06/25/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/22/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/zretta/

Document Description: Application Data Sheet to update/correct info
Doc Code: ADS.CORR

CORRECTED ADS FORM

Application Number	16833575
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

Inventor Information

****If no data is shown, no data has been corrected****

	Data of Record	Updated Data
Order Number		
Name		
Residence Information		
Residency		
City		
State		
Country of Residence		
Mailing Address of Inventor		
Address 1		
Address 2		
City,State/Province, Postal Code		
Country		

Document Description: Application Data Sheet to update/correct info
Doc Code: ADS.CORR

Application Information

	Data of Record	Updated Data
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	
Attorney Docket Number	10055UCIP2D1C1C1C1C1	
Entity Type	Regular Undiscounted	

Domestic Benefit/National Stage Information

****If no data is shown, no data has been corrected****

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121,365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S. C. 119(e) or 120, and 37 CFR 1.78(a).

		Data of Record	Updated Data
	Prior Application Status		
	Application Number		
	Continuity Type		
	Prior Application Number		
	Filing Date (YYYY-MM-DD)		
	Patent Number		
	Issue Date (YYYY-MM-DD)		

Foreign Priority Information

Bard Exhibit 1004.0244

Document Description: Application Data Sheet to update/correct info
Doc Code: ADS.CORR

****If no data is shown, no data has been corrected****

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

		Data of Record	Updated Data
	Application Number		
	Country		
	Filing Date		
	Access Code		

Applicant Information

****If no data is shown, no data has been corrected****
Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

	Data of Record	Updated Data
Applicant Type	ASG	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is		
Name of the Deceased or Legally Incapacitated Inventor		
Applicant is an Organization	Yes	
Name		
Organization Name	~~Medline Industries, Inc~~	Medline Industries, LP
Address 1		
Address 2		

Corrected ADS 1.0

City,State/Province,Postal Code	Northfield IL	
Country		
Phone Number		
Fax Number		
Email Address		

Assignee Information including Non-Applicant Assignee Information

****If no data is shown, no data has been corrected****
Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office

	Data of Record	Updated Data
Order		
Applicant is an Organization		
Name		
Organization Name		
Mailing Address		
Address 1		
Address 2		
City,State/Province,Postal Code		
Country		
Phone Number		
Fax Number		
Email Address		

Signature

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Philip H. Burrus, IV/	Registration Number	45432
First Name	Philip	Last Name	Burrus, IV

Bard Exhibit 1004.0247

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/833,575
Examiner:	Unknown
Art Group:	3736
Reference No.:	10055UCIP2D1C1C1C1C1
Appn. Filed:	March 28, 2020
First Inventor:	Jennifer E. Tomes
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

December 3, 2021

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

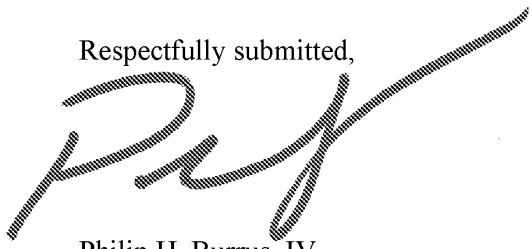
Request for Corrected Filing Receipt

Submitted herewith is a Supplemental Application Data Sheet for the above-referenced application. At the time of filing, the Applicant was a corporation. The Applicant entity type has changed to a limited partnership and is reflected as such on the amended Application Data Sheet. This change of name was recorded with the United States Patent and Trademark Office on October 31, 2021, at Reel 057977, Frame 0436.

Applicant respectfully requests an updated Filing Receipt. A Power of Attorney from Medline Industries, LP, is concurrently filed.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment of fees to Deposit Account No. 50-3608.

Respectfully submitted,



Philip H. Burrus, IV
Attorney for Applicant
Registration No.: 45,432
404-797-8111
404-880-9912 (fax)
pburrus@burrusiplaw.com

Electronic Acknowledgement Receipt

EFS ID:	44433975
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus
Filer Authorized By:	
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	03-DEC-2021
Filing Date:	28-MAR-2020
Time Stamp:	17:44:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet to update/ correct info	CorrectedADS.pdf	99688 964131a8bbf8f35381a4090197dc6fc0b3bede58	no	5

Warnings:

Information:					
2	Miscellaneous Incoming Letter	10055UCIP2D1C1C1C1C1_USA_2021-12-3_CorrectedFilingReceipt.pdf	104620 ce6b3c55adc368e7a8e22f12573ceb5319885fe4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	204308		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16833575
Filing Date	March 28, 2020
First Named Inventor	Jennifer E. Tomes
Title	Catheter Tray, Packaging System, Instruction Insert, and Associated Method s
Art Unit	3736
Examiner Name	
Attorney Docket Number	10055UCIP2D1C1C1C1C1

SIGNATURE of Applicant or Patent Practitioner

Signature	/Philip H. Burrus, IV/	Date (Optional)	2021-12-03
Name	Philip H. Burrus, IV	Registration Number	45432
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 27939

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Medline Industries, LP

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	David Noskowicz	Date (Optional)	11-18-2021
Name	David S. Noskowicz		
Title	Senior Patent Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	44434010
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus
Filer Authorized By:	
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	03-DEC-2021
Filing Date:	28-MAR-2020
Time Stamp:	17:46:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	10055UCIP2D1C1C1C1C1_USA_2021-12-3_POA.pdf	284755 a3c94871c5228167059db9e94be893880809622f	no	2

Warnings:

Information:	
Total Files Size (in bytes):	284755

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1

CONFIRMATION NO. 5069

27939
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

POA ACCEPTANCE LETTER

OC000000130260029

Date Mailed: 12/09/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 12/03/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/lqchau/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/833,575	03/28/2020	OPAP	1720	10055UCIP2D1C1C1C1C1	20	3

CONFIRMATION NO. 5069

CORRECTED FILING RECEIPT

27939
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

OC000000130280027

Date Mailed: 12/09/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Jennifer E. Tomes, Mundelein, IL;
Sarah Dickinson, Chicago, IL;
Deborah Adler, New York, NY;
Jack Maze, Long Grove, IL;
Alberto Savage, Buffalo Grove, IL;
Kenneth Chua, Glenview, IL;
Earl Wilson, Ingleside, IL;
John Kutsch, Harvard, IL;

Applicant(s)

Medline Industries, LP, Northfield, IL;

Power of Attorney: The patent practitioners associated with Customer Number 27939

Domestic Priority data as claimed by applicant

This application is a CON of 15/684,787 08/23/2017 PAT 10640243
which is a CON of 14/793,455 07/07/2015 PAT 9745088
which is a CON of 13/860,902 04/11/2013 PAT 9522753
which is a DIV of 13/155,026 06/07/2011 PAT 8448786
which claims benefit of 61/352,140 06/07/2010
and claims benefit of 61/352,155 06/07/2010
and claims benefit of 61/428,944 12/31/2010
and claims benefit of 61/437,796 01/31/2011
and is a CIP of 12/495,148 06/30/2009 PAT 8631935

Bard Exhibit 1004.0257

and is a CIP of 12/647,515 12/27/2009 ABN
and is a CIP of 13/153,265 06/03/2011 PAT 9795761
and is a CIP of 13/153,300 06/03/2011 ABN
and said 12/495,148 06/30/2009
claims benefit of 61/183,629 06/03/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 04/07/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/833,575**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No
Title

Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Bard Exhibit 1004.0258

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed

from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

Bard Exhibit 1004.0260

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1	5069

27939 7590 09/13/2022

Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3781	

NOTIFICATION DATE	DELIVERY MODE
09/13/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

kberry@burrusiplaw.com
pburrus@burrusiplaw.com

Office Action Summary	Application No. 16/833,575	Applicant(s) Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 28 March 2020 and 22 June 2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 28 March 2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Bard Exhibit 1004.0262

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 14 calls for "…wherein ***the at least some of*** the medical assembly comprises ***at least some of*** the Foley catheter." This language is ambiguous because it defines the medical assembly in terms of overlapping and intermediate degrees of both the medical assembly and Foley catheter. Examiner suggests to remove one of the "at least some of" qualifiers to clarify the claim.

Claims 15-17 are rejected for depending on a rejected parent claim.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 of this title, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Solazzo; Anthony (US 20060009742 A1) in view of Serany; Frank J. Jr. et al. (US 3329261 A).

Regarding claim 1, Solazzo discloses a medical procedure kit (¶ [0002], ergonomic urological catheterization/irrigation tray; ¶ [0011], [0038] , tray 1), comprising:

a tray (¶ [0011], tray 1);

comprising a compartment separated by a wall from a lubricating jelly application chamber (¶ [0040] Optional Foley catheter lubricating wells 31 and 33 are available for right handed and left handed users); and

an opening allowing access to the lubricating jelly application chamber (Figs. 1, 3-5 and 8, lubricating wells 31 and 33 are each accessible from their top surfaces);

a container of lubricating jelly disposed within the tray (¶ [0043] FIG. 8 … a tube of lubricant fluid 140); and

a Foley catheter, wherein the Foley catheter is disposed within the medical procedure kit (¶ [0043] FIG. 8 … catheter 120);

wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly (¶ [0040], that lubricating material could be applied to the catheter or other insertion device by filling the well with lubricant and then sliding the device through the lubricant in the well).

Regarding the limitation of an opening allowing access to the lubricating jelly application chamber, Solazzo shows that lubricating wells 31 and 33 are defined by a depressed or concave area with a top opening.

Solazzo teaches the invention substantially as claimed by Applicant but lacks a coiled tubing and a drain bag. Serany discloses a compact package containing sterile components for catheterization (col. 1, lines 25-30), comprising:

a tray comprising a compartment (col. 1, lines 60-65, a box 10 having an open top with a tray 12 mounted thereon); and

a container of lubricating jelly disposed within the tray (col. 3, lines 1-5, A plastic pouch accommodated in a depression 38 in the tray is removed from the latter and the contents including lubricating jelly in an individually sealed pouch 40); and

a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the package (col. 3, lines 20-25, Included in the box 10 beneath the tray 12 are a collapsible drainage bottle 46 and a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use).

Serany packages accessories for a catheterization procedure which safely store urine drained from a patient. One would be motivated to modify Solazzo with Serany's coiled tubing and drain bag in order to collect urine without spilling. A skilled artisan would have been able to modify Solazzo with Serany's coiled tubing and drain bag by including a coiled tubing and drain bag in Solazzo's tray instead of only a Foley catheter. Therefore, it would have been obvious to modify Solazzo with Serany's coiled tubing and drain bag in order to safely collect urine during a procedure.

Regarding claim 2, Solazzo lacks swabsticks. Serany discloses a kit further comprising one or more swabsticks disposed within the tray (col. 2, lines 55-65, The tray also has a depression 32 for balls 34 of cleansing material, e.g. rayon, … The balls are handled by forceps 36).

Serany adds accessories for cleaning a patient during a catheterization procedure. One would be motivated to modify Solazzo with Serany's swabsticks so that a caregiver can clean the patient before inserting a catheter and thereby prevent

infection. Therefore, it would have been obvious to modify Solazzo with Serany's swabsticks in order for a caregiver to clean a patient.

Regarding claim 3, Solazzo discloses a kit further comprising a syringe containing water disposed within the tray (¶ [0025] (e.) an inflation syringe for inflation of a catheter with fluid; ¶ [0043], urinary tract inflation syringe 10).

Solazzo does not explicitly dispose the syringe in the compartment with the Foley catheter. However, Solazzo shows that the Foley catheter is packaged with another container, which holds lubricant (Fig. 8, lubricant fluid 140). A skilled artisan would have been able to modify Solazzo by switching the locations of inflation syringe 10 and lubricant fluid 140. The tray offers a limited number of options for storing the two containers. The two containers could be placed in one of the two compartments (two options), or placed separately in the two compartments (two options). Selecting one of these four options would have been an obvious approach for storing accessories in the tray.

Claim 5 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Solazzo and Serany, further in view of Fischer; Herbert et al. (US 4554156 A).

Regarding claim 5, Solazzo and Serany do not disclose a syringe containing lubricating jelly. Fischer discloses a wound treating agent (col. 1, lines 5-20);

comprising a syringe containing a viscous fluid (col. 3, lines 40-50, it is also possible first to convert the powder with a limited amount of liquid into a paste-like

consistency and to apply the so obtained gel paste. Syringes are particularly suitable for applying the paste).

Fischer demonstrates that a syringe is also suitable for storing a viscous gel material in the context of applying a medical product to a patient (col. 3, lines 40-50, Application with a syringe containing such a gel paste is very simple in a hospital. The gel is extruded on to and into the wound and left there as long as appears to be expedient. For this purpose, pre-filled sterile ready-to-use syringes can also be employed). One would be motivated to modify Solazzo and Serany by storing lubricant in a syringe as taught by Fischer since a syringe can dispense a fluid with greater accuracy and convenience. Therefore, it would have been obvious to modify Solazzo and Serany with Fischer's lubricating jelly syringe in order to store a fluid in a standard container, and to dispense the lubricant more conveniently.

Double Patenting

The following copending and patented applications are relevant to the claimed invention:

- Dickinson; Sarah et al. US 11116937 B2
- Tomes; Jennifer E. et al. US 10624614 B2
- Lockwood; Robert et al. US 9795761 B2
- Lockwood; Robert et al. US 10946169 B2

Each application claims a medical procedure kit, tray or method. However, none of the cited applications claim an opening through a wall that allows access to a lubricating jelly application chamber. Therefore none of the references are cited in a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 13 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of Tomes '400; Jennifer E. et al. (US 9808400 B2).

Regarding pending claim 1, Tomes '400 claims all limitations in patented claim 1, including a lubricating jelly application chamber separated by a wall (claim 1, the single level tray including a barrier separating the first compartment from the second compartment); and

an opening allowing access to the lubricating jelly application chamber (claim 1, the opening of the barrier sized to receive a portion of the indwelling catheter when the indwelling catheter is passed from the second compartment into the first compartment to lubricate the indwelling catheter).

Regarding pending claim 13, Tomes '400 claims all limitations in patented claim 1, including a first syringe and a second syringe (claim 1, a first syringe containing an inflation fluid … a second syringe containing a lubricant);

a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 1, the first syringe disposed within the first compartment of the single level tray … the second syringe disposed within the single level tray); and

a second compartment for receiving at least a portion of the medical assembly (claim 1, the coiled tube, and the fluid receptacle disposed within the second compartment of the single level tray); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 1, the opening of the barrier sized to receive a portion of the indwelling catheter when the indwelling catheter is passed from the second compartment into the first compartment to lubricate the indwelling catheter).

Regarding pending claim 18, Tomes '400 claims all limitations in patented claims 1 and 2, including a first syringe and a second syringe disposed within a single compartment (claim 1, the first syringe disposed within the first compartment of the single level tray … the second syringe disposed within the single level tray); and

one or more swabsticks, a specimen container; the one or more swabsticks disposed within another compartment (claim 2, a third compartment configured to accommodate at least one of a specimen container or a skin cleanser);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber

lubricates at least a portion of a Foley catheter (claim 1, the opening of the barrier sized to receive a portion of the indwelling catheter when the indwelling catheter is passed from the second compartment into the first compartment to lubricate the indwelling catheter).

Although Tomes '400 does not explicitly claim swabsticks, Tomes '400 claims a skin cleanser (claim 2). Swabs or swab sticks are a common form of cleaning article provided in medical settings.

Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 7 of Tomes '812; Jennifer E. et al. (US 10251812 B2).

Regarding pending claim 1, Tomes '812 claims all limitations in patented claims 1, 2 and 7, including a lubricating jelly application chamber separated by a wall (claim 1, the tray comprising … a first compartment; claim 2, the first compartment defining a lubricating jelly applicator); and

an opening allowing access to the lubricating jelly application chamber (claim 7, the first barrier defining a first opening between the first compartment and the second compartment).

Regarding pending claim 13, Tomes '812 claims all limitations in patented claims 1 and 7, including a first syringe and a second syringe;

a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 1, a first syringe disposed within the first compartment of the tray; a second syringe disposed within the first compartment of the tray); and

a second compartment for receiving at least a portion of a medical assembly (claim 1, a catheter assembly comprising a fluid bag disposed within the second compartment of the tray); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 7, the first barrier defining a first opening between the first compartment and the second compartment).

Claim 18 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 12, 13 and 15 of Tomes '812; Jennifer E. et al. (US 10251812 B2) in view of House; Jamie Glen (US 20070225687 A1).

Regarding pending claim 18, Tomes '812 a kit in patented claims 7, 12, 13 and 15, including a first syringe and a second syringe disposed within a single compartment (claim 12, a first syringe and a second syringe disposed in the first compartment);

a specimen container; the specimen container disposed within another compartment (claim 13, a third compartment … further comprising a specimen container disposed in the third compartment);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of a Foley catheter (claim 7, the first barrier defining a first opening between the first compartment and the second compartment; claim 15, the barrier having a first barrier opening).

Tomes '812 does not explicitly claim swabsticks. House discloses an indwelling urinary catheter assembly (¶ [0014], [0040], FIG. 1A … assembly 100a); including swabsticks (¶ [0117] In addition to the sheathed catheter assembly, the kit preferably also contain one or more packaged antiseptic swabs 79 (e.g., swabs saturated with Betadine, Povidone-Iodine or other suitable antiseptic)).

House packages a catheter assembly with common accessories used during a catheterization procedure (¶ [0122], The packet 79 containing the antiseptic swabs is opened and the urethral area around the urethral opening is cleansed using the antiseptic swabs). One would be motivated to modify Tomes '812 with House's swabsticks to perform a cleaning step during a catheterization procedure to minimize the chance of infection. Therefore, it would have been obvious to modify Tomes '812 with House's swabsticks in order to minimize the risk of infection by cleaning a patient prior to a catheterization procedure.

Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29, 34, 36, 37 and 44 of Tomes '753; Jennifer E. et al. US 9522753 B2).

Regarding pending claim 1, Tomes '753 claims all limitations in patented claims 29, 34, 37 and 44, including a lubricating jelly application chamber separated by a wall (claim 29, a catheter package assembly; claim 34, at least three compartments separated by barriers and a perimeter wall … a first barrier separating the first compartment from the second compartment; claim 37, the first compartment defining a lubricating jelly application chamber); and

an opening allowing access to the lubricating jelly application chamber (claim 44, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening).

Regarding pending claim 13, Tomes '753 claims all limitations in patented claims 29, 36 and 44, including a first syringe and a second syringe (claim 29, a first syringe and a second syringe disposed within the single level tray);

a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 36, the first compartment to support the first syringe and the second syringe at different heights);

a second compartment for receiving at least a portion of a medical assembly (claim 36, the coiled medical device disposed within the second compartment); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 44, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening).

Claim 18 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 29, 36 and 44 of Tomes '753; Jennifer E. et al. (US 9522753 B2) in view of House; Jamie Glen (US 20070225687 A1).

Regarding pending claim 18, Tomes '753 claims all limitations in patented claims 3, 29, 36 and 44, including a first syringe and a second syringe disposed within a single compartment (claim 29, a first syringe and a second syringe disposed within the single

level tray; claim 36, the first compartment to support the first syringe and the second syringe at different heights);

one or more swabsticks; the one or more swabsticks disposed within another compartment (claim 3, wherein the one or more medical devices comprise gloves, hand sanitizer, alcohol wipes);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of a Foley catheter (claim 44, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening).

Regarding the limitation of swabsticks, Tomes '753 claims alcohol wipes (claim 3). Swabs or swab sticks are a common form of cleaning wipe provided in medical settings.

Tomes '753 does not explicitly claim a specimen container. House discloses an indwelling urinary catheter assembly (¶ [0014], [0040], FIG. 1A … assembly 100a); including a specimen container (¶ [0117], the kit preferably also contain … small urine specimen bottle (with cap) 78).

House packages a catheter assembly with common accessories used during a catheterization procedure (¶ [0125] After commencement of urine flow, outlet 18 of catheter 10 may be directed briefly into the specimen container 78, to collect a sterile specimen, if needed). One would be motivated to modify Tomes '753 with House's specimen container to collect a clean specimen during a catheterization procedure and optionally analyze it for infection or other problems. Therefore, it would have been

obvious to modify Tomes '753 with House's specimen container in order to collect a urine sample for later analysis.

Claims 1, 2, 4-13 and 16-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 20, 37-39, 46-49 and 54 of Tomes '088; Jennifer E. et al. US 9745088 B2).

Regarding pending claim 1, Tomes '088 claims all limitations in patented claims 1, 4 and 5, including a lubricating jelly application chamber separated by a wall (claim 1, a medical procedure kit … the at least two compartments comprising a first compartment to support the first syringe and the second syringe; claim 4, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening; claim 5, the first compartment defining a lubricating jelly application chamber); and

an opening allowing access to the lubricating jelly application chamber (claim 4, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening).

Regarding pending claim 13, Tomes '088 claims all limitations in patented claims 1 and 4, including a first syringe and a second syringe; a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 1, a medical procedure kit, comprising … a first syringe and a second syringe disposed within the tray);

a second compartment for receiving at least a portion of a medical assembly (claim 1, a tray having a compartment for receiving a medical assembly; claim 4, the at

least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening, further comprising a catheter assembly disposed within the second compartment, the catheter assembly comprising a fluid bag); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 4, a second compartment separated from the first compartment by a wall with an opening).

Regarding pending claim 18, Tomes '088 claims all limitations in patented claims 1, 4, 5, 49 and 54, including a first syringe and a second syringe disposed within a single compartment (claim 1, a medical procedure kit; claim 4, the first compartment to support the first syringe and the second syringe at different heights);

one or more swabsticks, a specimen container; the one or more swabsticks disposed within another compartment (claim 49, further comprising a specimen jar disposed within the single layer tray; claim 54, further comprising one or more swabsticks disposed within the single layer tray);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of a Foley catheter (claim 4, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening; claim 5, the first compartment defining a lubricating jelly application chamber).

Pending claims 2, 4-12, and 16-20 are rejected over patented claims 1, 4, 20, 37-39, 46-48 and 54 of Tomes '088 as shown in table 1.

Table 1: Tomes '088 double patenting			
Pending claim	Tomes '088	Pending claim	Tomes '088
2	54	10	48
4	4	11	37
5	46	12	39
6	37, 38	16	1, 4
7	37	17	20
8	37	19	54
9	47	20	1, 4

Claims 1, 13 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 11-13, 18 and 19 of Tomes '243; Jennifer E. et al. (US 10640243 B2).

Regarding pending claim 1, Tomes '243 claims all limitations in patented claims 1 and 4, including a lubricating jelly application chamber separated by a wall (claim 1, a medical procedure kit, comprising: a single layer tray comprising a compartment and a lubricating jelly application chamber separated by a wall with an opening); and

an opening allowing access to the lubricating jelly application chamber (claim 4, the opening in the wall located between the compartment and the lubricating jelly application chamber).

Regarding pending claim 13, Tomes '243 claims all limitations in patented claims 1, 4, 5, 7 and 11-13, including a first syringe and a second syringe (claim 1, a medical procedure kit; claim 11, wherein the first syringe and the second syringe are arranged in the single layer tray in accordance with their order of use during a Foley catheterization procedure);

a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 5, the container of lubricating jelly comprising a syringe containing the lubricating jelly; claim 7, further comprising a second syringe disposed within the single layer tray; claim 12, the lubricating jelly application chamber comprising one or more contours for accommodating flanges of one or more of the syringe or the second syringe);

a second compartment for receiving at least a portion of a medical assembly (claim 13, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the compartment); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 1. A medical procedure kit, comprising: a single layer tray comprising a compartment and a lubricating jelly application chamber separated by a wall with an opening; 4, the opening in the wall located between the compartment and the lubricating jelly application chamber).

Regarding pending claim 18, Tomes ‘243 claims all limitations in patented claims 1, 12, 18 and 19, including a first syringe and a second syringe disposed within a single compartment (claim 1, a medical procedure kit; claim 12, the lubricating jelly application chamber comprising one or more contours for accommodating flanges of one or more of the syringe or the second syringe);

one or more swabsticks, a specimen container; the one or more swabsticks disposed within another compartment (claim 18, one or more medical devices disposed within the single layer tray, claim 19, wherein the one or more medical devices comprise one or more of: one or more swabsticks, or a specimen container);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of a Foley catheter (claim 1, a single layer tray comprising a compartment and a lubricating jelly application chamber separated by a wall with an opening).

Claims 1, 13 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of Tomes '992; Jennifer E. et al. US 10946992 B2).

Regarding pending claim 1, Tomes '992 claims all limitations in patented claim 1, including a lubricating jelly application chamber separated by a wall (claim 1, a medical procedure kit, comprising: a single layer tray comprising a first compartment, a second compartment, and a third compartment, the first compartment being separated from the second compartment by a wall … the first compartment defining a lubricating jelly application chamber);

a container of lubricating jelly (claim 3, wherein the first syringe contains lubricating jelly);

an opening allowing access to the lubricating jelly application chamber (claim 1, the wall defining an opening through which the portion of the Foley catheter can be passed to lubricate the portion of the Foley catheter).

Regarding pending claim 13, Tomes '992 claims all limitations in patented claim 1, including a first syringe and a second syringe; a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 1, a medical procedure kit,

comprising: a single layer tray comprising a first compartment, a second compartment … the first compartment being separated from the second compartment by a wall; a first syringe and a second syringe each disposed within the single layer tray);

a second compartment for receiving at least a portion of a medical assembly (claim 1, a Foley catheter coupled to a fluid drain bag via a coiled tubing, the Foley catheter disposed within the second compartment such that the fluid drain bag is between a base member of the single layer tray and the Foley catheter); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 1, the first compartment defining a lubricating jelly application chamber … the wall defining an opening through which the portion of the Foley catheter can be passed to lubricate the portion of the Foley catheter).

Regarding pending claim 18, Tomes '992 claims all limitations in patented claim 1, including a first syringe and a second syringe (claim 1, a first syringe and a second syringe each disposed within the single layer tray);

one or more swabsticks, a specimen container; the one or more swabsticks disposed within another compartment (claim 1, one or more swabsticks; and a specimen container, one or both of the one or more swabsticks and the specimen container being disposed within the third compartment);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of a Foley catheter (claim 1, the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of the Foley catheter,

the wall defining an opening through which the portion of the Foley catheter can be passed to lubricate the portion of the Foley catheter).

Tomes '992 does not explicitly claim that the first and second syringes are disposed within a single compartment. However, this would have been an obvious choice since the number of options are limited. Tomes '992 claims that the kit comprises three compartments (claim 1, a first compartment, a second compartment, and a third compartment), and that the Foley catheter and bag occupy the second compartment (claim 1, the Foley catheter disposed within the second compartment) . Placing both of the syringes in the first compartment will enable the syringes to fit in the remaining open space.

Claims 1, 13 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 9, 11 and 13 of Tomes '352; Jennifer E. et al. US 9283352 B2).

Regarding pending claim 1, Tomes '352 claims all limitations in patented claims 1, 9 and 11, including a lubricating jelly application chamber separated by a wall (claim 1, a catheterization procedure system … the first compartment defines a lubricating jelly application compartment);

a container of lubricating jelly (claim 1, a lubricating jelly application compartment to receive lubricating jelly from the one of the first syringe or the second syringe); and

an opening allowing access to the lubricating jelly application chamber (claim 9, the wall to separate the first compartment from other compartments of the at least two compartments, the wall defining an opening; claim 11, at least one opening defined in

the single level tray to allow the catheter to pass from the second compartment into the lubrication channel).

Regarding pending claim 13, Tomes '352 claims all limitations in patented claims 1, 9 and 11, including a first syringe and a second syringe (claim 1, a first syringe and a second syringe);

a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 1, the first syringe and the second syringe are disposed within the first compartment);

a second compartment for receiving at least a portion of a medical assembly (claim 1, the catheter and the fluid bag are disposed within the second compartment); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 9, the wall to separate the first compartment from other compartments of the at least two compartments, the wall defining an opening; claim 11, at least one opening defined in the single level tray to allow the catheter to pass from the second compartment into the lubrication channel).

Regarding pending claim 18, Tomes '352 claims all limitations in patented claims 1, 6, 9, 11 and 13, including a first syringe and a second syringe disposed within a single compartment (claim 1, the first syringe and the second syringe are disposed within the first compartment);

one or more swabsticks and a specimen container; the one or more swabsticks disposed within another compartment (claim 6, further comprising a specimen

container; claim 13, a third compartment, further comprising one or more swabsticks disposed within the third compartment);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of a Foley catheter (claim 9, the wall to separate the first compartment from other compartments of the at least two compartments, the wall defining an opening; claim 11, at least one opening defined in the single level tray to allow the catheter to pass from the second compartment into the lubrication channel).

Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Tomes '596; Jennifer E. et al. US 9808596 B2).

Regarding pending claim 1, Tomes '596 claims all limitations in patented claim 1, including a lubricating jelly application chamber separated by a wall (claim 1, a catheterization kit … the single level tray including a barrier and a perimeter wall … the barrier defining an opening … the first compartment configured to receive the lubricating jelly from the second syringe);

a container of lubricating jelly (claim 1, the first compartment configured to receive the lubricating jelly from the second syringe); and

an opening allowing access to the lubricating jelly application chamber (claim 1, the opening of the barrier sized to receive a portion of the Foley catheter when a tip of the Foley catheter is passed from the second compartment into the first compartment to lubricate the tip of the Foley catheter).

Regarding pending claim 13, Tomes '596 claims all limitations in patented claim 1, including a first syringe and a second syringe (claim 1, the first syringe containing an inflation fluid … the second syringe containing a lubricating jelly);

a tray comprising a first compartment for receiving the first syringe and the second syringe (claim 1, a first syringe disposed in the first compartment … a second syringe disposed in the first compartment);

a second compartment for receiving at least a portion of a medical assembly (claim 1, a Foley catheter disposed in the second compartment); and

an opening allowing passage of at least some of the medical assembly into a lubricating jelly application chamber (claim 1, the opening of the barrier sized to receive a portion of the Foley catheter when a tip of the Foley catheter is passed from the second compartment into the first compartment to lubricate the tip of the Foley catheter).

Claim 18 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Tomes '596; Jennifer E. et al. US 9808596 B2) in view of House; Jamie Glen (US 20070225687 A1).

Regarding pending claim 18, Tomes '596 claims a kit including a first syringe and a second syringe disposed within a single compartment (claim 1, a first syringe disposed in the first compartment … a second syringe disposed in the first compartment);

multiple compartments (claim 1, a single level tray defining a first compartment and a second compartment);

a tray defining an opening allowing passage of at least some of coiled tubing into a lubricating jelly application chamber when the lubricating jelly application chamber lubricates at least a portion of a Foley catheter (claim 1, the opening of the barrier sized to receive a portion of the Foley catheter when a tip of the Foley catheter is passed from the second compartment into the first compartment to lubricate the tip of the Foley catheter).

Tomes '596 does not explicitly claim swabsticks or a specimen container. House discloses an indwelling urinary catheter assembly (¶ [0014], [0040], FIG. 1A … assembly 100a); including swabsticks (¶ [0117] In addition to the sheathed catheter assembly, the kit preferably also contain one or more packaged antiseptic swabs 79 (e.g., swabs saturated with Betadine, Povidone-Iodine or other suitable antiseptic)); and

a specimen container (¶ [0117], the kit preferably also contain … small urine specimen bottle (with cap) 78).

House packages a catheter assembly with common accessories used during a catheterization procedure (¶ [0122], [0125]). One would be motivated to modify Tomes '596 with House's swabsticks and specimen container to cleanse the patient's urethral area prior to inserting a catheter, and to collect a clean specimen and optionally analyze it for infection or other problems. Therefore, it would have been obvious to modify Tomes '596 with House's swabsticks and specimen container in order to clean a patient prior to catheterization and to collect a urine sample for later analysis.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Zoland; Mark P. et al. US 20110017621 A1
- Malessa; Ralf et al. US 20100272669 A1
- Dominguez; Angel I. et al. US 20110225726 A1
- Horan; Robert et al. US 5339955 A
- Schommer; Philip E. et al. US 5887749 A

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8am-4pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached at 571-272-1115. The fax phone number for the organization where this application is assigned is 571-273-8300.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov.

Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

Notice of References Cited	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20110017621-A1	01-2011	Zoland; Mark P.	A61B50/13	211/85.13
*	B	US-20100272669-A1	10-2010	Malessa; Ralf	A61P17/00	264/161
*	C	US-20110225726-A1	09-2011	Dominguez; Angel I.	A61M3/0287	4/650
*	D	US-5339955-A	08-1994	Horan; Robert	A61B50/33	206/370
*	E	US-5887749-A	03-1999	Schommer; Philip E.	A47G19/02	220/575
*	F	US-4554156-A	11-1985	Fischer; Herbert	A61L26/0052	514/704
	G					
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	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Bard Exhibit 1004.0289

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/833,575	Tomes et al.
	Examiner	Art Unit
	Adam M Marcetich	3781

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B50/30, A61B50/33, A61M25/00, A61M25/002, A61B2050/3008, A61J2205/50, A61M5/002, A61M25/0017, A61M2209/06	09/06/2022	AMM
B65B11/00, A61L2202/18, A61L2202/182	09/06/2022	AMM

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
Inventor search in US-PGPUB, USPAT	09/06/2022	AMM
Review cited art for related cases 12495148, 12647515, 13153265, 13153300, 13155026, 13860902, 14793455, 15684787	09/06/2022	AMM
Review Inter Partes Review cases IPR2015-00509, IPR2015-00511, IPR2015-00513, IPR2019-00035, IPR2019-00036, IPR2019-00109	09/06/2022	AMM

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

/Adam Marcetich/ Primary Examiner, Art Unit 3781	

Bard Exhibit 1004.0290

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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L224	7	L209 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe	(USPAT)	OR	ON	ON	2022/09/06 04:22 PM
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L229	304	L228 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe	(USPAT)	OR	ON	ON	2022/09/07 07:45 AM
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L232	5	L207 AND (tubing coil coiled catheter) near3 (opening through hole).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 11:14 AM
L233	0	L207 AND (third further extra) near3 (swab swabstick swabsticks).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 11:16 AM

There are no Interference searches to show.

Receipt date: 07/14/2020

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		"Final Written Decision", IPR 2019-00035; Patent No. 9,745,008; Entered April 8, 2020; Docket No. 10055U CIP2 D1 C1,	
		"Final Written Decision", IPR 2019-00036; Patent No. 9,745,008; Entered April 8, 2020; Docket No. 10055U CIP2 D1 C1,	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

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		"Final Written Decision", IPR 2019-00109; Mailed May 4, 2020; Patent No. 9,795,761,	
		"Final Written Decision", IPR 2019-00208; Patent No. 9,808,400; Entered June 3, 2020; Docket No. 10055U D1 C1,	
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		POTHIER, ANDREW , "Office Action", Canadian Application No. 2,837,289; Mailed February 27, 2020,	
		POTHIER, ANDREW , "Office Action", Canadian Application No. 2822905; Mailed February 27, 2020,	

EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	09/02/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2020-7-14
Name/Print	Philip H. Burrus	Registration Number	45,432

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		2715296		1955-08-16	Petit, Frank	
		2781611		1957-02-19	West, Bill	
		2886316		1959- 05-12	Ayala, Carl	
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		3013656		1961-12-19	Murphy, Jr., William P	
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		3166189		1965-01-19	Disston	

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	Examiner Name	
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		3315802		1967-04-25	Maro	
		3329261		1967-07-04	Serany, Jr., F. J., et al.	
		D209641		1967-12-19	Goldberg, D	
		3379339		1968-04-23	Asenbauer, Donald	
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		3965900		1976-06-29	Boedecker, Steven	
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		3998221		1976-12-21	Collins, Robert F.	
		4011944		1977-03-15	Cooley	
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		4075782		1978-02-28	Neuschatz, Joseph	
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		D249362		1978-09-12	Forsman et al.	
		4140127		1979-02-20	Ciani et al.	
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		4458705		1984-07-10	Cawood, Charles	
		D275886		1984-10-09	Sheward et al.	
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		D287760		1987-01-13	Discko, Jr., John J.	
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		IPR Petition 2001, Declaration of Meyst dated January 11, 2019; IPR 2019-00035, IPR-2019-00036,	
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		IPR Petition Exhibit 2001, Declaration of Meyst dated February 22, 2019; IPR2019-00109,	
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		Medline Industries Inc. vs C.R Bard, Inc: Exhibit F to C.R. Bard's LPR 2.3 Contentions; Civil Action No. 1.17-cv-7216; Judge Sara L. Ellis; Filed January 16.2018.,	
		Medline Industries Inc. vs C.R Bard. Inc., Exhibit 4 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529: Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline Industries Inc. vs C.R Bard. Inc., Exhibit C to Declaration of Nicole Smith in Support of Bard Reply to Claim Construction Brief; Civil Action No. 1.16-cv-03529; Judge Sharon Johnson Coleman. Filed January 12. 2018.,	
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		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit C to Declaration of Nicole Smith in Support of Bard Reply to Medline Claim Construction Brief; Civil Action No. 116-cv-03529; Judge Sharon Johnson Coleman; Filed January 27,2017,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit F to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman: Filed December 9, 2016.,	

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		Medline Industries Inc. vs C.R. Bard, Inc; Exhibit A (List of Invalidating Prior Art) to C R. Bard's LPR 2 3 Contentions; Civil Action No. t:17-cv-7216; Judge Sara L. Ellis; Filed January 16.2018.,	
		Medline Industries inc. vs C R. Bard, Inc; Exhibit E to Declaration of Dylan Raife in Support of Motion for Leave to Add Counterclaims; Civil Action No. 1:17-cv-7216; Judge Sara L. Ellis; Filed February 27.2018.,	
		Medline industnes Inc, vs C.R Bard, Inc.; Exhibit A to Declaration of Nicole M. Smith; Civil Action No. 1:14-cv-03618; Judge John 2. Lee: Filed June 4, 2016.,	
		Medline industnes Inc. vs C R. Bard, Inc; C.R Bard's LPR 2 3 Contentions; Civil Action No. 1:17-cv-7216, Judge Sara L. Ellis; Filed January 16,2018.,	
		Medline Industnes Inc. vs C R. Bard, Inc; Declaration oi Nicole M Smith in Support of Bard Opening Claim Construction Brief; Civil Action No. 1:14-cv-03618: Judge John 2. Lee; Filed June 4,2016.,	
		Medline industnes Inc. vs C R. Bard, Inc; Exhibit B to Declaration of Dylan Raife in Support of Motion for Leave to Add Counterclaims; Civil Action No. 1:17-cv7216; Judge Sara L. Ellis; Filed February 27,2018.,	
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		Medline Industries Inc. vs C.R Bard, Inc., Declaration of Barbara Weintraub re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 22.2017.,	
		Medline industries Inc. vs C.R Bard, Inc., Declaration of Dylan J Raife in Support of Bard Opening Claim Construction Brief; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 17, 2017.,	
		Medline Industries Inc. vs C.R Bard, Inc., Declaration of Nicole Smith in Support of Bard Reply to Medline Claim Construction Brief; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed January 27,2017.,	
		Medline Industries Inc. vs C.R Bard, Inc., Exhibit 1 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline Industries Inc. vs C.R Bard, Inc., Exhibit 2 lo Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9,2016.,	

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		Medline Industries Inc. vs C.R Bard, Inc., Exhibit 7 to Declaration of Richard Meyst Regarding Claim Construction: Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8.2016.,	
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		Medline Industries Inc. vs C.R Bard, Inc., Exhibit A to Declaration of Kevin A. Lake. Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R Bard, Inc., Exhibit B to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529: Judge Sharon Johnson Coleman: Filed December 9,2016.,	
		Medline industries Inc. vs C.R Bard, inc., Exhibit F to Declaration of Dyian J. Raife in Support of Bard Opening Claim Construction Brief, Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 11, 2016.,	
		Medline Industries Inc. vs C.R Bard, Inc., Exhibit F to Declaration of Nicole Smith in Support of Bard Reply to Medline Claim Construction Brief; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed January 27,2017.,	
		Medline Industries Inc. vs C.R Bard, Inc., Exhibit H to Declaration of Kevin A. Lake; Civil Action No. 1:14-cv-03618: Judge John Z. Lee; Filed July 8,2016.,	
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		Medline Industries Inc. vs C.R Bard, Inc.. Exhibit 10 to Declaration of Richard Meyst Regarding Claim Construction: Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R Bard, Inc.. Exhibit 2 to Declaration of Brian Eutermoser in Support of Medline Surrepiy: Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed September 7,2016.,	
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		Medline Industries Inc. vs C.R Bard, Inc.. Exhibit E to Declaration of Nicole Smith in Support of Bard Reply to Medline Claim Construction Brief; Civil Action No 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed January 27.2017.,	
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		Medline Industries Inc. vs C.R Bard, Inc.; Bard Reply to Medline Claim Construction Brief; Civil Action No 1 l6-cv-03529; Judge Sharon Johnson Coleman; Filed January 27,2017.,	
		Medline Industries Inc. vs C.R Bard, Inc.; C. R. Bard's Reply in Support of Claim Construction Brief; Civil Action No. 1.14-cv-03618, Judge John Z. Lee; Filed August 15,2016.,	
		Medline Industries Inc. vs C.R Bard, Inc.; Declaration of Karl L Leinsing in Support of Bard's Rebuttal on Claim Construction; Civil Action No 1:16-CV-03529; Judge Sharon Johnson Coleman; Filed January 12, 2018,	
		Medline Industries Inc. vs C.R Bard, Inc.; Declaration of Karl L. Leinsing in Support of Bard's Rebuttal on Claim Construction; Civil Action No. 1.14-cv-03618. Judge John Z. Lee; Filed August 15,2016.,	
		Medline Industries Inc. vs C.R Bard, Inc.; Declaration of Richard Meyst re Claim Construction; Civil Action No. 1.16-cv-03529. Judge Sharon Johnson Coleman; Filed December 9,2016.,	
		Medline Industries Inc. vs C.R Bard, Inc.; Exhibit 1 to Declaration of Karl L Leinsing in Support of Bard's Rebuttal on Claim Construction; Civil Action No. 1.14-cv-03618; Judge John Z. Lee, Filed August 15, P016,	
		Medline Industries Inc. vs C.R Bard, Inc.; Exhibit 1 to Declaration of Karl R Leinsing in Support of Bard Reply to Medline Claim Construction Brief; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed January 27.2017,	
		Medline Industries Inc. vs C.R Bard, Inc.; Exhibit 3 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee, Filed July 8.2016.,	

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		Medline Industries Inc. vs C.R Bard, Inc.; Exhibit 4 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee. Filed July 8.2016.,	
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		Medline Industries Inc. vs C.R Bard, Inc.; Exhibit H to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9, 2016.,	
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		Medline Industries Inc. vs C.R Bard, Inc.; Medline Memo of Law re Expert Testimony in Claim Construction Proceedings; Civil Action No. 1;14-cv-03618; Judge John Z. Lee. Filed January 25,2017.,	
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		Medline Industries Inc. vs C.R Bard, Inc: Exhibit G to C.R Bard's LPR 2.3 Contentions; Civil Action No. 1.17-cv-7216; Judge Sara L Ellis; Fiied January 16.2013.,	
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	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		Medline Industries Inc. vs C.R Bard. Inc.. Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John 2. Lee; Filed July 8.2016.,	
		Medline Industries Inc. vs C.R Bard. Inc.. Exhibit 11 to Declaration of Richard Meyst re Claim Construction: Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9,2016.,	
		Medline Industries Inc. vs C.R Bard. Inc.. Exhibit A to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1;14-cv-03618; Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R Bard. Inc.. Medline Motion lo Supplement Record on Claim Construction with Leinsing Testimony; Civil Action No 1:14-w-03618; Judge John Z. Lee; Filed March 23,2017.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Bard Reply Claim Construction Brief; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed January 12,2018.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Bard Response to Memo of Law re Expert Testimony in Claim Construction Proceedings; Civil Action No. 1:14-cv-03618; Judge John Z. Lee. Filed February 8, 2017.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction Brief. Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 22,2017,	
		Medline Industries Inc. vs C.R Bard. Inc.; Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction Brief. Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 22,2017,	

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		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit 3 to Declaration of Peter Sauer in Support of Medline's Motion to Supplement Record; Civil Action No. 1:14-cv-03618: Judge John Z. Lee. Filed March 23.2017.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit 8 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit C to Declaration of Kevin A. Lake; Civil Action No. 1 14-cv-03618. Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit G to Declaration of Dylan J. Raife in Support of Bard Opening Claim Construction Brief, Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 17,2017.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit G to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline industries Inc. vs C.R Bard. Inc.; Exhibit H to Declaration of Dylan J Raife in Support of Bard Opening Claim Construction Brief, Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 17,2017.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed Decembers, 2016,	

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		Medline Industries Inc. vs C.R Bard. Inc.; Transcript of Deposition of Barbara A Weinlraub; Civil Action Mo. 1:16-cv-03529; January 20.2017.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Transcript of Deposition of Karl Leinsing; Civil Action No. 1:16-cv-03529; February 17,2017,	
		Medline industries Inc. vs C.R Sard, Inc.; Exhibit 9 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc., Bard Response to Medline Surreply re Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed September 13.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit 2 to Declaration of Karl L. Lansing in Support of Bard's Rebuttal on Claim Construction: Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed August 15. 2016,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit B to Declaration of Kevin A. Lake. Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit D to Declaration of Nicole Smith in Support of Bard Reply to Claim Construction Brief; Civil Action No. 116-cv-03529; Judge Sharon Johnson Coleman. Filed January 12.2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc., Exhibit J to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529: Judge Sharon Johnson Coleman; Filed December 9.2016.,	

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		Medline Industries Inc. vs C.R. Bard, Inc.. Exhibit 1 to Declaration of Peter Sauer in Support of Medline's Motion to Supplement Record; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed March 23.2017,	
		Medline Industries Inc. vs C.R. Bard, Inc.. Exhibit 9 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8. 2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.. Exhibit L to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529: Judge Sharon Johnson Coleman: Filed December 9,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.. Medline Response to Bard Claim Construction Brief. Civil Action No. 1:14~cv-03618: Judge John Z. Lee; Filed July 8,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.: Exhibit 2 to C.R. Bard's LPR 2.3 Contentions; Civil Action No. 117-CV-7216; Judge Sara L Eiiis; Filed January 16.2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Declaration of Barbara Weintraub re Claim Construction: Civil Action No. 1.16-cv-03529. Judge Sharon Johnson Coleman; Filed December 9,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9, 2016,	

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		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 10 lo Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 2 to Declaration of Peter Sauer in Support of Medline's Motion to Supplement Record; Civil Action No. 1:14-cv-03618; Judge John Z. Lee. Filed March 23. 2017.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 5 to Declaration of Richard Meyst re Claim Construction: Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman, Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 6 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman. Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit 7 to Declaration of Richard Meyst re Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit C to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9,2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit E to Declaration of Brian Eutermoser in Support of Medline Response to Bard Opening Claim Construction; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 9,2016.,	

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		Medline Industries Inc. vs C.R. Bard. Inc., Exhibit 2 to Declaration of Richard Meyst Regarding Claim Construction: Civil Action No. 1:14-cv-03618; Judge John 2. Lee. Filed July 8.2016.,	
		Medline Industries Inc. vs C.R. Bard. Inc.; Exhibit 5 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee. Filed July 8.2016.,	
		Medline Industries Inc. vs C.R. Bard. Inc.; Exhibit 6 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee. Filed July 8, 2016,	
		Medline industries Inc. vs C.R. Bard. Inc.; Medline Response to Bard Opening Claim Construction Brief; Civil Action No. t:16-cv-03529; Judge Sharon Johnson Coleman; Filed December 22,2017.,	
		Medline Industries Inc. vs OR. Bard, Inc.; Exhibit E to Declaration of Dylan J Raife in Support of Bard Opening Claim Construction Brief; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 11.2016.,	
		Medline Industries Inc. vs C.R Bard, Inc, Exhibit I to C.R. Bard's LPR 2.3 Contentions. Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed January 16.2018.,	
		Medline Industries Inc. vs C.R Bard, Inc., Declaration of Dylan J Raife in Support of Bard Opening Claim Construction Brief; Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 11,2016.,	

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		Medline Industries Inc. vs C.R Bard, Inc.. Declaration of Kevin A. Lake in Support of Medline Response to Bard Claim Construction Brief: Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed July 8.2016.,	
		Medline Industries Inc. vs C.R Bard, Inc.; Declaration of Barbara Weintraub Regarding Claim Construction; Civil Action No. 1:14-cv-03618; Judge John Z. Lee. Filed July 8,2016.,	
		Medline Industries Inc. vs C.R Bard, inc.; Exhibit D to Declaration of Dylan J. Raife in Support of Bard Opening Claim Construction Brief. Civil Action No. 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 11,2016.,	
		Medline Industries Inc. vs C.R Bard. Inc.; Exhibit 1 to Declaration of Richard Meyst Regarding Claim Construction; Civil Action No. 1:14-cv-036l8; Judge John Z. Lee; Filed July 8.2016.,	
		Medline Industries Inc. vs C.R. Bard, Inc, Exhibit 4 to C.R. Bard's LPR 2 3 Contentions; Civil Action No. 1:17-cv-7216; Judge Sara L. Ellis; Filed January 16.2018.,	
		Medline IndustriesfInc. vs C.R. Bard, Inc., Declaration of Peter Sauer in Support of Medline's Motion to Supplement Record; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed March 23,20l7,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit D lo Declaration of Kevin A. Lake; Civil Action No. 1:14-cv-03618. Judge John Z. Lee; Filed July 8,2016.,	

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		Medline Industries Inc. vs C.R. Bard. Inc., Exhibit 1 to Declaration of Brian Eutermoser in Support of Medline Surreply; Civil Action No. 1:14-cv-03618; Judge John 2. Lee; Filed September 7,2016.,	
		Medline Industries Inc. vs C R. Bard, Inc.; Exhibit B to Declaration of Nicole M. Smith; Civil Action No. 1:14~cv43618; Judge John 2. Lee; Filed June 4, 2016.,	
		Medline Industries Inc. vs C R. Bard, inc.; Exhibit D to Declaration of Nicole M Smith; Civil Action No. 1:14-cv-03618; Judge John 2. Lee; Filed June 4, 2016.,	
		Medline Industries Inc. vs C R. Bard, Inc.; Exhibit E to Declaration oi Nicole M. Smith; Civil Action No, 1:14-cv-03618: Judge John 2. Lee; Filed June 4, 2016.,	
		Medline Industries Inc. vs C R. Bard, Inc.; Exhibit F to Declaration of Nicole M. Smith; Civil Action No. 1:14-cv-03618; Judge John 2. Lee; Filed June 4, 2016.,	
		Medline Industries Inc. vs C R. Bard, Inc; C R. Bard's Opening Claim Construction Bnel; Civil Action No. 1:14-cv-03618; Judge John 2. Lee; Filed June 4, 2016.,	
		Medline Industries Inc. vs C R. Bard, inc; C.R Bard's Motion for Leave to Add Counterclaims; Civil Action No. 1:17-cv-7216; Judge Sara L. Ellis; Filed February 27,2018,	
		Medline Industries Inc. vs C R. Bard, Inc; Declaration of Dylan Raife in Support of Motion for Leave to Add CounterClaims; Civil Action No. 1:17-cv-7216; Judge Sara L. Eliis; Filed February 27,2018.,	

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		Medline Industries Inc. vs C.R Bard, Inc.; Exhibit B lo Declaration of Nicole Smith in Support of Bard Reply to Medline Claim Construction Brief; Civil Action No. 1.16-cv-03529; Judge Sharon Johnson Coleman; Filed January 27.2017,	
		Medline Industries Inc. vs C.R. Bard, Inc.; C R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit A – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit B – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit C– C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	

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		Medline Industries Inc. vs C.R. Bard, Inc.; Exhibit T – C. R. Bard's Final LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed July 24, 2018.,	
		Medline Industries Inc. vs C.R. Bard, Inc; C.R. Bard's LPR 3.1 Contentions; Civil Action No. 1:16-cs-3529; Judge Sharon Johnson Coleman; Filed August 26, 2016,	
		Medline Industries Inc. vs C.R. Bard, Inc; Exhibit B to C R. Bard's LPR 2.3 Contentions; Civil Action No 1:17-cv-7216; Judge Sara L. Ellis; Filed January 16.2018.,	
		Medline Industries vs. CR Bard, Inc; No 14-cv-3618; C.R. Bard's LPR 3.1 Contentions; Filed November 24, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Defendant C.R. Bards, Inc's Second Amended Answer to Second Amended Complaint; Filed September 25, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Medline Industries Inc's Opposition to C.R.Bard Inc's Motion For Leave to File Second Amended Answer to Add Counterclaim; Filed October 20, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Medline Industries, Inc.'s Response to C.R. Bard's Initial Invalidity Contentions; Exhibits A-H; Dated September 19, 2014,	

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	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Notice of Medline Industries Inc's Motion to Dismiss C.R. Bard Inc's Inequitable Conduct Counterclaim and to strike affirmative defense for the '786 Patent; Filed October 20, 2015,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-03618; Response to Medline Industries, Inc.'s First Set of Interrogatories; Dated September 26, 2014,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:14-cv-3618; Responses to Medline Industries, Inc.'s First set of Requests for the Production of Documents; Dated September 26, 2014,	
		Medline Industries, Inc. vs C.R. Bard, Inc; No. 1:17-cv-03618; Medline's Supplemental Responses to Bard's Interrogatory No. 1-24 (redacted), dated April 20, 2016; Filed as IPR Petition Exhibit 2013 in IPR2019-00035 and IPR2019-00036,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 1:17-cv-3539; Medline's Second Supplemental Responses to Bard's Interrogatory No. 11, 14, and 15 (redacted), dated October 26, 2017; Filed as IPR Petition Exhibit 2014 in IPR2019-00035 and IPR2019-00036,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 1:17-cv-7216; Medline's Objection and Response to Bard's First Set of Interrogatories (redacted), dated October 1, 2018; Filed as IPR Petition Exhibit 2012 in IPR2019-00035 and IPR2019-00036,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 14-cv-3618; C.R. Bard's LPR 2.3 Contentions - Initial Non-Infringement; Exhibits 1 and A-H; Dated September 5, 2014,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; No. 14-cv-3618; Memorandum in Support of C.R. Bard's Motion for Leave to File Second Amended Answer to Add Counterclaim; Filed September 25, 2015,	

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		Medline Industries, Inc. vs. C.R. Bard, Inc.: Transcript of Proceedings - Claim Construction Hearing: Civil Action No. 1:14-cv-3618. Judge John Z. Lee; Dated January 11, 2017.	
		Naming Characters on Cards website. URL:<https://web.archive.org/web/20060219171403/http://www.hubbardscupboard.org/brown_bear_brown_bear.html>. (2006)...Retrieved form Internet 11 Dec. 2013.	
		Notice of Allowance; EP Application No. 10251025.2-1501; Reference P112645EP00; Attorney Docket No. BPMDL0005JT EP (10055U EP); Mailed February 18, 2016,	
		Inter Partes Review - Patent Owner's Prelim. Response; Patent 9,808,596; Inter Partes Review No. IPR2019-00223; Filed March 7, 2019,	
		Medline Industries Inc. vs. C.R Bard, Inc. Bard Opening Claim Construction Brief; Civil Action No 1:16-cv-03529; Judge Sharon Johnson Coleman; Filed November 17, 2017.	
		Webster's Dictionary Definition of "Intend"; Webster's Third New International Dictionary of the English Language unabridged (1961); filed as IPR Petition Exhibit 2016 in IPR 2019-00035,	
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		"Article 94(3) EPC Examination", European Application No. 10 251 025.2-1501; Reference P112645EP00; Attorney Docket No. BPMDL0005JT.EPO (10055U EP); Mailed March 13, 2015,	

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		"Australian First Exam Report", AU Patent Application No. 2011351971; Patent Examination Report No. 1; Mailed 25JL2015,	
		"Bard IPR Exhibit", "Inter Partes Review Petition", IPR Exhibit - Carrow Declaration for US Patent No. 8,631,935; Susan Carrow Declaration; Mailed December 30, 2014,	
		"Bard Medical Division Care & Catheterization Script", Care & Catheterization/Preventing UTI Script for education video; Preventing UTI: Care and Catheterization Techniques; Copyright 2006; AV0512-06 R12/05 XXX,	
		"Bard Publication", "A few important words about Catheter Care"; C.R. Bard, Inc.; Copyright 2001 C.R. Bard, Inc.,	
		"Bardex I.C. Complete Care StateLock Device 350 ml Urine Meter Foley Tray with Bacteriostatic Collection System", Bard Infection Control System; Bardex I.C. Complete Care Directions for Use; Copyright Dated September 2006,	
		"Bardex I.C. Infection Control 350ml Urine Meter Foley Tray", Bard Infection Control System; Bardex I.C. Urine Meter Foley Tray Directions for Use; Copyright Dated 2006,	
		"Bardex I.C. Infection Control Foley Tray", Bard Infection Control System; Bardex I.C. Directions for Use Infection Control Foley Tray; Copyright Dated 2006,	
		"Decision Instituting Inter Partes Review", IPR2019-00035; Patent No. 9,745,088; Mailed April 10, 2019,	

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		"Decision Instituting Inter Partes Review", IPR2019-00036; Patent No. 9,745,088; Mailed April 10, 2019,	
		"Decision Instituting IPR", IPR 2019-00208; Patent No. 9,808,400; Dated June 6, 2019,	
		"Decision Instituting Review", IPR 2019-00223; Patent No. 9,808,596; Dated June 6, 2019,	
		"DVD", Entitled "Preventing UTI: Care and Catheterization Techniques"; Publication Date unknown but believed to be prior to 2007,	
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		"Examiner's Answer", USSN 13/153,265; Filed June 3, 2011; Attorney Docket No. BPMDL0005JT.P5 (10055U CIP5); Mailed December 17, 2013,	
		"Expert Report of Barbara Weintraub", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated June 14, 2019,	
		"Expert Report of Barbara Weintraub", Civil Action No. 1:16-cv-03529; Confidential Information Redacted Pursuant to Court Order; Dated August 1, 2019,	

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	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		"Expert Report of Dr. Edward Yun", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated June 13, 2019,	
		"Expert Report of Dr. Edward Yun", Civil Action No. 16-cv-3529; Confidential Information Redacted Pursuant to Court Order; Dated August 1, 2019,	
		"Expert Report of Dr. Edward Yun Related to Damages, Non-Infringement, and New Evidence of Alleged Secondary Considerations", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated July 23, 2019,	
		"Expert Report of Dr. John Abraham", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated June 14, 2019,	
		"Expert Report of Dr. John Abraham", Civil Action No. 1:16-cv-03529; Confidential Information Redacted Pursuant to Court Order; Dated August 1, 2019,	
		"Expert Report of Dr. Steven Brooks", Civil Action No. 14-cv-3618; Confidential Information Redacted Pursuant to Court Order; Dated July 25, 2019,	
		"Expert Report of Karl R Leinsing, MSME, PE Regarding Alleged Evidence of Secondary Considerations", Civil Action No. 1:14-cv-3618; Confidential Information Redacted Pursuant to Court Order; Dated June 14, 2019,	
		"Expert Validity Report of Dr. John Abraham", Civil Action No. 1:14-cv-03618; Confidential Information Redacted Pursuant to Court Order; Dated July 25, 2019,	

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	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		"Extended EPO Exam Report", EPO App No.: 10251025.2; Filed June 2, 2010; Attorney Docket No. BPMDL0005JT.EPO (10055U EP); Mailed December 17, 2013,	
		Medline Industries, Inc. vs. C.R. Bard, Inc.; Exhibit J to Declaration of Nicole M. Smith; Civil Action No. 1:14-cv-03618; Judge John Z. Lee; Filed June 4, 2016.	
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		"Intent to Grant", Chinese Application No. 201180066491.4; Filed December 30, 2011; Attorney Docket No. BPMDL005JT.P4.CHIN (10055U CIP4 CN); Mailed July 6, 2016,	
		"Intent to Grant", European Application No. 16177903.8-1501; Reference No. SJG/P112645EP02; Mailed September 18, 2017,	
		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent 8,631,935; Inter Partes Review No. IPR2015-00513; Filed April 21, 2015,	
		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent No. 8,448,786; IPR2015-00509; Filed April 22, 2015,	
		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent No. 8,631,935; Inter Partes Review No. IPR2015-00511; Filed April 22, 2015,	

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		"Inter Partes Review - Patent Owner Response", Inter Partes Review - Patent Owner Response; Patent No. 8,678,190; Inter Partes Review No.: IPR2015-00514; Filed April 21, 2015,	
		"Inter Partes Review - Patent Owner's Prelim Response", Patent 9,745,088; Inter Partes Review No. IPR2019-00035; Filed January 11, 2019,	
		"Inter Partes Review - Patent Owner's Prelim Response", Patent 9,745,088; Inter Partes Review No. IPR2019-00036; Filed January 11, 2019,	
		"Inter Partes Review No. IPR2019-00109", Petition for Review; Patent No. 9,795,761; Filed October 24, 2018,	
		"Inter Partes Review Petition", Exhibit - Amendment filed on April 3, 2013 for USSN 12/495,148; Attorney Docket No. BPMDL0005JT (10055U); Application Filed June 30, 2009,	
		"Inter Partes Review Petition", Exhibit - Bard DFU; Bardex Infection Control Foley Tray; Copyright 2006, publication date unknown,	
		"Inter Partes Review Petition", Exhibit - Bardex DFU; Directions for Use/Patient Education Information - Urology; Unknown Publication Date,	
		"Inter Partes Review Petition", Exhibit - Declaration of Susan Carrow for US Patent No. 8,631,935 claims 1-4 and 11-20; Mailed December 30, 2014,	

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	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		"Inter Partes Review Petition", Exhibit - Dorland's Definition of Bag; Dorland's Illustrated Medical Dictionary; 31st Edition; Publication Date Unknown,	
		"Inter Partes Review Petition", Exhibit - EC Guideline 1998; "A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use"; Published September 29, 1998 (29.09.98); Mailed December 30, 2014,	
		"Inter Partes Review Petition", Exhibit - Encyclopedia Dictionary of Medicine, Nursing and Allied Health; Miller Keane, Seventh Edition,	
		"Inter Partes Review Petition", Exhibit - FAQs "Catheter-Associated Urinary Tract Infection"; Unknown Publisher; Unknown Publication Date,	
no date cited, reference not considered		"Inter Partes Review Petition", Exhibit - FDA Article; "Guidance for the Content of Premarket Notifications fro Conventional and Antimicrobial Foley Catheters; http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080884.htm; Unknown Publication Date,	
		"Inter Partes Review Petition", Exhibit - Health Protection Scotland; CAUTI Maintenance Bundel; Version 2, February 2008,	
		"Inter Partes Review Petition", Exhibit - Infection Control Today Article; Medical Center Cuts Catheterizations by 21 Percent with Foley Catheter Management System; Published 2010,	
		"Inter Partes Review Petition", Exhibit - Kimmel Declaration for US Patent No. 8,631,935 claims 1-4 and 11-20; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	

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		"Inter Partes Review Petition", Exhibit - Medical News Today Article; "'Getting to Zero:' Medline's' Erase Cauti Program Helps Hospitals Reduce Catheter Use by 20 Percent; Article Date April 13, 2011,	
		"Inter Partes Review Petition", Exhibit - Medline Initial Infringement Contentions; Medline Industries vs. C.R. Bard; Dated August 22, 2014,	
		"Inter Partes Review Petition", Exhibit - Morning Start Article; "Floyd Medical Center Reduces Catheter-Associated Urinary Tract Infections 83 Percent and Catheter Use by 23 Percent"; Published January 2011,	
		"Inter Partes Review Petition", Exhibit - Mosby's Pocket Guide Excerpt; Mosby's Pocket Guide to Basic Skills and Procedures; Sixth Edition; Perry & Potter; "Urinary Catheter: Indwelling, Straight, Care and Removal"; Unknown Publication Date,	
		"Inter Partes Review Petition", Exhibit - Nursing Standard; Article in Learning Zone - Continue Professional Development; "Reducing the risks associated with urinary catheters"; Published March 25, 2009,	
		"Inter Partes Review Petition", Exhibit - RCE Filed November May 31, 2011 for USSN 12/495,148; Attorney Docket No. BPMDL0005JT (10055U); Application Filed June 30, 2009,	
		"Inter Partes Review Petition", Exhibit - Response to Office Action in USSN 12/495,148; Attorney Reference No. BPMDL0005JT (10055U); Application Filed June 30, 2009; Response Filed November 19, 2010,	
no date cited, reference not considered		~~"Inter Partes Review Petition", Exhibit - Soroka Glossary 'Bag'; Illustrated Glossary of Packaging Terminology, second edition; Walter Soroka; publication unknown,~~	

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no date cited, reference not considered		~~"Inter Partes Review Petition", Exhibit - Soroka Glossary_wrap; Illustrated Glossary of Packaging Terminology, second edition; publication date unknown,~~	
		"Inter Partes Review Petition", Exhibit - The Journal of Healthcare Contracting, October 2012; "Catheter-associated urinary tract infections",	
		"Inter Partes Review Petition", Exhibit - Webster's Dictionary Definition of Dispose; Webster's Third New International Dictionary; Copyright 2003; publication date unknown,	
		"Inter Partes Review Petition", Exhibit; Carrow CV - Susan Carrow CV; Mailed December 30, 2014,	
		"Inter Partes Review Petition", Exhibit; EC Guideline 2009; "Guideline on the Readability of the Labeling and Package Leaflet of Medicinal Products for Human Use"; Revision 1 Published January 12, 2009 (12.1.2009); Mailed December 30, 2014,	
		"Inter Partes Review Petition", Exhibit; Kimmel CV - Dr. Robert M. Kimmel; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Carrow Declaration for US Patent No. 8,631,935 claims 1-4 and 11-20; Susan Carrow Declaration; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Carrow Declaration for US Patent No. 8,768,190; Declaration of Susan Carrow; Mailed December 30, 2014,	

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		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration 8,448,786 Patent; Dr. Robert M. Kimmel Declaration; Received December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration for US Patent No. 8,631,935 claims 1-4 and 11-20; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration for US Patent No. 8,631,935 claims 7-8, 10, 21-23, 25, 27-28, and 30-34; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Kimmel Declaration for US Patent No. 8,768,190; Declaration of Dr. Robert M. Kimmel; Mailed December 30, 2014,	
		"Inter Partes Review Petition", IPR Exhibit - Susan Carrow Declaration 8,448,786 patent; mailed December 30, 2014,	
		"Inter Partes Review Petition for 8,448,786", US Patent No. 8,448,786; Filed December 30, 2014; Mailed December 30, 2014,	
		"Inter Partes Review Petition for 8,631,935", Inter Partes Review Petition for 8,631,935 for claims 1-4 and 11-20; Filed December 30, 2014,	
		"Inter Partes Review Petition for 8,631,935", Inter Partes Review Petition for 8,631,935 for Claims 7-8, 10, 21-23, 25, 27-28, and 30-34; Filed December 30, 2014,	

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		"Inter Partes Review Petition for 8,678,190", Inter Partes Review Petition for 8,678,190; Filed December 30, 2014,	
		"Inter Partes Review Petition for US Patent No. 9,745,088", IPR-0036; Filed October 4, 2018,	
		"Inter Partes Review Petition for US Patent No. 9,745,088", IPR2019-0035, filed October 4, 2018,	
		"IPR 2015-00514 - Patent Owner's Objection to Evidence", IPR 2015-00514 - Patent Owner's Objection to Evidence Submitted During a Preliminary Proceeding; Patent No. 8,678,190; Mailed July 13, 2015,	
		"IPR 2015-00514 - Patent Owner's Request for Adverse Judgment", Patent No. 8,678,190; Mailed July 23, 2015,	
		"IPR 2015-00514 - Request for Rehearing Denied", IPR2015-00514; Patent No. 8,678,190; Decision on Request for Rehearing - Denied; Mailed July 16, 2015,	
		"IPR 2015-00514 Petitioner's Request for Rehearing", IPR 2015-00514 Petitioner's Request for Rehearing; Patent 8678,190; Dated July 10, 2015,	
		"IPR 2019-00109", Exhibit 1031 - Declaration of Jennifer Tomes filed in USSN 12/647,515 dated December 7, 2012,	

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	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

		"IPR 2019-00109", Patent No. 9,795,761; Filed October 24, 2018; Declaration of Dr. Edward Yun,	
		"IPR Decision Instituting Inter Partes Review", IPR2019-00109; Patent 9,795,761; Mailed May 6 2019,	
		"IPR Exhibit 1002", Declaration of Pliska; IPR2019-0035, Filed October 4, 2018,	
		"IPR Exhibit 1003", Declaration of Yun; IPR2019-0035; Filed October 4, 2018,	
		"IPR Exhibit 1022", Email from Medline counsel re claims constructions; IPR2019-0035; Filed October 4, 2018,	
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		"IPR2015-00513 - Patent Owner's Request for Adverse Judgment", Patent No. 8,631,935; Mailed July 23, 2015,	
		"IPR2015-00513 Institution Decision", IPR2015-00513 Institution Decision; Patent 8,631,935; Entered July 15, 2015; Decision Institution of Inter Partes Review,	
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		"IPR2019-00109", Exhibit 1026 - Bard's Opening Claim Construction Brief; Civil Action No. 1:17-cv-07216; Dated October 10, 2018; Filed October 24, 2018 as exhibit 1026,	
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		"IPR2019-00109", Patent No. 9,795,761; Filed October 24, 2018; Exhibit 1002 Declaration of Michael Plishka,	
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		"Notice of Allowance", Canadian Application No. 2,705,647; Filed May 27, 2010; Attorney Docket No. 10055U CA; Mailed October 12, 2017,	
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	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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		"Opening Expert Report of Karl R Leinsing, MSME, PE", Civil Action No. 1:14-cv-3618; Confidential Information Redacted Pursuant to Court Order; Dated June 14, 2019,	
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	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	09/02/2022

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 06/22/2021

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	**Application Number**	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		"Summons to Attend Oral Proceedings", EP Application 11854003.8; Mailed December 22, 2020; 10055U CIP4 EP,	
		"Summons to Attend Oral Proceedings", EP Application 12792423.1; Mailed December 22, 2020; 10055U CIP6 EP,	
		"Summons to Attend Oral Proceedings", EP Application 12793939.5; Mailed December 23, 2020; 10055U CIP5 EP,	
		ARBLE, JESSICA , "Final OA", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed August 5, 2020,	
		ARBLE, JESSICA , "NonFinal Office Action", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed April 28, 2020,	

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	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

		ARBLE, JESSICA , "NonFinal Office Action", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed February 3, 2021,	
		ARBLE, JESSICA , "Notice of Allowance", USSN 15/977,944; Filed May 11, 2018; Attorney Docket No. 10055U NP1; Mailed August 17, 2021,	
		POON, ROBERT , "Final Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket No. 10055U D1 C2 C1; Mailed July 15, 2020,	
		POON, ROBERT , "NonFinal Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket NO. 10055U D1 C2 C1; Mailed March 31, 2021,	
		POON, ROBERT , "Notice of Allowance", USSN 15/703,514; Filed September 13, 2017; Attorney Docket No. 1037-002-09US; Mailed November 23, 2020,	
		POON, ROBERT , "Notice of Allowance", USSN 15/803,383; Filed November 3, 2017; Attorney Docket No. 1037-002-08US; Mailed November 27, 2020,	

EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	09/02/2022

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Doc code: IDS
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PTO/SB/08a (01-10)
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Filing Date	Mar 28, 2020
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2021-6-22
Name/Print	Philip H. Burrus	Registration Number	45,432

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Doc Code: PA..
Document Description: Power of Attorney

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Application Number	16833575
Filing Date	March 28, 2020
First Named Inventor	Jennifer E. Tomes
Title	Cather Tray, Packaging Sytem, Instruction Insert, and Associated Methods
Art Unit	
Examiner Name	
Attorney Docket Number	10055UCIP2D1C1C1C1C1

SIGNATURE of Applicant or Patent Practitioner

Signature	/Philip H. Burrus, IV/	Date (Optional)	2022-09-16
Name	Philip H. Burrus, IV	Registration Number	45432
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

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Application Number	Filing Date

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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Medline Industries, LP

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	David Noskowicz	Date (Optional)	
Name	David Noskowicz		
Title	Associate General Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

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Electronic Acknowledgement Receipt

EFS ID:	46633130
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	27939
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	16-SEP-2022
Filing Date:	28-MAR-2020
Time Stamp:	13:04:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	10055U_CIP2D1C1C1C1C1_2022-9-16_CustNo189038.pdf	288762 fb55483dab1494ebd36cf0e1c5dbc26b63d0b368	no	2

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

Courtesy Reminder for
Application Serial No: 16/833,575

Attorney Docket No:
10055UCIP2D1C1C1C1C1
Customer Number: 27939
Date of Electronic Notification: 09/13/2022

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1

CONFIRMATION NO. 5069

27939
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC
222 12th Street NE
Suite 1803
Atlanta, GA 30309

POWER OF ATTORNEY NOTICE

OC000000136357375

Date Mailed: 09/23/2022

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/16/2022.

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/nhassani/

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1

CONFIRMATION NO. 5069

189038
Philip H. Burrus, IV
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POA ACCEPTANCE LETTER

OC000000136357392

Date Mailed: 09/23/2022

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

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/nhassani/

EXHIBIT 13

United States Patent [19]

Rauschenberger

[11] **4,160,505**

[45] **Jul. 10, 1979**

[54] **CATHETERIZATION TRAY**

[75] Inventor: **Richard A. Rauschenberger,** Brookfield, Wis.

[73] Assignee: **Will Ross Inc.,** Milwaukee, Wis.

[21] Appl. No.: **862,074**

[22] Filed: **Dec. 19, 1977**

[51] **Int. Cl.**[2] **B65D 85/54**

[52] **U.S. Cl.** **206/571;** 206/564

[58] **Field of Search** 128/348–351; 206/364, 370, 560–565, 570, 571

[56] **References Cited**

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2,319,556	5/1943	Rhein	206/570 X
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Primary Examiner—Davis T. Moorhead

Attorney, Agent, or Firm—John A. Dhuey

[57] **ABSTRACT**

A urethral catheterization tray providing a sterile, self-contained catherization package and work area is described.

2 Claims, 3 Drawing Figures

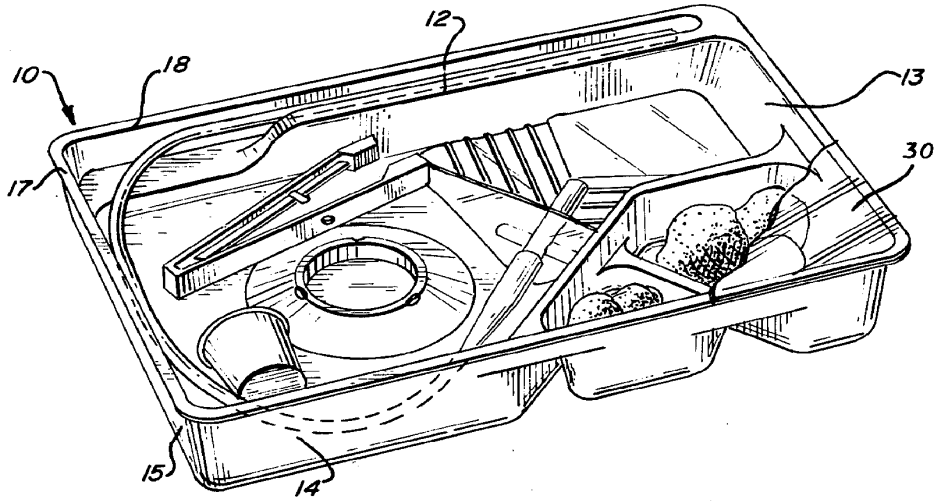
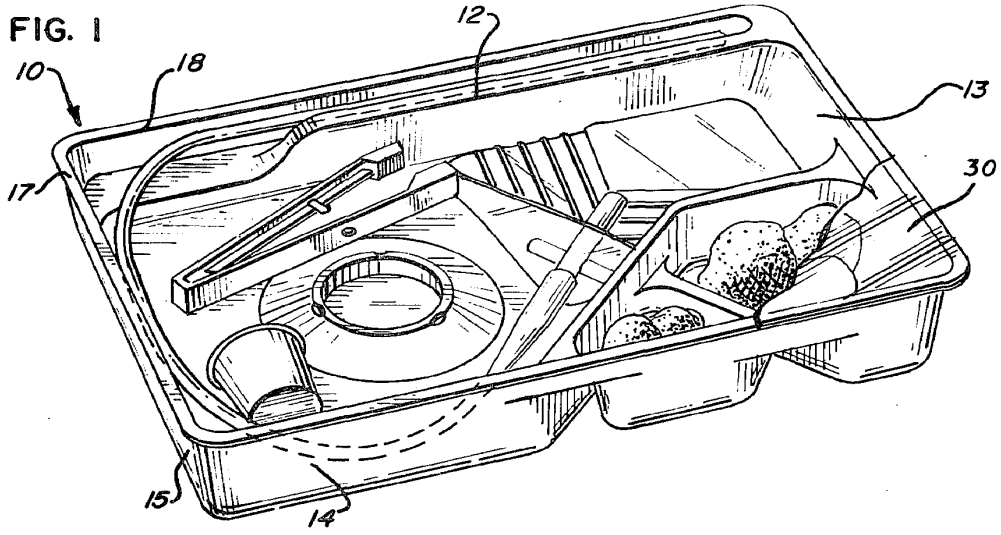


FIG. 1



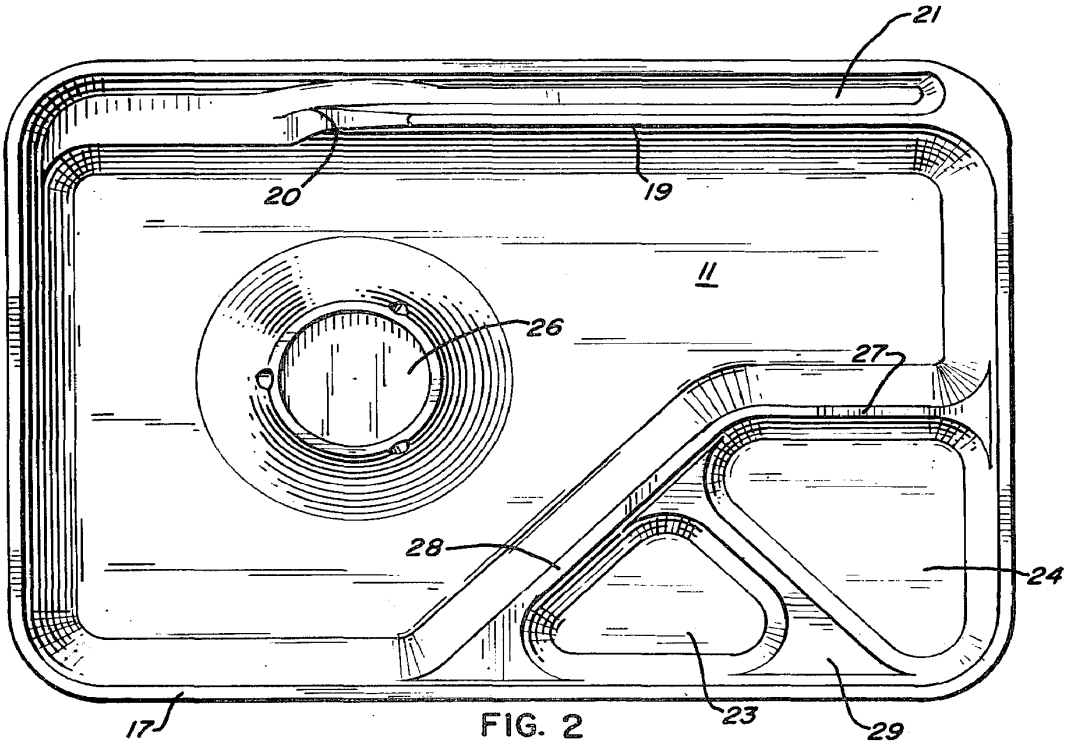
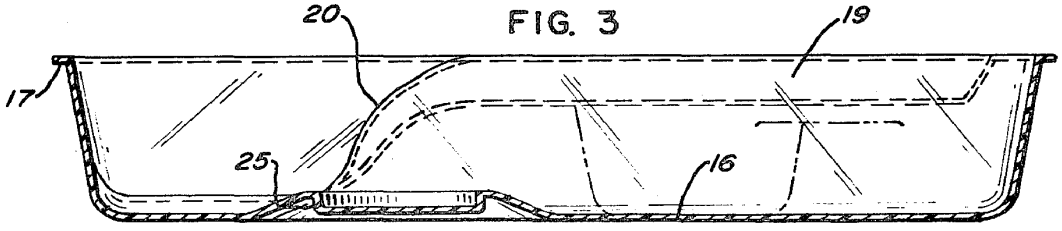


FIG. 2

FIG. 3



CATHETERIZATION TRAY

This invention is concerned with catheterization trays. More particularly, it is concerned with a sterile, self-contained catheterization package which permits the catheterization procedure to take place within the sterile work area defined by the tray.

Prior art devices have generally employed a tray containing the catheterization implements, i.e. catheter, lubricant, antiseptic, absorbent material such as gauze or cotton, gloves, specimen container, towel and forceps, covered with a sterile folded central supply room (CSR) wrap. In use the CSR wrap is unfolded from the tray to provide a sterile work area about the tray, the area taken up by the extended wrap generally being 1–2 square feet. The attending person then dons the rubber gloves, extracts a lubricant packet from the tray and places an amount of lubricant on the CSR wrap. Next the absorbent pads contained in a cup are removed from the tray by means of the forceps and placed on the wrap. Antiseptic solution then is applied to the pads and the patient is cleansed. Remaining dry absorbent pads then are utilized to dry the patient. The catheter is removed and the insertion end placed into the lubricant on the wrap and inserted into the patient. When catherization is completed, the specimen container is removed from the tray and placed on the wrap. Then a specimen from the bag is allowed to drain onto the container.

It is apparent from the above outlined procedures that less than ideal circumstances are created. For example, the large area taken up by the CSR wrap necessitates a large work area near the patient. Such a substantial area must usually be found on the bed where indavertent movement by the patient could contaminate the sterile work area. During the procedure lubricant jelly, antiseptic solution, and wet absorbent pads are placed on the CSR wrap, where they can be contacted either by the patient or the attending personnel. Furthermore, the chances of spilling urine when attempts are made to fill the specimen container are substantial and soiling of the immediate area is a distinct and unpleasant possibility.

The present invention is intended to eliminate the above-noted deficiencies and is best understood with reference to the following drawings in which:

FIG. **1** is a perspective view of the assembly;

FIG. **2** is a topview of the tray; and

FIG. **3** is a cross-sectional view of the tray.

Tray **10** is formed with a dished portion **11** defined generally by outside walls **12, 13, 14, 15** and **18** and bottom wall **16**. The top edge of walls **12, 13, 14, 15** and **18** are integral with a flange **17** which extends about the periphery of tray **10**. Walls **12** and **18** jointly form one full outside wall on tray **10** and wall **12** is inset from wall **18** and the outer edge of flange **17**. Flange **17** and wall **12** are connected by a channel **21** which has a horizontal section **19** and an inclined section **20** forming a ramp. Wall **12** correspondingly is inclined in the area of secton **20** and cooperates with wall **18** to form the channel **21** in that portion of dish **11**.

Channel **21** is adapted to receive a conventional urethral catheter which is positioned within channel **21** with its insertion end in the horizontal section. The remainder of the catheter extends down the ramp section **20** and around the sides of dish **11**. Channel **21** optionally can be provided with a cross-channel in its horizontal section.

Compartments **23** and **24** are defined within dish **11** by walls **27, 28** and **29**. Those walls are conveniently formed by directionally varying outside wall **14**. Since the tray **10** usually will be molded as a unit structure, such variations present no problem. Compartments **23** and **24** are independent and adapted to hold absorbent pads separately from each other.

A further compartment in the tray is provided by wall **25** which creates a generally circular compartment **26** in the bottom of dish **11**. Conveniently wall **25** is formed by dropping bottom wall **16** appropriately to provide recess **26**. Again, fabrication is facilitated by the molding operation which permits direct formation of wall **25**.

In its packaged configuration the catheterization implements are placed in tray **10** as shown in FIG. **1** and sealed with a cover sheet **30** about flange **17**. Cover sheet **30** is formed of conventional peelable lid stock such as coated paper or plastic which is permeable to sterilizing gases. The catheter is located in groove **21** and absorbent material is located in compartments **23** and **24**. The remaining componetns generally are arranged sequentially from the top of the tray on down in the order: gloves, lubricant, antiseptic solution, fenestrated drape, forceps, drainage bag and specimen container. For purposes of clarity, not all of the components are shown in the drawings.

In use the attendant places the tray at a convenient location. The seal lid then is removed and discarded. Gloves are donned and a lubricant packet is utilized to put lubricant on the catheter in channel **21**. The catheter then is rotated within channel **21** to spread lubricant about it insertion end. Ramp section **20** supports the catheter during its rotational movement and minimized the danger of the catheter being dislocated from channel **21**. If the optional cross channel has been provided, the attendant's finger may be placed in cross-channel to further hold the catheter within groove **21** and also assist in rotation. It has been found that the most preferred manner is to grasp the catheter near the bottom of ramp **20** and rotate the catheter between the finger and the thumb.

After the catheter has been lubricated, antiseptic solution is applied to the absorbent pads in one, but not both, of the compartments **23** and **24**. Since compartments **23** and **24** are independent, the saturation of one set of absorbent pads does not affect the other set. Then the fenestrated drape is removed from tray **10** and placed over the patient area. Next the patient is cleansed with the saturated absorbent pads by holding with the forceps. The remaining dry pads subsequently are used to dry the patient. Both sets of pads and the tweezers, along with the empty packets are discarded after use. Conveniently, they are placed in the compartments **23** and **24** which are no longer needed. The patient is catheterized and the urine collected in the drainage bag. While the urine is being collected, the specimen container is opened and placed upright in recess **26**, which is sized appropriately to receive and stabilize it. After the urine has been collected, a sample is removed from the bag into the upstanding container. It is noted that any spillage which occurs will be directed into tray **10** and not contaminate the surrounding area.

Although the invention has been described with reference to the drawings, they are presented as illustrations of preferred embodiments of the invention and not meant to limit the invention either in spirit or in scope.

What is claimed is:

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1. A catheterization tray providing a sterile, self-contained catheterization package and work area comprising:

a generally rectangular dish having a bottom, four upstanding side walls and a continuous outwardly extending flange integral with the top of said walls,

at least two independent compartments within said dish for separately retaining absorbent material in each compartment;

a wall on the bottom of said dish defining a circular recess for receiving and holding upright a specimen container;

a raised wall section in said dish extending substantially the length of said dish and having a horizontal portion and an inclined portion;

a channel adapted to receive a catheter located in the top of said raised wall and extending substantially the length of said horizontal and inclined portions; and

a releasable cover sheet sealed to said flange, said cover sheet being permeable to sterlizing gases.

2. A catheterization package providing a sterile, self-contained work area comprising:

a generally rectangular dish having a bottom, four upstanding side walls and a continuous outwardly extending flange integral with the top of said walls;

at least two independent compartments within said dish for separately retaining absorbent material in each compartment, said compartments being adjacent to each other and separated by a wall preventing fluid flow therebetween;

a wall on the bottom of said dish defining a circular recess for receiving and holding upright a specimen container;

a raised wall section in said dish extending substantially the length of said dish and having a horizontal portion and an inclined portion;

a channel for receiving a catheter located in the top of said wall and extending substantially the length of said horizontal portion; and

a releasable cover sheet sealed to said flange, said dish containing a catheter at least partialy located within said channel, gloves, lubricant, antiseptic solution, drape, forceps, drainage bag, specimen container adapted to be retained in an upright position in said recess, and absorbent material in each of said independent compartments.

* * * * *

EXHIBIT 14

United States Patent [19]

Beddow

[11] **4,226,328**

[45] **Oct. 7, 1980**

[54] **CATHETERIZATION PACKAGE**

[75] Inventor: **David V. Beddow**, Lake Villa, Ill.

[73] Assignee: **Baxter Travenol Laboratories, Inc.**, Deerfield, Ill.

[21] Appl. No.: **28,516**

[22] Filed: **Apr. 9, 1979**

[51] **Int. Cl.**[3] **B65D 81/24**

[52] **U.S. Cl.** **206/364**; 206/571; 206/514; 206/560; 220/354; 220/408

[58] **Field of Search** 206/363, 364, 365, 366, 206/546, 570, 571, 514, 560; 220/410, 408, 354, 6

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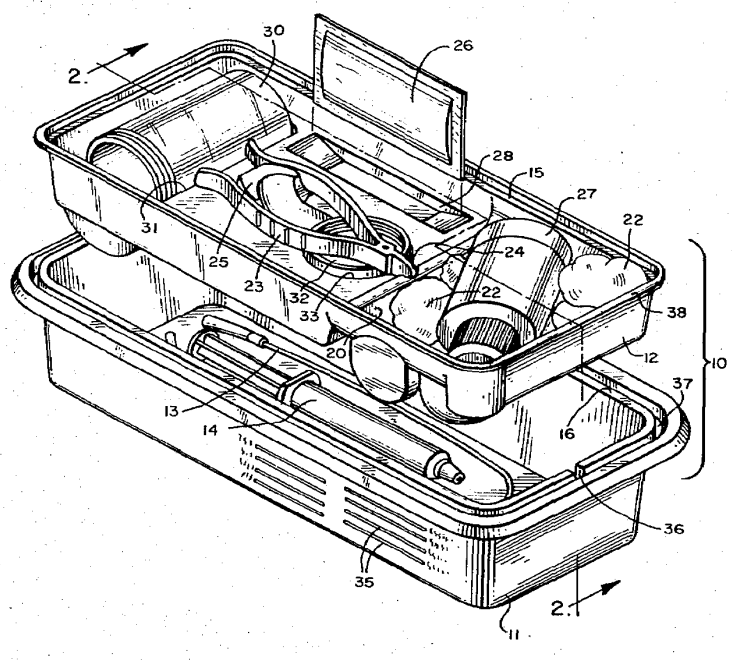
Primary Examiner—Joseph Man-Fu Moy
Attorney, Agent, or Firm—Henry W. Collins; Eugene M. Cummings; Paul C. Flattery

[57] **ABSTRACT**

A single-use disposable catheterization package containing the components required for accomplishing a catheterization procedure includes an outer tray and an inner tray. During storage the inner tray is nested within the outer tray and the components required for the catheterization procedure are organized within respective recesses provided on the inner tray. Upon use, the trays are separated and liquid collected as a result of the procedure is received in the outer tray. To prevent spillage, the inner tray is inverted and attached to the outer tray to provide a closed compartment. Rim portions on the inner and outer trays provide a locking leak-resistant engagement between the trays.

2 Claims, 6 Drawing Figures



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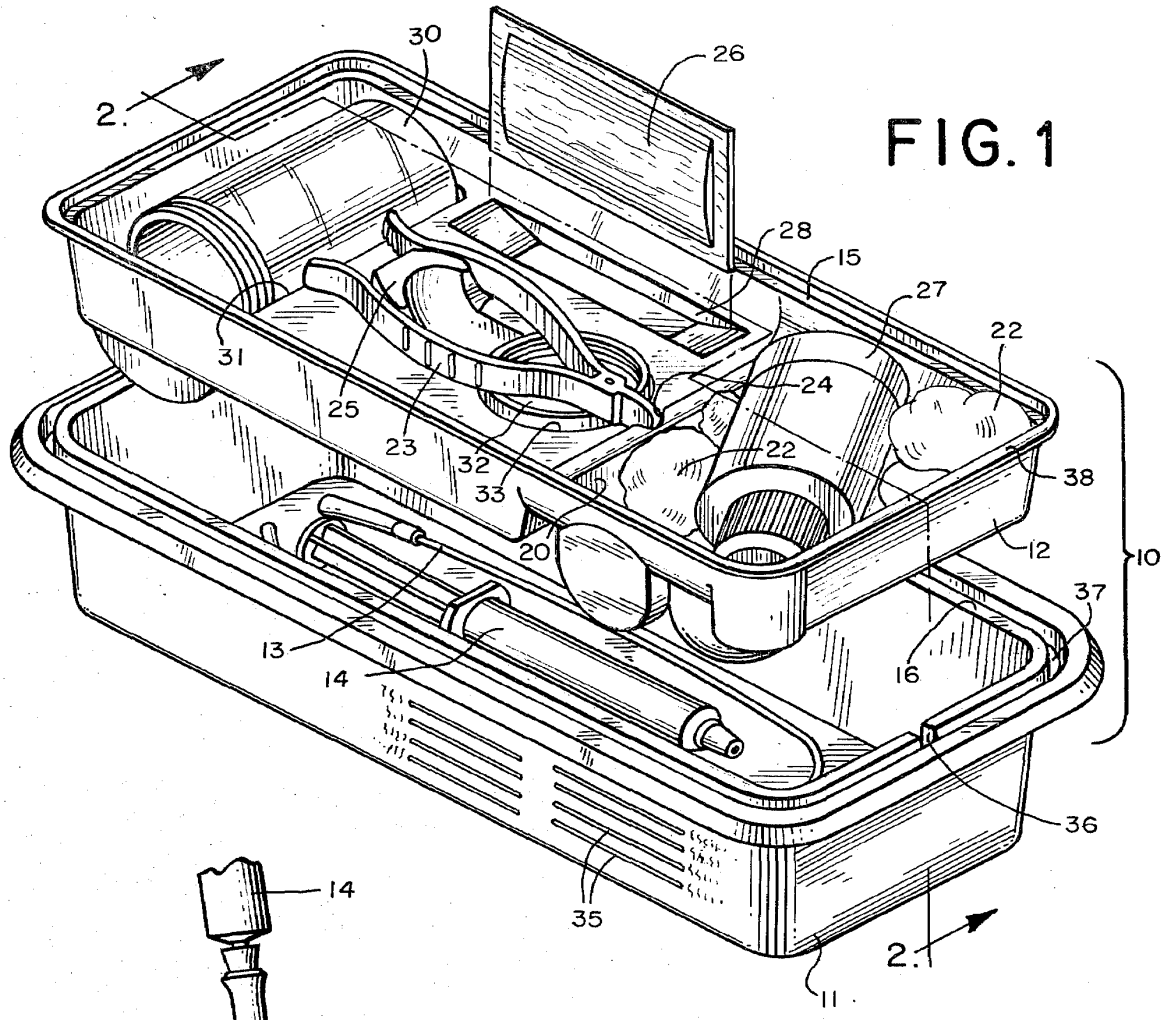
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FIG. 1

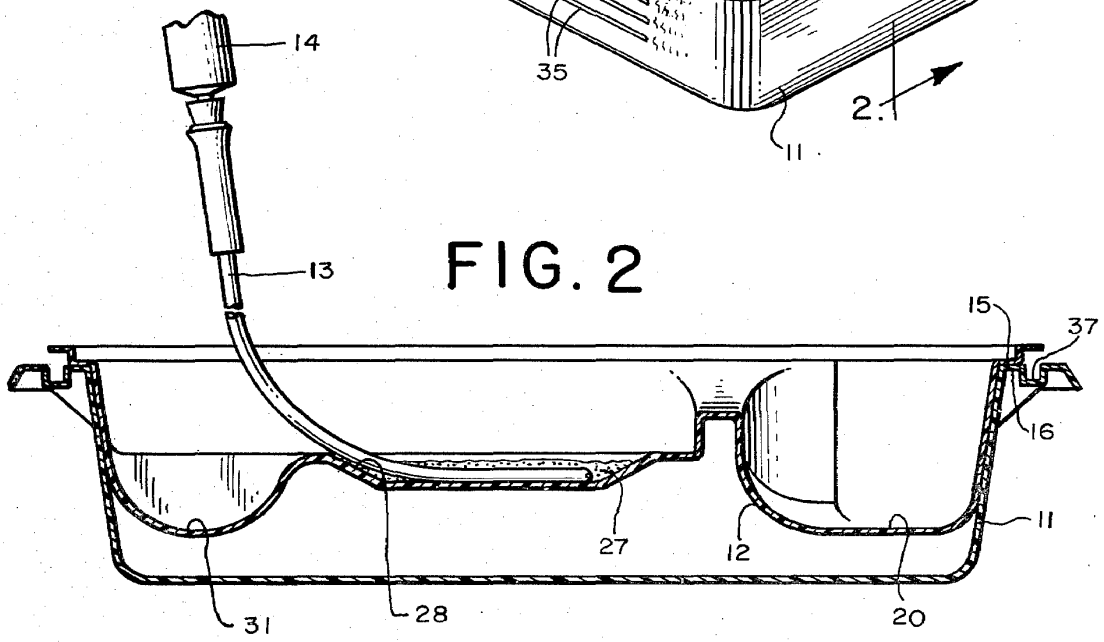
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FIG. 2

FIG. 3

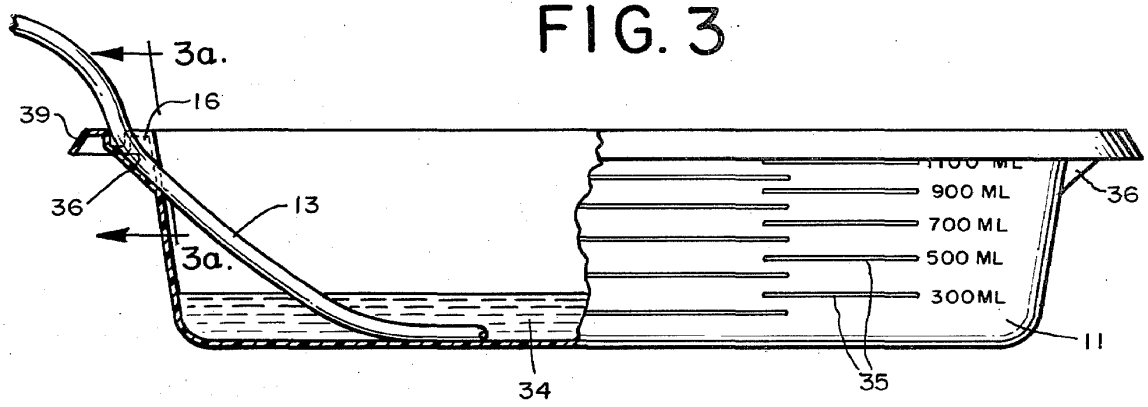


FIG. 3a

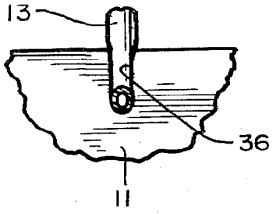
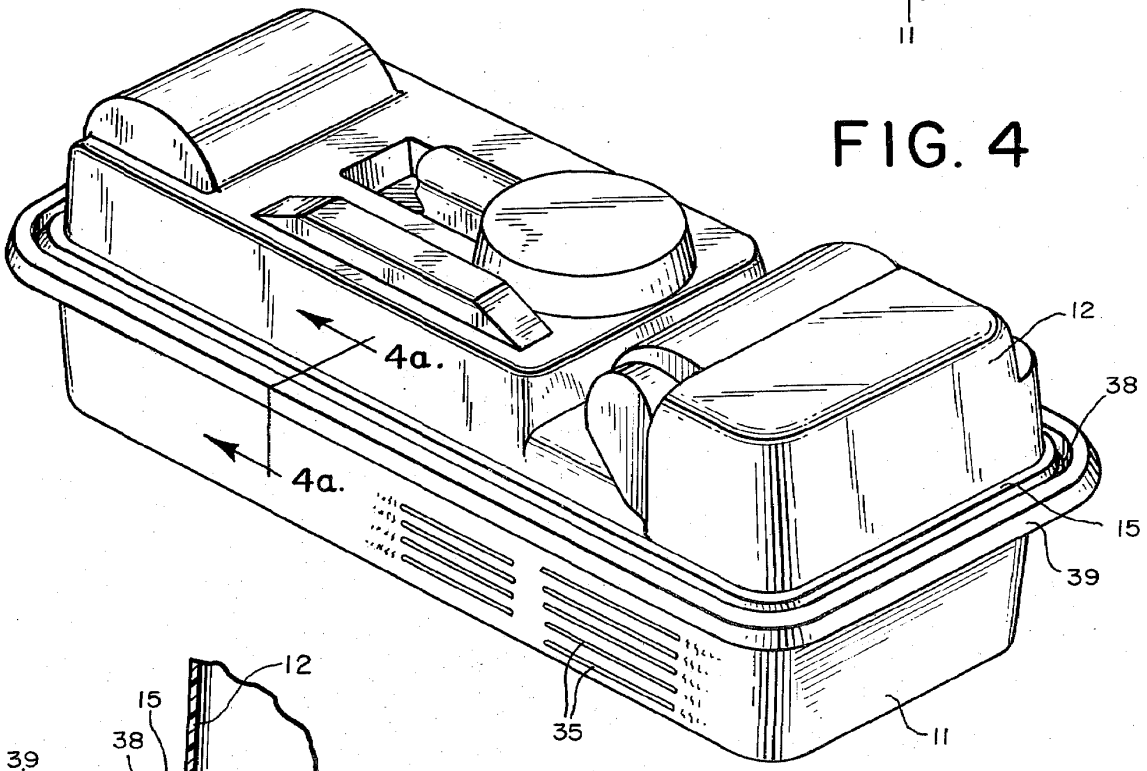


FIG. 4



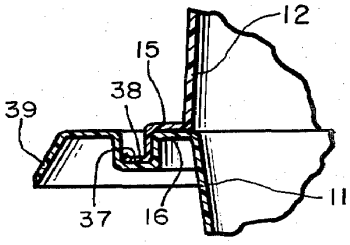


FIG. 4a

CATHETERIZATION PACKAGE

BACKGROUND OF THE INVENTION

This invention relates generally to a catheterization package, and more particularly to a catheterization package which provides a closed container for liquids collected as a result of a catheterization procedure.

Single-use disposable catheterization packages generally consist of a tray in which all of the components necessary for accomplishing a catheterization procedure, including preparation items, catheter and collection bottle, are arranged in their preferred order of use. The tray is sealed in a suitable pouch so that in using the package the physician or nurse is assured that all items necessary for the procedure are present and in a sterile condition. Examples of prior art catheterization packages of this nature are described in U.S. Pat. Nos. 3,978,983, 3,851,649, 3,329,261, 3,166,189, 3,013,656 and 2,346,636.

Ordinarily, in a catheterization procedure it is desired to collect in a closed container a small sample of liquid for analysis, and prior art catheterization packages have typically included a small specimen bottle and cover for this purpose. However, no closed container has been provided in these packages for liquid collected in excess of that required for the sample, and the physician has heretofore been forced to either collect and transport the excess liquid in an open portion of the package housing, or to provide a separate closed container for this purpose.

The present invention is directed to a package construction which obviates this problem by providing a closed leak-resistant collection reservoir for the excess liquid. This is accomplished without adding additional components to the package, and at a reduction in cost compared to the expense of a separate container for this purpose.

Accordingly, it is a general object of the present invention to provide a new and improved catheterization package.

It is a more specific object of the present invention to provide an improved catheterization package which provides for collection of excess liquids in a closed spillresistant container.

SUMMARY OF THE INVENTION

The invention is directed to a catheterization package which includes an outer tray including a circumferential rim portion and an inner tray including a circumferential rim portion dimensioned to engage the rim portion of the outer tray whereby the inner tray is suspended within the outer tray during storage of the package, and a plurality of recesses on the top surface thereof for receiving the components of the catheterization package. To provide a closed leak-resistant container for liquid collected during use of the catheterization package, the rim portion of the inner tray is adapted for locking engagement with the rim portion of the outer tray when the inner tray is inverted and assembled over the outer tray.

BRIEF DESCRIPTION OF THE DRAWINGS

The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with the further objects and advantages thereof, may best be understood by reference to the following description taken in

conjunction with the accompanying drawings, in the several figures of which like reference numerals identify like elements, and in which:

FIG. **1** is a perspective view of a catheterization package constructed in accordance with the invention showing the inner and outer tray portions thereof separated prior to use.

FIG. **2** is a cross-sectional view taken along line **2—2** of FIG. **1** showing the catheter of the catheterization package being lubricated prior to use.

FIG. **3** is a side elevational view of the outer tray portion of the catheterization package partly in cross-section to show the collection of liquid therein.

FIG. **3***a* is an enlarged perspective view of a portion of the bottom tray showing the attachment between the catheter tubing and the outer tray during collection of liquid.

FIG. **4** is a perspective view of the catheterization package showing the inner and outer tray portions thereof assembled following the catheterization procedure to provide a closed reservoir for collected liquid.

FIG. **4***a* is an enlarged cross-sectional view of the interlocking rims of the inner and outer trays when assembled as shown in FIG. **4**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the Figures, and particularly to FIG. **1**, a catheterization package **10** constructed in accordance with the invention is seen to include a generally rectangular box-like outer tray **11** having an open top within which a generally rectangular inner tray **12** is suspended. Prior to use, the assembled inner and outer trays are preferably enclosed within an appropriately dimensioned pouch (not shown), which is sealed to maintain the sterility of the components within the catheterization package. The pouch may be formed of a transparent and flexible plastic film and an appropriate wrapping may be provided between the assembled trays and the pouch. The various foldable materials required for the catheterization procedure, including a water proof underpad (not shown), a pair of pre-powdered gloves (not shown), and protective drape (not shown) may be arranged in a flat condition between the wrap and the trays.

Prior to use, the plastic pouch is opened and the wrap, underpad, plastic gloves and drape are removed, unfolded and placed in position on the patient in a manner well known to the art. Inner tray **12** is then lifted from outer tray **11**, as shown in FIG. **1**, exposing the catheter **13** and syringe **14** for use. As best shown in FIG. **2**, the inner tray **12** includes a flat horizontal rim portion **15** which engages a similarly dimensioned horizontal rim portion **16** on outer tray **11**. The base and tray portions may be thermoformed by conventional methods from a thin plastic material.

Inner tray **12** is formed with a plurality of compartments or recesses which accommodate the various components required by the catheterization procedure. A first recess **20** is provided to accommodate a bottle **21** of cleansing solution, and to hold the bottle in place the recess may include an appropriately dimensioned section at one end for receiving the neck and cap of the bottle, and an appropriately dimensioned section at its other end to receive the bottom end of the bottle. Recess **20** may include a central section which is wider than bottle **21** to facilitate access to the bottle, and to

Bard Exhibit 1004.0410

provide an area for storing balls of cleansing material 22, which are used in preparing the patient for catheterization. Prior to use the balls of cleansing material are saturated with cleansing solution by removing bottle 21 from compartment 20, and pouring the contents of the bottle over the balls of cleansing material while the balls are in their stored position in recess 20. After saturization, the balls are handled by a forceps 23 which is securely stored in tray 12 by means of a notch 24 and abutment 25 provided on the tray surface.

To provide for lubrication of the catheter, the catheterization package 10 includes an individually sealed foil container 26 of lubricating jelly 27 packed within an elongated rectangular recess 28. In use, this container is removed from recess 27 and torn open, and the lubricating jelly contained therein is deposited in the recess. Catheter 13 and syringe 14 are now removed from outer tray 11 and prepared for use. After the patient has been prepared, the catheter is lubricated with the lubricating jelly 27 by positioning the catheter tip in the jelly-filled recess 28, as shown in FIG. 2, and the catheterization procedure is carried out in a conventional manner.

A sample of liquid collected as a result of the catheterization procedure may be collected in a specimen bottle 30 (FIG. 1) which is contained in a recess 31 in the inner tray. A cap 32, which is in a recess 33 in the inner tray, is utilized to close the specimen bottle.

As shown in FIG. 3, after the desired specimen has been collected in specimen bottle 30, the excess collected liquid 34 is collected in outer tray 11. A plurality of volume-indicating marks 35 may be provided in embossed or printed form on one or more side walls of the outer tray to indicate the volume of liquid collected. Although marks reading from 300 milliliters to 1100 milliliters are shown in the preferred embodiment, it will be appreciated that other volumetric indications may be provided to accommodate various sizes of outer trays and units of volume.

The rim of outer tray 11 may be provided with one or more channels 36 to secure the end of catheter 13 during collection of fluid in the tray. As seen in FIG. 3, these channels extend between the rim and sidewall portions of tray 11, and, as such provide an angled walled bridge element which firmly grips the catheter tubing and adds to the rigidity of the tray. As best seen in FIG. 3*a*, the walls of the channel are preferably spaced to slightly compress the catheter tubing so as to prevent the tubing from being inadvertently pulled loose during collection of liquid 34.

After the excess liquid has been collected in outer tray 11, the outer tray may be conveniently closed by inverting inner tray 12 and securing the two trays together as shown in FIG. 4. The result is an enclosed container for the collected liquid 34 which may be transported for storage or disposal without risk of the liquid being spilled. As illustrated in FIG. 4*a*, a leak-resistant interlocking fit is obtained between the two trays by providing a circumferential channel 37 on the rim portion of tray 11 within which a circumferential lip portion 38 provided on the rim portion of tray 12 is received. In practice, the channel and lip portions are dimensioned to obtain an engagement which is sufficiently tight to resist leakage and prevent inadvertent separation, but not so tight as to present difficulty to the physician or nurse in assembling or disassembling the trays.

To provide a smooth edge for handling purposes, a rounded circumferential flange portion 39 is provided on tray 11 external to channel 37. This flange portion is angled downwardly with respect to the top surface of the tray, and as shown in FIG. 4*a*, is cut at an angle in a vertical plane such that an edge free of potentially abrasive corners is obtained. The resulting rim construction adds additional rigidity to tray 11 and provides convenient handle means for carrying the tray.

Thus, a sterile one-use catheterization package has been described which includes all of the components necessary to carry out a catheterization procedure. An inner tray portion of this package stores the components so as to provide protection against damage during shipment and to render the components readily available when called for by the procedure. An outer tray portion provides a similar storage function for the catheter and syringe, and doubles as a closed spill-resistant container for liquid collected as a result of the procedure. The inner and outer trays may be conveniently and economically formed by conventional thermoforming techniques of thin molded plastic, the various recesses provided therein serving to enhance the overall structural strength of the trays.

While a particular embodiment of the invention has been shown and described, it will be obvious to those skilled in the art that changes and modifications may be made without departing from the invention in its broader aspects, and, therefore, the aim in the appended claims is to cover all such changes and modifications as fall within the true spirit and scope of the invention.

I claim:

1. A disposable catheterization package of the type containing components for a catheterization procedure, comprising:

an outer tray including side walls and a circumferential rim portion;

an inner tray including a circumferential rim portion dimensioned to engage said outer tray rim portion whereby said inner tray is nestingly suspended within said outer tray during storage of said package, said inner tray including a plurality of recesses on the surface thereof for receiving at least a portion of the components contained in the package;

said outer tray rim portion including a channel and inner and outer generally flat horizontal flange portions on either side of said channel;

said inner tray rim portion including a flat horizontal flange portion and a lip portion upstanding therefrom;

said inner flange portion of said outer tray rim and said flange portion of said inner tray rim being disposed for engaging in an abutting relationship when said inner tray is nested within said outer tray;

a notch-like recess along said inner flange portion of said outer tray rim for receiving in supporting relationship a portion of a catheter used in the catheterization procedure;

said lip portion of said inner tray rim being receivable within said channel of said outer tray rim when said inner tray is inverted, to provide a closed spill-resistant container between said tray portions for liquid collected during the catheterization procedure.

2. A disposable catheterization package in accordance with claim 1 wherein the edge of said outer flange portion of said outer tray rim is downturned.

* * * * *

Bard Exhibit 1004.0411

EXHIBIT 17

US009745088B2

(12) **United States Patent**
Tomes et al.

(10) **Patent No.: US 9,745,088 B2**
(45) **Date of Patent: *Aug. 29, 2017**

(54) **CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS**

(71) Applicant: **Medline Industries, Inc.**, Mundelein, IL (US)

(72) Inventors: **Jennifer E. Tomes**, Mundelein, IL (US); **Sarah Dickinson**, Chicago, IL (US); **Deborah Adler**, New York, NY (US); **Jack Maze**, Long Grove, IL (US); **Alberto Savage**, Buffalo Grove, IL (US); **Kenneth Chua**, Glenview, IL (US); **Earl Wilson**, Ingleside, IL (US); **John Kutsch**, Harvard, IL (US)

(73) Assignee: **Medline Industries, Inc.**, Northfield, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 234 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/793,455**

(22) Filed: **Jul. 7, 2015**

(65) **Prior Publication Data**

US 2015/0335855 A1 Nov. 26, 2015

Related U.S. Application Data

(60) Continuation of application No. 13/860,902, filed on Apr. 11, 2013, now Pat. No. 9,522,753, which is a (Continued)

(51) **Int. Cl.**
A61M 25/00 (2006.01)
B65B 11/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***B65B 11/00*** (2013.01); ***A61B 50/30*** (2016.02); ***A61B 50/33*** (2016.02); ***A61M 25/00*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 2050/3008; A61B 2050/3015; A61B 42/00; A61B 46/00; A61B 50/30;
(Continued)

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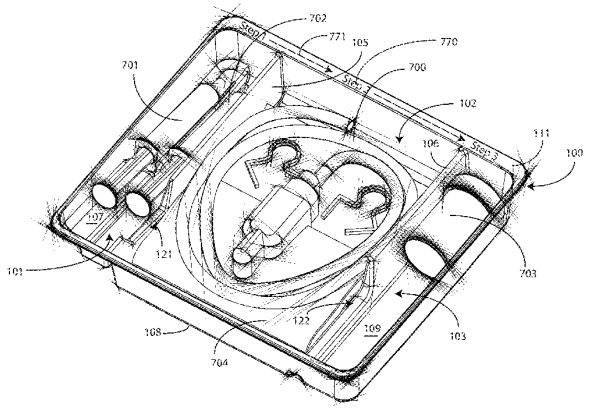
Primary Examiner — Adam Marcetich
(74) *Attorney, Agent, or Firm* — Philip H. Burrus, IV

(57) **ABSTRACT**

A tray (**100**) for accommodating a coiled medical device, such as a catheter assembly (**700**), includes a first compartment (**101**), a second compartment (**102**), and a third compartment (**103**). The catheter assembly (**700**) and devices associated with a catheterization procedure, such as syringes (**701**,**702**) containing sterile water and lubricating jelly and a specimen container (**703**) can be disposed within the tray. Printed instructions (**1001**) can be included with the tray (**100**). One or more layers of wrap material (**2200**) can be
(Continued)



folded about the tray (**100**) to enclose the tray (**100**) and other items, such as an additional layer of wrap material (**2701**), packaged liquid hand sanitizer (**2401**), and packaged gloves (**2402**). When a health care services provider (**3101**) unfolds the wrap material, the same can be used to create a sterile field beneath a patient (**3201**).

92 Claims, 35 Drawing Sheets

Related U.S. Application Data

division of application No. 13/155,026, filed on Jun. 7, 2011, now Pat. No. 8,448,786, which is a continuation-in-part of application No. 12/495,148, filed on Jun. 30, 2009, now Pat. No. 8,631,935, and a continuation-in-part of application No. 12/647,515, filed on Dec. 27, 2009, and a continuation-in-part of application No. 13/153,265, filed on Jun. 3, 2011, and a continuation-in-part of application No. 13/153,300, filed on Jun. 3, 2011, now abandoned.

(60) Provisional application No. 61/352,140, filed on Jun. 7, 2010, provisional application No. 61/352,155, filed on Jun. 7, 2010, provisional application No. 61/428,944, filed on Dec. 31, 2010, provisional application No. 61/437,796, filed on Jan. 31, 2011.

(51) **Int. Cl.**

A61B 50/33	(2016.01)
A61M 5/00	(2006.01)
A61B 50/30	(2016.01)
A61B 42/00	(2016.01)
A61B 46/00	(2016.01)

(52) **U.S. Cl.**

CPC ***A61M 25/002*** (2013.01); *A61B 42/00* (2016.02); *A61B 46/00* (2016.02); *A61B 2050/3008* (2016.02); *A61B 2050/3015* (2016.02); *A61J 2205/40* (2013.01); *A61J 2205/50* (2013.01); *A61L 2202/18* (2013.01); *A61L 2202/182* (2013.01); *A61M 5/002* (2013.01); *A61M 25/0017* (2013.01); *A61M 2209/06* (2013.01)

(58) **Field of Classification Search**

CPC ... A61B 50/33; A61M 2209/06; A61M 25/00; A61M 25/0017; A61M 25/002; A61M 5/002; A61M 5/003; A61M 2205/6081; B65B 11/00; A61L 2202/18; A61L 2202/182; B65D 1/36; A61J 2205/20; A61J 2205/40; A61J 2205/50

See application file for complete search history.

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Bard Exhibit 1004.0419

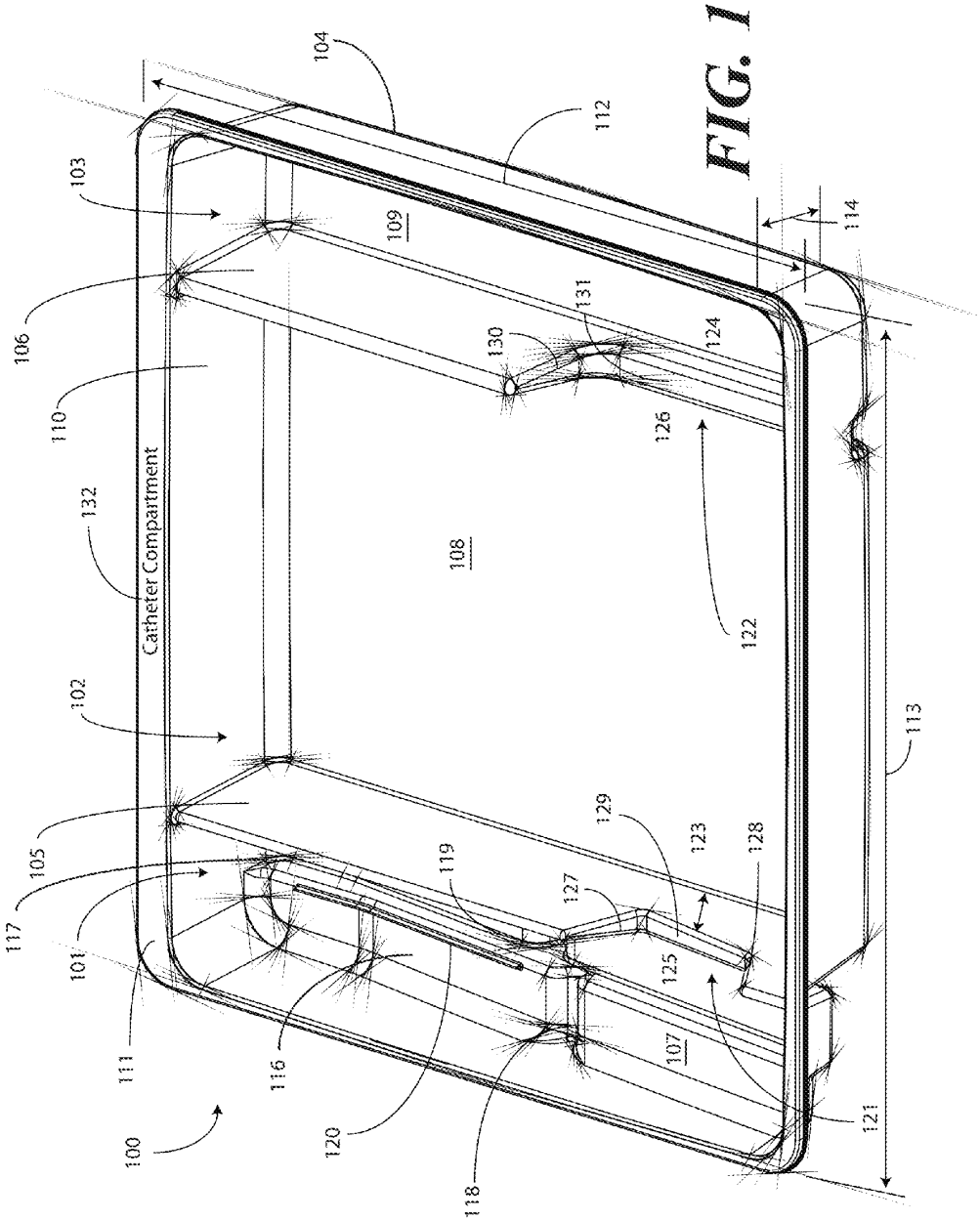
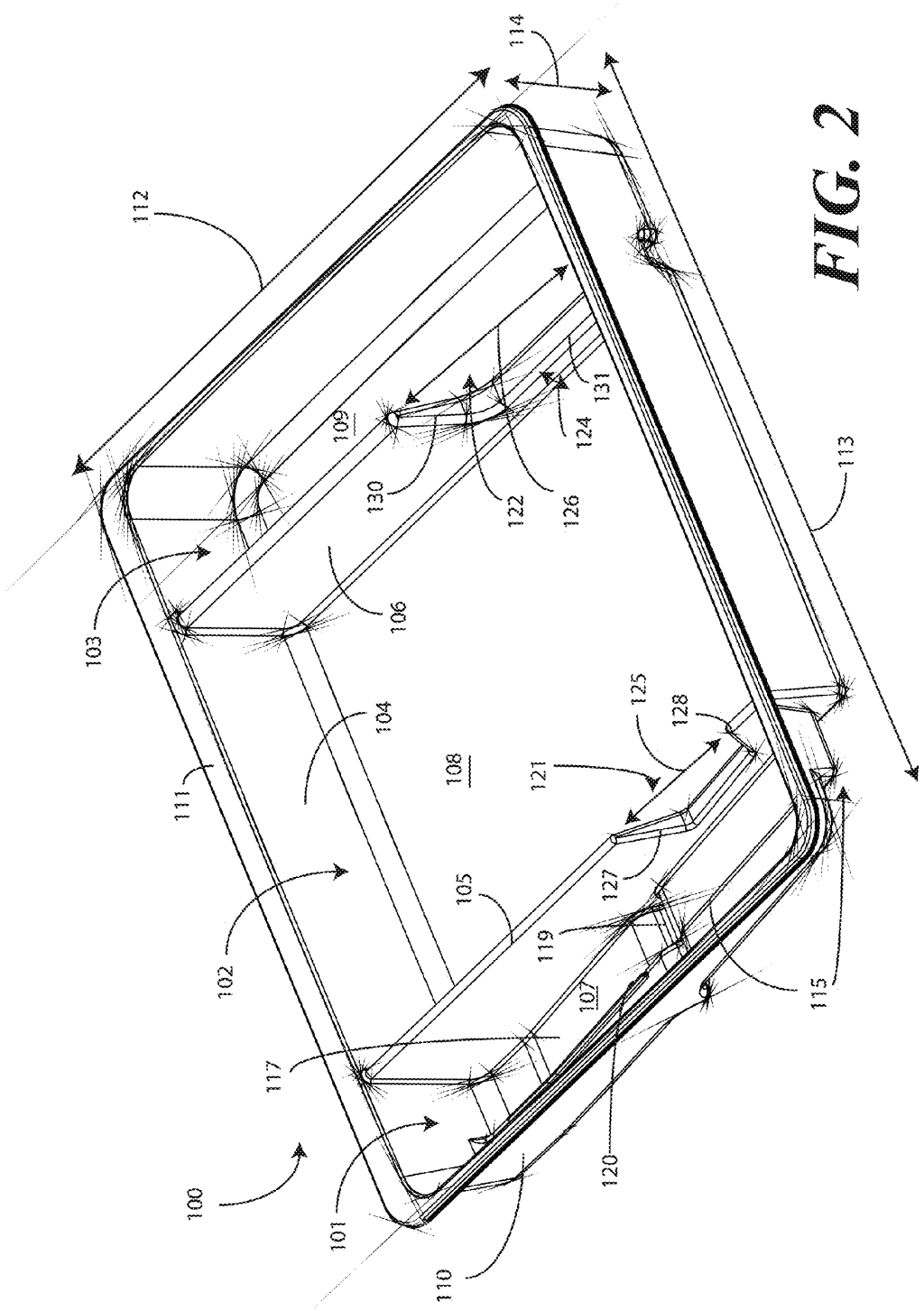


FIG. 1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117
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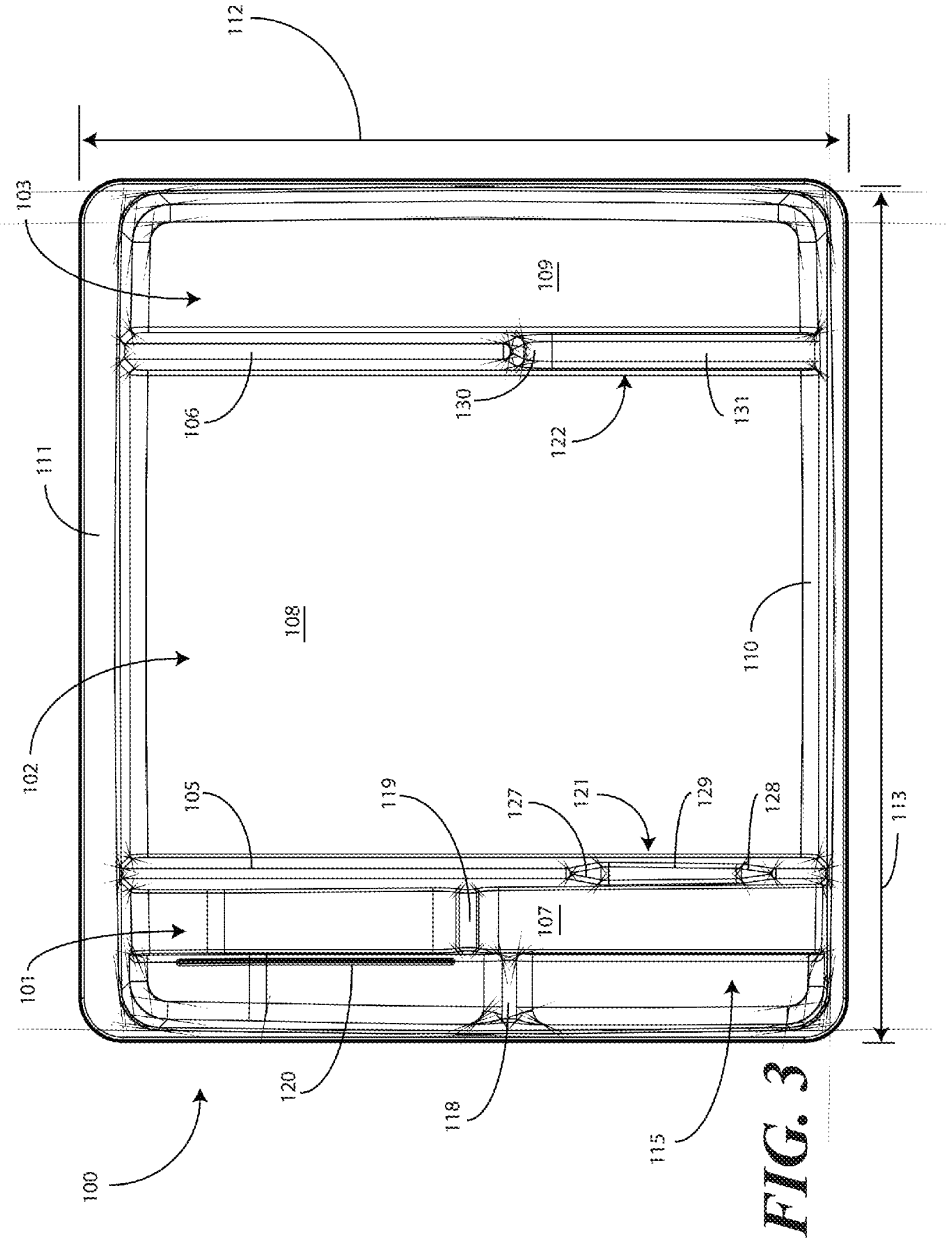
101
110

FIG. 2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118
115
100

FIG. 3

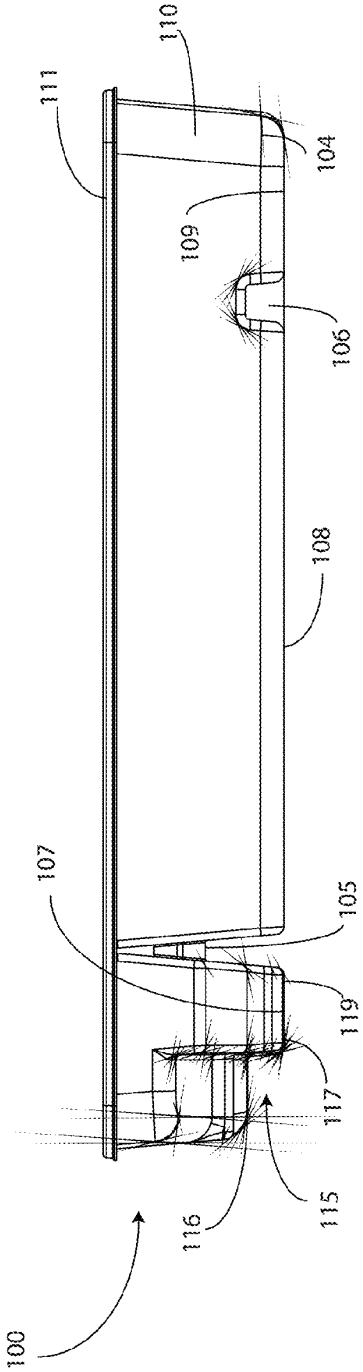
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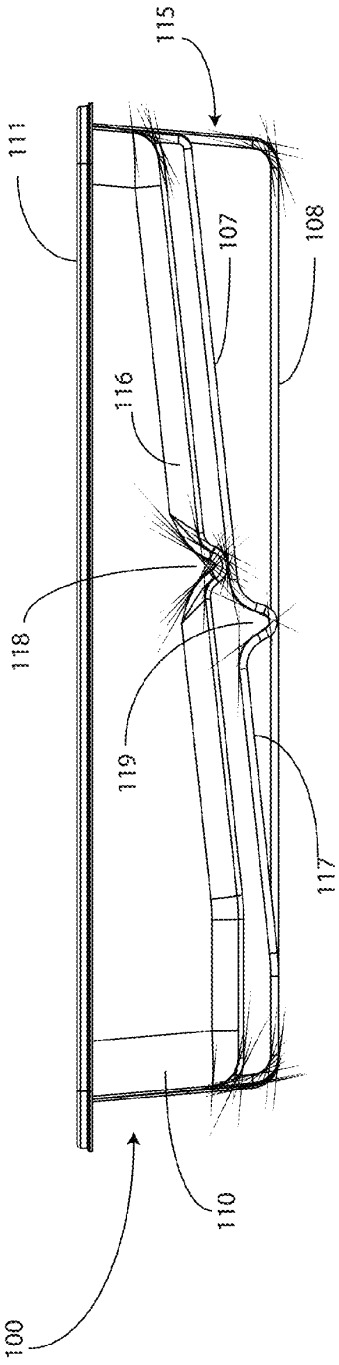
FIG. 4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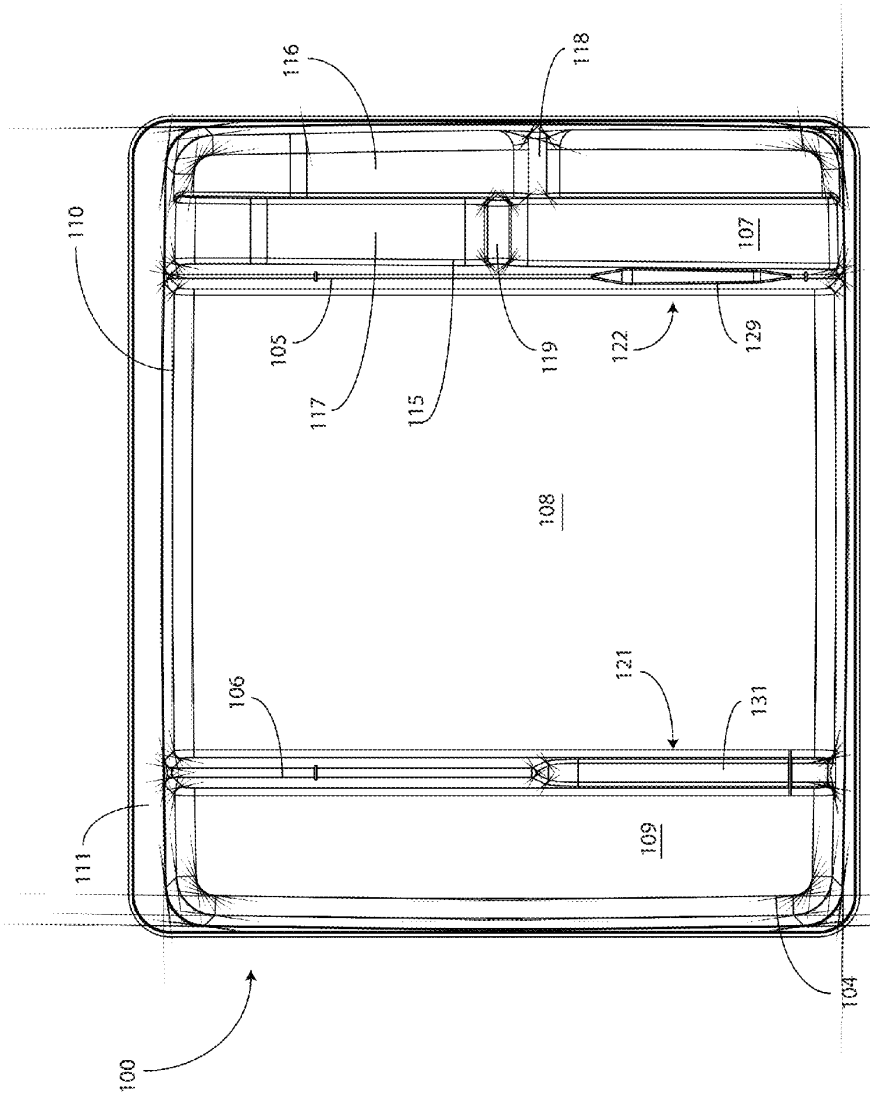
118
119
117
110
100

FIG. 5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121
106
131
111
109
104
100

FIG. 6

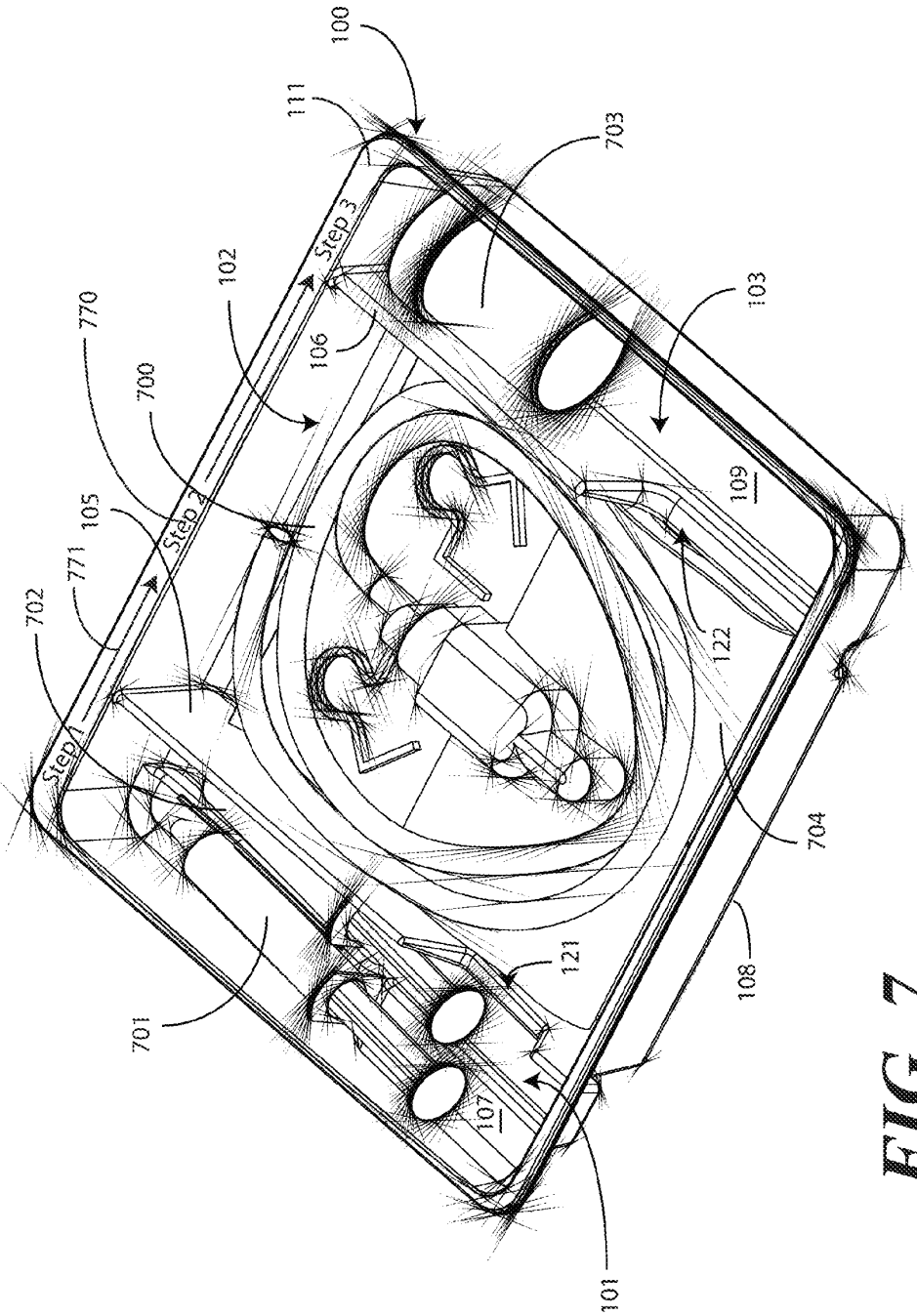
100
111
703
Step 3
102
103
770
106
700
109
105
Step 2
771
702
122
Step 1
704
121
108
701
107
101

FIG. 7

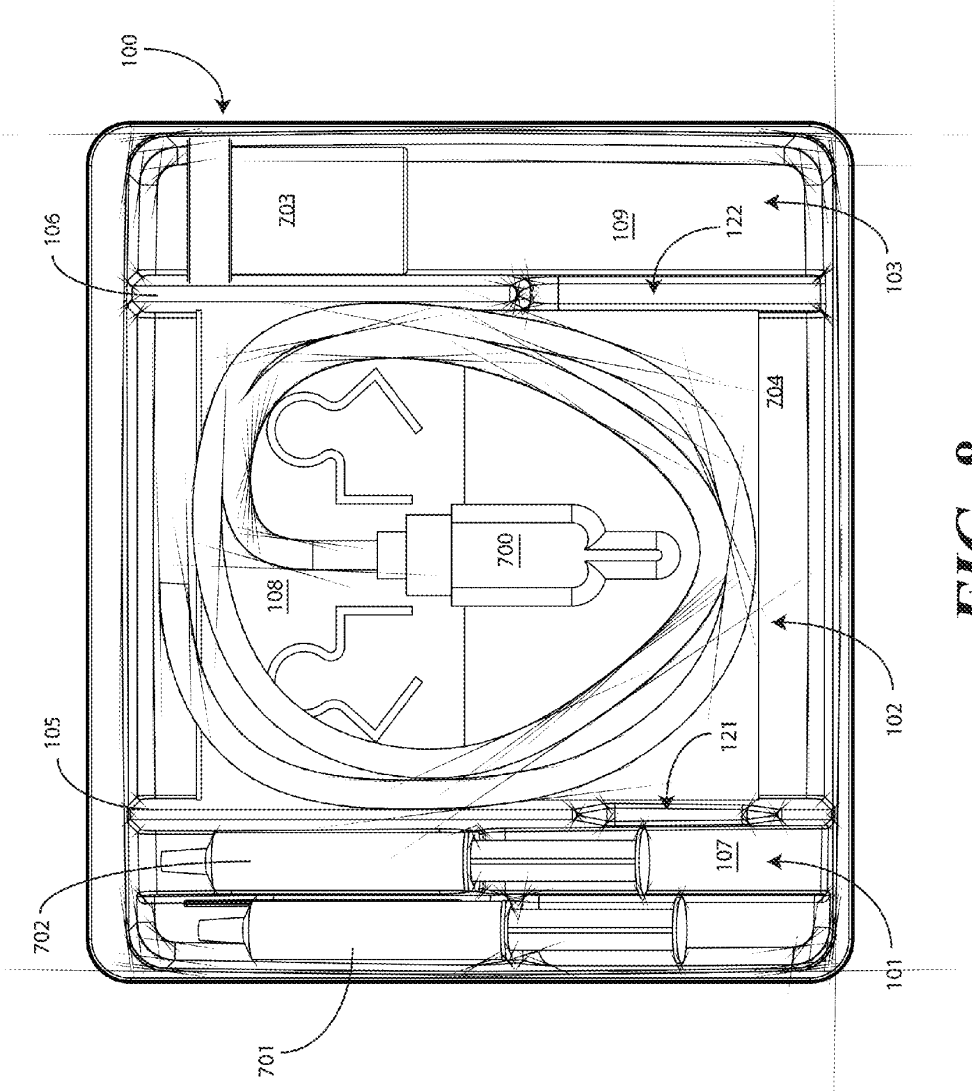

FIG. 8

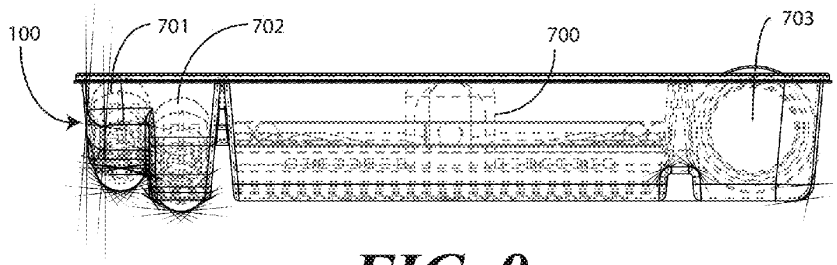
100
701
702
700
703

FIG. 9

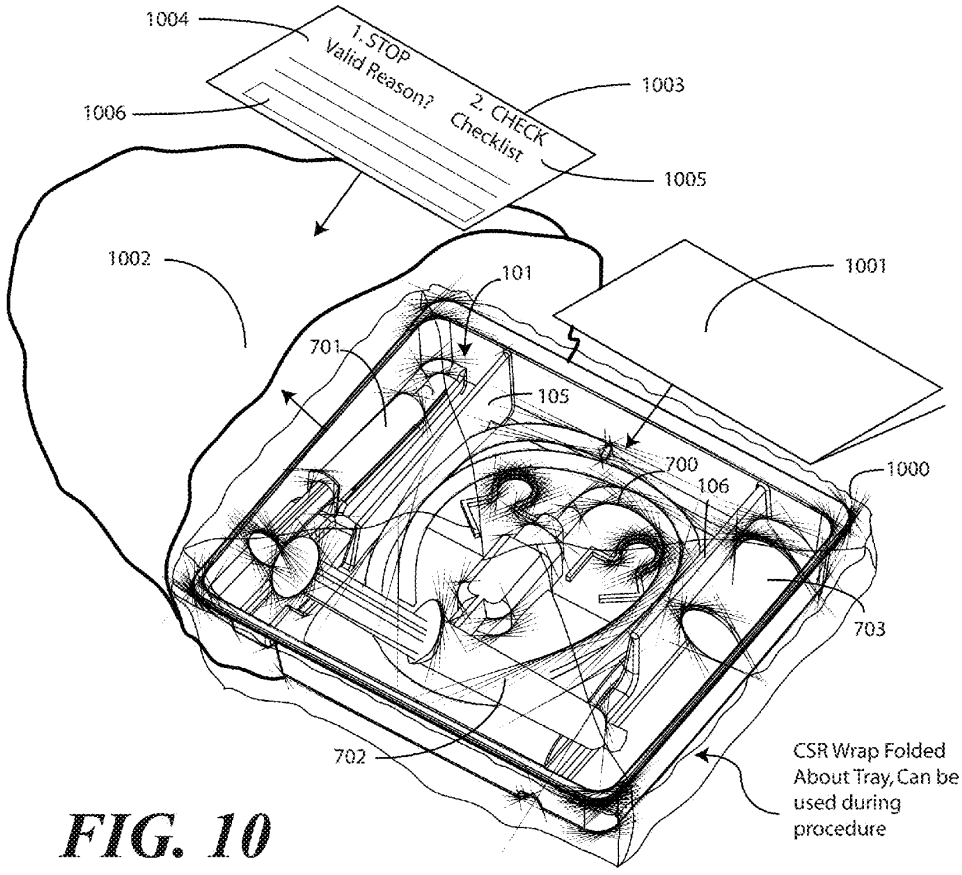
1004
1. STOP Valid Reason?
2. CHECK Checklist
1003
1006
1005
1002
101
1001
701
105
700
106
1000
703
702
CSR Wrap Folded About Tray, Can be used during procedure

FIG. 10

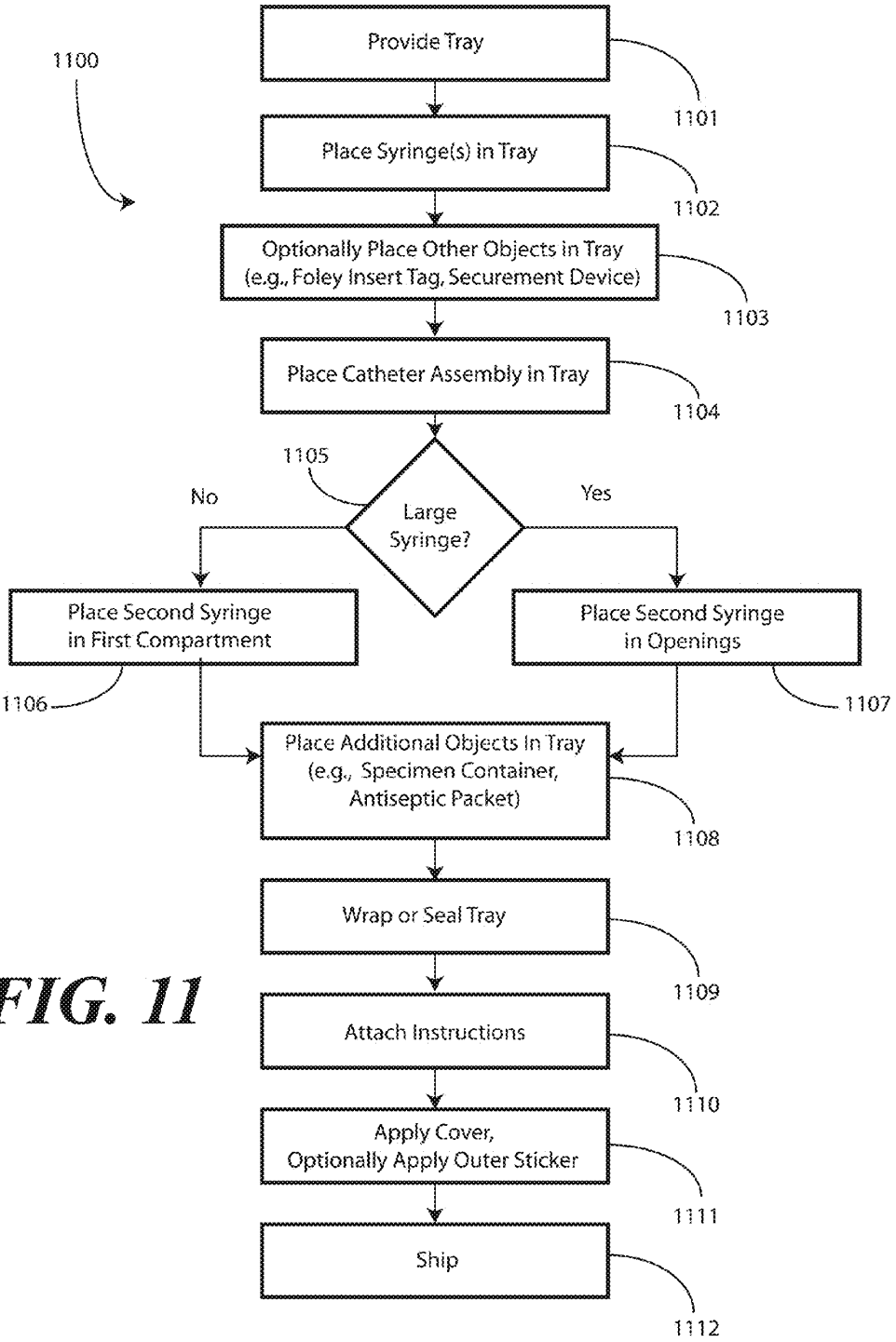
1100
Provide Tray
1101
Place Syringe(s) in Tray
1102
Optionally Place Other Objects in Tray
(e.g., Foley Insert Tag, Securement Device)
1103
Place Catheter Assembly in Tray
1104
1105
Large Syringe?
No
Yes
Place Second Syringe in First Compartment
1106
Place Second Syringe in Openings
1107
Place Additional Objects in Tray
(e.g., Specimen Container, Antiseptic Packet)
1108
Wrap or Seal Tray
1109
Attach Instructions
1110
Apply Cover,
Optionally Apply Outer Sticker
1111
Ship
1112

FIG. 11

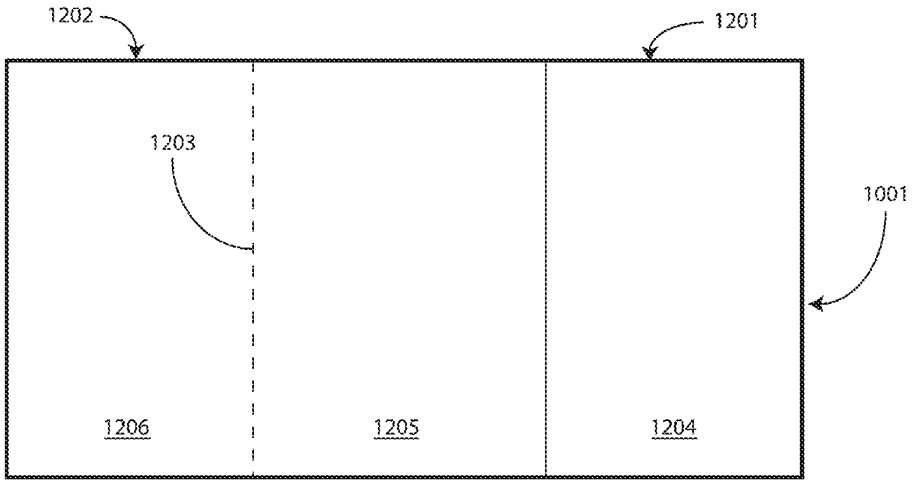
1202
1201
1203
1001
1206
1205
1204

FIG. 12

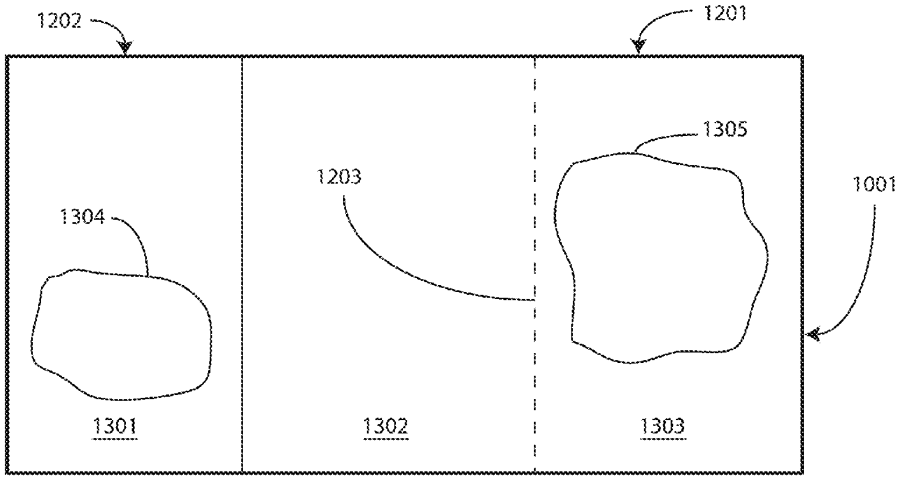
1202
1201
1305
1203
1001
1304
1301
1302
1303

FIG. 13

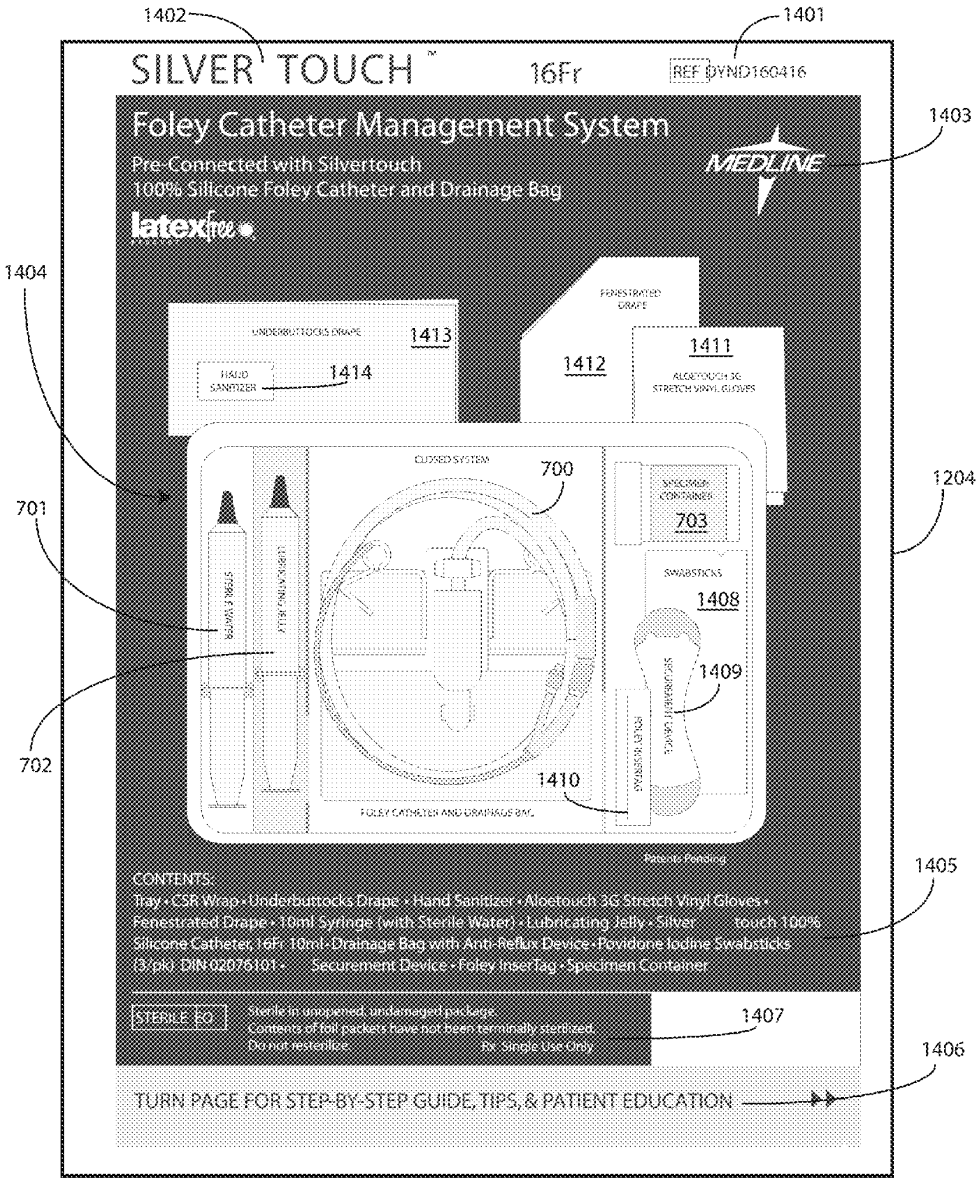
1402
1401
SILVER TOUCH
16Fr
REF DYND160416
Foley Catheter Management System
Pre-Connected with Silvertouch
100% Silicone Foley Catheter and Drainage Bag
latex free
MEDLINE
1403
1404
1413
1414
1412
1411
700
703
1408
1409
1410
701
702
1204
CONTENTS:
Tray • CSR Wrap • Underbuttocks Drape • Hand Sanitizer • Aloetouch 3G Stretch Vinyl Gloves • Penestrated Drape • 10ml Syringe (with Sterile Water) • Lubricating Jelly • Silver Touch 100% Silicone Catheter 16Fr 10ml • Drainage Bag with Anti-Reflux Device • Povidone Iodine Swabsticks (3 pk) DIN 02076101 • Securement Device • Foley InserTag • Specimen Container
1405
STERILE EO
Sterile in unopened, undamaged package.
Contents of foil packets have not been terminally sterilized.
Do not resterilize
Rx Single Use Only
1407
1406
TURN PAGE FOR STEP-BY-STEP GUIDE, TIPS, & PATIENT EDUCATION

FIG. 14

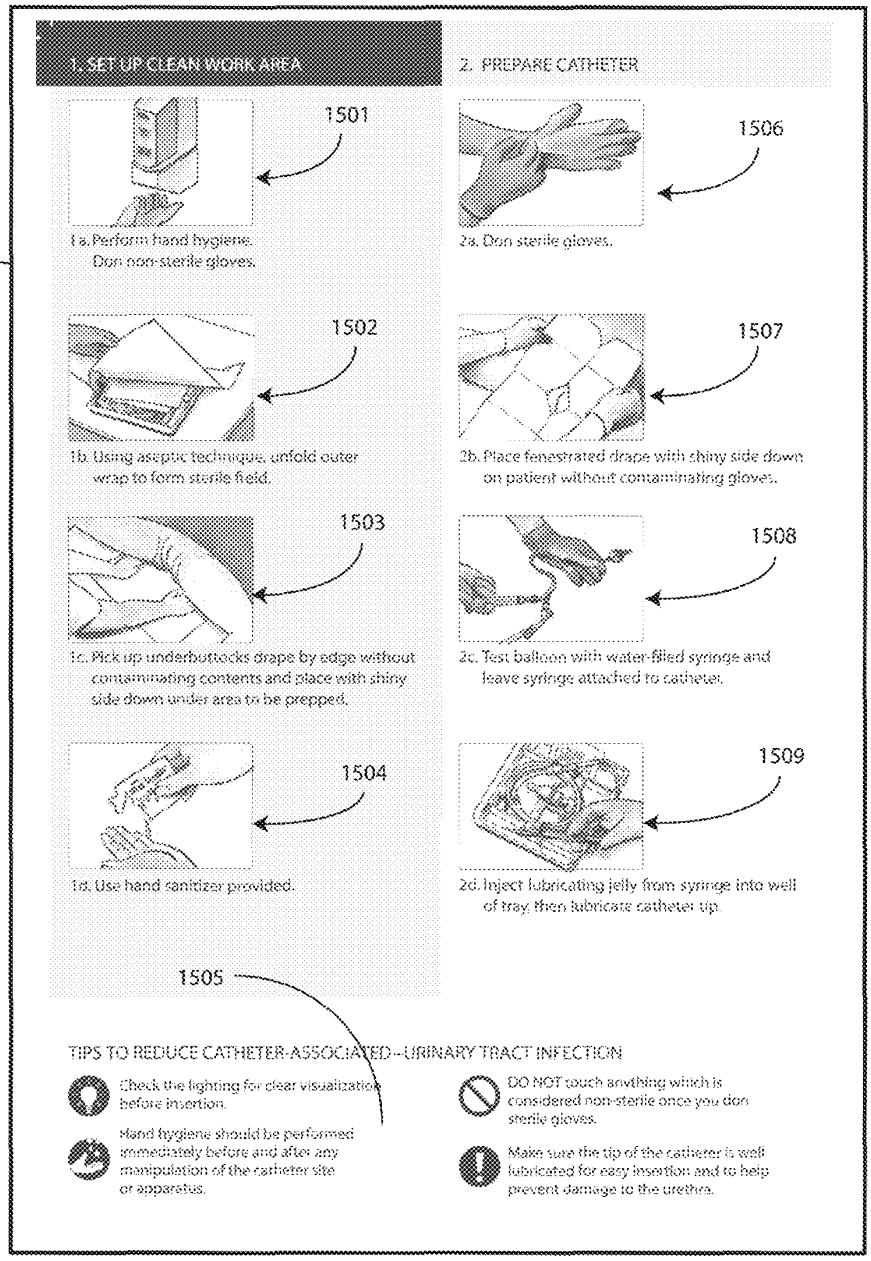
1. SET UP CLEAN WORK AREA
2. PREPARE CATHETER
1301
1501
1a. Perform hand hygiene. Don non-sterile gloves.
1502
1b. Using aseptic technique, unfold outer wrap to form sterile field.
1503
1c. Pick up underbuttocks drape by edge without contaminating contents and place with shiny side down under area to be prepped.
1504
1d. Use hand sanitizer provided.
1506
2a. Don sterile gloves.
1507
2b. Place fenestrated drape with shiny side down on patient without contaminating gloves.
1508
2c. Test balloon with water-filled syringe and leave syringe attached to catheter.
1509
2d. Inject lubricating jelly from syringe into well of tray, then lubricate catheter up.
1505
TIPS TO REDUCE CATHETER-ASSOCIATED–URINARY TRACT INFECTION
Check the lighting for clear visualization before insertion.
Hand hygiene should be performed immediately before and after any manipulation of the catheter site or apparatus.
DO NOT touch anything which is considered non-sterile once you don sterile gloves.
Make sure the tip of the catheter is well lubricated for easy insertion and to help prevent damage to the urethra.

FIG. 15

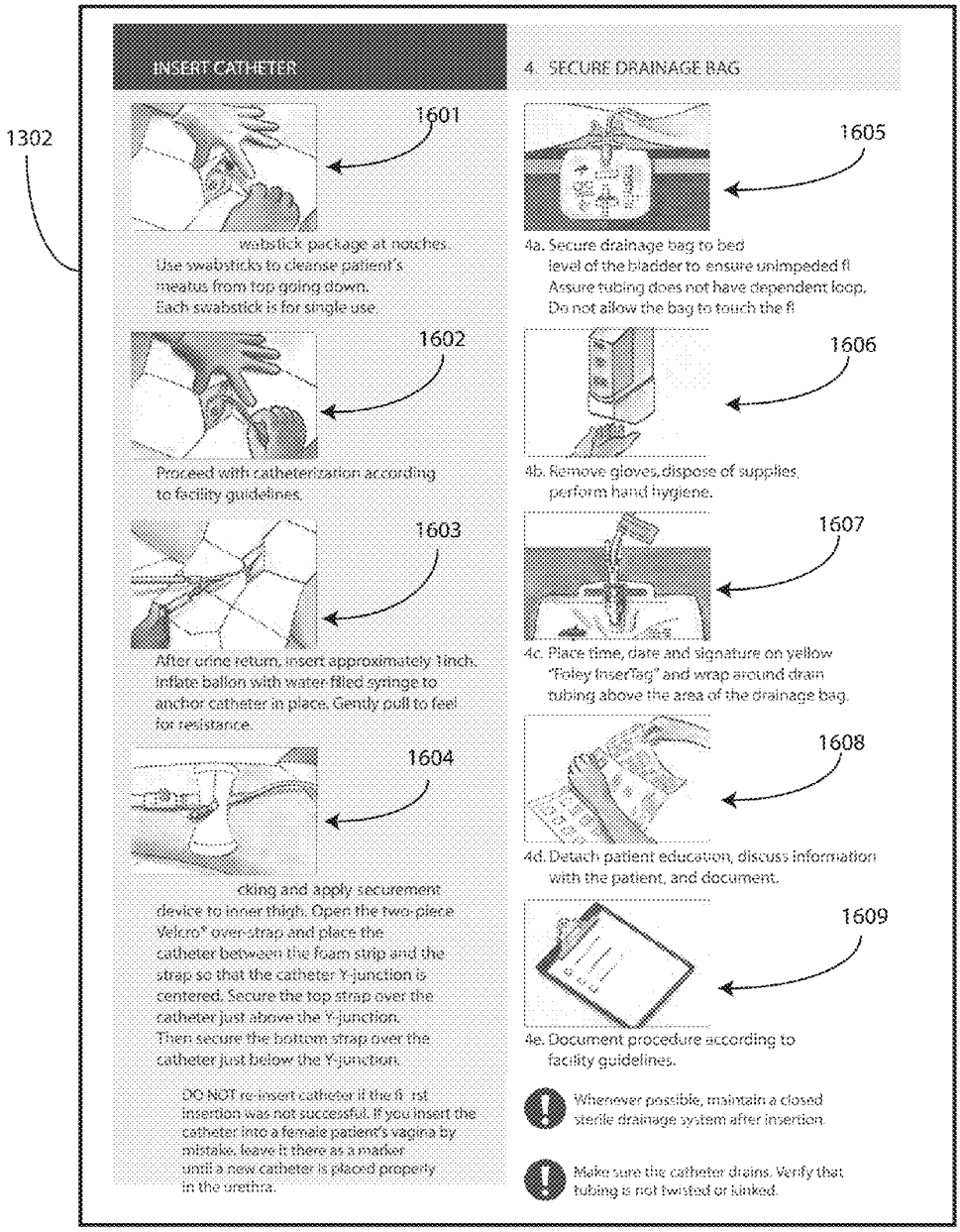
1302
INSERT CATHETER
1601
wabstick package at notches.
Use swabsticks to cleanse patient's
meatus from top going down.
Each swabstick is for single use.
1602
Proceed with catheterization according
to facility guidelines.
1603
After urine return, insert approximately 1inch.
Inflate ballon with water-filled syringe to
anchor catheter in place. Gently pull to feel
for resistance.
1604
cking and apply securement
device to inner thigh. Open the two-piece
Velcro® over-strap and place the
catheter between the foam strip and the
strap so that the catheter Y-junction is
centered. Secure the top strap over the
catheter just above the Y-junction.
Then secure the bottom strap over the
catheter just below the Y-junction.
DO NOT re-insert catheter if the fi rst
insertion was not successful. If you insert the
catheter into a female patient's vagina by
mistake, leave it there as a marker
until a new catheter is placed properly
in the urethra.
4. SECURE DRAINAGE BAG
1605
4a. Secure drainage bag to bed
level of the bladder to ensure unimpeded fl
Assure tubing does not have dependent loop.
Do not allow the bag to touch the fl
1606
4b. Remove gloves, dispose of supplies,
perform hand hygiene.
1607
4c. Place time, date and signature on yellow
"Foley InserTag" and wrap around drain
tubing above the area of the drainage bag.
1608
4d. Detach patient education, discuss information
with the patient, and document.
1609
4e. Document procedure according to
facility guidelines.
Whenever possible, maintain a closed
sterile drainage system after insertion.
Make sure the catheter drains. Verify that
tubing is not twisted or kinked.

FIG. 16

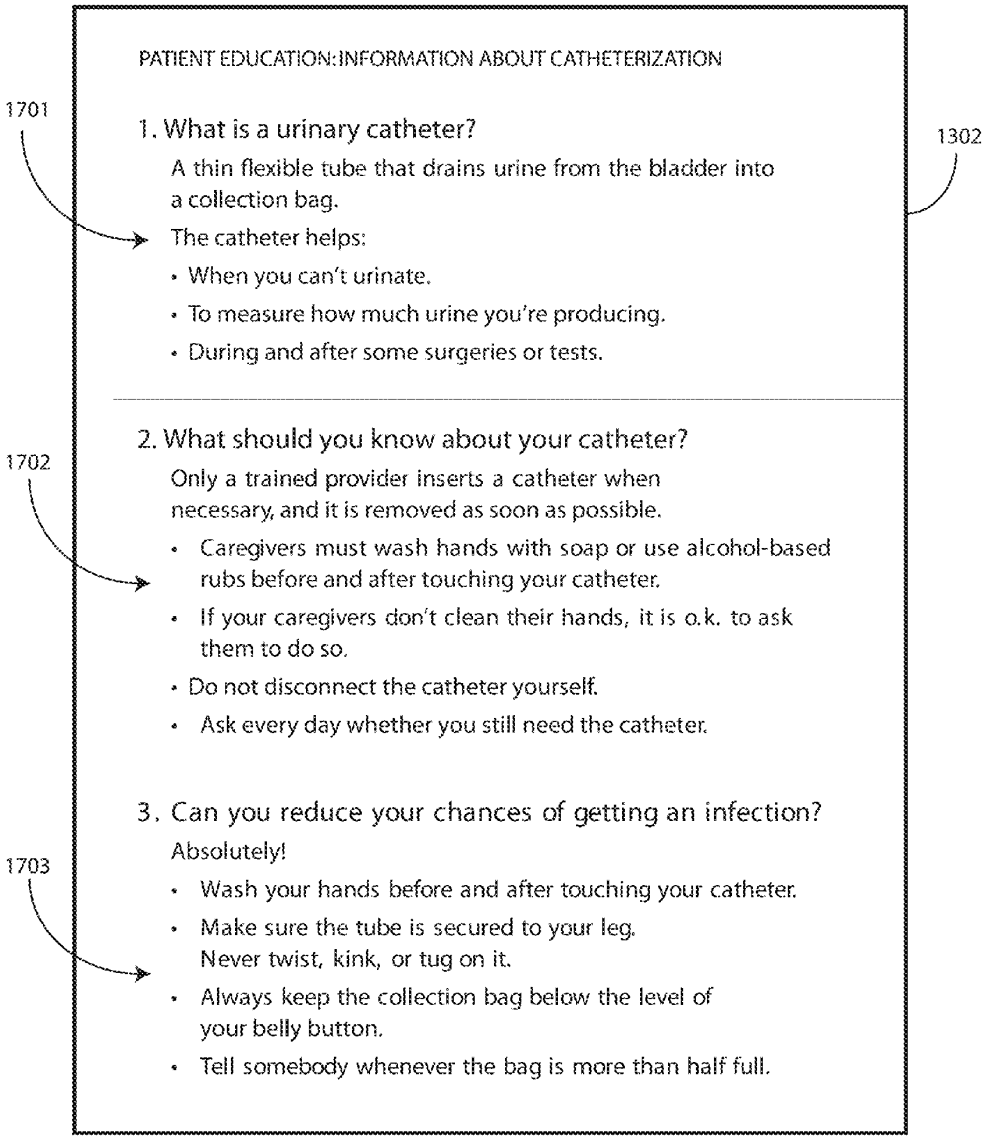
PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1701
1. What is a urinary catheter?
A thin flexible tube that drains urine from the bladder into a collection bag.
The catheter helps:
• When you can't urinate.
• To measure how much urine you're producing.
• During and after some surgeries or tests.
1302
2. What should you know about your catheter?
1702
Only a trained provider inserts a catheter when necessary, and it is removed as soon as possible.
• Caregivers must wash hands with soap or use alcohol-based rubs before and after touching your catheter.
• If your caregivers don't clean their hands, it is o.k. to ask them to do so.
• Do not disconnect the catheter yourself.
• Ask every day whether you still need the catheter.
3. Can you reduce your chances of getting an infection?
1703
Absolutely!
• Wash your hands before and after touching your catheter.
• Make sure the tube is secured to your leg. Never twist, kink, or tug on it.
• Always keep the collection bag below the level of your belly button.
• Tell somebody whenever the bag is more than half full.

FIG. 17

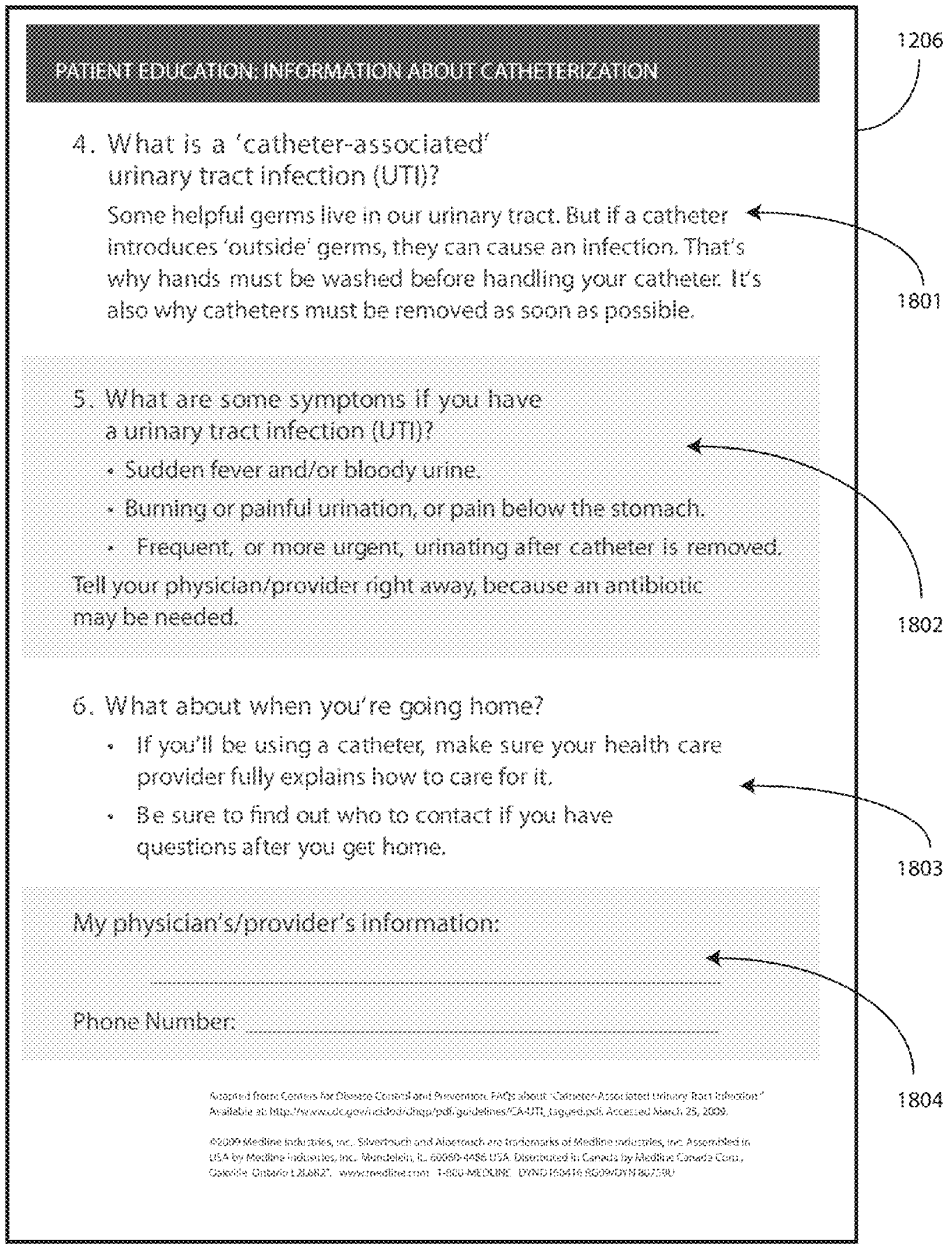
PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1206
4. What is a 'catheter-associated' urinary tract infection (UTI)?
Some helpful germs live in our urinary tract. But if a catheter introduces 'outside' germs, they can cause an infection. That's why hands must be washed before handling your catheter. It's also why catheters must be removed as soon as possible.
1801
5. What are some symptoms if you have a urinary tract infection (UTI)?
• Sudden fever and/or bloody urine.
• Burning or painful urination, or pain below the stomach.
• Frequent, or more urgent, urinating after catheter is removed.
Tell your physician/provider right away, because an antibiotic may be needed.
1802
6. What about when you're going home?
• If you'll be using a catheter, make sure your health care provider fully explains how to care for it.
• Be sure to find out who to contact if you have questions after you get home.
1803
My physician's/provider's information:
Phone Number:
1804

FIG. 18

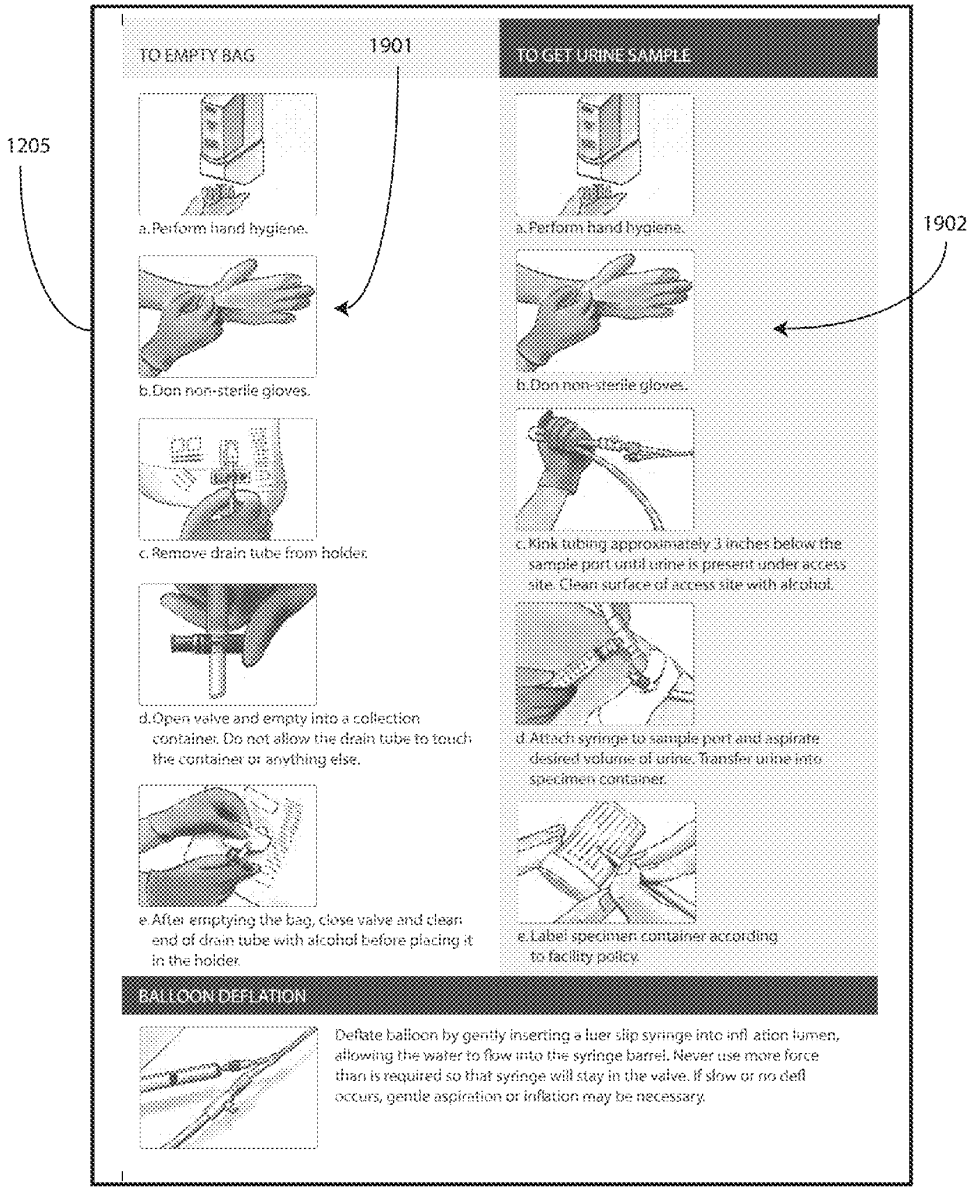
1205
1901
1902
TO EMPTY BAG
a. Perform hand hygiene.
b. Don non-sterile gloves.
c. Remove drain tube from holder.
d. Open valve and empty into a collection container. Do not allow the drain tube to touch the container or anything else.
e. After emptying the bag, close valve and clean end of drain tube with alcohol before placing it in the holder.
TO GET URINE SAMPLE
a. Perform hand hygiene.
b. Don non-sterile gloves.
c. Kink tubing approximately 3 inches below the sample port until urine is present under access site. Clean surface of access site with alcohol.
d. Attach syringe to sample port and aspirate desired volume of urine. Transfer urine into specimen container.
e. Label specimen container according to facility policy.
BALLOON DEFLATION
Deflate balloon by gently inserting a luer slip syringe into inflation lumen, allowing the water to flow into the syringe barrel. Never use more force than is required so that syringe will stay in the valve. If slow or no deflation occurs, gentle aspiration or inflation may be necessary.

FIG. 19

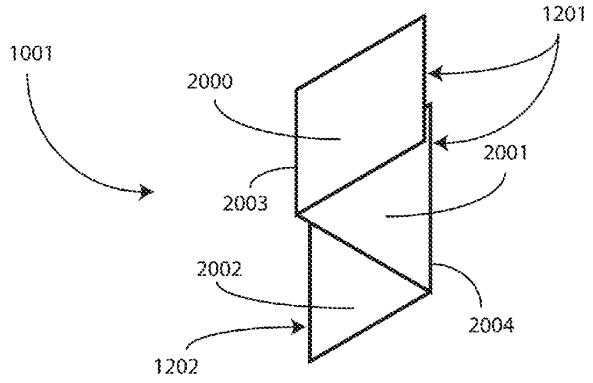
1001
1201
2000
2001
2003
2002
2004
1202

FIG. 20

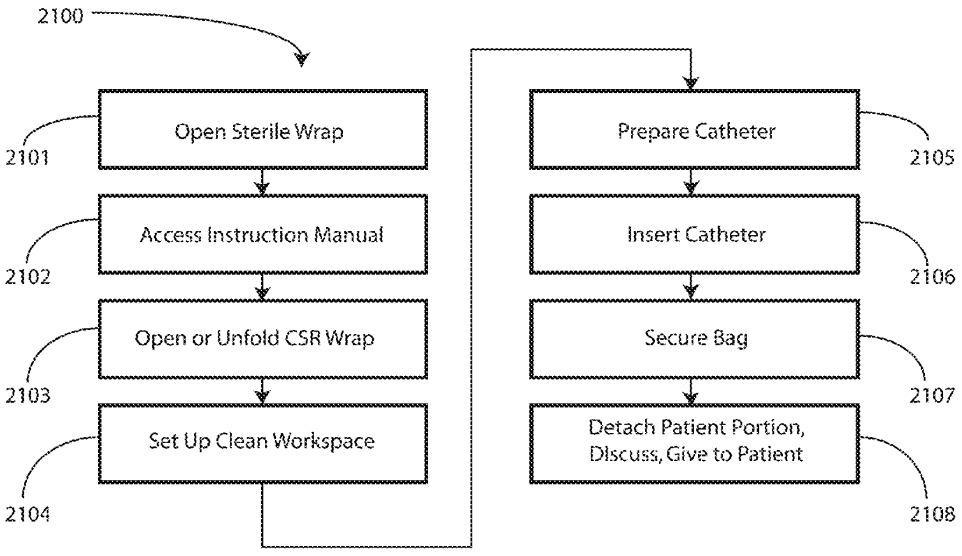
2100
Open Sterile Wrap
2101
Access Instruction Manual
2102
Open or Unfold CSR Wrap
2103
Set Up Clean Workspace
2104
Prepare Catheter
2105
Insert Catheter
2106
Secure Bag
2107
Detach Patient Portion, Discuss, Give to Patient
2108

FIG. 21

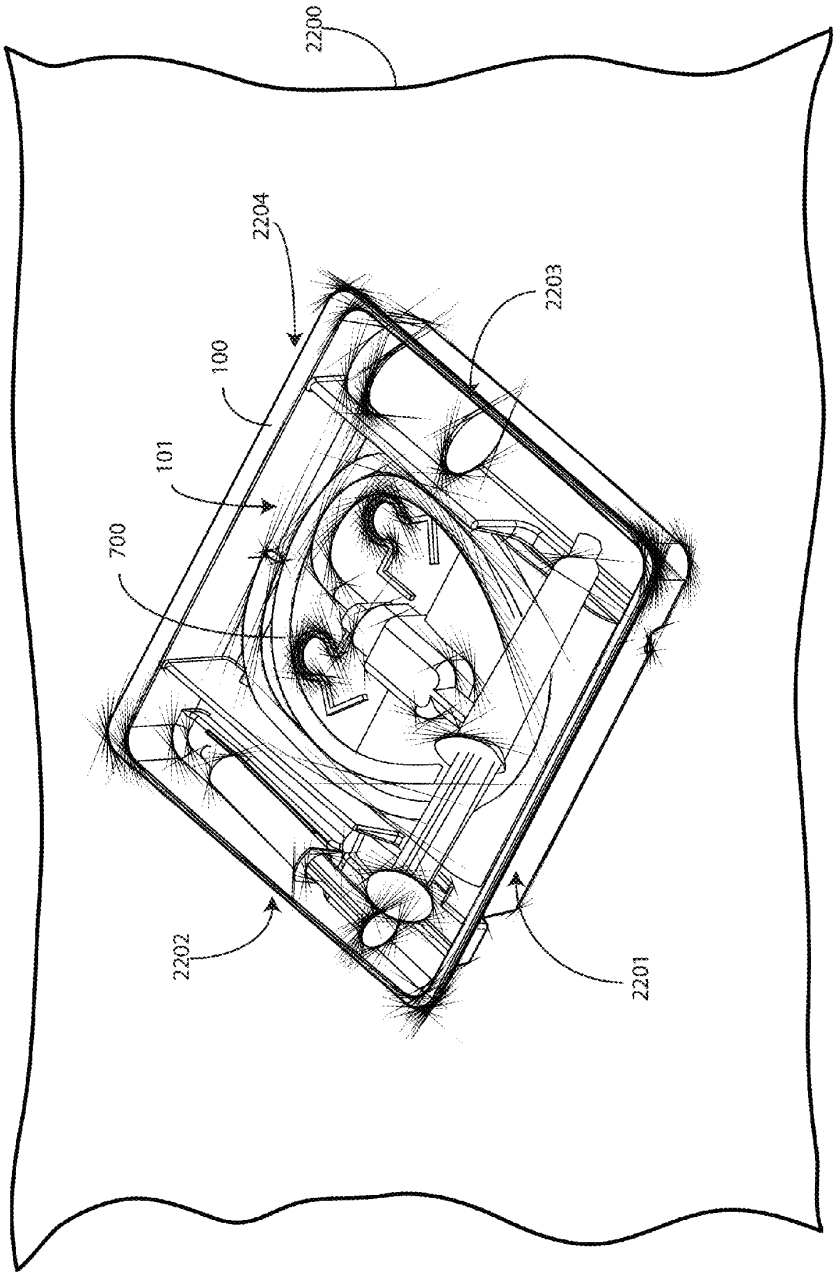

FIG. 22

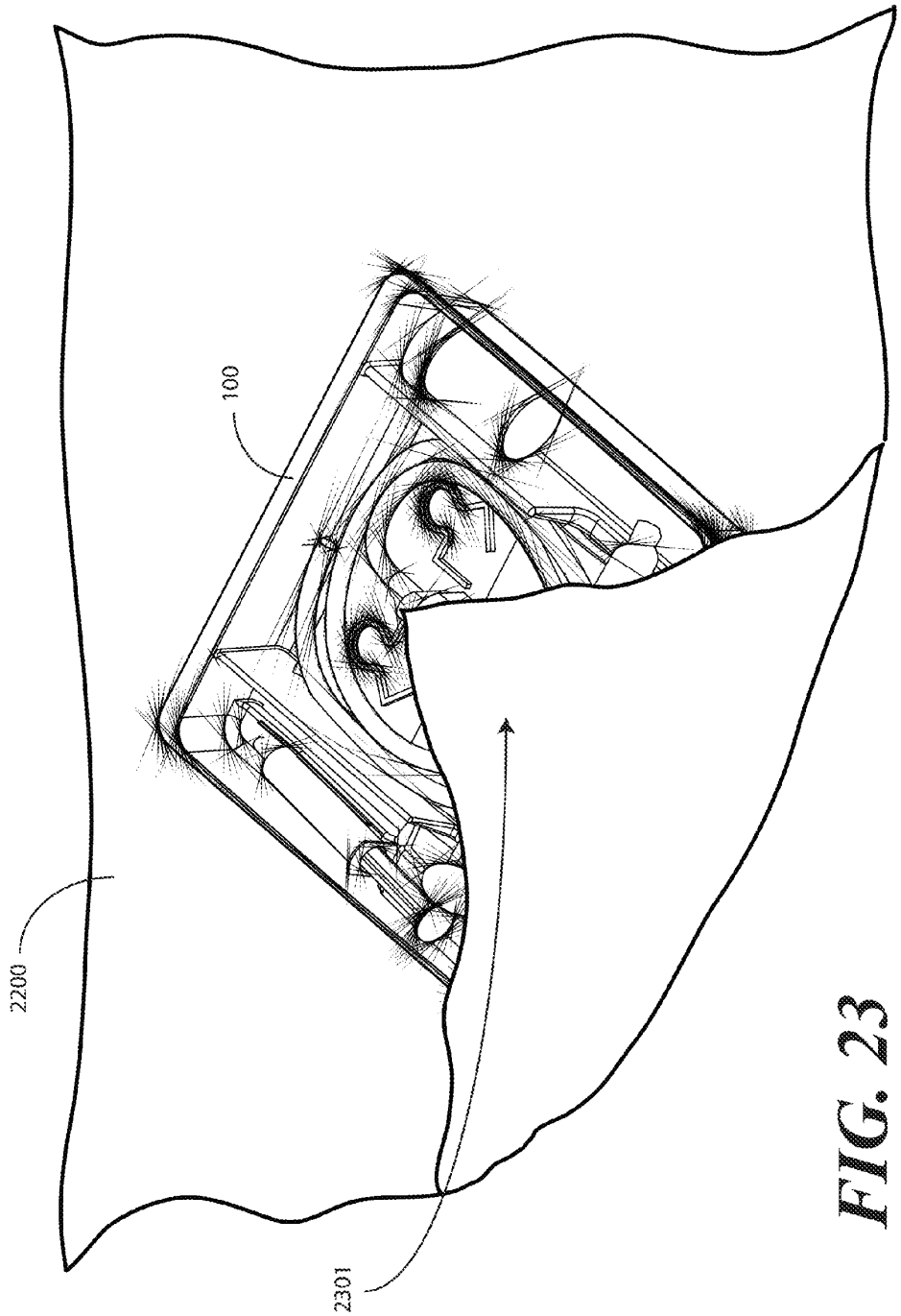

FIG. 23

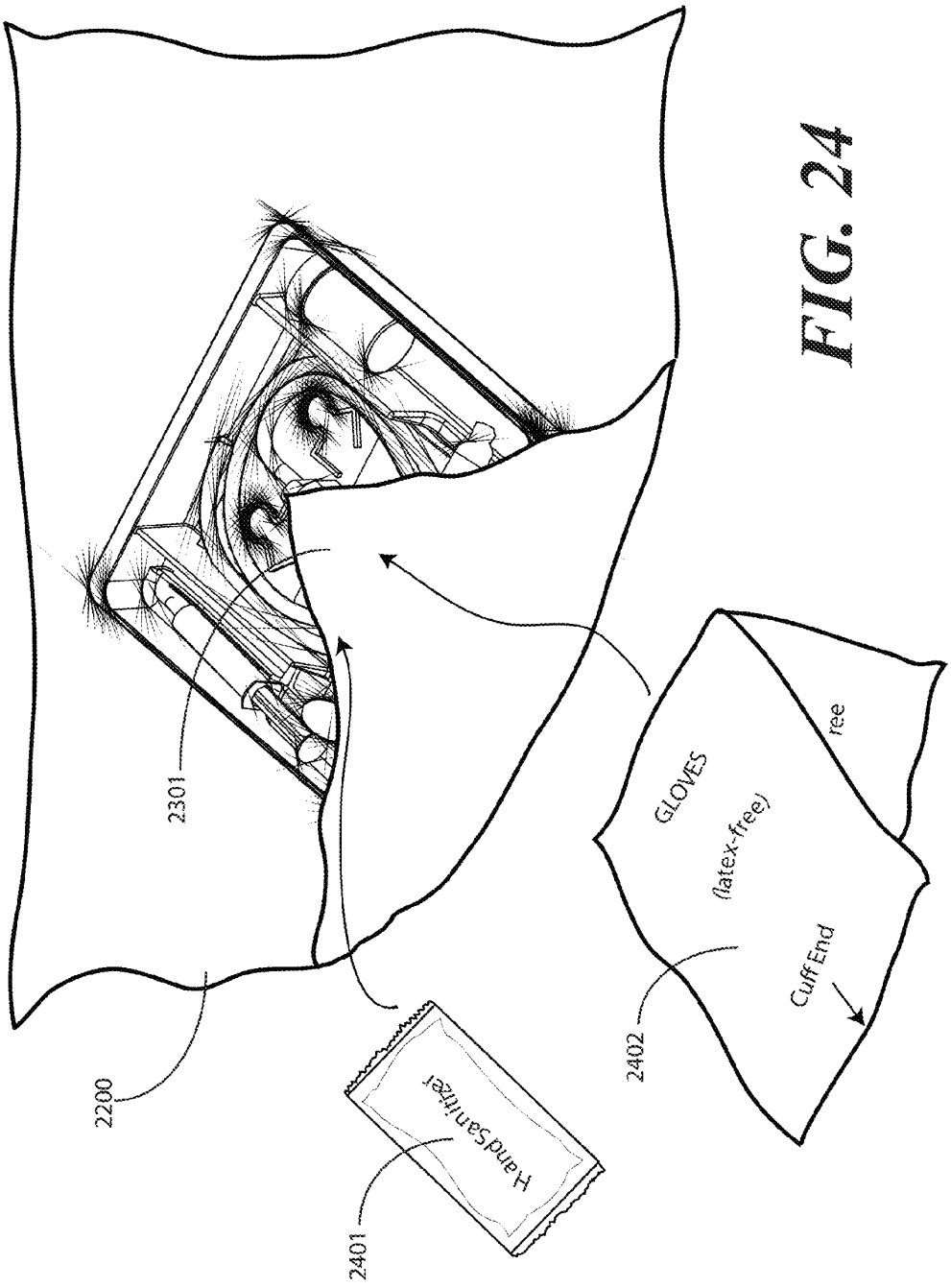
2301
GLOVES
(latex-free)
Cuff End
2402
Hand Sanitizer
2401
2200

FIG. 24

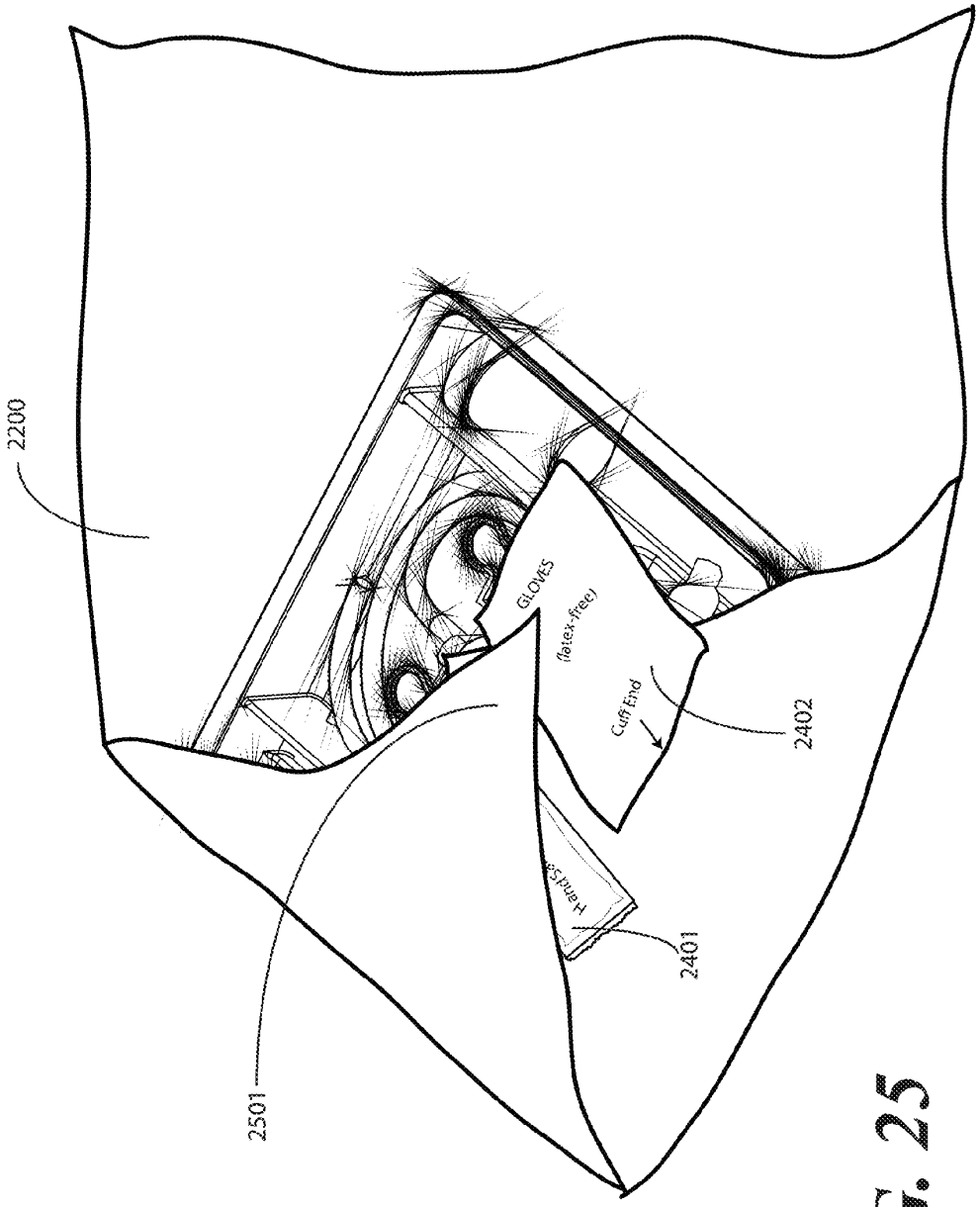

FIG. 25

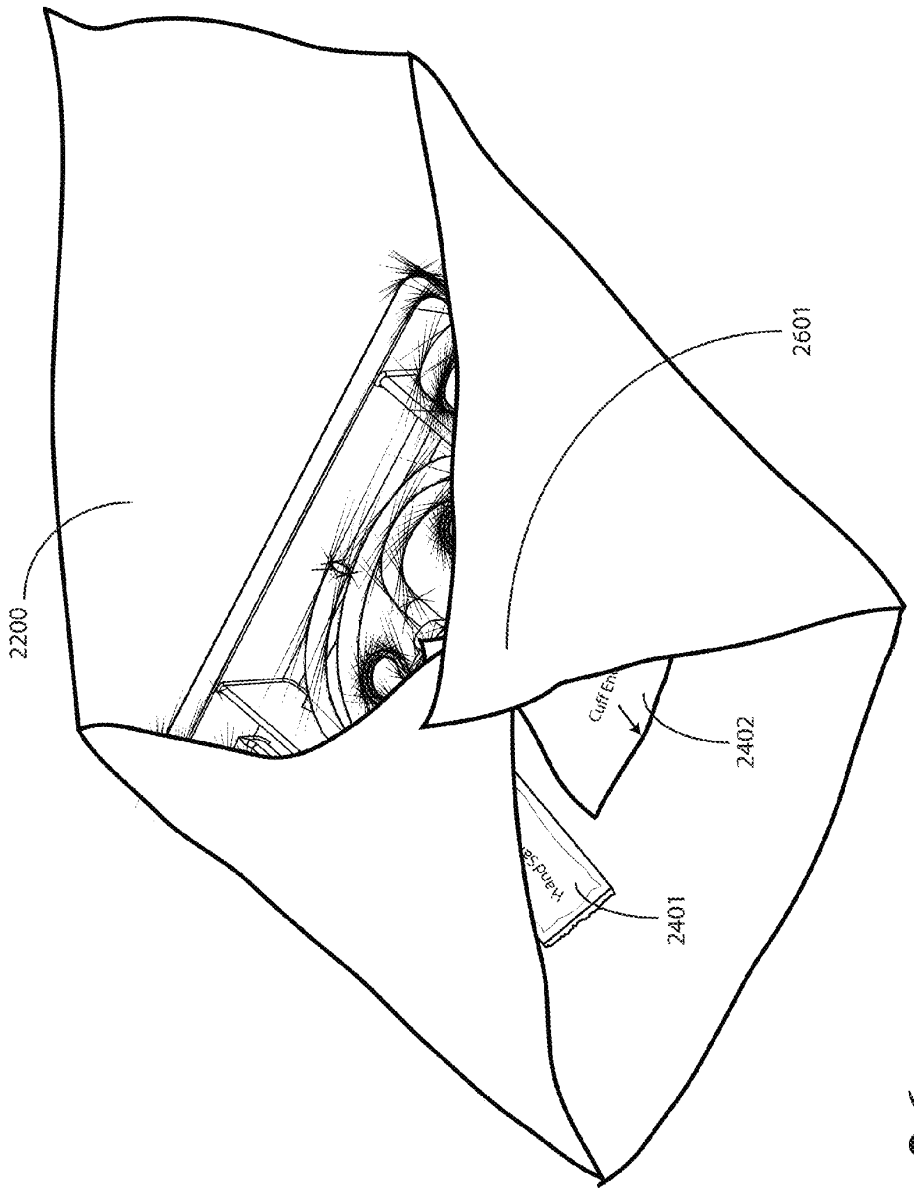

FIG. 26

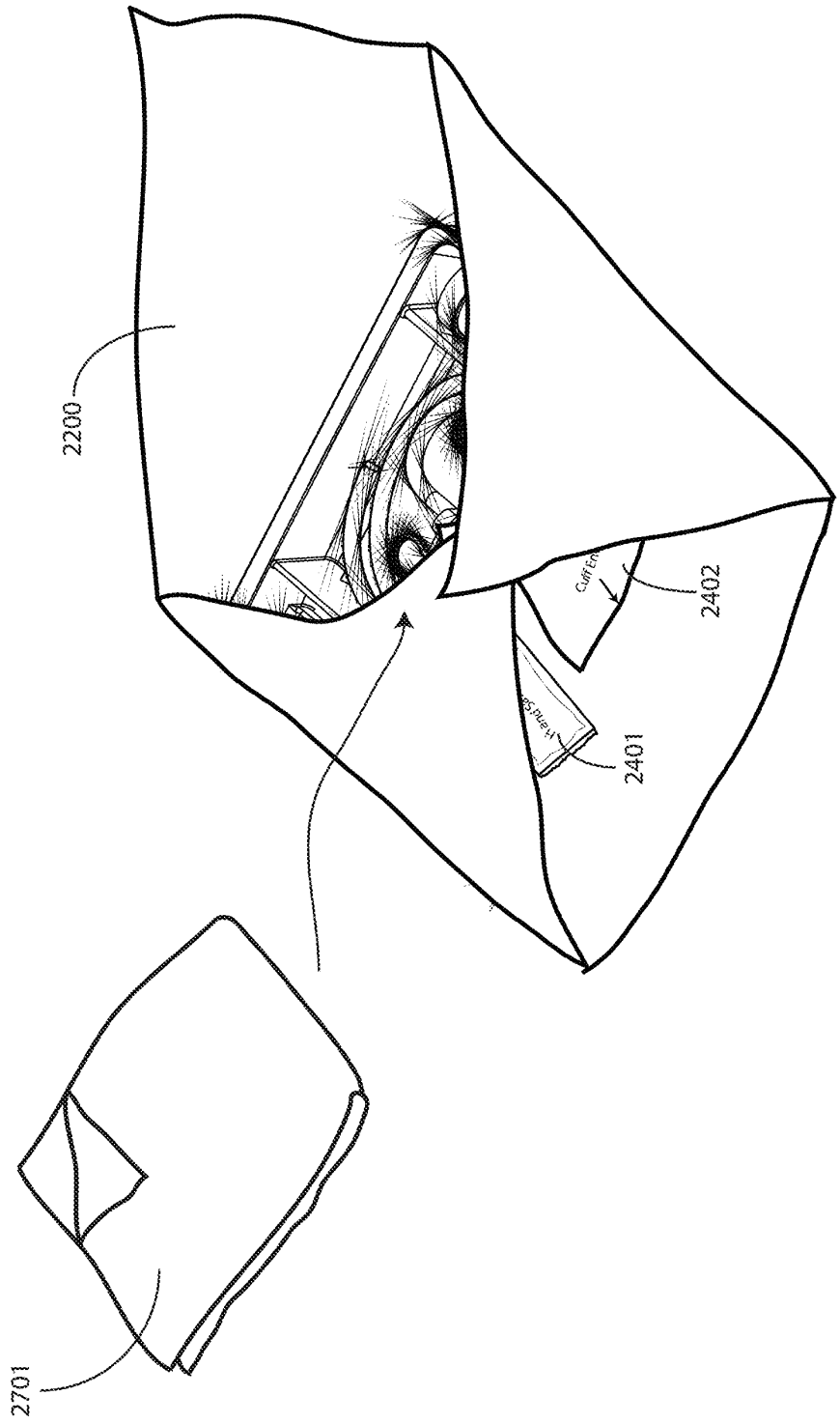

FIG. 27

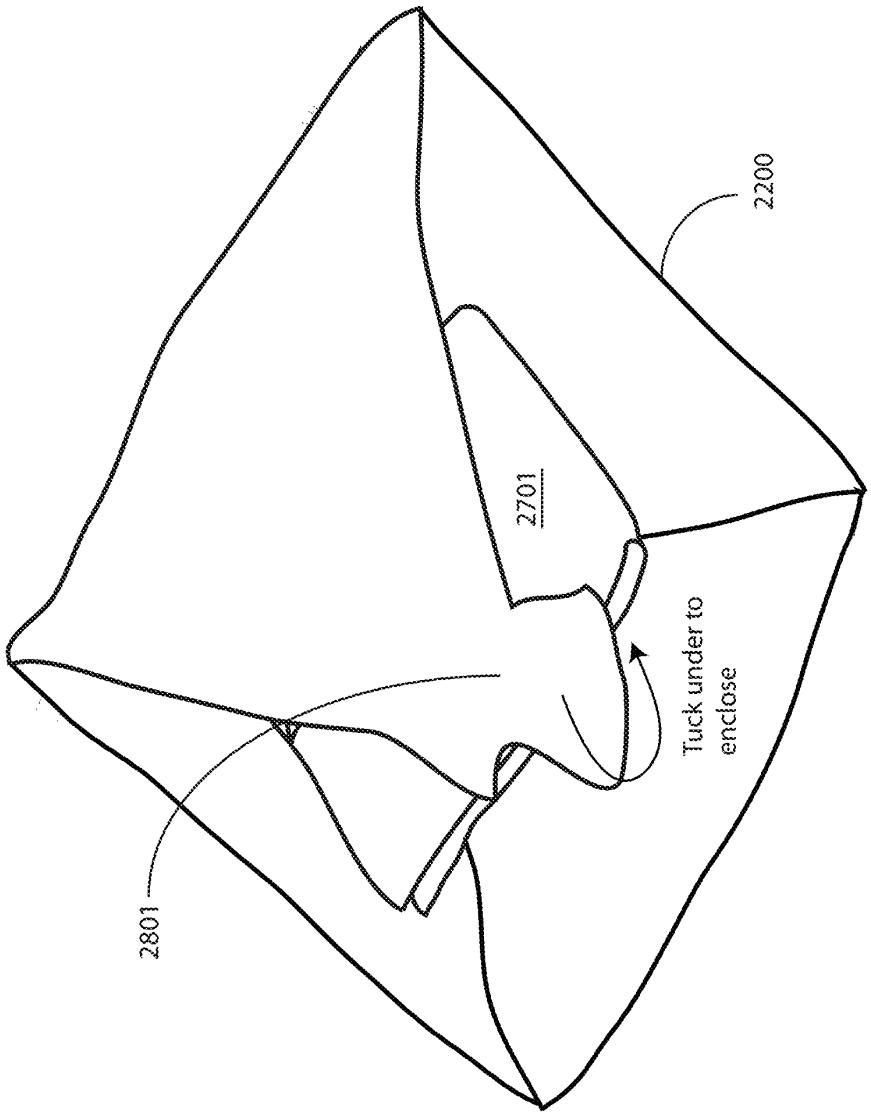

FIG. 28

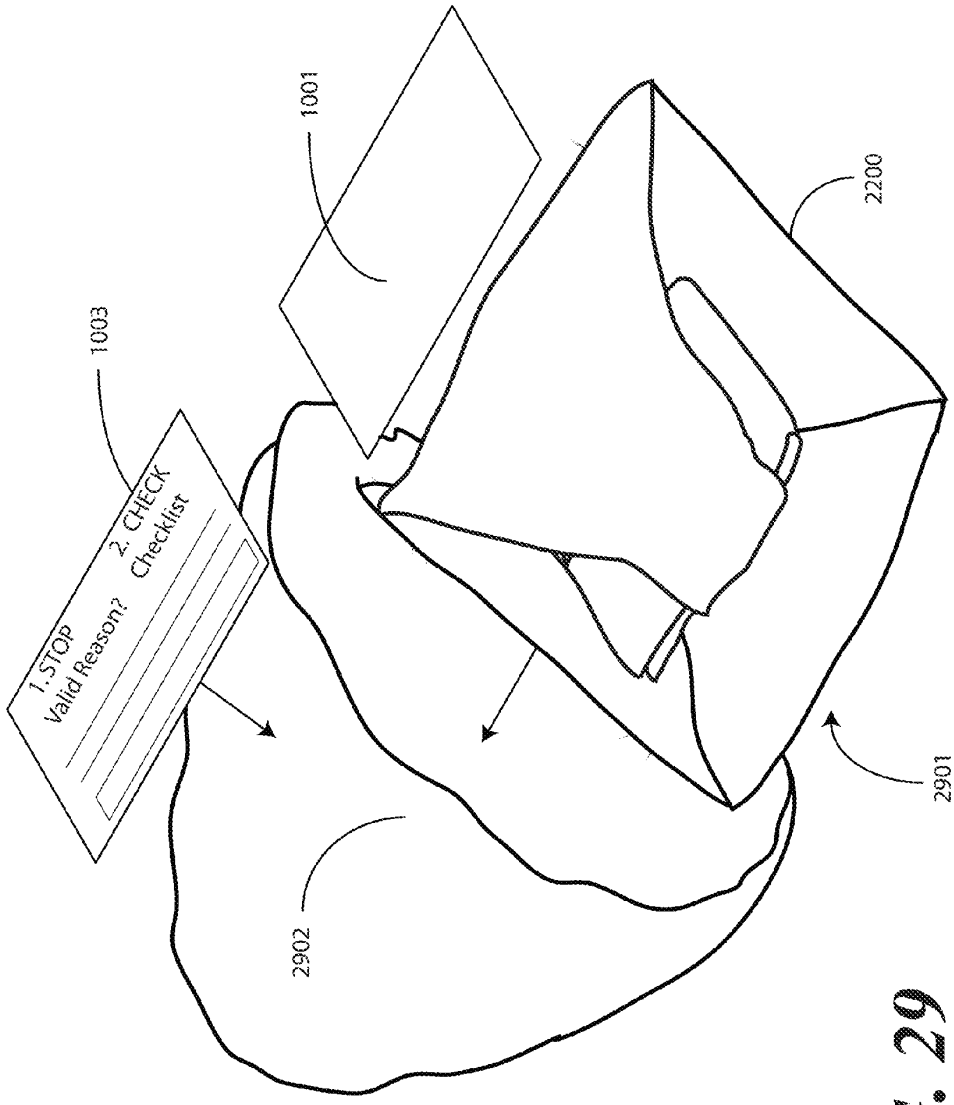
1001
2200
1003
1. STOP
Valid Reason?
2. CHECK
Checklist
2902
2901

FIG. 29

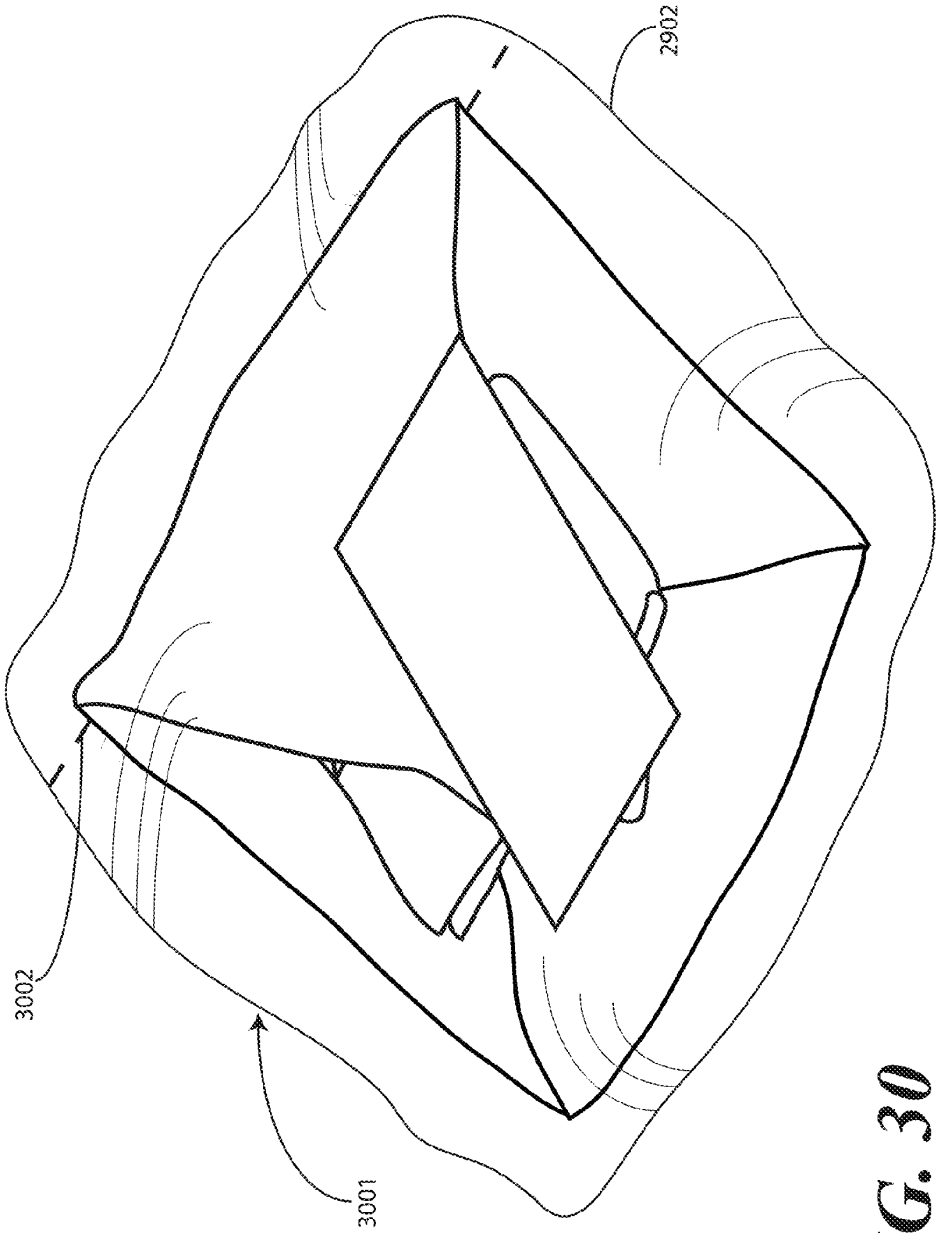

FIG. 30

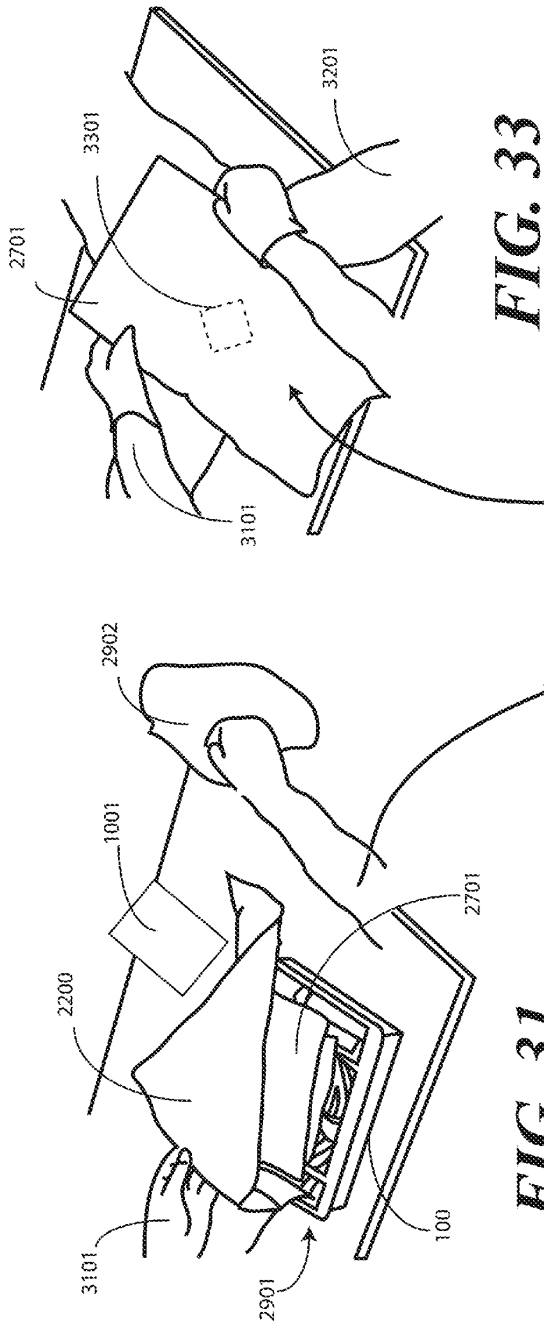

FIG. 31

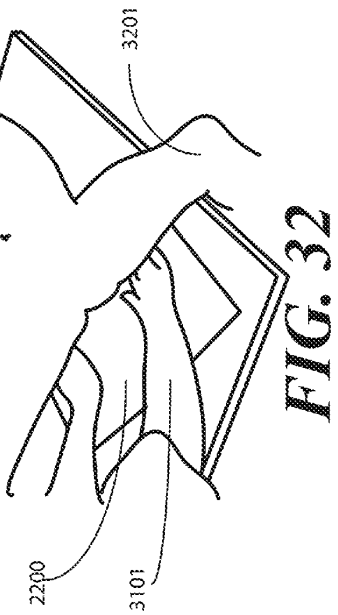

FIG. 32

FIG. 33

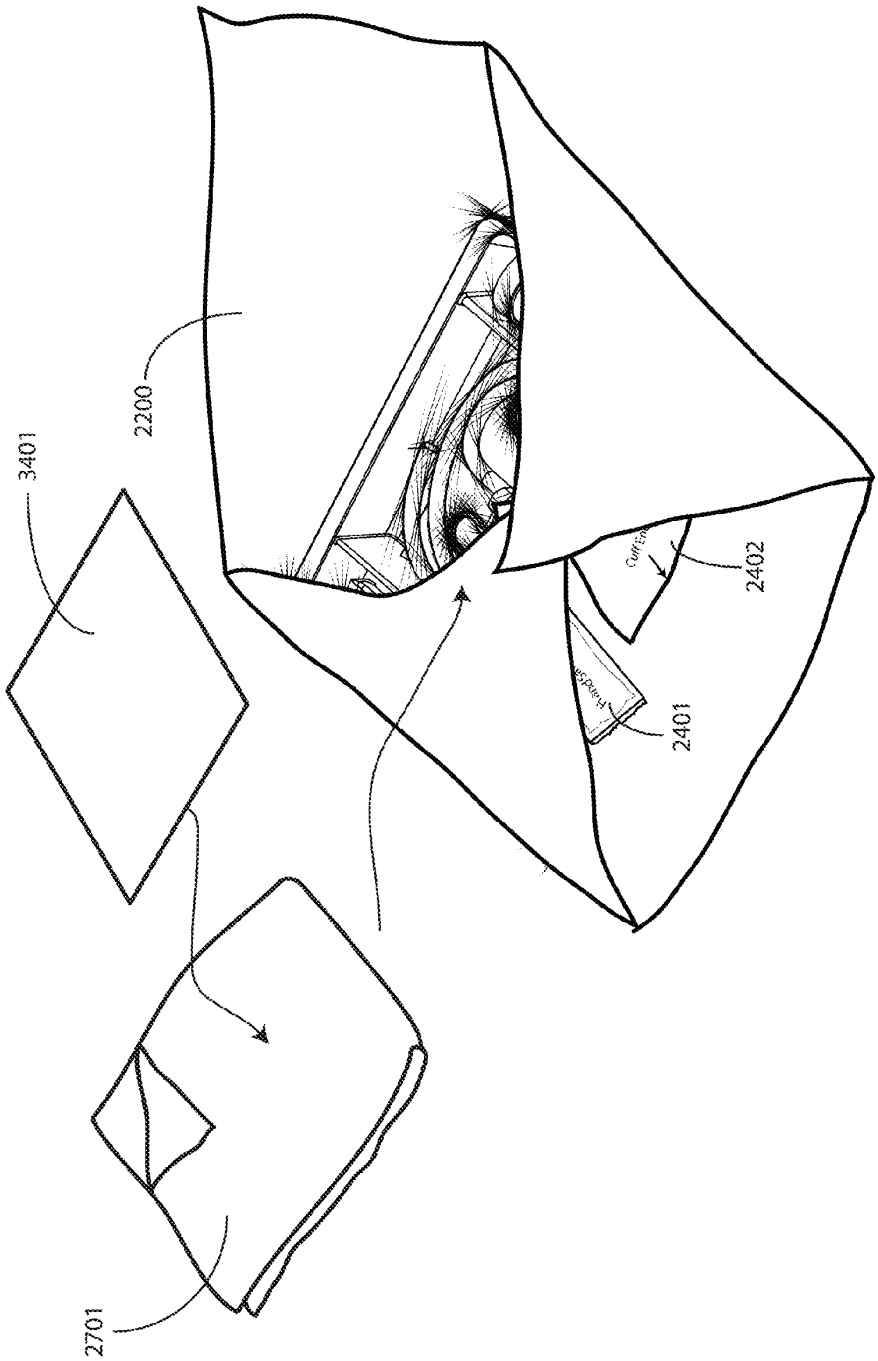

FIG. 34

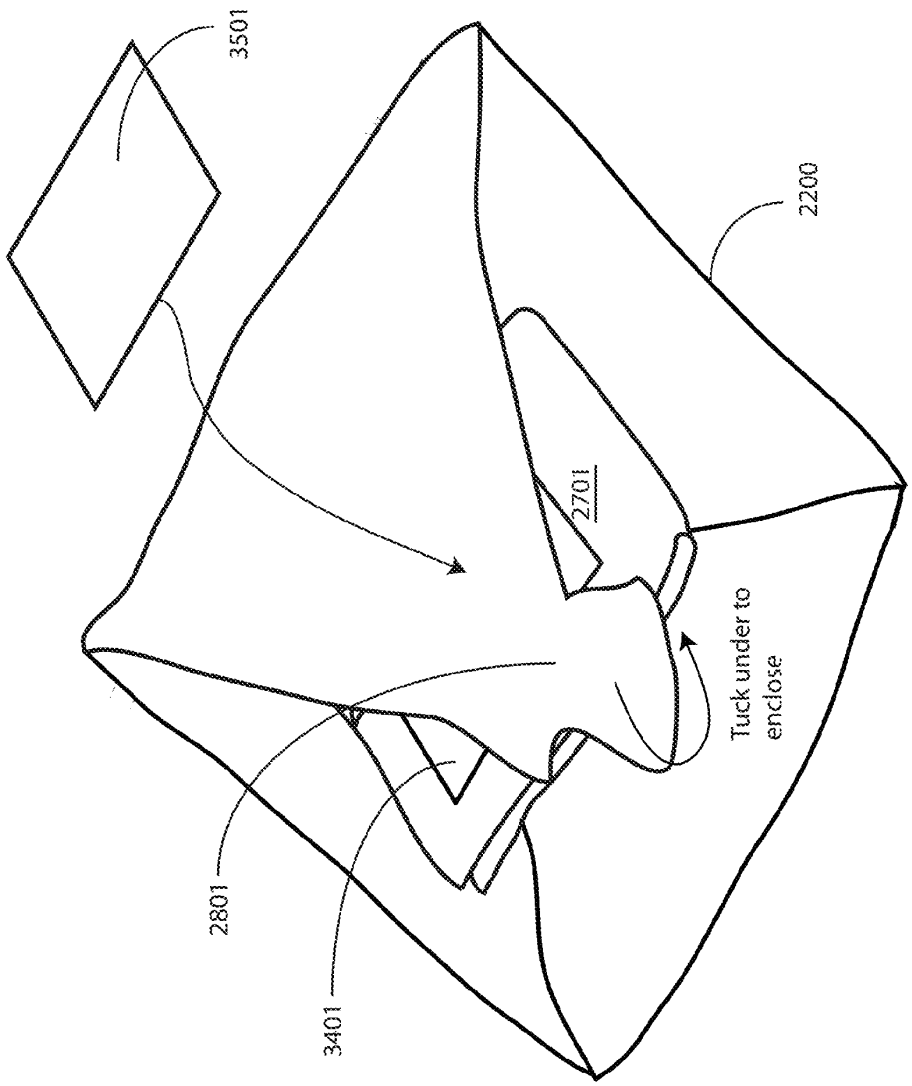

FIG. 35

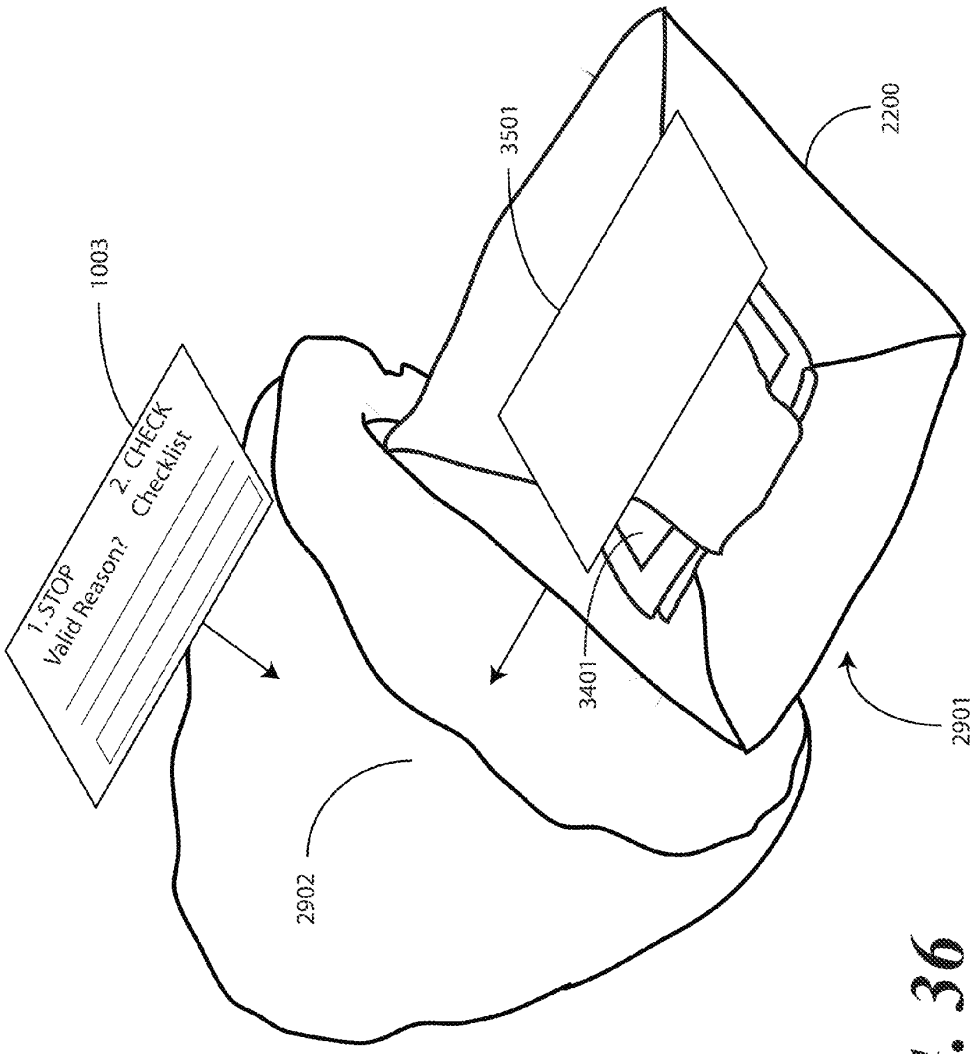
1003
1. STOP
Valid Reason?
2. CHECK
Checklist
3501
2200
3401
2901
2902

FIG. 36

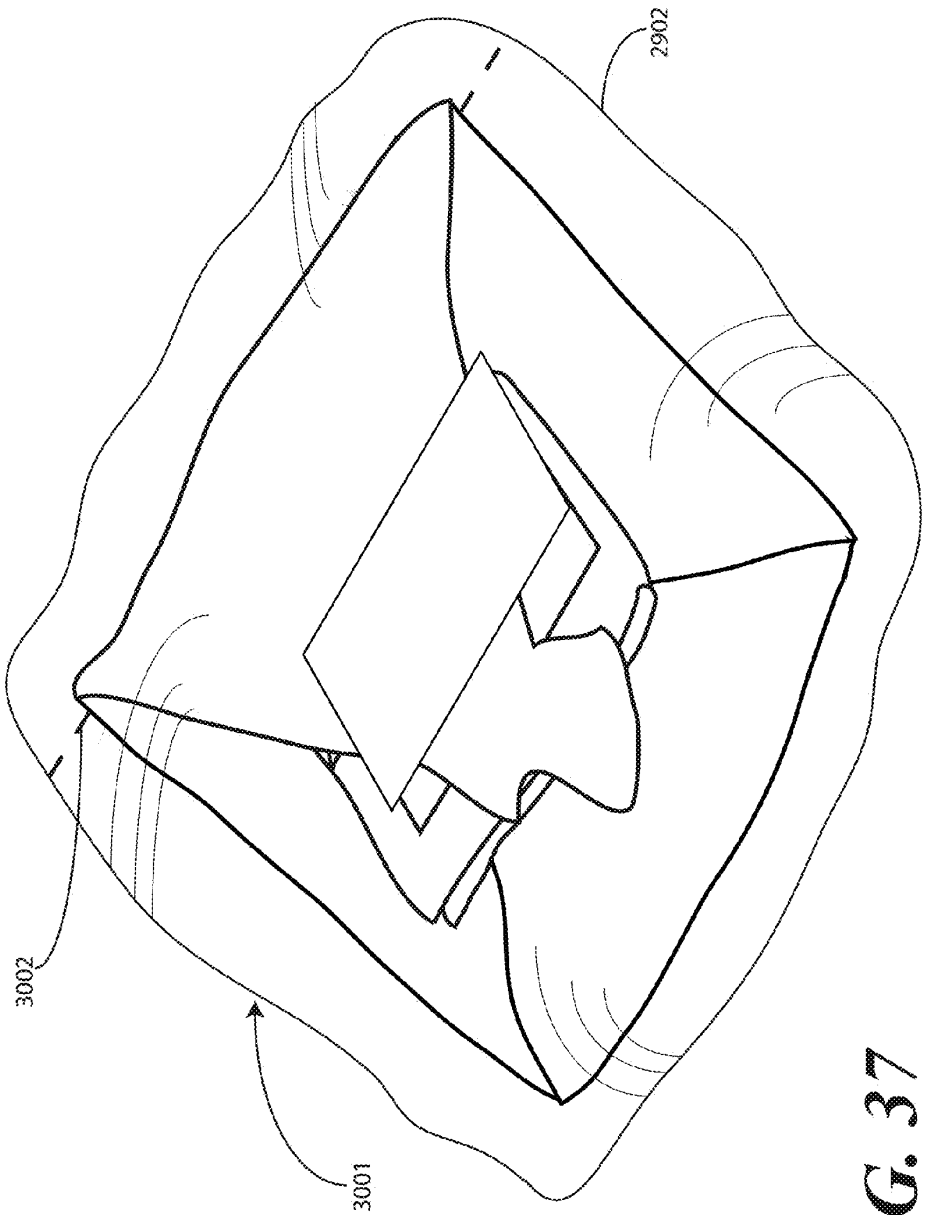

FIG. 37

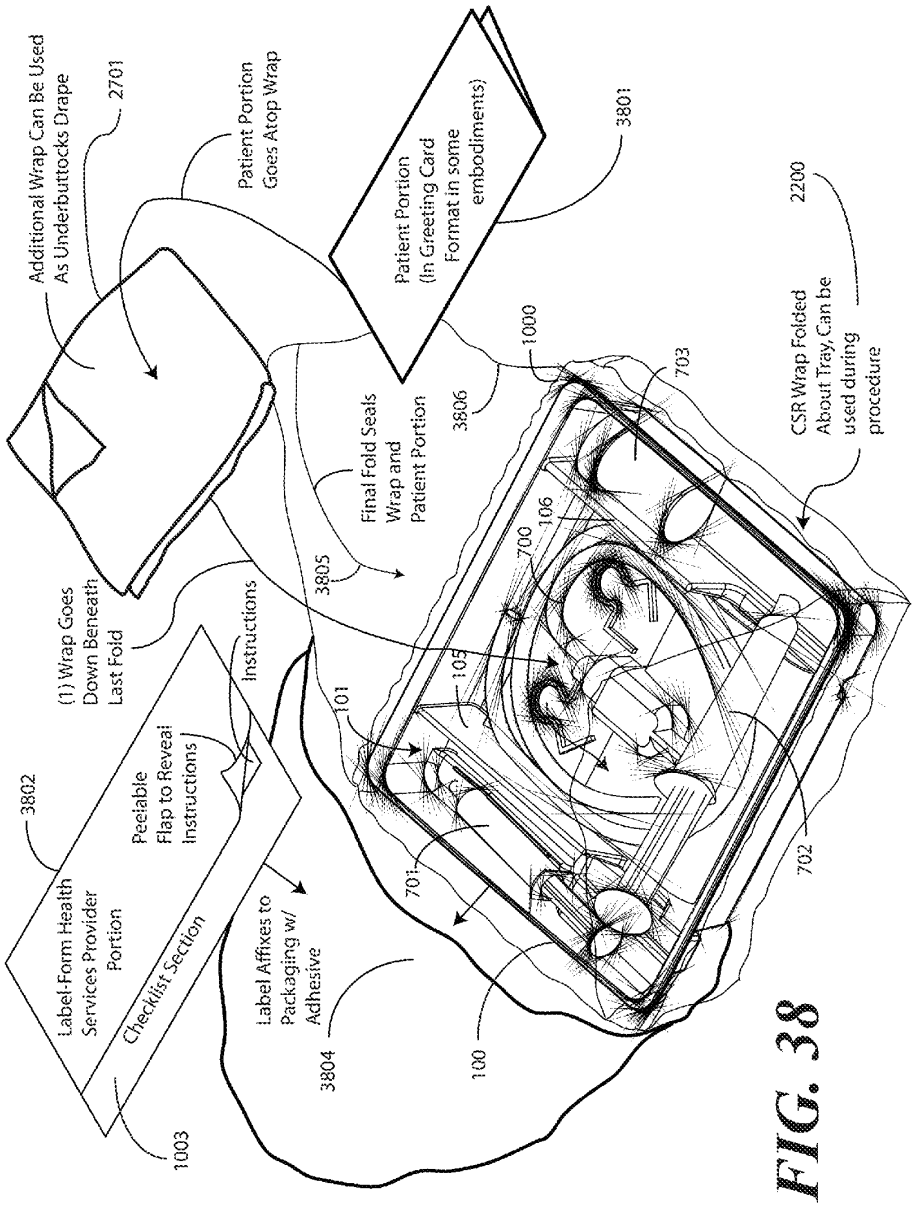

FIG. 38

Bard Exhibit 1004.0450

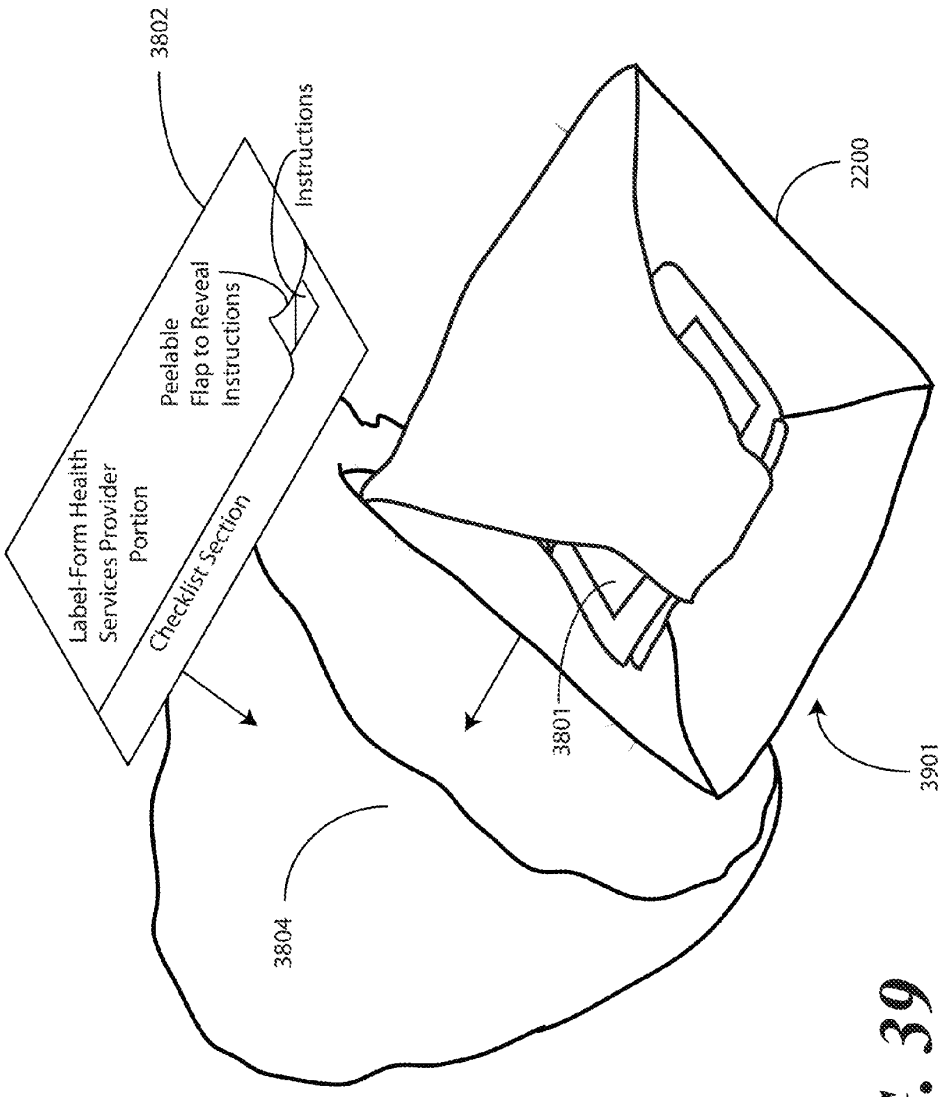
3802
Instructions
Peelable Flap to Reveal Instructions
Label-Form Heaith Services Provider Portion
Checklist Section
2200
3801
3901
3804

FIG. 39

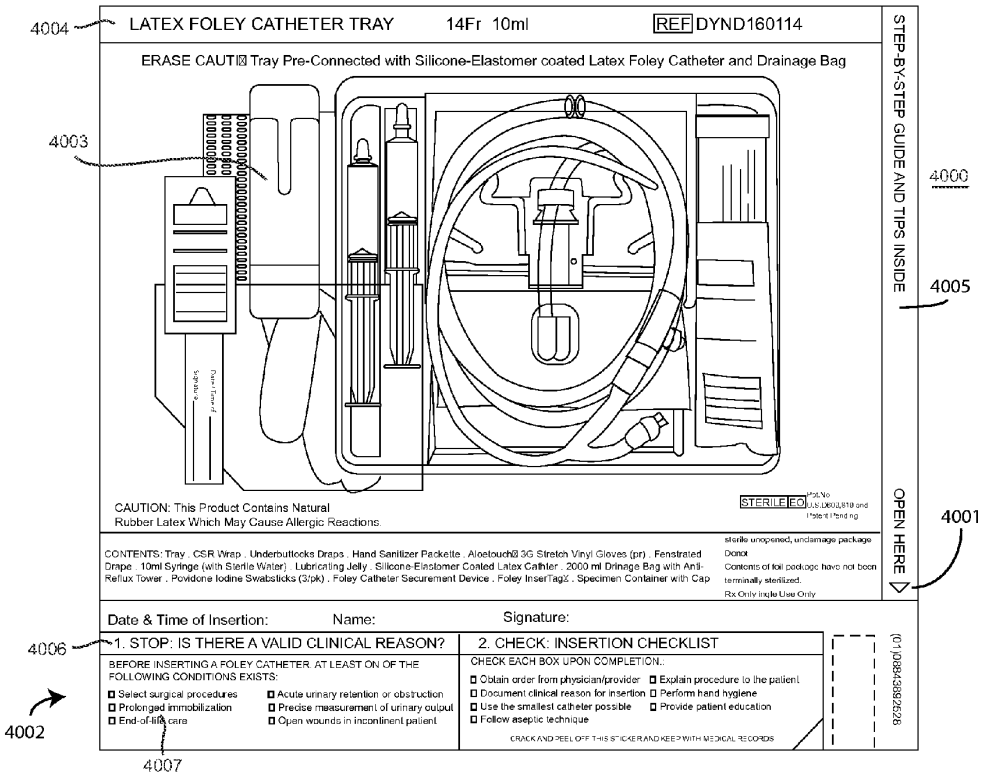
4004
LATEX FOLEY CATHETER TRAY 14Fr 10ml REF DYND160114
ERASE CAUTI Tray Pre-Connected with Silicone-Elastomer coated Latex Foley Catheter and Drainage Bag
4003
STEP-BY-STEP GUIDE AND TIPS INSIDE
4000
4005
CAUTION: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions
STERILE EO
OPEN HERE
4001
CONTENTS: Tray . CSR Wrap . Underbuttocks Drape . Hand Sanitizer Packette . Aloetouch 3G Stretch Vinyl Gloves (pr) . Fenestrated Drape . 10ml Syringe (with Sterile Water) . Lubricating Jelly . Silicone-Elastomer Coated Latex Catheter . 2000 ml Drainage Bag with Anti-Reflux Tower . Povidone Iodine Swabsticks (3/pk) . Foley Catheter Securement Device . Foley InserTag2 . Specimen Container with Cap
sterile unopened, undamage package
Donot
Contents of foil package have not been terminally sterilized.
Rx Only Ingle Use Only
Date & Time of Insertion: Name: Signature:
4006
1. STOP: IS THERE A VALID CLINICAL REASON?
BEFORE INSERTING A FOLEY CATHETER, AT LEAST ON OF THE FOLLOWING CONDITIONS EXISTS:
Select surgical procedures
Prolonged immobilization
End-of-life care
Acute urinary retention or obstruction
Precise measurement of urinary output
Open wounds in incontinent patient
2. CHECK: INSERTION CHECKLIST
CHECK EACH BOX UPON COMPLETION:
Obtain order from physician/provider
Document clinical reason for insertion
Use the smallest catheter possible
Follow aseptic technique
Explain procedure to the patient
Perform hand hygiene
Provide patient education
CRACK AND PEEL OFF THIS STICKER AND KEEP WITH MEDICAL RECORDS
(01)00884388282626
4002
4007

FIG. 40

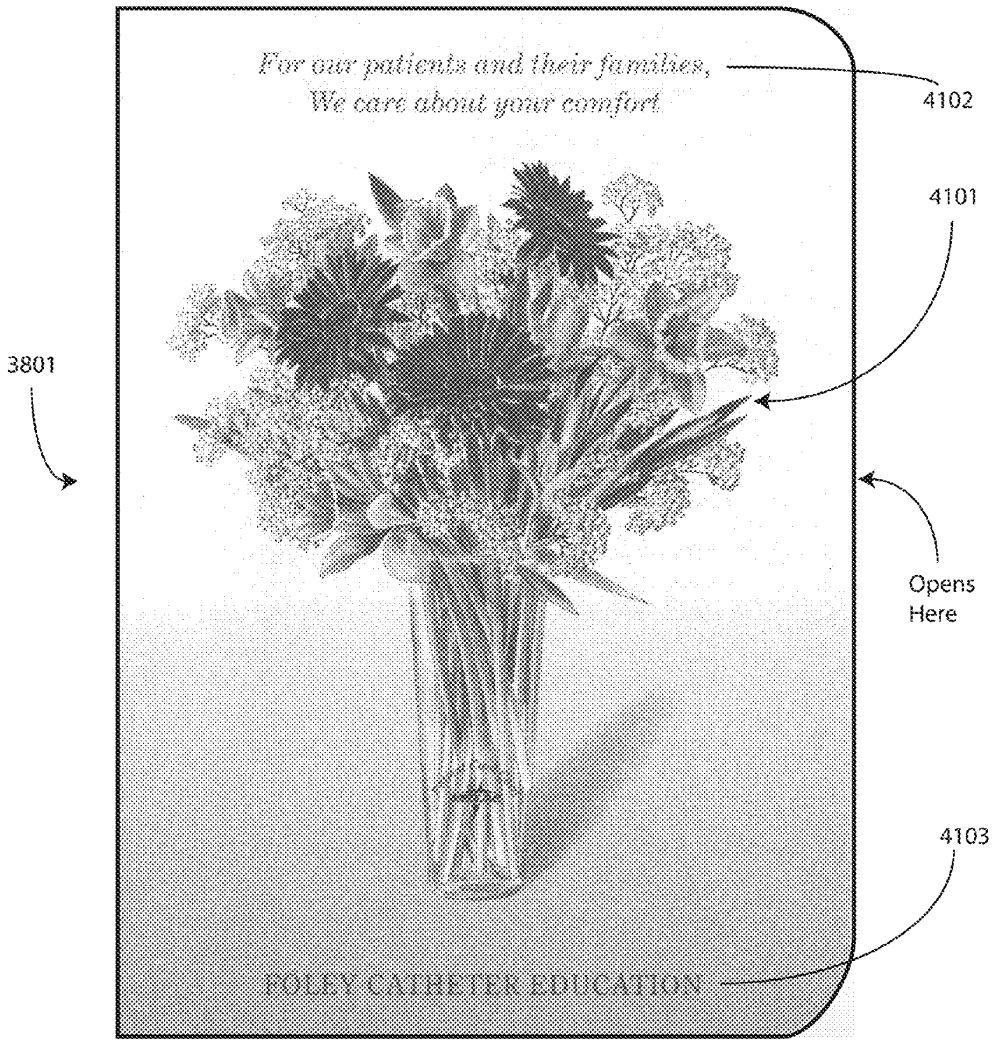
For our patients and their families,
We care about your comfort
4102
4101
3801
Opens
Here
4103
FOLEY CATHETER EDUCATION

FIG. 41

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS

CROSS REFERENCE TO PRIOR APPLICATIONS

This application is a continuation application claiming priority to Ser. No. 13/860,902, filed Apr. 11, 2013, which is a divisional application from Ser. No. 13/155,026, filed Jun. 7, 2011, which claims priority and benefit under 35 U.S.C. §119(e) from U.S. Provisional Application Ser. No. 61/352,140, filed Jun. 7, 2010; Ser. No. 61/352,155, filed Jun. 7, 2010; Ser. No. 61/428,944, filed Dec. 31, 2010; and Ser. No. 61/437,796, filed Jan. 31, 2011, each of which is incorporated herein by reference. Moreover, Ser. No. 13/155,026 is further a continuation in part of: Ser. No. 12/495,148, filed Jun. 30, 2009; Ser. No. 12/647,515, filed Dec. 27, 2009; Ser. No. 13/153,265, filed Jun. 3, 2011; and Ser. No. 13/153,300, filed Jun. 3, 2011. As the present application claims priority to Ser. No. 13/155,026, the present application also, by law, claims priority to each of Ser. No. 12/495,148, Ser. No. 12/647,515, Ser. No. 13/153,265, and Ser. No. 13/153,300 through its priority claim to Ser. No. 13/155,026.

This application is related to commonly assigned U.S. Pat. No. 7,624,869 to Primer, which is incorporated herein by reference. This application is related to commonly assigned U.S. patent application Ser. No. 12/004,796, filed Dec. 21, 2007, which is incorporated herein by reference.

BACKGROUND

Technical Field

This invention relates generally to storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices, as well as an instruction manual included therewith.

Background Art

Medical devices, including surgical instruments, supplies, and so forth, are generally shipped from manufacturer to medical services provider in sterile packaging. For example, a scalpel may be shipped to a surgeon in a plastic, vacuum-sealed, sterile package. Similarly, bandages may be shipped in paper, plastic, or paper composite sterile wrappers. When the medical services provider is ready to use the medical supply, the sterile package is removed. The medical services provider then uses the object in accordance with the procedure being performed.

While conventional packaging works well for objects having a generally unchanging form factor, special considerations have to be taken into consideration for some medical supplies. By way of example, catheter assemblies and other flexible equipment is generally shipped in a coiled configuration. Once the sterile packaging is removed, the catheter must be uncoiled prior to use. Care must be taken in shipping, unwrapping, and using the catheter. For instance, if a catheter is inadvertently bent, kinked, or otherwise damaged, it may no longer be suitable for use. Compounding this issue, catheters are available in a variety of lengths ranging from 100 centimeters to over 250 centimeters.

Traditional catheters are packaged, for example, in individual packaging. The catheter and card are then sealed in a sterile plastic wrap. These catheters are prone to damage in shipment, storage, and when being unpacked, as the card and wrap provide little physical protection.

Some manufacturers have started shipping catheters and other similar devices in flat plastic trays. For example, U.S. Pat. No. 6,068,121 to McGlinch teaches one such tray. The tray has several specifically contoured loops such that one universal tray will accommodate several different sized catheters. Such packaging presents a problem, however, in that large amounts of storage space are taken with a universal tray, especially when a relatively short catheter is shipped therein. Additionally, when in use, these trays occupy large amounts of a medical service provider's sterile workspace or table, leaving little room for related components, such as lubricants, fluid bags, and so forth.

There is thus a need for an improved container for flexible medical devices or catheters that facilitates more effective and simpler deployment of the device during a procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying figures, where like reference numerals refer to identical or functionally similar elements throughout the separate views and which together with the detailed description below are incorporated in and form part of the specification, serve to further illustrate various embodiments and to explain various principles and advantages all in accordance with the present invention.

FIG. **1** illustrates a top, front, right perspective view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. **2** illustrates a top, front, left perspective view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. **3** illustrates a top plan view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. **4** illustrates a front elevation view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. **5** illustrates a cut-away, left elevation view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. **6** illustrates a bottom plan view of one embodiment of a tray for a catheter or similar assembly in accordance with embodiments of the invention.

FIG. **7** illustrates a top, front, right perspective view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. **8** illustrates a top plan view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. **9** illustrates a transparent, front elevation view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. **10** illustrates a perspective view of one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, along with instructions and packaging, in accordance with embodiments of the invention.

FIG. **11** illustrates a method of manufacturing one embodiment of a tray for a catheter or similar assembly, with a catheter and corresponding procedural devices disposed therein, in accordance with embodiments of the invention.

FIG. **12** illustrates one embodiment of printed instructions in accordance with embodiments of the invention.

FIG. **13** illustrates one embodiment of printed instructions in accordance with embodiments of the invention.

FIGS. **14-19** illustrate exemplary panels of printed instructions in accordance with embodiments of the invention.

FIG. **20** illustrates a physical configuration of printed instructions in accordance with one embodiment of the invention.

FIG. **21** illustrates a method in accordance with embodiments of the invention.

FIGS. **22-30** illustrate various stages of a method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

FIGS. **31-33** illustrate various stages of a method of deploying a medical procedure kit configured in accordance with embodiments of the invention.

FIGS. **34-37** illustrate various stages of an alternative method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

FIGS. **38-39** illustrate various stages of an alternative method of enclosing a medical procedure kit configured in accordance with embodiments of the invention.

FIG. **40** illustrates an alternate health care services provider portion of printed materials configured as an adhesive label with an opening flap in accordance with one embodiment of the invention.

FIG. **41** illustrates an alternative patient portion of printed instructions configured as a greeting card and having patient information therein, in accordance with one embodiment of the invention.

Skilled artisans will appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the invention are now described in detail. Referring to the drawings, like numbers indicate like parts throughout the views. As used in the description herein and throughout the claims, the following terms take the meanings explicitly associated herein, unless the context clearly dictates otherwise: the meaning of "a," "an," and "the" includes plural reference, the meaning of "in" includes "in" and "on." Relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. Also, reference designators shown herein in parenthesis indicate components shown in a figure other than the one in discussion. For example, talking about a device (**10**) while discussing figure A would refer to an element, **10**, shown in figure other than figure A.

Embodiments of the present invention provide a medical procedure kit that includes medical products for performing a medical procedure. In one embodiment, the medical procedure kit is configured for a catheterization procedure. Such an embodiment will be used herein for illustration purposes. However, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments of the invention are not so limited. Other medical procedure kits for performing other procedures could be substituted for the illustrative catheterization tray disclosed herein by substituting other medical implements for the catheterization implements. In the illustrative embodiment, a tray is configured to accommodate a medical device or assembly. In an illustrative embodiment, the medical device is a coiled device, such as a catheter or catheter assembly. In addition to accommodating the coiled medical device, embodiments of the present invention are also configured to contain devices and materials intended for use with the coiled medical device.

Using a catheter assembly as an example, when a catheter assembly is inserted into a patient, sterile water may be used to inflate the catheter. Additionally, the catheter may be coated in a lubricating jelly prior to insertion into the patient. Fluids and other samples may then be monitored and obtained from the patient via the catheter. Embodiments of the present invention provide a single container configured to accommodate not only the catheter assembly and fluid bag, but also syringes containing sterile water or lubricants. Further, the tray can accommodate a sterile specimen jar for capturing samples taken from the patient via the catheter.

In addition to simply accommodating these corresponding medical devices, in one embodiment the tray is configured to provide the medical services provider with mnemonic devices instructing them in which order to use each device. For example, a compartment containing syringes, in one embodiment, includes an inclined, stair-stepped bottom member to present the plungers of each syringe at an easy to reach angle and at different heights based upon order of use.

Another advantage of embodiments of the present invention is that compartments have multi-purpose functionality. For example, in one embodiment, a container configured to accommodate a syringe having lubricating jelly disposed therein is also configured to be used as a lubricating jelly applicator. A medical services provider first dispenses the lubricating jelly into the syringe compartment. The medical services provider then passes the catheter from another compartment through an opening in a barrier separating the compartments into the lubricating jelly. As such, the tray not only serves as a shipping and storage container for an assembly of devices used with a catheter procedure, but also as an application device to assist a medical services provider in using those products together.

Turning now to FIGS. **1-6**, illustrated therein are views of one embodiment of a tray **100** configured to accommodate a catheter assembly in accordance with embodiments of the invention. FIG. **1** illustrates a top, front right perspective view of the tray **100**. FIG. **2** illustrates a top, front, left perspective view of the tray **100**. FIG. **3** illustrates a top plan view of the tray **100**. FIG. **4** illustrates a front elevation view of the tray **100**. FIG. **5** illustrates a cut-away, left elevation view of one embodiment of a tray **100**. Likewise, FIG. **6** illustrates a bottom plan view of the tray **100**. For simplicity of discussion, these figures will be referred to collectively with like reference numerals referring to identical or functionally similar elements throughout the separate views.

The tray **100**, in one embodiment, is formed by a contoured surface **104** that defines the various features and compartments of the tray **100**. The contoured surface **104** of the tray **100** can be manufactured in various ways. For example, in one embodiment, the tray **100** can be thermally formed on a mold from a soft thermoplastic, such as styrene or polystyrene. In another embodiment, the tray **100** can be injection molded. In another embodiment, the tray can be poured on a mold using a quick setting plastic, epoxy, or

resin. Other methods of manufacture will be obvious to those of ordinary skill in the art having the benefit of this disclosure.

Exemplary dimensions for one embodiment of the tray **100** are as follows: The length **112** can be between nine and twelve inches, such as ten inches. One illustrative length **112** may be 10.380 inches. Similarly, the width **113** can be between eight and eleven inches, such as nine inches. One illustrative width **113** is 9.250 inches. The height **114** can be between one and three inches. One illustrative height **114** is 1.750 inches.

In one embodiment, the tray **100** includes three main compartments: a first compartment **101**, a second compartment **102**, and a third compartment **103**. The first compartment **101** is separated from the second compartment **102** by a first barrier **105**. The second compartment **102** is separated from the third compartment **103** by a second barrier **106**.

In one embodiment, the compartments are open from the top of the tray **100**—the top being opposite the base members of the tray **100**—and are bounded on the bottom by a first base member **107**, a second base member **108**, and a third base member **109**. The compartments are bounded on the sides by a perimeter wall **110**. In the illustrative "open top" embodiment of FIG. **1**, the perimeter wall **110** ends in a horizontal flange **111** extending substantially orthogonally from the perimeter wall **110**. It will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments other than that shown in FIG. **1** are possible without departing from the spirit and scope of the invention. For instance, the top of the tray **100** could have a hinged or snap-coupled lid that is opened or removed to reveal the compartments there beneath.

In one illustrative embodiment, the tray **100** is configured to hold or otherwise accommodate all of the necessary devices and materials to perform a catheter-based procedure on a patient. Said differently, the tray **100** is configured to hold not only the catheter assembly, but the medical devices corresponding to catheter use as well. Using one illustrative procedure as an example, the following devices will be used: a syringe holding sterile water, a syringe holding lubricating jelly or another equivalent lubricant, a catheter assembly, skin cleansing or preparation materials, and a specimen jar. The various compartments and features of the tray **100** shown in FIGS. **1-6** will be described for use with these devices. As will be described in more detail below, additional objects can be included with the tray, such as one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, swab sticks, a securement device, a Foley insert tag, a printed instruction pamphlet, and so forth. The syringe holding sterile water, syringe holding lubricating jelly, catheter assembly, and specimen jar are used for illustration purposes only, as it will be clear that other objects may be added to or substituted for these objects. Further, subsets of these objects may be used.

In one embodiment suitable for procedures using the syringe holding sterile water, syringe holding lubricating jelly, catheter assembly, and specimen jar, in one embodiment, the tray **100** is configured such that these objects are ordered in accordance with their use during the procedure. For example, in one embodiment the tray **100** includes a first compartment **101** for accommodating one or more syringes, a second compartment **102** for accommodating the catheter assembly, and a third compartment **103** for accommodating the specimen jar. These devices stowed in the various compartments will be illustrated and described with respect to FIGS. **7-10** below. The discussion of FIGS. **1-6** will include the features of the tray **100** that make the tray **100** suitable for accommodating these devices.

For example, in one embodiment the first compartment base member **107** includes a stair-stepped contour **115** suitable for accommodating a plurality of syringes at different heights. For example, a first step portion **116** of the stair-stepped contour **115** may be at a different height within the tray **100** than a second step portion **117** of the stair-stepped contour. In the illustrative embodiment of FIGS. **1-6**, the first step portion **116**—which is disposed farther from the first barrier **105** than the second step portion **117**—is shallower than the second step portion **117**. Said differently, the second step portion **117** is disposed at a greater depth within the tray **100** than the first step portion **116**.

The stair-stepped contour **115** can be used as mnemonic device when multiple syringes are stored within the first compartment **101**. For example, it may be intuitive that a syringe placed on a higher step portion may need to be used first. This intuition is further enforced when the higher step portion is disposed farther to the left in a left-to-right usage configuration. Thus, a user receives a mnemonic reminder to use a syringe disposed on the first step portion **116** prior to a syringe disposed on the second step portion **117**, as it is both higher and farther to the left.

Where syringes are stowed in the first compartment **101**, the first compartment base member **107** can further be configured for syringe ease of use. For example, in one embodiment the first compartment base member **107** is inclined relative to other compartment base members. In the illustrative embodiment of FIGS. **1-6**, the second compartment base member **108** and third compartment base member **109** are substantially coplanar with each other. Further, the second compartment base member **108** and third compartment base member **109** are generally flat in these views, although it will be clear to those of ordinary skill in the art having the benefit of this disclosure that contours could be incorporated into one or both of these base members.

In this illustrative embodiment, however, the first compartment base member **107** is configured to be inclined relative to one or both of the second compartment base member **108** and third compartment base member **109**. As such, the stair-stepped contour **115** forms a ramp upon which syringes may be placed so that the plunger of each syringe is predisposed to project upward and out of the tray **100**. Said differently, the stair-stepped contour **115** is configured such that the first step portion **116** and the second step portion **117** are disposed in a non-parallel orientation relative to the second compartment base member **108**. This configuration makes it easier for a medical services provider to grasp the syringes and remove them from the tray **100**.

The first compartment base member **107** may include other features suitable for accommodating one or more syringes as well. In one embodiment, one or both of the first step portion **116** and second step portion **117** include recesses **118**,**119** for accommodating a syringe flange. These recesses **118**,**119** generally function to prevent the syringes from sliding lengthwise within the first compartment **101**. Similarly, in one embodiment one or both of the first step portion **116** and the second step portion **117** include protrusions **120** that help to prevent the syringes from sliding laterally within the first compartment **101**.

In one embodiment, one or both of the first barrier **105** and the second barrier **106** include openings disposed therein. In the illustrative embodiment shown in FIGS. **1-6**, the first barrier **105** includes a first opening **121** between the first compartment **101** and the second compartment **102**. Simi-

larly, the second barrier **106** includes a second opening **122** between the second compartment **102** and the third compartment **103**. Each of these openings has an opening depth associated therewith. Similarly, each opening has an opening width associated therewith. In the illustrative embodiment of FIGS. **1-6**, the first opening **121** is bounded by a first opening base member **129** and two inclined first opening side members **127**,**128**, while the second opening **122** is bounded by a second opening base member **131**, an inclined second opening side member **130**, and the perimeter wall **110**.

While the opening depths can be the same, in one embodiment the opening depths are different. For example, in the illustrative embodiments of FIGS. **1-6**, the first opening **121** has a first opening depth **123** that is less than the second opening depth **124** of the second opening **122**. Similarly, in one embodiment the opening widths are different. For example, in the illustrative embodiments of FIGS. **1-6**, the first opening **121** has a first opening width **125** that is less than the second opening width **126** of the second opening **122**. Such a disparity in opening depths and widths, as well as the inclusion of inclined opening side members, provides an advantage in some applications.

For instance, in many catheter procedures a pair of syringes—such as syringes having a one-half inch diameter—fits easily into the first compartment **101** when the tray **100** is made with the illustrative dimensions set forth above. However, some procedures require one or more of the syringes to be larger. For example, some syringes are larger in diameter. These larger syringes are capable of nesting within the first opening **121** and second opening **122**. The inclined opening side members prevent the syringe from moving lengthwise, while the disparate opening heights present the plunger of the syringe to the medical services provider for easy removal from the tray **100**.

The stair-stepped contour **115**, working in tandem with the first opening **121**, gives the tray additional advantages over prior art catheter containers. For instance, when the first compartment **101** has a first compartment base member **107** configured with a stair-stepped contour **115**, the first compartment **101** can be used as a lubricant applicator for the catheter.

Specifically, the medical services provider may dispense the lubricating jelly along the second step portion **117**. As the second step portion **117** is lower in the tray **100** than the first step portion **116**, the second step portion **117** serves as a channel in which the lubricating jelly may spread. A medical services provider may then pass the catheter through the first opening **121**, through the channel formed by the second step portion **117**, i.e., along the second step portion **117** through the dispensed lubricating jelly, and out the top of the tray **100** to the patient. This feature of the tray **100** greatly eases the application of lubricating jelly to the catheter when compared to prior art solutions. In one embodiment, the tray **100** is packaged with printed instructions showing the medical services provider how to apply lubricating jelly in this manner. The printed instructions will be described in more detail below with respect to FIGS. **12-23**.

It will be clear to those of ordinary skill in the art having the benefit of this disclosure that alternative methods may be used to apply the lubricating jelly as well. For example, in another embodiment, the lubricating jelly is dispensed directly onto the catheter tubing while the tubing is in or above the first compartment **101**. Excess lubricant falling from the catheter tubing can then collect, and be retained, in the second step portion **117**.

This particular feature highlights another advantage of the "compartmentalized" structure of various embodiments of the invention. As the tray **100** includes multiple compartments, various tasks associated with a catheterization procedure can be completed while keeping the catheter within the tray **100**. The ability to keep the catheter in the tray **100** reduces the risk that the catheter or corresponding devices will be contaminated with bacteria or microbes on other objects within the procedure room. For example, when the first compartment **101** is used to apply lubricating jelly to the catheter, the lubricating jelly can be applied while the catheter is contained within the tray **100**, thereby reducing the risk that the catheter will become contaminated. This correspondingly reduces the risk of infection for the patient receiving the catheter.

Prior art systems, for example such as those in which the catheterization procedure components are shipped in separate containers, may contribute to substandard techniques in that the catheter can become contaminated when moving it from its shipping container. Consequently, the patient can be at an elevated risk of infection as the catheter is moved from one tray to another. Embodiments of the present invention solve this problem by providing a single level tray **100** with compartments. Further, in one embodiment the first compartment **101** includes the first opening **121** so the catheter can stay in place during and after lubrication. By having easy access to the components disposed in the single level tray **100**, the medical services provider can more easily prepare and use the components within the tray **100**. This helps to minimize the risk of contaminating the patient or the sterile field during the procedure.

In one embodiment, the second step portion **117** is configured to be inclined at a shallower angle than the first step portion **116** in at least a portion opposite the recess **119** from the first opening **121**. When configured in such a fashion, the second step portion **117** includes a "cutdown" so that the catheter can stay within the channel both during and after lubrication.

Additionally, the catheter can be placed in both the first opening **121** and second opening **122** during lubrication. When positioned in this configuration, the second opening **122** helps to align the catheter with the first opening for easy passage through the lubrication channel formed by the second step portion **117**.

The tray **100** of FIGS. **1-6** includes additional advantages over prior art catheter packaging as well. For example, in one embodiment, instructions **132** or other graphical indicia can be printed, placed upon, or molded into the horizontal flange **111**. In one embodiment, compartment designations can be placed above each compartment to ensure the medical services provider uses the correct device or material at the correct time. In another embodiment, expiratory dates for materials or devices disposed within the tray **100** may be placed on the horizontal flange **111**. It will be obvious to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. Any number of various text or picture combinations can be printed on, placed upon, or molded into various parts of the tray. For instance, graphical indicia can be applied to the compartment base members in addition to the horizontal flange **111**. Note that the horizontal flanges, in one embodiment, can terminate in downwardly protruding vertical flanges for increased stability during the printing process.

Another advantage of the tray **100** is that its compartmentalized configuration helps to reduce the risk of contaminating a patient or compromising the sterile nature of the components stored in the tray **100**. Since both the

catheter assembly and medical devices corresponding to catheter use are stored within the same tray **100**, the risk of cross-contamination between sterile work areas and non-sterile spaces is minimized. Further, by having the catheter assembly and the devices corresponding to catheter use stowed in a one-level tray rather than a multi-level, stacked configuration, the medical services provider can more easily prepare and use the catheter and corresponding devices disposed within the tray **100**.

Turning now to FIGS. **7-9**, illustrated therein is a tray having a catheter assembly **700**, syringes **701**,**702**, and a specimen container **703** stored therein as a catheter packaging system in accordance with one embodiment of the invention. As with FIGS. **1-6**, FIGS. **7-9** will be referred to collectively with like reference numerals referring to identical or functionally similar elements throughout the separate views. FIG. **7** illustrates a top, front, right perspective view of the catheter packaging system, while FIG. **8** illustrates a top plan view of the catheter packaging system. FIG. **9** illustrates a transparent, front elevation view of the catheter packaging system.

The illustrative catheter packaging system of FIGS. **7-9** includes a tray **100** having a first compartment **101**, a second compartment **102**, and a third compartment **103**. In this illustrative embodiment, the first compartment **101** is configured to accommodate syringes **701**,**702**. The second compartment **102** is configured to accommodate a coiled medical device, such as catheter assembly **700**. The third compartment **103** is configured to accommodate the specimen container **703**. The third compartment **103** can accommodate other materials as well, including skin sanitizers and cleansing liquids, solutions, or gels. As mentioned above, additional devices corresponding to catheter use, including towels, drapes, rubber gloves, and so forth, can be disposed in the tray **100** as well. As an illustration of this flexibility, a towel **704** is disposed beneath the catheter assembly **700**.

As noted above, in one embodiment the flange **111** can include instructions **770** or other graphical indicia. As also noted above, the implements disposed in the various compartments **101**,**102**,**103** can have implements therein arranged in accordance with use. In one embodiment, shown illustratively in FIG. **7**, the instructions **770** can be coordinated with this arrangement, indicating that components disposed in the first compartment **101** should be used first, components disposed in the second compartment **102** should be used next, and so forth. To assist the user in understanding workflow, arrows **771** or other directional elements can be included on the flange **111** as well.

As illustrated in FIGS. **1-6**, each compartment of the tray **100** includes a compartment base member. Further, each compartment is separated by a barrier having an opening therein. A first barrier **105** having a first opening **121** therein separates the first compartment **101** from the second compartment **102**. Similarly, a second barrier **106** having a second opening **122** therein separates the second compartment **102** from the third compartment.

Syringes **701**,**702** are disposed in the first compartment, with one syringe **701** being supported at a different elevation within the tray than the other syringe **702**. The different elevations can be relative to each syringe **701**,**702**, or to other components of the tray **100**, such as the second compartment base member **108**. Said differently, one syringe **701** is supported by the first compartment base member **107** at a shallower depth within the tray **100** than the depth of the second compartment base member **108**. Further, where the first compartment base member **107** is inclined relative to other base members, one or both syringes **701**,**702** will be supported in a non-parallel configuration relative to the second compartment base member **108**. This is most readily seen in FIG. **9**.

As noted above, some medical procedures will call for more materials than can be accommodated by a syringe capable of fitting within the first compartment **101**. For such procedures, the tray **100** can be packed with larger syringes. A large syringe (not shown) can be supported laterally within the tray **100** when it is placed across the tray **100** such that it lies within both the first opening **121** of the first barrier **105** and the second opening **122** of the second barrier **106**. Such a syringe will pass across the top of the catheter assembly **700**, but will be held in place by the side members of each opening.

Turning now to FIG. **10**, illustrated therein is an exploded view of the tray **100** having the catheter assembly **700**, a pair of syringes **701**,**702**, and a specimen container **703** disposed therein. While only a specimen container **703** is shown as being disposed in the third compartment, note that additional items could also be included within the third compartment, including swab sticks. Other devices could also be inserted into the tray **100** in various compartments as well. For example, in one embodiment, a catheter securement device, and a Foley insertion tag, which is a dated and/or time stamped label that is secured to the catheter tubing once the catheter is inserted, can be inserted into the second compartment **102**. Also, note that the pair of syringes **701**,**702** can be configured as shown in FIG. **10**, or alternatively can be both inserted in the first compartment, as described above. In the configuration of FIG. **10**, rather than having both syringes **701**,**702** disposed within the first compartment **101**, one syringe **702** is disposed laterally in the first opening **121** and the second opening **122** of the first barrier **105** and second barrier **106**, respectively. This configuration is illustrative only.

Once the necessary components are disposed within the tray **100**, the tray can be sealed with a wrap **1000** to keep the internal components sterile. The wrap **1000** can be any of a number of types of material. In one embodiment, the wrap **1000** comprises a Central Sterile Reprocessing (CSR) wrap that is used widely by medical professionals in hospitals, ambulatory surgical centers, and the like during medical procedures. While a CSR wrap is one example of a wrap that can be used, it will be clear to those of ordinary skill in the art that other wraps, such as plastic, cotton, linen, paper, or combinations thereof, can be substituted without departing from the spirit and scope of the invention.

Using a CSR wrap as an illustrative example, in one embodiment as indicated in FIG. **10**, the CSR wrap **1000** is folded about the tray **100** for sealing, and can be correspondingly unfolded to reveal the tray **100**. Once unfolded, the CSR wrap **1000** can then be used in the catheter insertion process. For example, an unfolded CSR wrap **1000** can be used to provide a sterile field in which the tray **100** sits for unloading and subsequent use. This process will be explained in more detail in the discussion of FIGS. **22-30** below.

Printed instructions **1001** can then be attached to, disposed upon, or disposed within the tray **100**. In one embodiment, the printed instructions **1001** include a health care services portion and a patient portion, as will be shown in FIGS. **12-13** below. The health care services portion can include instructions telling the health care services provider, for example, how to set up a sterile or otherwise clean work environment, how to prepare the catheter assembly **700** disposed within the tray, how to use the other devices within the tray, how to insert the catheter, how to secure the

drainage bag to the catheter, how to empty the drainage bag, how to obtain a urine sample, and so forth. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

The patient portion can include helpful suggestions or instructions for the patient. The patient portion can be detachably coupled to the health care services portion, such as by a perforated line that is easily torn to separate the patient portion from the health care services portion. Examples of suggestions or instructions that may be included in the patient portion include information on what a catheter is, what the patient should understand about the catheter, how to reduce the chance of getting an infection, information about infections commonly associated with catheters, symptoms of infections commonly associated with catheters, and suggestions for home use of the catheter assembly **700**. In one embodiment, the health care services portion may include an instruction for the health care services provider to detach the patient portion from the health care services portion and instructions to discuss the patient portion with the patient.

The health care services portion can tell the medical services provider how to perform a standard catheterization procedure. For instance, in one embodiment, the tray **100** is equipped with an adhesive label that can be used to identify the patient or specimen in the specimen container **703**. Further, a label can be included to mark or otherwise identify the material in the fluid bag attached to the catheter. Such labels can include pre-printed fields, such as date, time and name. Further the printed instructions **1001** can notify the medical services provider that the devices disposed within the tray **100** are ordered corresponding to use during the catheterization procedure.

In another embodiment, the printed instructions **1001** can inform the medical services provider of special instructions. For instance, in one embodiment the printed instructions **1001** can inform the medical services provider not to leave a catheter in a patient for more than forty-eight hours without a physician's approval. Where the printed instructions **1001** include such information, the labels included in the tray **100** may have pre-printed fields for the time of insertion that can be filled in by the medical services provider performing the catheterization procedure.

Once the printed instructions **1001** have been affixed to, or placed with, within, or atop the tray **100**, the assembly can be sealed in a sterile wrap **1002** such as a thermally sealed bag. The thermally sealed bag can optionally include a preformed opening. For example, in one embodiment, the opening can include one or more tabs that a health care services provider is instructed to pull to open the bag. Inclusion of a sterile wrap **1002** not only keeps the contents within the bag sterile, but also allows the instructions to be included with the tray assembly, yet outside the CSR wrap **1000**.

In one embodiment the printed instructions **1001** are disposed atop the CSR wrap **1000** such that the health care services portion of the printed instructions **1001** is disposed on the top of the printed instructions **1001**, with the patient portion being disposed adjacent to the CSR wrap **1000**, such as when the printed instructions **1001** are configured as an accordion-style folded instruction pamphlet. While the printed instructions **1001** of one embodiment are configured as a folded, printed, separate article disposed atop the CSR wrap **1000**, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. For example, in one embodiment the sterile wrap **1002** can be optional. In one embodiment, rather than including separate printed instructions **1001**, the instructions for use can be printed on the CSR wrap **1000** as well.

Additional instruction materials may be included with the completed assembly as well. For example, in one embodiment an adhesive instruction tag **1003** can be affixed to the sterile wrap **1002**. In another embodiment the instruction tag may be adhered to an outer packaging, that encloses the tray, the sterile wrap material or both. For example, in one embodiment the instruction tag **1003** can include information regarding whether a catheter procedure is needed. Text **1004** such as "Is there a valid clinical reason?" may be included under an instruction to "Stop" that includes the following information:

Before inserting the Foley catheter, at least one of the following conditions should exist:
Acute urinary retention or obstruction
Precise measurement of urinary output needed
Select surgical procedures
Open sacral or perineal wounds in incontinent patient
Prolonged immobilization
End of life care

Further, checklist text **1005** may be included, such as "Checklist for Foley Catheter Insertion" included under the word "Check" that includes the following information:

Check Each Box Upon Completion:
Obtain order from physician/provider
Document clinical reason for insertion
Explain procedure to patient
Use smallest catheter possible
Perform hand hygiene
Follow aseptic technique

Additional information may also be included, such as a fillable form **1006** that provides fields for the date and time of insertion of the catheter to be recorded, the name of the health care services provider, and the signature of the health care services provider. The above text **1004** for the instruction tag **1003** is illustrative only, and may be customized as desired by the manufacturer.

Turning now to FIG. **11**, illustrated therein is a method **1100** for manufacturing a packaged catheter assembly in accordance with embodiments of the invention. At step **1101**, the manufacturer provides a tray (**100**) having at least a first compartment (**101**) for accommodating one or more syringes (**701**,**702**) and a second compartment (**102**) for accommodating a flexible medical device, such as a catheter assembly (**700**). As noted above, in one embodiment the first compartment (**101**) will have a first compartment base member (**107**) having an inclined, stair-stepped contour (**115**). The first compartment (**101**) and second compartment (**102**) can be separated by a first barrier (**105**) having an opening (**121**) therein.

Once the tray (**100**) is procured, the manufacturer can dispose at least one syringe (**701**) in the first compartment (**101**) at step **1102**. Optionally, at step **1103**, the manufacturer may include additional components with the tray (**100**). For example, a catheter securement device, a Foley insert tag, or other complementary components may be included at this step **1103**.

In one embodiment, as determined at decision **1105**, a second syringe (**702**) will be disposed in the first compartment (**101**) at step **1106**. In another embodiment, the second syringe (**702**) will be disposed laterally within the first opening (**121**) and, where present, a second opening (**122**) at step **1107**.

At step **1104**, the manufacturer will place the catheter assembly (**700**) in the second compartment (**102**). Other components may be disposed in the tray (**100**) as well,

including a specimen container (**703**) that is disposed in a third compartment (**103**) at step **1108**. Further, other devices may be included, such as towels, drapes, printed instructions, one or more antiseptic packets, and so forth. These other devices can be disposed in various compartments within the tray (**100**).

At step **1109**, the tray (**100**) is sealed. This can be accomplished by folding a CSR wrap about the tray (**100**). In such an embodiment, the CSR wrap can be used during the catheter insertion procedure as well. At optional step **1110**, the manufacturer can enclose printed instructions (**1001**). In one embodiment, the printed instructions (**1001**) will direct a user to discharge contents of at least one syringe into the first compartment (**101**) and to pass at least a portion of the catheter assembly (**700**) through the opening and into the contents to lubricate the catheter.

At step **1111**, the manufacturer can place a sterile wrap about the tray (**100**) and the printed instructions (**1001**), where included. A sticker or other sealing device can be applied that indicates the contents to be sterile as well. At step **1112**, the completed assembly can be shipped to a medical services provider.

Turning now to FIGS. **22-30**, illustrated therein is a method of packaging a catheter assembly and corresponding tray in accordance with embodiments of the invention. FIGS. **22-30** illustrate one exemplary method graphically, which each figure representing one or more steps of the method, as the illustrations serve to better explain these steps than would a flow chart or other diagram. While FIGS. **22-30** illustrate one method of packaging a tray and catheter assembly, it will be clear to those of ordinary skill in the art having the benefit of this disclosure that other methods can be used as well. Further, in creating this article of manufacture, i.e., the packaged catheter assembly, the steps of FIGS. **22-30** may be either manual or automated. A person can execute the steps to create the article of manufacture in one embodiment. Alternatively, industrial machinery, equipment, and robotics can be designed and programmed to execute the steps with the assistance of one or more processors and executable instructions stored in memory.

Beginning with FIG. **22**, in this step, a tray **100** is provided. The tray includes at least one compartment, such as the first compartment **101** that is configured for receiving the catheter assembly **700**. As described above, the tray **100** can include additional compartments as well, such as those for receiving syringes, specimen jars, and so forth.

At this step, the catheter assembly **700** is placed within the first compartment **101** as previously described. The tray is then placed upon one or more layers of wrap material **2200**. In one embodiment, the wrap material **2200** can be CSR wrap. For example, in the illustrative embodiment of FIG. **22**, the wrap material **2200** comprises a white layer of CSR wrap measuring 24 inches square. As previously noted, other materials can be used as well, including plastic materials, cotton materials, paper materials, synthetic materials and so forth. The wrap material **2200** can be of different shapes and sizes as well.

While the tray **100** can be sealed with a simple layer of plastic adhered to the top of the tray **100**, providing the wrap material **2200** can be advantageous in many applications. For example, as will be explained below with respect to FIGS. **31-33**, when the wrap material **2200** is a medically usable material, such as CSR wrap, a medical services provider may unfold the wrap about the tray **100** to create a sterile field for the catheterization procedure. For this reason, one or more layers of wrap material **2200** are simply folded about the tray **100** in this illustrative embodiment.

Note that for reference and ease of explanation, the tray **100** will be described as having four sides: a first side **2201**, a second side **2202**, a third side **2203**, and a fourth side **2204**. As these sides will not be visible in every view, due to the folding of the wrap material **2200** about the tray **100**, they are initially noted here. Note that four sides are used because the illustrative tray **100** is rectangular in shape. Were the tray a triangle, there would be three sides. Were the tray ovular or circular, there would be an infinite number of sides.

Turning now to FIG. **22**, at this step a first portion **2301** of the one or more layers of wrap material **2200** is folded about a first side (**2201**) of the tray **100**. In this illustrative embodiment, the tray **100** is oriented at a rotation of approximately forty-five degrees relative to the one or more layers of wrap material **2200**, with both the wrap material **2200** and the tray **100** being rectangular in shape. As such, the first portion **2301** comprises a first corner of the wrap material **2200**. It will be clear to those of ordinary skill in the art having the benefit of this disclosure, however, that embodiments of the invention are not so limited. For example, the wrap material **2200** can be configured as a circle or oval. Executing the step shown in FIG. **22**, a first portion of that material could be folded about a first side of the tray **100** in similar fashion.

Turning to FIG. **23**, illustrated therein is an optional step that can be included in the method of packaging the catheter assembly. As noted above, in one embodiment the one or more layers of wrap material **2200** can be unfolded to create a sterile field about the tray **100**. A patient can be placed atop this sterile field for the catheterization procedure. Even if the surface below the wrap material **2200** is also sterile, the use of the wrap material **2200** as a foundation for the procedure further ensures that the sterile field will not be breached.

Turning now to FIG. **24**, to help ensure that the health care provider does not inadvertently breach the sterile field, in one embodiment a package of liquid hand sanitizer **2401** or other cleanser and/or a package of rubber gloves **2402** may be included. Alternatively, other medical implements such as alcohol wipes or other materials could be enclosed as well. In such an embodiment, upon opening the packaged catheter assembly, the health care services provider may—before ever touching the catheter assembly or tray contents—apply the liquid hand sanitizer **2401** to their hands and dawn rubber gloves. The inclusion of these accessories in the packaging eliminates the need for the health care services provider to have to leave the sterile field to wash their hands, obtain gloves, and so forth.

In the illustrative embodiment of FIG. **23**, the package of liquid hand sanitizer **2401** and package of rubber gloves **2402** are simply placed atop the first portion **2301** of the one or more layers of wrap material **2200**. As will be shown below, they will be held in place by other portions of the one or more layers of wrap material **2200** by way of subsequent folding steps. Other methods of holding them in place, including light adhesives or the design of pockets in the one or more layers of wrap material **2200** may also be used. The sanitizer **2401** and gloves **2402** are shown placed atop the first portion **2301**, but may be alternatively placed atop, and therefore outside of the sterile field, other layers of the wrap as well, (for example, **2501**, **2601**, **2801** or the like).

Turning now to FIG. **25**, at this step a second portion **2501** of the one or more layers of wrap material **2200** is folded about a second side (**2202**) of the tray **100**. Where the optional package of liquid hand sanitizer **2401** and package of rubber gloves **2402** are included, the second portion **2501** of the one or more layers of wrap material **2200** may be folded so as to cover or partially cover these items.

Turning now to FIG. **26**, at this step of the method a third portion **2601** of the one or more layers of wrap material **2200** is folded about a second side (**2203**) of the tray **100**. Where the optional package of liquid hand sanitizer **2401** and package of rubber gloves **2402** are included, the third portion **2601** of the one or more layers of wrap material **2200** may be folded so as to cover or partially cover these items.

Turning now to FIG. **27**, illustrated therein is another optional step of the method of packaging the catheter assembly and tray. In many catheterization procedures, a first layer of material will be placed under the patient, while a second layer of material is placed atop the patient. For such applications, the packaged catheter assembly can include an additional layer of wrap material **2701**. In the illustrative embodiment of FIG. **25**, the additional layer of wrap material **2701** comprises a folded layer of CSR wrap measuring 17 by 17.5 inches. The additional layer of wrap material **2701** in this illustrative embodiment is folded as a **4** by **2** matrix.

The one or more layers of wrap material **2200** and the additional layer of wrap material **2701** can be the same type of material. Alternatively, the one or more layers of wrap material **2200** and the additional layer of wrap material **2701** can be different. In one embodiment, for example, the additional layer of wrap material **2701** can be a fenestrated wrap with one or more pre-formed openings suited to the catheterization procedure.

In one embodiment, the additional layer of wrap material **2701** is configured to be visibly distinguishable from the one or more layers of wrap material **2200**. For example, in one embodiment, the additional layer of wrap material **2701** is a different color than the one or more layers of wrap material **2200**. The one or more layers of wrap material **2200** can be white, for instance, while the additional layer of wrap material **2701** can be light blue or light green. Other color combinations can equally be used.

As with the package of liquid hand sanitizer **2401** and package of rubber gloves **2402**, in one embodiment the additional layer of wrap material **2701** can be placed atop portions of the one or more layers of wrap material **2200**. In such an embodiment, the additional layer of wrap material **2701** can be held in place by way of subsequent folding steps, as the additional layer of wrap material **2701** is disposed along other folded portions of the one or more layers of wrap material **2200** prior to folding a fourth portion of the one or more layers of wrap material about the fourth side (**2204**) of the tray (**100**).

As will be shown below, medical procedure kits configured in accordance with embodiments of the invention can include printed instructions. The printed instructions can include a patient portion and a health care services provider portion. The health care services provider portion can include information such as how to use the medical procedure kit, what is included therein, checklists, and so forth. The patient portion can include helpful information for the patient, such as information about the procedure, questions to ask, and post procedure care suggestions. These two portions can be detachably coupled together. Alternatively, they can be separate.

In one embodiment of the invention where the health care services portion of the printed instructions are physically separated from the patient portion, it can be advantageous to stage the various portions at different locations within the assembled medical procedure kit. One advantage offered by embodiments of the invention is that the medical devices and implements can be staged within the kit in accordance with an order of use. Accordingly, the health care services provider can draw out each device in order of use.

Turning now briefly to FIG. **34**, illustrated therein is an alternate embodiment of the stage shown in FIG. **27**. The embodiment of FIG. **34** is well suited to situations in which the health care services portion is physically separated from the patient portion.

In FIG. **34**, another optional step corresponding to a method of packaging a medical procedure kit is shown. As with FIG. **27**, the medical procedure kit of FIG. **34** illustrates a packaged catheter assembly. Also as with FIG. **27**, the packaged catheter assembly can include an additional layer of material **2701**, which may be a patient drape, under-buttocks drape, or a combination thereof disposed within one or more layers of wrap material **2200**. As noted above, the additional layer of material **2701** can be configured to be visibly distinguishable from the one or more layers of wrap material **2200**. For example, in one embodiment, the additional layer of material **2701** is a different color than the one or more layers of wrap material **2200**.

The package of liquid hand sanitizer **2401** and package of rubber gloves **2402**, optionally the additional layer of material **2701**, and the separated health care services portion **3401** of the printed instructions can be placed atop portions of the one or more layers of wrap material **2200**. In such an embodiment, the package of liquid hand sanitizer **2401**, the rubber gloves **2402**, the additional layer of material **2701**, and the separated health care services portion **3401** can be held in place by way of subsequent folding steps, as they are disposed along other folded portions of the one or more layers of wrap material **2200** prior to folding a fourth portion of the one or more layers of wrap material about the fourth side (**2204**) of the tray (**100**). Accordingly, the health care services provider will be readily able to access these devices after unfolding a single fold of the one or more layers of wrap material **2200**.

Turning now to FIG. **28**, the tray (**100**) is enclosed in the one or more layers of wrap material **2200** by folding a fourth portion **2801** of the one or more layers of wrap material **2200** about a fourth side (**2204**) of the tray (**100**) and then tucking at least one of the first portion (**2301**), the second portion (**2501**), the third portion (**2601**), or the fourth portion **2801** of the one or more layers of wrap material **2200** beneath at least another of the first portion (**2301**), the second portion (**2501**), the third portion (**2601**), or the fourth portion **2801** of the layer of wrap material **2200**. In the illustrative embodiment of FIG. **28**, a part of the fourth portion **2801** is tucked beneath parts of each of the (**2301**), the second portion (**2501**), and the third portion (**2601**). This step of tucking encloses both the additional layer of wrap material **2701** and the package of liquid hand sanitizer (**2401**) and the package of gloves (**2402**) within the one or more layers of wrap material **2200**.

Turning briefly to FIG. **35**, illustrated therein is a variation of FIG. **28** in which the printed instructions include a health care services portion and a patient portion, wherein these portions are separate. In FIG. **35**, as with FIG. **28**, the tray (**100**) is enclosed in the one or more layers of wrap material **2200** by folding a fourth portion **2801** of the one or more layers of wrap material **2200** about a fourth side (**2204**) of the tray (**100**) and then tucking at least one of the first portion (**2301**), the second portion (**2501**), the third portion (**2601**), or the fourth portion **2801** of the one or more layers of wrap material **2200** beneath at least another of the first portion (**2301**), the second portion (**2501**), the third portion (**2601**), or the fourth portion **2801** of the layer of wrap material **2200**.

The separated health care services portion **3401** of the printed instructions is thus tucked within the fourth portion **2801**.

The separated patient portion **3501** is then placed atop the fourth portion **2801**. The health care services provider is therefore able to access the separated patient portion **3501** and deliver it to, and possibly discuss it with, a patient prior to unfolding the fourth portion **2801**. The step of tucking shown in FIG. **34** encloses each of the additional layer of wrap material **2701**, the separated health care services portion **3401**, the package of liquid hand sanitizer (**2401**) and the package of gloves (**2402**) within the one or more layers of wrap material **2200**, while leaving the patient portion **3501** outside the various folds of the one or more layers of wrap material **2200**.

Turning now to FIG. **29**, the packaged catheter assembly **2901** can be sealed in a bag **2902** as was described in FIG. **10**. Prior to depositing the packaged catheter assembly **2901** into the bag **2902**, optional printed instructions **1001** can be attached to or disposed upon the packaged catheter assembly **2901** as well. As with FIG. **10**, the printed instructions **1001** can include a health care services portion and a patient portion as shown in FIGS. **12-13**. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

Turning briefly to FIG. **36**, illustrated therein is an alternative to FIG. **29**, which is used when printed instructions including a health care services provider portion and a patient portion, each physically separate from the other, is included. In FIG. **36**, the packaged catheter assembly **2901** having the tucked-in, separated health care services portion **3401** of the printed instructions is sealed in a packaging material. The packaging material of FIG. **36** is illustratively shown as a bag **2902**.

Prior to depositing the packaged catheter assembly **2901** into the bag **2902**, the separated patient portion **3501** of the optional printed instructions can be attached to or disposed upon the packaged catheter assembly **2901** as described in FIG. **35**.

Once the printed instructions **1001** have been affixed to, or placed with or atop the packaged catheter assembly **2901**, as in either FIG. **29** or **36**, the assembly can be sealed in a sterile wrap such as a bag **2902**, which may be thermally or otherwise sealed. The completed assembly **3001** is shown in FIGS. **30** and **37**, where an outer packaging material is shown. In FIGS. **30** and **37**, the outer packaging material is a thermally sealed bag **2902**. It will be understood that this outer packaging is but one embodiment of the various packaging materials that can be used in accordance with embodiments of the invention. In FIGS. **30** and **37**, the thermally sealed bag **2902** optionally includes a preformed opening **3002**. For example, in one embodiment, the preformed opening **3002** can include one or more tabs that a health care services provider is instructed to pull to open the bag **2902**. Inclusion of a sterile wrap not only keeps the contents within the bag sterile, but also allows the printed instructions **1001** to be included with the tray assembly, yet outside the one or more layers of wrap material (**2200**).

Turning back to FIG. **29**, in one embodiment the printed instructions **1001** are disposed atop the one or more layers of wrap material **2200** such that the health care services portion of the printed instructions **1001** is disposed on the top of the printed instructions **1001**, with the patient portion being disposed adjacent to the one or more layers of wrap material **2200**. As with FIG. **10**, additional instruction materials may be included with the completed assembly as well. For example, in one embodiment an adhesive instruction tag **1003** can be affixed to the bag **2902**.

Turning now to FIGS. **38** and **39**, illustrated therein are steps of method of assembling yet another embodiment of medical procedure kit in accordance with embodiments of the invention. In FIGS. **38** and **39**, the printed instructions are physically separated into a patient portion **3801** and a health care services provider portion **3802**, as was the case in FIGS. **34-37**. However, unlike FIGS. **34-37**, the embodiment of FIGS. **38** and **39** has the health care services provider portion **3802** configured as an adhesive label with the checklist **1003** forming an extension thereof. Further, as will be shown in more detail in FIG. **40**, the health care services provider portion **3802** has a picture of the contents of the medical procedure kit on the top, and has a peelable flap **3803** that may be opened to reveal instructions and other indicia therein.

Another difference in the embodiment of FIGS. **38** and **39** involves the patient portion **3801**. While some embodiments provide a patient portion that is very straight-forward, informational, and clinical in nature, in the embodiment of FIGS. **38** and **39**, the patient portion **3801** is configured as a greeting card. Experimental testing has shown that when the patient portion is configured as an instruction or informational sheet, it is less likely that the patient portion will be delivered to the patient. However, by configuring the patient portion **3801** as a greeting card, such as with a pleasant picture of flowers or similar objects on the front and stylized text providing the information therein, it is more likely to be given to the patient. The patient portion **3801** will be described in more detail below.

Beginning with FIG. **38**, illustrated therein is an exploded view of a tray **100** suitable for use in a medical procedure kit. The tray **100** has the catheter assembly **700**, a pair of syringes **701**,**702**, and a specimen container **703** disposed therein. While only a specimen container **703** is shown as being disposed in the third compartment, note that additional items could also be included within the third compartment, including swab sticks. Other devices could also be inserted into the tray **100** in various compartments as well. For example, in one embodiment, a catheter securement device, and a Foley insertion tag can be inserted into the second compartment **102**. Also, note that the pair of syringes **701**,**702** can be configured as shown in FIG. **38**, or alternatively can be both inserted in the first compartment, as described above. In the configuration of FIG. **38**, rather than having both syringes **701**,**702** disposed within the first compartment **101**, one syringe **702** is disposed laterally in the first opening **121** and the second opening **122** of the first barrier **105** and second barrier **106**, respectively. This configuration is illustrative only.

Once the necessary components are disposed within the tray **100**, the tray can be enclosed with a wrap **1000**. The wrap **1000** can be one or more layers in number, and further can be any of a number of types of material. In one embodiment, the wrap **1000** comprises a CSR wrap.

Using a CSR wrap as an illustrative example, in one embodiment as indicated in FIG. **38**, the CSR wrap **1000** is folded about the tray **100** for sealing, and can be correspondingly unfolded to reveal the tray **100** and other implements. Once unfolded, the CSR wrap **1000** can then be used in the catheter insertion process. For example, an unfolded CSR wrap **1000** can be used to provide a sterile field in which the tray **100** sits for unloading and subsequent use. This process is explained in more detail in the discussion of FIGS. **22-30**.

Printed instructions can then be attached to, disposed upon, or disposed within the tray **100**. In the illustrative

embodiment of FIG. **38**, the printed instructions are configured as a physically separate health care services portion **3802** and a patient portion **3801**, as will be shown in more detail in FIGS. **40-41** below. The health care services portion **3802** can include instructions telling the health care services provider, for example, how to set up a sterile or otherwise clean work environment, how to prepare the catheter assembly **700** disposed within the tray, how to use the other devices within the tray, how to insert the catheter, how to secure the drainage bag to the catheter, how to empty the drainage bag, how to obtain a urine sample, and so forth. The instructions can include pictures or illustrations showing visually how the various steps should be done as well.

In the embodiment of FIG. **38**, the health care services portion **3802** is configured with a checklist **1003** extending therefrom. Further, the health care services portion **3802** includes, in one embodiment, a photograph of the contents disposed within the medical procedure kit. When viewing the health care services portion **3802** from the top, the health care services provider is able to easily inventory what contents are disposed therein.

In one embodiment, the health care services portion **3802** includes a peelable flap **3803**. By pulling back the peelable flap **3803**, the health care services portion **3802** opens to reveal instructions and other information therein. For example, in one embodiment, the interior of the health care services portion **3802** can include one or more of the panels shown in FIGS. **15-19**. In one embodiment, the health care services portion **3802** may include an instruction for the health care services provider to give the patient portion **3801** to the patient, and in one embodiment, instructions to discuss the patient portion **3801** with the patient.

The patient portion **3801** can include helpful suggestions or instructions for the patient. The patient portion **3801** can be configured as a greeting card to make the information more pleasantly received by a patient. Examples of suggestions or instructions that may be included in the patient portion include information on what a catheter is, what the patient should understand about the catheter, how to reduce the chance of getting an infection, information about infections commonly associated with catheters, symptoms of infections commonly associated with catheters, and suggestions for home use of the catheter assembly **700**.

In the embodiment of FIG. **38**, the patient portion **3801** is disposed within the packaging **3804**, while the health care provider portion **3803** is affixed to the outside of the packaging **3804**. As with FIG. **34**, the medical procedure kit of FIG. **38** can include an additional layer of wrap material **2701** disposed within one or more layers of wrap material **2200**. As noted above, the additional layer of wrap material **2701** can be configured to be visibly distinguishable from the one or more layers of wrap material **2200**. For example, in one embodiment, the additional layer of wrap material **2701** is a different color than the one or more layers of wrap material **2200**.

The package of liquid hand sanitizer and package of rubber gloves described above (not shown in FIG. **38** for simplicity) can then be placed under the additional layer of wrap material **2701**. The patient portion **3801** can be placed atop the additional layer of wrap material **2701**. In such an embodiment, the package of liquid hand sanitizer (where used), the rubber gloves (where used), the additional layer of wrap material **2701**, and the patient portion **3801** can be held in place by way of a final folding step **3805**. Accordingly, they will be held in place by a folded portion **3806**. The health care services provider will be readily able to access these implements after unfolding the folded portion **3806** shown in FIG. **38**.

The health care services portion **3802** can be affixed to the packaging **3804**. The packaging **3804** can optionally include a preformed opening. For example, in one embodiment, the opening can include one or more tabs that a health care services provider is instructed to pull to open the packaging **3804**.

Turning now to FIG. **39**, illustrated therein is the medical procedure kit **3901** of FIG. **38** having the patient portion **3802** tucked-into the one or more layers of wrap **2200**. The health care services portion **3802** is affixed to the packaging **3804**. The packaging **3804** of FIG. **39** is illustratively shown as a thermally or adhesively sealed bag.

Turning now to FIGS. **12-13**, illustrated therein is one embodiment of the printed instructions **1001** in accordance with embodiments of the invention. The printed instructions **1001** can be configured as an instruction manual suitable for inclusion with a tray (**100**) as described above. FIG. **12** illustrates a view of a first side of the instruction manual, while FIG. **13** illustrates a view of a second side of the instruction manual.

In one embodiment, the printed instructions **1001** are configured as a two-portion instruction manual having a health care services portion **1201** and a patient portion **1202**. In the illustrative embodiment of FIGS. **12-13**, the patient portion **1202** is detachably coupled to the health care services portion **1201**, and is thus separated from the health care services portion **1201**, by a perforation **1203**. For example, where the printed instructions **1001** are configured as a printed material on a paper-based stock, the perforation **1203** can be a perforated line running along a dimension of the printed instructions **1001** such that the printed instructions **1001** can be easily torn along the perforation **1203** to separate the patient portion **1202** from the health care services portion **1201**. Note that the embodiment of FIGS. **12** and **13** is but one illustrative embodiment of the invention. The patient portion **1202** need not be detachably coupled to the health care services portion **1201**. As will be shown in FIGS. **27-34** below, the patient portion **1202** may be physically separate from the health care services portion **1201** as well. In the separated configuration, the health care services portion **1201** and patient portion **1202** can be disposed at different locations within a medical procedure kit.

In one embodiment, the printed instructions **1001** are configured as a plurality of panels **1204**,**1205**,**1206**,**1301**, **1302**,**1303**. As will be shown in FIG. **20**, in one embodiment the printed instructions **1001** can be configured as an instruction manual that is formed with an accordion-style fold, with each of the panels **1204**,**1205**,**1206**,**1301**,**1302**,**1303** forming a page of the instruction manual. In the illustrative embodiment of FIGS. **12-13**, panels **1204**,**1205** and panels **1301**, **1302** form the health care services portion **1201**, while panels **1206**,**1303** form the patient portion. Panels **1206**, **1303** are separated from panels **1204**,**1205** and panels **1301**, **1302** by the perforation **1203** such that the patient portion **1202** is tearably separable from the health care services portion **1201**.

In one embodiment, the health care services portion **1201** includes instructions **1304** for using the catheter assembly and other corresponding medical devices disposed within the accompanying tray. The instructions **1304** can include text and/or figures or illustrations showing how to use the catheter assembly and corresponding medical devices on the patient, as well as instructions on preparation, taking

samples, preventing infection, and so forth. The instructions **1304**, in one embodiment, also include an instruction to detach the patient portion **1202**, give the patient portion **1202** to the patient, as well as an instruction to discuss the information disposed on the patient portion **1202** with the patient.

Similarly, the patient portion **1202** may also include instructions **1305** and/or helpful suggestions for the patient who is undergoing the catheterization procedure. For instance, this information can include any one or more of the following: a description of what a catheter is, what the patient should know about the catheter, how to reduce the chance of getting an infection from the catheterization procedure, what infections commonly associated with catheterization procedures typically are, the symptoms associated with infections commonly associated with catheterization procedures, and information about using the catheter at home. Additionally, the patient portion **1202** may include custom information as well. For example, in one embodiment the patient portion **1202** includes an informational section configured such that the health care service provider's name and contact information can be written thereon. It will be clear to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited. For example, additional types of health care service instructions or patient instructions or suggestions can also be included.

Turning now to FIGS. **14-19**, illustrated therein are exemplary panels **1204**,**1205**,**1206**,**1301**,**1302**,**1303**. These panels **1204**,**1205**,**1206**,**1301**,**1302**,**1303** are intended to illustrate exemplary instructions for the health care services portion (**1201**) and patient portion (**1202**) of an illustrative instruction manual for a catheter assembly and corresponding medical devices included with an accompanying tray (**100**). It will be clear that these panels **1204**,**1205**,**1206**,**1301**,**1302**, **1303** and the information printed thereon can be varied in any number of ways without departing from the spirit and scope of the invention as described herein and recited in the following claims. For example, the number of panels can be varied. Additionally, the information printed thereon can be condensed, expanded, or altered without departing from the spirit and scope of the invention. Also, the exemplary information may be moved from the panels shown to other panels, as a particular application may warrant.

Beginning with FIG. **14**, illustrated therein is one exemplary panel **1204**. In one embodiment, panel **1204** will be configured such that when the catheter package assembly within which the instruction manual is disposed is initially opened, panel **1204** will be readily viewable. For example, where the catheter package assembly is assembled as shown in FIG. **10** above, once the sterile wrap (**1002**) is removed, the panel **1204** will be viewable prior to removal of the CSR wrap (**1000**).

Panel **1204** can include general information about the catheter assembly and corresponding medical devices disposed within the tray. For example, this information can include part number information **1401**, trade name information **1402**, and manufacturer information **1403**. A diagram **1404** of the contents of the package assembly may be included as well. The illustrative diagram **1404** of FIG. **14** illustrates a tray **100** having a catheter assembly **700** and corresponding medical devices disposed therein. The corresponding medical devices of this illustrative embodiment include a pair of syringes **701**,**702** and a specimen container **703**. Additionally swab sticks **1408**, a catheter securement device **1409**, a Foley insert tag **1410**, vinyl gloves **1411**, a fenestrated drape **1412**, an underbuttocks drape **1413**, and a hand sanitizer **1414** solution or wipe are disposed within the tray **100**.

In addition to a diagram **1404**, panel **1204** can also include a written description **1407** of the elements included in the tray **100**. Further, sterility information **1407** can be included. Panel **1204** can even include instructional material **1406** on how to use the instruction manual as well.

Turning now to FIG. **15**, illustrated therein is one embodiment of panel **1301**. As will be described below with respect to FIG. **20**, in one embodiment the printed instructions (**1001**) are configured as an accordion-style folded instruction manual. In such a configuration, panel **1301** can be disposed on the back of panel **1204**. Panel **1301** will therefore be visible upon a health care services provider opening the instruction manual.

Panel **1301** can include instructions for using the catheter assembly and the corresponding medical devices. As can be seen from this illustrative embodiment, panel **1301** can include instructions for setting up a clean work area. The instructions can include text, pictures, illustrations, or combinations of these.

In one embodiment, the instructions for setting up a clean work area include a hygiene performance step **1501**, which may include instructions to wash hands, optionally put on gloves (which at this step can be non-sterile gloves), and so froth. The instructions may then include information on opening the remainder of the catheter package assembly. For instance, in FIG. **15** step **1502** indicates that the health care provider should remove the CSR wrap (**1000**), which in this case is folded about the tray (**100**). Note that in this illustrative embodiment, as the CSR wrap (**1000**) is folded about the tray (**100**), removal of the CSR wrap (**1000**) by unfolding creates a sterile field about the tray (**100**).

Step **1503** then instructs the health care provide to pick up the underbuttocks of the patient and to place the underbuttocks wrap beneath the patient. Step **1504** then instructs the health care provider to use the hand sanitizing solution provided with the catheter package assembly.

As with other panels shown in FIGS. **14-19**, the various panels may include suggestions **1505** for preventing a catheter associated urinary tract infection. Some of this information is illustratively shown in FIG. **15**. It will be understood that this information can be placed on one or more panels.

In addition to information for setting up a clean work area, in one embodiment panel **1301** includes instructions for preparing the catheter assembly (**700**) as well. For example, step **1506** instructs the health care services provider to don sterile gloves, as the hands were sanitized at step **1504**. Step **1507** tells the health care services provider to place the fenestrated drape with a shiny side down on the patient without contaminating the sterile gloves donned at step **1506**. Step **1508** instructs the health care services provider to test the balloon of the catheter assembly with the water-filled syringe stored in the first compartment. Step **1508** also instructs the health care services provider to leave the syringe connected to the catheter assembly.

Step **1509** then provides instructions on using the first compartment of the tray as a lubricant application chamber as described above. Specifically, in this illustrative embodiment, step **1509** instructs the health care services provider to inject the lubricating jelly found in the second syringe of the first compartment into the first compartment. Step **1509** also instructs the health care services provider to pass the tip of the catheter through the first opening in the wall separating

the first compartment and second compartment into the lubricating jelly, thereby lubricating the tip of the catheter.

Turning now to FIG. **16**, illustrated therein is an exemplary embodiment of panel **1302**. The instructions printed thereon continue to provide the health care services provider with information regarding use of the catheter assembly. For example, in one embodiment, this information includes instructions on inserting the catheter.

At step **1601**, the instructions direct the health care services provider to tear open the swab stick package and to use the swab sticks to clean the patient from the top down. The instruction also notes that each swab stick is intended for one use only to properly maintain the sterile field. Step **1602** directs the health care services provider to initiate the catheterization process by inserting the catheter assembly into the patient. Steps **1603** and **1604** continue this process as shown in FIG. **16**.

Step **1605** directs the health care services provider to secure the drainage bag to the catheter assembly. Step **1606** directs the health care services provider to clean up upon completion of the catheterization process. Step **1607** provides instructions on completing the label on the Foley insertion tag included with the catheter package assembly and attaching it to the tubing or drain bag attached to the catheter assembly.

At step **1608**, the health care services provider is instructed to detach the patient portion (**1202**) from the health care services portion (**1201**) by tearing the two apart along the perforation (**1203**). Step **1609** further instructs the health care services provider to discuss the patient information printed upon the patient portion (**1202**) with the patient. Step **1609** instructs that documentation of the entire procedure should be completed.

Turning now to FIG. **17**, illustrate therein is one embodiment of panel **1303**, which represents a first side of the patient portion (**1202**). This panel **1303** includes information **1701** describing what a catheter is and why a catheter might be used. The panel **1303** also includes information **1702** describing what the patient should know regarding catheters and catheter use. For example, this information **1702** might notify the patient that the health care services provider should wash hands prior to inserting the catheter, and that it is acceptable to ask them to do so if they have not done so before the patient.

The panel **1303** also includes information **1703** regarding how the patient can reduce the chances of getting an infection. This information **1703** can include a statement that the patient should wash their hands prior to touching the catheter assembly. The information **1703** may also include a statement that the drainage bag should always be kept at a level beneath the patient's navel, and that the patient should inform a helper when the bag is more than half full.

Turning to FIG. **18**, illustrated therein is one embodiment of panel **1206**. In this illustrative embodiment, panel **1206** forms the second side of the patient portion (**1202**) of the instruction manual, and accordingly, includes additional information that a patient may wish to know when using a catheter assembly.

By way of example, information **1801** informs the patient as to what common infections associated with catheter use are and how they are contracted. Information **1802** provides symptoms of these common infections, such as fever, blood in the urine, burning or painful urination, or frequent or more urgent urination after catheter removal. Information **1803** informs the patient of what they should know prior to going home after a catheter procedure.

Information **1804** comprises an informational section configured such that a health care provider's name and contact information may be written thereon. This is helpful to the patient in the event that the symptoms recited in information **1802** should arise after the procedure, in that the patient has readily available access to the information required to contact a physician or other health care provider. An advantage of having this information **1804** on the patient portion (**1202**) when the patient portion (**1202**) is detachable is that the patient can take it with them upon completion of the procedure.

Turning now to FIG. **19**, which is a portion of the health care services portion (**1201**), illustrated therein is one embodiment of panel **1205** that provides additional health services information. For example, information **1901** for emptying the drain bag and information **1902** describing how to obtain a urine sample can be included.

Turning now to FIG. **20**, illustrated therein is one physical configuration in which the printed instructions **1001** can be delivered along with the catheter package assembly in accordance with embodiments of the invention. FIG. **20** is but one of many configurations, and embodiments of the invention are not to be limited in this respect, as FIG. **20** is illustrative only.

In FIG. **20**, the printed instructions **1001** are configured as a tri-section, accordion style bi-folded panel. Three sections **2000**,**2001**,**2002** are folded in an accordion style, with two folds **2003**,**2004** existing between the sections **2000**,**2001**, **2002**. When the printed instructions **1001** are configured as shown in FIGS. **12-13**, folding the printed instructions **1001** in this manner allows the health care services portion **1201** to be disposed atop the patient portion **1202**. Further, when the printed instructions are disposed atop a CSR wrap (**1000**) as shown in FIG. **10**, by disposing the patient portion **1202** adjacent to the CSR wrap (**1000**), the health care services provider removing the sterile wrap (**1002**) off of the catheter package assembly will be assured of seeing the health care services portion **1201** first.

Turning now to FIG. **40**, illustrated therein is an alternate embodiment of printed instructions **4000** configured in accordance with embodiments of the invention. The printed instructions **4000** of FIG. **40** are suitable for use as the health care services portion (**3802**) of FIGS. **38-39**, in that it can be configured as an adhesive label with a peelable flap **4001**. Further, the illustrative embodiment includes a checklist **4002** as described above in FIG. **38**.

In the embodiment of FIG. **40**, the top cover of the printed instructions **4000** include a picture **4003** of the contents of the medical procedure kit. In one embodiment, the picture **4003** is a color photograph set on a black background to make visibility simple. Above the picture is a title bar **4004**. In one embodiment, the title bar **4004** tells a health care services provider what type of medical procedure kit is disposed therein, and is white text on a blue background.

A flap indicator **4005** indicates that more information is located within the printed instructions **4000**. The additional information, which can be one or more of the panels shown in FIGS. **15-19** above, can be accessed by the peelable flap **4001**. In one embodiment, the flap indicator is configured with black text on a yellow background.

The checklist **4002** can be configured as described above. In the embodiment of FIG. **40**, a red warning bar **4006** having white text thereon is disposed above a checklist section **4007** that is yellow, having black text and white check boxes in this illustrative embodiment.

Turning now to FIG. **41**, illustrated therein is one embodiment of a patient portion **3801** configured as a greeting card

as was described with FIGS. **38-39**. The patient portion **3801** in this illustrative embodiment includes an inspirational phrase **4103** on the front cover, along with an aesthetically pleasing image **4101**. The aesthetically pleasing image **4101** of FIG. **41** is a vase of flowers, although it will be clear to those of ordinary skill in the art having the benefit of this disclosure that embodiments of the invention are not so limited. Other aesthetically pleasing images include puppies, sunsets, mountain streams, and so forth. The bottom of the patient portion **3801** includes in identifier **4103** that tells the patient the purpose of the patient portion **3801**.

The interior of the patient portion **3801** can include text. For example, in one embodiment where the patient portion **3801** is to be included with a catheter assembly, the interior includes the following illustrative text:

Here is some simple information about foley catheterization:

1. What is a Urinary Catheter?

A thin flexible tube that drains urine from the bladder into a collection bag. The catheter helps:

When you can't urinate.

To measure how much urine you're producing.

During and after some surgeries or tests.

2. What should you know about your catheter?

Only a trained technician inserts a catheter when necessary, and it is removed as soon as possible.

Caregivers must wash hands with soap or use alcohol-based rubs before and after touching your catheter.

If your caregivers don't clean their hands, politely ask them to.

Do not disconnect the catheter yourself.

Inquire every day whether you still need the catheter.

3. What is 'catheter-associated' urinary tract infection (CAUTI)?

If a catheter introduces 'outside' germs into your urinary tract, they can cause an invention. If a UTI is acquired, you may experience:

Sudden fever and/or bloody urine.

Burning or painful urination, or pain below the stomach.

Frequent, or more urgent, urinating after catheter is removed.

Tell your provider right away. An antibiotic may be needed.

4. Can you reduce your chances of an infection? Absolutely!

Wash your hands before and after touching your catheter.

Make sure the tube is secured to your leg. Never twist, or tug on it.

Always keep the collection bag below the level of your belly button.

Do not disconnect the catheter yourself.

Ask your doctor every day whether you still need the catheter.

The above information on the patient portion **3801** can be printed in multiple languages, such as in Spanish or in English. Where two languages are used, the back portion may be the same as the image shown in FIG. **41**, but with the inspirational phrase **4102** and identifier **4103** set forth in a different language. Further, alternatives and variations of the information can be substituted for the example set forth above.

Turning now to FIG. **21**, illustrated therein is a method **2100** of using the printed instructions (**1001**) as described herein. At step **2101**, a health care services provider removes the sterile wrap (**1002**) disposed about the catheter package assembly. Where the catheter package assembly is configured as shown in FIG. **10**, removal of the sterile wrap (**1002**) will reveal the printed instructions (**1001**). Where the printed instructions (**1001**) are configured as described in FIG. **20**, with the patient portion (**1202**) disposed adjacent to the CSR wrap (**1000**), the health care services provider will see the health care services portion (**1201**) first.

At step **2102**, the health care services provider accesses the printed instructions (**1001**) and begins to read the panels, which in one embodiment are panels configured in accordance with those described in FIGS. **14-19** above.

At step **2103**, the health care services provider unfolds the outer CSR wrap (**1000**), which in one embodiment is then used to create a sterile field about the tray (**100**). At step **2104**, the health care services provider prepares the workspace, which in one embodiment may be in accordance with steps (**1501**,**1502**,**1503**,**1504**) of panel (**1301**) in FIG. **15**. For example, this may include donning non-sterile gloves, as shown at step (**1501**) of FIG. **15**. This may further include picking up the underbuttocks drape, included with the tray (**100**), by the edge without contaminating the contents and placing the shiny side down under the area of the patient to be prepped as shown at step (**1503**) of FIG. **15**. This may further include using the hand sanitizer as shown at step (**1504** of FIG. **15**.

At step **2105**, the health care services provider prepares the catheter, which in one embodiment may be in accordance with steps (**1506**,**1507**,**1508**,**1509**) of panel (**1301**) as described in FIG. **15**. For example, this can include donning sterile gloves as shown at step (**1506**) of FIG. **15**. This may include placing a fenestrated drape, included with the tray (**100**), with the shiny side down on the patient without contaminating the sterile gloves, as shown at step (**1507**) of FIG. **15**. This may include filling a test balloon of the catheter assembly with water as shown at step (**1508**) of FIG. **15**, and injecting lubricating jelly from a syringe into the first compartment of the tray (**100**) as shown at step **1509** of FIG. **15**.

At step **2106**, the health care services provider inserts the catheter. In one embodiment, this can be in accordance with steps (**1601**,**1602**,**1603**,**1604**) of panel (**1302**) as described in FIG. **16**. At step **2107**, the health care provider secures the drain bag to the catheter assembly, which can be in accordance with steps (**1605**,**1606**,**1607**) described with respect to FIG. **16**.

At step **2108**, the health care services provider detaches the patient portion (**1202**) of the printed instructions (**1001**) from the health care services portion (**1201**). In one embodiment, this occurs by tearing the patient portion (**1202**) from the health care services portion (**1201**) along the perforation (**1203**), thereby transforming the printed instructions (**1001**) or instruction manual from a singular or unitary object into a two-piece object consisting of the patient portion (**1202**) and the health care services portion (**1201**). As described, above, the health care services provider may then discuss the patient portion (**1202**) with the patient and further give the patient portion (**1202**) to the patient to take home after the procedure.

Turning now to FIGS. **31**, **32**, and **33**, illustrated therein is one embodiment of a method of using the packaged catheter assembly **2901** of FIG. **29**. At FIG. **31**, a health care services provider **3101** opens the outer bag **2902** that is disposed about the tray **100** and removes the bag **2902** to reveal the packaged catheter assembly **2901** therein. The health care services provider **3101** can then access the instruction manual **1001** that is disposed atop the packaged catheter assembly **2901** in this illustrative embodiment.

The health care services provider **3101** can then unfold the one or more layers of wrap material **2200**. Where an

additional layer of wrap material **2701** is included, this unfolding step reveals and makes accessible the additional layer of wrap material **2701**. Note that portions of the additional layer of wrap material **2701** may be visible, as shown in FIG. **29**, prior to the steps of unfolding.

As noted above, in one embodiment the one or more layers of wrap material **2200** can be unfolded to form a sterile field. Turning now to FIG. **32**, illustrated therein is a step of the method that utilizes this sterile field. Specifically, in FIG. **32** the health care services provider **3101** places the one or more layers of wrap material **2200** beneath the patient **3201**, thereby transforming the area beneath the patient from a non-sterile field to a sterile field. Said differently, by placing the patient **3201** atop the one or more layers of wrap material **2200**, the patient is effectively moved from a location that may have not been a sterile field to the sterile field atop the one or more layers of wrap material **2200**.

Turning now to FIG. **33**, illustrated therein is a step of the method that may be used when an additional layer of wrap material **2701** is included with the packaged catheter assembly **2901**. In FIG. **33**, the health care services provider **3101** is placing the additional layer of wrap material **2701** atop the patient **3201**. Note that in the illustrative embodiment of FIG. **33**, the additional layer of wrap material **2701** is fenestrated, in that it includes a perforated opening **3301** suitable for performing a catheterization procedure.

In the foregoing specification, specific embodiments of the present invention have been described. However, one of ordinary skill in the art appreciates that various modifications and changes can be made without departing from the scope of the present invention as set forth in the claims below. Thus, while preferred embodiments of the invention have been illustrated and described, it is clear that the invention is not so limited. Numerous modifications, changes, variations, substitutions, and equivalents will occur to those skilled in the art without departing from the spirit and scope of the present invention as defined by the following claims. Accordingly, the specification and figures are to be regarded in an illustrative rather than a restrictive sense, and all such modifications are intended to be included within the scope of present invention. The benefits, advantages, solutions to problems, and any element(s) that may cause any benefit, advantage, or solution to occur or become more pronounced are not to be construed as a critical, required, or essential features or elements of any or all the claims.

What is claimed is:

1. A medical procedure kit, comprising:

a tray having a compartment for receiving a medical assembly;

a first syringe and a second syringe disposed within the tray;

at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and

an outer packaging disposed about both the tray and the at least one layer of wrap material, wherein:

the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and

the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe; and

the first compartment comprising a base member that defines a mnemonic device indicating which of the first syringe or the second syringe should be used first in the catheterization procedure.

2. The medical procedure kit of claim **1**, the first syringe and the second syringe ordered within the tray in accordance with their use during the catheterization procedure.

3. The medical procedure kit of claim **1**, further comprising one or more of an instruction set, one or more medical devices, or combinations thereof disposed within the one or more folds.

4. The medical procedure kit of claim **1**, wherein:

the first syringe and the second are ordered within the tray in accordance with their use during the catheterization procedure;

the tray comprises a surface defining at least two compartments, the at least two compartments comprising the first compartment to support the first syringe and the second syringe at different heights;

the at least two compartments bounded by a perimeter wall less than three inches in height;

the first compartment defines one or more contours for accommodating flanges of one or more of the first syringe or the second syringe; and

the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening, further comprising a catheter assembly disposed within the second compartment, the catheter assembly comprising a fluid bag.

5. The medical procedure kit of claim **4**, the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of the catheter assembly.

6. The medical procedure kit of claim **1**, the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.

7. The medical procedure kit of claim **1**, the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.

8. The medical procedure kit of claim **1**, the first compartment to support the first syringe at a shallower depth within the tray than the second syringe.

9. The medical procedure kit of claim **1**, the first compartment to support the first syringe and the second syringe at different heights based upon use during the catheterization procedure.

10. The medical procedure kit of claim **1**, wherein a higher of the first syringe or the second syringe is for use in the catheterization procedure before a lower of the first syringe or the second syringe.

11. The medical procedure kit of claim **10**, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening, further comprising a catheter assembly disposed within the second compartment.

12. The medical procedure kit of claim **11**, the at least two compartments bounded by a perimeter wall less than three inches in height.

13. The medical procedure kit of claim **12**, the tray comprising a single tray.

14. The medical procedure kit of claim **13**, the catheter assembly comprises a fluid bag.

15. The medical procedure kit of claim **14**, the fluid bag disposed within the second compartment.

16. The medical procedure kit of claim **1**, the tray comprising a surface defining at least two compartments, the at least two compartments comprising the first compartment to support the first syringe.

17. The medical procedure kit of claim **16**, the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.

18. The medical procedure kit of claim 17, further comprising printed instructions for using the tray.

19. The medical procedure kit of claim 18, the printed instructions to instruct application of lubricating jelly to the catheter assembly using the lubricating jelly application chamber.

20. The medical procedure kit of claim 17, the at least two compartments further comprising a second compartment separated from the first compartment by a wall with an opening, the printed instructions instructing passage of at least some of the catheter assembly through the opening into lubricating jelly to lubricate the at least some of the catheter assembly.

21. The medical procedure kit of claim 20, the first compartment defining a lubricating jelly application compartment.

22. The medical procedure kit of claim 21, the lubricating jelly application compartment to receive the lubricating jelly from one of the first syringe or the second syringe to lubricate at least some of the catheter assembly when the catheter assembly is passed from the second compartment to the first compartment.

23. The medical procedure kit of claim 22, the tray comprising printed instructions disposed thereon to dispense the lubricating jelly into the compartment.

24. The medical procedure kit of claim 23, the printed instructions one or more of printed, placed upon, or molded into the tray.

25. A medical procedure kit, comprising:

a tray having a compartment for receiving a medical assembly;

a first syringe and a second syringe disposed within the tray;

at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and

an outer packaging disposed about both the tray and the at least one layer of wrap material, wherein:

the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and

the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe;

the first compartment to support the first syringe and the second syringe at different heights according to predetermined steps of the catheterization procedure.

26. The medical procedure kit of claim 25, the first syringe and the second syringe ordered within the tray in accordance with their use during the catheterization procedure.

27. The medical procedure kit of claim 25, further comprising one or more of an instruction set, one or more medical devices, or combinations thereof.

28. The medical procedure kit of claim 25, the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a Foley catheter.

29. The medical procedure kit of claim 25, the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.

30. The medical procedure kit of claim 25, the first compartment to support the first syringe at a shallower depth within the tray than the second syringe.

31. The medical procedure kit of claim 25, wherein a higher of the first syringe or the second syringe is for use in the catheterization procedure before a lower of the first syringe or the second syringe.

32. The medical procedure kit of claim 25, the at least two compartments further comprising a second compartment, further comprising a Foley catheter disposed within the second compartment.

33. The medical procedure kit of claim 32, the Foley catheter coupled to a fluid bag.

34. The medical procedure kit of claim 33, the fluid bag disposed within the second compartment.

35. The medical procedure kit of claim 32, further comprising printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment.

36. The medical procedure kit of claim 25, the tray comprising a single tray.

37. A medical procedure kit, comprising:

a tray having a compartment for receiving a medical assembly;

a first syringe and a second syringe disposed within the tray;

at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and

an outer packaging disposed about both the tray and the at least one layer of wrap material, wherein:

the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and

the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe;

wherein steps of the catheterization procedure use a higher of the first syringe or the second syringe before a lower of the first syringe or the second syringe.

38. The medical procedure kit of claim 37, the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.

39. The medical procedure kit of claim 37, the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.

40. The medical procedure kit of claim 37, the tray comprising a single tray.

41. The medical procedure kit of claim 40, the tray comprising a surface defining a second compartment, further comprising a Foley catheter disposed within the second compartment.

42. The medical procedure kit of claim 41, further comprising a fluid bag disposed within the second compartment.

43. The medical procedure kit of claim 42, further comprising printed instructions for using the tray.

44. The medical procedure kit of claim 43, the printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment.

45. A medical procedure kit, comprising:

a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly;

a first syringe and a second syringe disposed within the first compartment;

the medical assembly disposed in the second compartment, wherein the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter;

at least one layer of wrap material enclosing the single layer tray within one or more folds of the at least one layer of wrap material; and

an outer packaging disposed about both the single layer tray and the at least one layer of wrap material.

46. The medical procedure kit of claim **45**, wherein one of the first syringe or the second syringe contains lubricating jelly.

47. The medical procedure kit of claim **46**, wherein another of the first syringe or the second syringe contains water.

48. The medical procedure kit of claim **47**, wherein the water is sterile.

49. The medical procedure kit of claim **45**, further comprising a specimen jar disposed within the single layer tray.

50. The medical procedure kit of claim **45**, the single layer tray comprising a lubricating jelly application compartment.

51. The medical procedure kit of claim **50**, the lubricating jelly application compartment to receive lubricating jelly from one of the first syringe or the second syringe to lubricate at least some of the Foley catheter.

52. The medical procedure kit of claim **45**, further comprising printed instructions for using the single layer tray.

53. The medical procedure kit of claim **52**, the printed instructions to instruct application of lubricating jelly to the Foley catheter using a lubricating jelly application compartment of the single layer tray.

54. The medical procedure kit of claim **45**, further comprising one or more swabsticks disposed within the single layer tray.

55. The medical procedure kit of claim **45**, further comprising a Foley catheter securement device disposed within the single layer tray.

56. The medical procedure kit of claim **45**, further comprising an underbuttocks drape disposed within the outer packaging.

57. The medical procedure kit of claim **45**, further comprising gloves disposed within the outer packaging.

58. The medical procedure kit of claim **45**, further comprising hand sanitizer disposed within the outer packaging.

59. The medical procedure kit of claim **45**, further comprising a diagram of contents of the medical procedure kit.

60. The medical procedure kit of claim **45**, further comprising a fenestrated drape disposed within the outer packaging.

61. A medical procedure kit, comprising:

a surface defining a single layer tray having a first compartment separated by a barrier from a second compartment, the second compartment configured for receiving a medical assembly comprising a Foley catheter, a coiled tubing, and a fluid drain bag;

a first syringe and a second syringe disposed within the first compartment;

the medical assembly disposed in the second compartment;

at least one layer of wrap material enclosing the single layer tray within one or more folds of the at least one layer of wrap material; and

an outer packaging disposed about both the single layer tray and the at least one layer of wrap material.

62. The medical procedure kit of claim **61**, wherein one of the first syringe or the second syringe contains lubricating jelly.

63. The medical procedure kit of claim **62**, wherein another of the first syringe or the second syringe contains water.

64. The medical procedure kit of claim **63**, wherein the water is sterile.

65. The medical procedure kit of claim **64**, further comprising a specimen jar disposed within the single layer tray.

66. The medical procedure kit of claim **61**, the single layer tray comprising a lubricating jelly application compartment.

67. The medical procedure kit of claim **66**, the lubricating jelly application compartment to receive lubricating jelly from one of the first syringe or the second syringe to lubricate at least some of the Foley catheter.

68. The medical procedure kit of claim **61**, further comprising printed instructions for using the single layer tray.

69. The medical procedure kit of claim **68**, the printed instructions to instruct application of lubricating jelly to the Foley catheter using a lubricating jelly application compartment of the single layer tray.

70. The medical procedure kit of claim **61**, further comprising one or more swabsticks disposed within the single layer tray.

71. The medical procedure kit of claim **61**, further comprising a Foley catheter securement device disposed within the single layer tray.

72. The medical procedure kit of claim **71**, further comprising an underbuttocks drape disposed within the outer packaging.

73. The medical procedure kit of claim **71**, further comprising gloves disposed within the outer packaging.

74. The medical procedure kit of claim **73**, further comprising hand sanitizer disposed within the outer packaging.

75. The medical procedure kit of claim **73**, further comprising a diagram of contents of the medical procedure kit.

76. The medical procedure kit of claim **73**, further comprising a fenestrated drape disposed within the outer packaging.

77. A medical procedure kit, comprising:

a single layer tray having a first compartment separated by a barrier from a second compartment configured for receiving a medical assembly;

a first syringe and a second syringe disposed within the first compartment;

the medical assembly disposed in the second compartment, the medical assembly consisting essentially of a Foley catheter coupled to a coiled tubing, wherein the coiled tubing is coupled to a fluid drain bag;

at least one layer of wrap material enclosing the single layer tray within one or more folds of the at least one layer of wrap material; and

an outer packaging disposed about both the single layer tray and the at least one layer of wrap material.

78. The medical procedure kit of claim **77**, wherein one of the first syringe or the second syringe contains lubricating jelly.

79. The medical procedure kit of claim **78**, wherein another of the first syringe or the second syringe contains water.

80. The medical procedure kit of claim **79**, wherein the water is sterile.

81. The medical procedure kit of claim **77**, further comprising a specimen jar disposed within the single layer tray.

82. The medical procedure kit of claim **77**, the single layer tray comprising a lubricating jelly application compartment.

83. The medical procedure kit of claim **82**, the lubricating jelly application compartment to receive lubricating jelly from one of the first syringe or the second syringe to lubricate at least some of the Foley catheter.

84. The medical procedure kit of claim **77**, further comprising printed instructions for using the single layer tray.

85. The medical procedure kit of claim 84, the printed instructions to instruct application of lubricating jelly to the Foley catheter using a lubricating jelly application compartment of the single layer tray.

86. The medical procedure kit of claim 77, further comprising one or more swabsticks disposed within the single layer tray.

87. The medical procedure kit of claim 77, further comprising a Foley catheter securement device disposed within the single layer tray.

88. The medical procedure kit of claim 87, further comprising an underbuttocks drape disposed within the outer packaging.

89. The medical procedure kit of claim 77, further comprising gloves disposed within the outer packaging.

90. The medical procedure kit of claim 89, further comprising hand sanitizer disposed within the outer packaging.

91. The medical procedure kit of claim 90, further comprising a diagram of contents of the medical procedure kit.

92. The medical procedure kit of claim 90, further comprising a fenestrated drape disposed within the outer packaging.

* * * * *

Electronic Acknowledgement Receipt

EFS ID:	46861890
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	20-OCT-2022
Filing Date:	28-MAR-2020
Time Stamp:	16:53:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit13.pdf	522830 a3923307540431ed94bee5eee2107704392a7e7c	no	5

Warnings:

Information:					
2	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit14.pdf	810043 4f0a8e637fcea6aee5c90805250ed6e2d33fc640	no	6
Warnings:					
Information:					
3	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit15.pdf	4347489 845d711b5babb96f5ce9a8c12a7c77bad4f4434e	no	44
Warnings:					
Information:					
4	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit16.pdf	624726 e8744da938b2c808624c0393a0945ff46a809269	no	5
Warnings:					
Information:					
5	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit17.pdf	6641813 82db0ccdb21063e710f55a6802d96406d1952904	no	59
Warnings:					
Information:					
6	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit18.pdf	3500022 158be631efd9558449f1d16c687c9c4745a83143	no	37
Warnings:					
Information:					
7	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit19.pdf	897144 5a825e32c41a484a326e1a8e564dca0707fcafec	no	14
Warnings:					
Information:					
8	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit20.pdf	1193413 a94993d02914f552280850f3b2221d2aa9e08a4a	no	15
Warnings:					
Information:					

9	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit21.pdf	4065070 671e7fb375d5de8c2ce957b9c462a6a2502b1f71	no	48
Warnings:					
Information:					
10	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit22.pdf	134415 b023abe09919ec3cdb8a4e2e9f769f587e82b3df	no	2
Warnings:					
Information:					
11	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit23.pdf	215735 32e014687f4869cba70bac957a469642182d2a5d	no	4
Warnings:					
Information:					
12	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit24.pdf	6591329 1a95d440e60d17f627dc975d6b1df007a09593cd	no	179
Warnings:					
Information:					
13	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit25.pdf	755310 9b56c3f68fabd2ad6276cf51d1c0c5c7ea9f50eb	no	13
Warnings:					
Information:					
14	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit26.pdf	371350 ba8531e7cc8cd547100a1b29add2e6db431e003b	no	7
Warnings:					
Information:					
15	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit27.pdf	232681 b4b48a1edc24ffd9d5aba12c6166991db9b004f7	no	5
Warnings:					
Information:					

16	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit28.pdf	3962921 b71b1125a6429c53158e1c456a892bb8be4cab42	no	57
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Information:					
			Total Files Size (in bytes):	34866291	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marceitch
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		3650393		1972-03-21	Reiss, Robert E.	
		4085845		1978-04-25	Perfect, Alan	

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		20070197998		2007-08-23	Itou, Yasushi	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	**Application Number**	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
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	Examiner Name	Adam M Marceitch
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
		C. R. Bard, Inc. v. Medline Industries, Inc., 2020-1900, 2020-1905, 2020-1908, 2020-1910 Slip Opinion (Fed. Cir. 2021). Dated August 13, 2021,	
		"Ex Parte Reexamination Request", Reexmination Control No 90/015,051 for Patent No. 9522753; Mailed June 28, 2022; Request and Exhibits 1-28,	
		"Request for Ex Parte Reexamination", Reexam Control No. 90/014,964 for Patent No. 8,448,786; Mailed March 8, 2022; Request and Exhibits 1-35,	
		POON, ROBERT , "Final Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket No. 10055U D1 C2 C1; Mailed October 7, 2021,	
		POON, ROBERT , "Final Office Action", USSN 16/986,803; Filed August 6, 2020; Attorney Docket 1037-001-03US; Mailed July 5, 2022,	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marceitch
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

		POON, ROBERT , "Final Office Action", USSN 17/180,680; Filed February 19, 2021; Attorney Docket No. 1037-002-10US; Mailed September 16, 2022,	
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		REIP, DAVID OWEN , "Ex Parte Reexamination Order - Request Granted", Reexam Control No. 90/014,964 for Patent No. 8,448,786; Mailed April 19, 2022,	
		REIP, DAVID OWEN , "Ex Parte Reexamination Order - Request Granted", Reexmination Control No 90/015,051 for Patent No. 9522753; Mailed July 7, 2022,	
		REIP, DAVID OWEN , "Reexam NonFinal Office Action", USSN 90/014,964; Filed February 24, 2022; Attorney Docket 10055U CIP2 48010-28031.00; Mailed September 29, 2022,	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marceitch
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

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☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2022-10-20
Name/Print	Philip H. Burrus	Registration Number	45,432

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	**Application Number**	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marceitch
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

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EXHIBIT 5

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(12) **United States Patent**
Solazzo

(10) **Patent No.: US 7,278,987 B2**
(45) **Date of Patent: Oct. 9, 2007**

(54) **ERGONOMIC UROLOGICAL CATHETERIZATION/IRRIGATION TRAY**

(76) Inventor: **Anthony Solazzo**, 100 Acorn Rd., Watchung, NJ (US) 07069

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 11 days.

(21) Appl. No.: **10/888,659**

(22) Filed: **Jul. 9, 2004**

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(51) **Int. Cl.**

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A61M 1/00	(2006.01)
B65D 69/00	(2006.01)
E03C 1/01	(2006.01)
A61M 29/00	(2006.01)

(52) **U.S. Cl.** **604/356**; 206/571; 604/319; 4/640

(58) **Field of Classification Search** 604/356, 604/317, 319, 326; 206/571; 4/640, 650, 4/660

See application file for complete search history.

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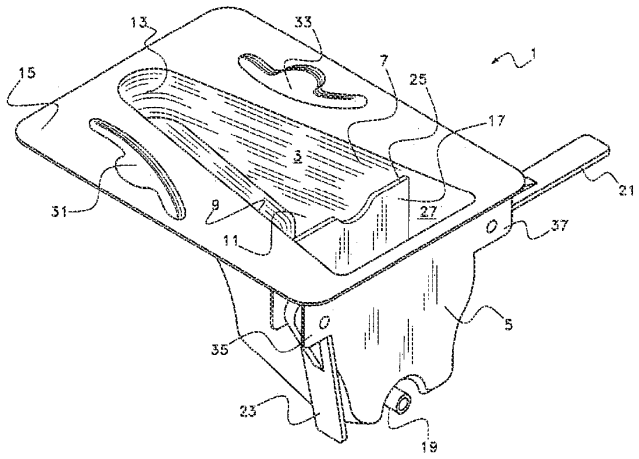
Primary Examiner—Tatyana Zalukaeva
Assistant Examiner—Paula L. Craig
(74) *Attorney, Agent, or Firm*—Kenneth P. Glynn, Esq.

(57) **ABSTRACT**

The present invention relates to an ergonomic urological catheterization/irrigation tray. The tray includes a tray structure having a recessed area that includes at least a bottom, opposite side walls, a front and a back, wherein the front has a first width of a predetermined dimension and the back has a second width of a predetermined dimension less then the first width, such that the recessed area is wider at the front than it is at the back. The recessed area has at least one drain located at a lower area thereof. The tray further includes a top flange extending at least outwardly each of the opposite side walls, wherein a user may rest the flange on front upper portions of legs when in a supine position, for urinary bladder evacuation into the tray. Surgical kits contain the aforementioned tray and specified components.

16 Claims, 8 Drawing Sheets



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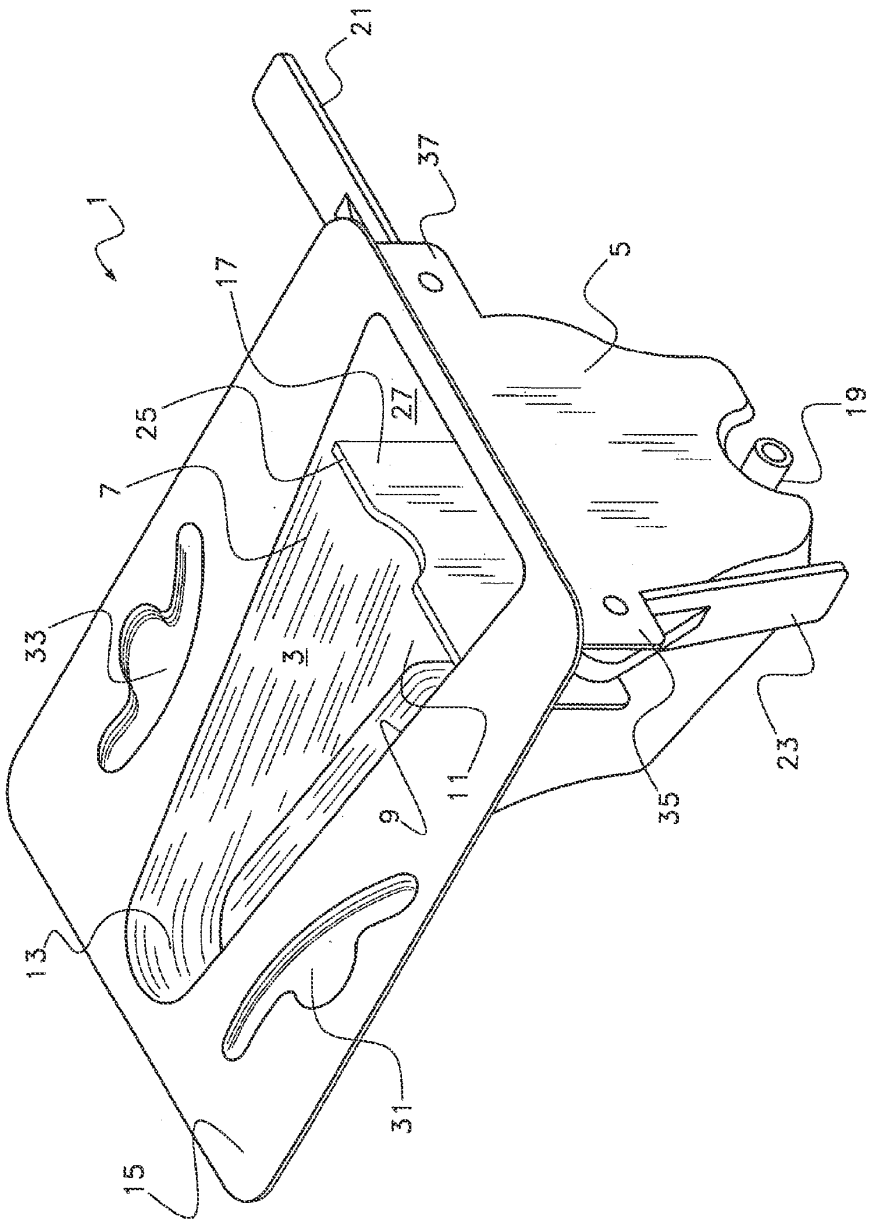


Fig. 1

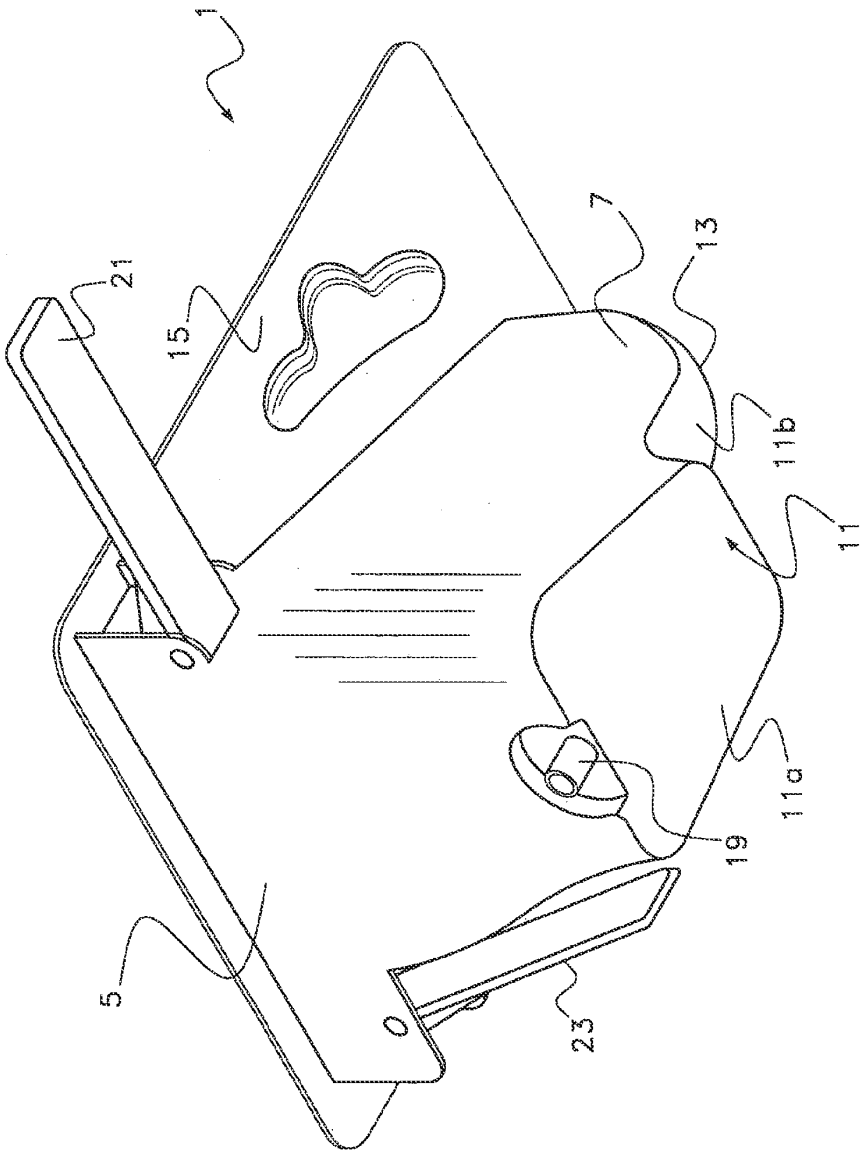
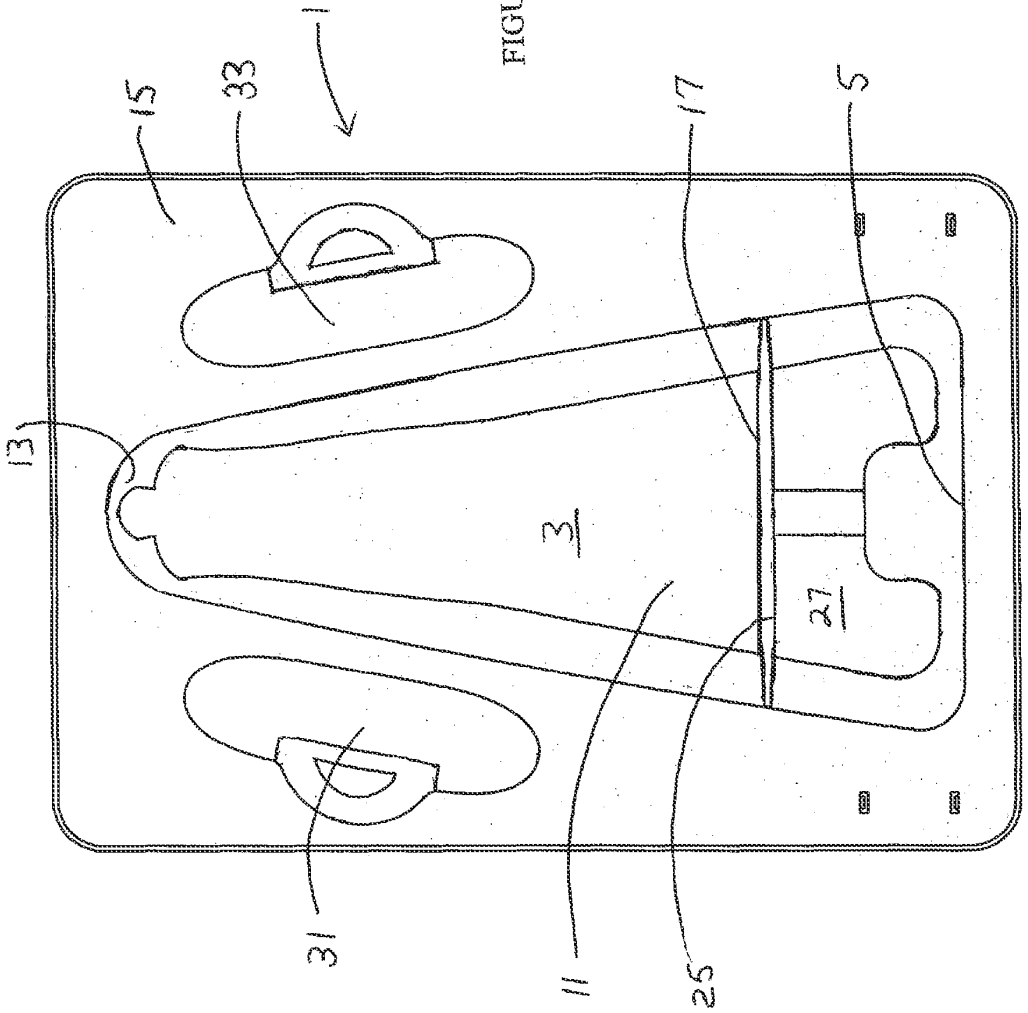


Fig. 2

FIGURE 3



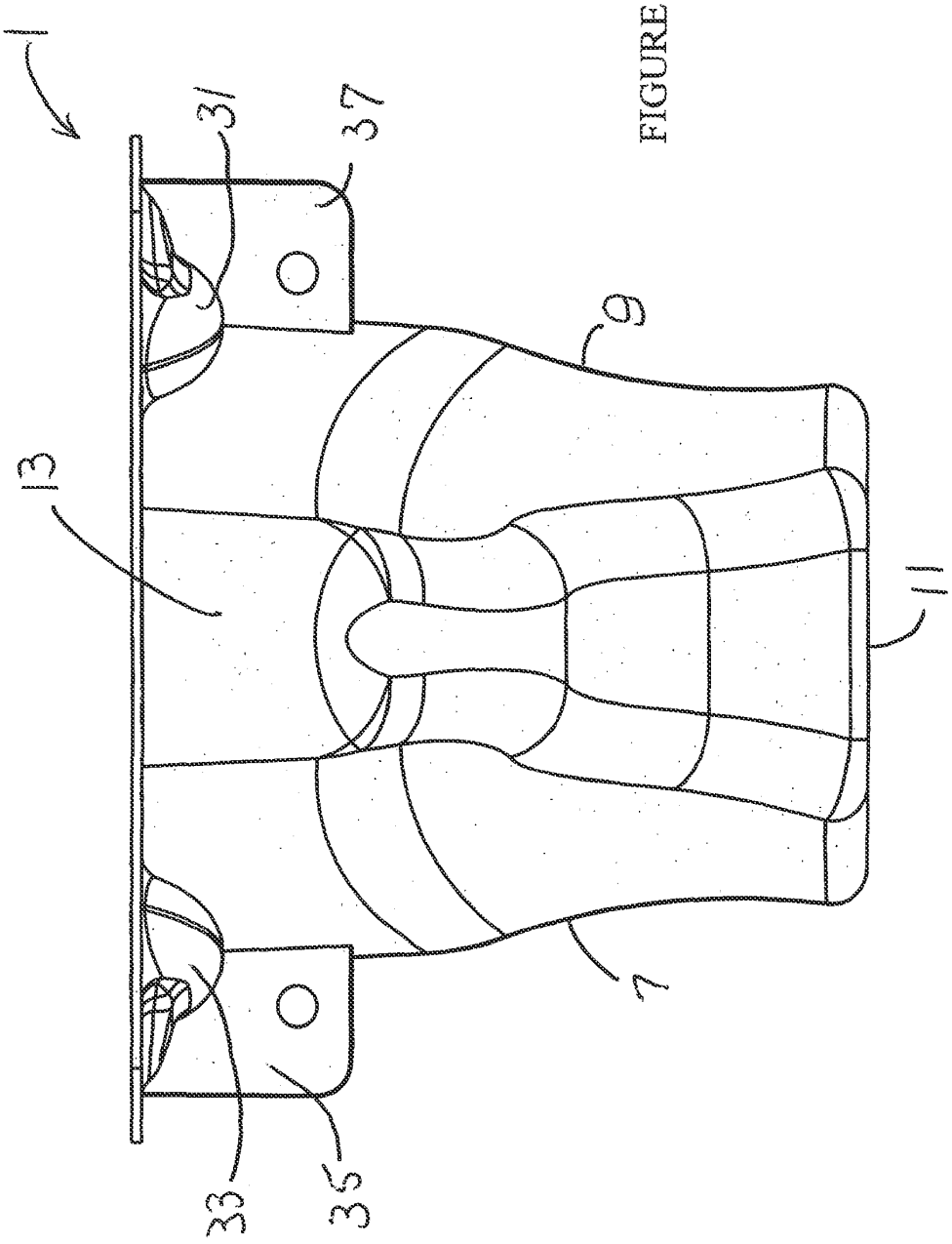


FIGURE 4

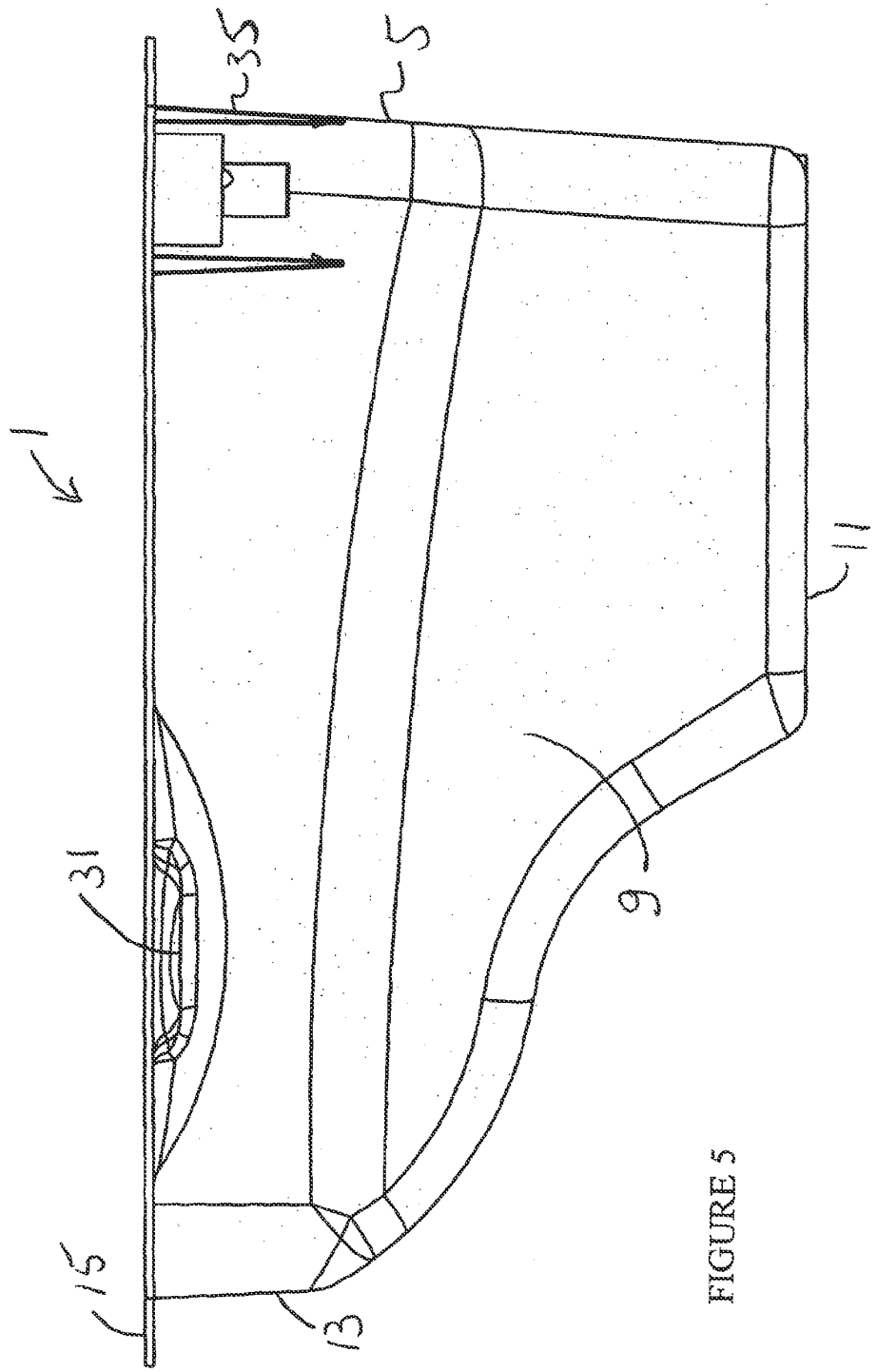


FIGURE 5

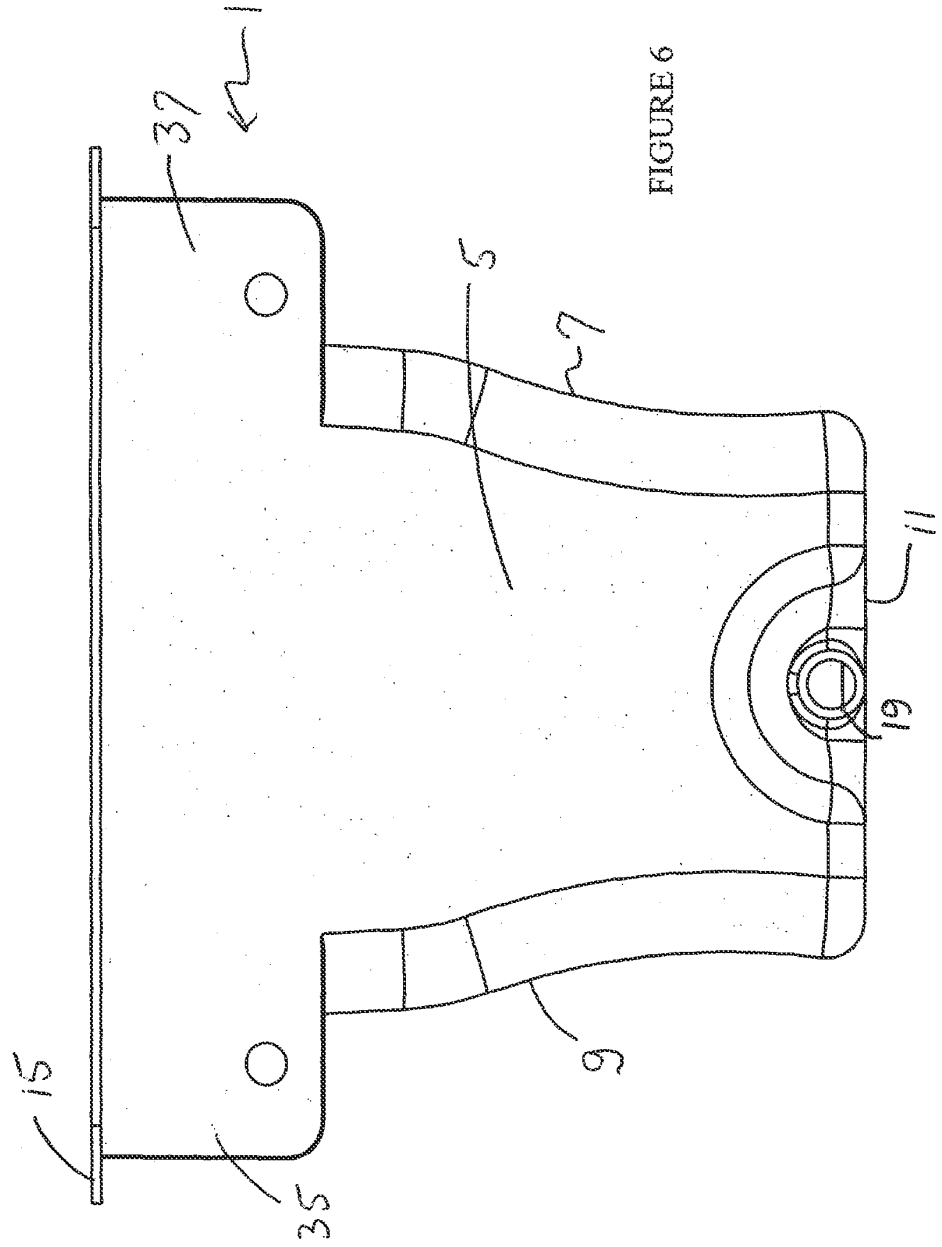


FIGURE 6

FIGURE 7

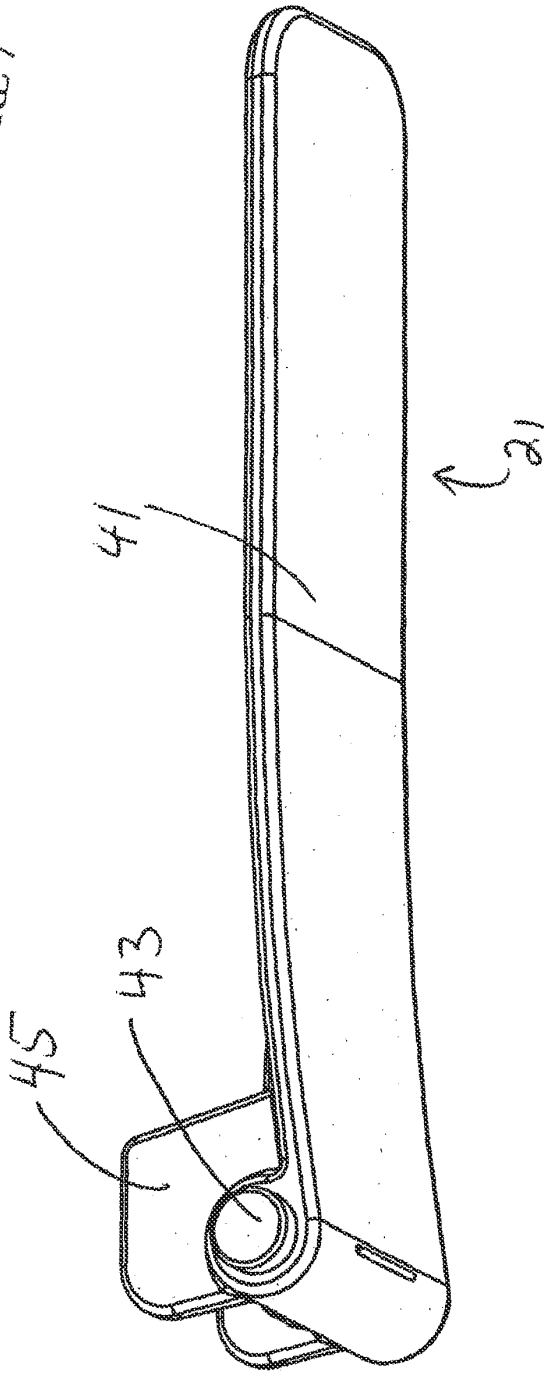
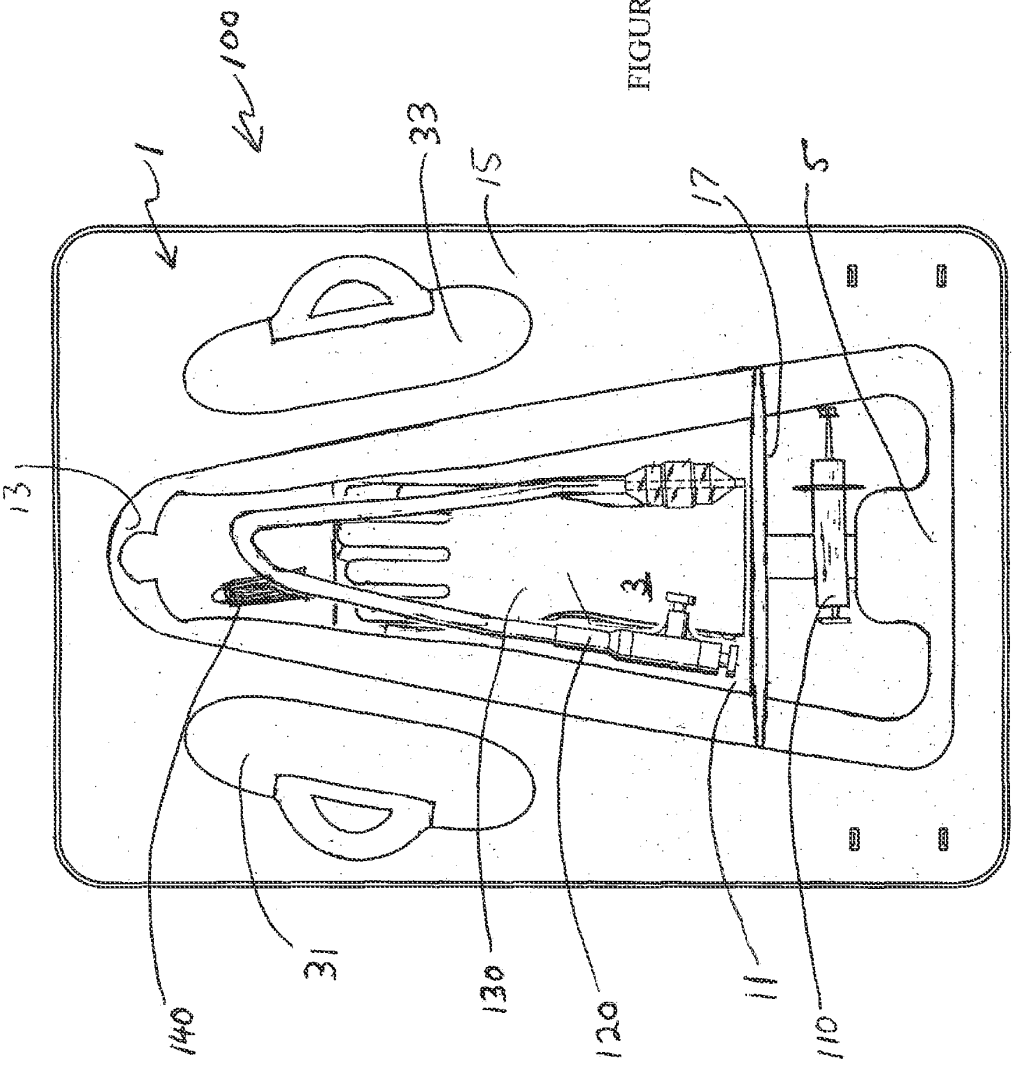


FIGURE 8



ERGONOMIC UROLOGICAL CATHETERIZATION/IRRIGATION TRAY

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is an ergonomic urological catheterization/irrigation tray. The tray has a shape that will fit between the legs of a patient, has a contoured or terraced recess so as to create a tapered wall/bottom arrangement (easier to rest atop upper leg areas when the patient is seated). Further, the present invention has support wings, drainage accommodations, and accessory accommodations.

2. Information Disclosure Statement

The following prior art is representative of the state of the art in the field of catheterzation trays, kits and systems:

U.S. Pat. No. 3,851,649 discloses a catheterization package comprising a rigid container including a generally flat rear panel and a front panel parallel to and spaced from one another with a top wall, side walls and a bottom wall extending there between, said front panel having a recessed catheter drainage port with a catheter connected thereto adjacent the upper and one side wall of said container, said catheter being positioned within an open sided recess in said one wall with said port at one end thereof a container drainage port having a removable closure positioned in said front wall adjacent the upper and the other side wall of said container, a plurality of discrete recesses in said front wall carrying therein a plurality of catheterization components and cover means releasable retained adjacent said front wall for retaining said components including said catheter within their individual recesses, said container upon removal of said components being utilize for collection of liquid drained through said catheter.

U.S. Pat. No. 4,160,505 discloses a urethral catheterization tray providing a sterile, self-contained catheterization package and work area.

U.S. Pat. No. 4,811,847 discloses a package for an urinary catheter that consists of a generally rectangular tray with an open top, to which a peel-back cover is bonded, containing a catheter assembly, a syringe prefilled with bacteriostatic water, and two gloves. The catheter assembly is designed such that a urinary catheter may be simply and efficiently placed into the bladder under sterile conditions. The catheter assembly consists of a heat shrunk seal to hold the end cap, three intermediate caps with antiseptic soaked sponge tips bonded to the ends, and the tube-like guide in proximity therewith. The catheter passes through the guide after removal of the heat shrunk seal and the systematic removal and utilization of the end cap and the three intermediate caps. A protective shroud encloses the distal end of the catheter, as it is bonded to the guide. A biocompatible lubricant is contained between the third intermediate cap and the guide.

U.S. Pat. No. 5,242,398 discloses a catheter and a sheath enclosing the catheter to preserve the sterility thereof, the sheath being provided with a plurality of fold lines which form accordion-like pleats to enable a collapse of the sheath at a point of insertion of the catheter into a patient. The sheath is provided at a distal end of the catheter with a flange for engaging a patient during an insertion of the catheter into the patient. A catheter assembly also comprises an anchor balloon attached to the catheter at a distal end thereof, an ancillary balloon attached to the catheter at a point spaced in a proximal direction from the anchor balloon, a tube connecting the ancillary balloon to the anchor balloon so as to enable communication therebetween, and a flow stop

mounted to the catheter for preventing fluid from returning to the tube from the anchor balloon upon a pressurization of the anchor balloon with fluid forced from the tube by an application of pressure to the ancillary balloon. A hollow catheter plug defining a flash chamber and having a transparent wall is connected to the catheter at a proximal end thereof for communicating with the catheter. A valve is connected to the plug for preventing fluid flow from the flash chamber.

U.S. Pat. No. 6,090,075 discloses a disposable self-lubricating catheterization assembly for inserting a catheter into the urethra of an individual for the purpose of evacuating the bladder. The catheter assembly includes a substantially rigid catheter introducer member for positioning the introducer against the urethral opening, a flexible catheter and a flexible thin-walled sheath surrounding the catheter introducer comprises a reservoir portion, a guide portion, lubricant and a membrane. The lubricant essentially fills the reservoir and is prevented by the membrane from prematurely coating the catheter, in order to facilitate grasping of the catheter and feeding of the tube along the urethra and into the bladder. A catheterization assembly in accordance with the present invention is suitable for use for self-catheterization and subsequent infection of the urinary tract. The improved easy-to-use disposable catheterization kit is also economically practical for use for temporary catheterization in hospitals, mobile emergency facilities, doctors' offices, rehabilitation facilities, nursing homes and the like.

Notwithstanding the prior art, the present invention is neither taught nor rendered obvious thereby.

SUMMARY OF THE INVENTION

The present invention relates to an ergonomic urological catheterization/irrigation tray. The tray includes a tray structure having a recessed area that includes at least a bottom, opposite side walls, a front and a back, wherein the front has a first width of a predetermined dimension and the back has a second width of a predetermined dimension less then the first width, such that the recessed area is wider at the front than it is at the back. The recessed area has at least one drain located at a lower area thereof. The tray further includes a top flange extending at least outwardly each of the opposite side walls, wherein a user may rest the flange on front upper portions of legs when in a supine position, and may discharge or be relieved into the tray.

The ergonomic urological catheterization/irrigation tray, in preferred embodiments, has a recessed area formed by the bottom, opposing sidewalls, front and back with a top view in a substantially trapezoidal shape.

In preferred embodiments, the present invention ergonomic urological catheterization/irrigation tray further includes at least two folding wing supports adapted to be folded into alignment with one of the opposing sidewalls, the front and the back, and adapted to be unfolded so as to be in a substantially horizontal orientation and extending outwardly from the tray for resting on front upper positions of legs. The at least two folding wing supports may be hingedly connected to the flange of the tray structure.

The ergonomic urological catheterization/irrigation tray wherein recessed area includes a divider wall creating two separate compartments. The divider wall has a minimum height that is less than minimum heights of all of the opposing sidewalls, the front and the back.

The ergonomic urological catheterization/irrigation tray wherein the at least two folding wing supports are hingedly

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connected to the flange of the tray structure, e.g. with hinge pins or unistructurally molded living hinges.

The ergonomic urological catheterization/irrigation tray kit wherein the at least two folding wing supports are hingedly connected to the back of the tray.

The ergonomic urological catheterization/irrigation tray wherein the at least two folding wing supports are hingedly connected to the front of the tray structure.

The ergonomic urological catheterization/irrigation tray wherein the tray has tapered sidewalls adapted to accommodate legs.

The ergonomic urological catheterization/irrigation tray kit wherein the bottom has non-flat topography.

The present invention also includes an ergonomic urological catheterization/irrigation tray kit. The kit includes:

(a.) the tray described above;

(b.) a Foley catheter;

(c.) a urinary tract lubricant;

(d.) surgical gloves;

(e.) an inflation syringe for inflation of a catheter with fluid;

(f.) irrigation syringe;

(g.) evacuation tubing; and,

(h.) antiseptic solutions.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention should be more fully understood when the specification herein is taken in conjunction with the drawings appended hereto wherein:

FIG. **1** shows a top oblique view of one embodiment of the present invention ergonomic urological catheterization/irrigation tray;

FIG. **2** shows a bottom oblique view of the present invention device shown in FIG. **1**;

FIG. **3** shows a top view of the present invention device show in FIG. **1**;

FIG. **4** illustrates a backend view of the present invention device shown in FIG. **1**;

FIG. **5** illustrates a side view of the present invention device shown in FIG. **1**;

FIG. **6** shows a front view of the present invention device shown in FIG. **1**;

FIG. **7** shows a bottom oblique view of one embodiment of a support wing used with a present invention tray; and,

FIG. **8** shows a top view of a present invention ergonomic urological catheterization/irrigation try kit.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

FIG. **1**, showing a top oblique view, FIG. **2** showing a bottom oblique view, FIG. **3** showing a top view, FIG. **4** showing a backend view, FIG. **5** showing a side view, FIG. **6** showing a front view, taken together illustrate a present invention catheterization/irrigation tray **1**. It includes a recessed area **3** that includes a front **5**, opposing side walls **7** and **9**, bottom **11**, back **13** and flange **15**. The back **13** has a width that is significantly less than the width of front **5** such that opposing side walls **7** and **9** are non-parallel and tapered towards each other from front **5** to back **13**. Thus, recessed area **3** has a generally trapezoidal footprint from a top view. Note also that, in this embodiment bottom **11** is not horizontally and, thus recessed area **3**, has a non constant depth. In this embodiment bottom **11** has terraced arrangement with low area **11**A and shallow area **11**B (FIG. **2**). Top flange **15** extends outwardly from opposing side walls **7** and **9** and acts in part so that a patient may have flange **15** rest on front upper portions of the patient's legs when in a seated position.

Optionally, but preferred, folding wing supports **21** and **23** are hingedly connected to side walls **7** and **9**, respectively, and have two distinct positions. Wing support **21** is open so as to be substantially horizontally and wing support **23** is closed and thus in alignment with side wall **9**. When not in use, both would be closed (folded down) and when in use would be opened. Drain **19** is located near bottom **11** for liquid drainage and may be directly connected to one or two drain holes in bottom **11**. Drain **19** may be connected to flexible tubing and into a receiving receptance or safe drain, or may otherwise be used in accordance with acceptable standards and procedures. Optional divider wall **17** creates two separate compartments. The top **25** of divider wall **17** is lower than the top edges of recessed area **3**. Thus, should fluids totally fill the volume behind divider wall **17**, fluids will over flow into compartment **27** rather than spill over flange **15**.

Optional Foley catheter lubricating wells **31** and **33** are available for right handed and left handed users so that lubricating material could be applied to the catheter or other insertion device by filling the well with lubricant and then sliding the device through the lubricant in the well.

A patient requiring an urological procedure may be positioned with tray **1** at back **13** below the scrotum and penis with flange **15** preventing the back portion of tray **1** from sliding or dropping downwardly between the patient's legs by resting the front upper portions of the legs while support wings **21** and **23** will perform a similar function for the front portion of tray **1**. The surgeon will proceed to evacuate the bladder of its contents, urine and/or clots.

Bracket sets **35** and **37** are integrally formed into the device with orifices adapted to receive the support wings. FIG. **7** shows support wing **21** from a bottom, oblique view in its open position, it includes, a main rest bar **41**, pivot axle **43** that inserts directly into the orifices of the bracket sets and stops such as stop **45** to maintain a firm horizontal position when open.

FIG. **8** shows a top view of the present invention kit **100**. It includes tray **1** described above with identical components identically numbered. Also included is urinary tract inflation syringe **10**, catheter **120**, surgical gloves **130** and a tube of lubricant fluid **140**. The kit is used as described generally above. The gloves being worn by the surgeon, the catheter being lubricated, inserted and then inflated with fluid using the syringe.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. An ergonomic urological catheterization/irrigation tray which comprises:

a tray structure having a recessed area that includes at least a bottom, opposite side walls, a front and back, wherein said front has a first width of a predetermined dimension and said back has a second width of a predetermined dimension less than said first width, such that said recessed area is wider at the front than it is at the back, said recessed area having at least one drain located at a lower area thereof, said tray including a flange extending outwardly from each of said opposing side walls, and including at least two folding wing supports adapted to be folded into alignment with one

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of said opposing sidewalls, said front and said back, and adapted to be unfolded so as to be in a substantially horizontal orientation and extending outwardly from said tray, wherein said flange and said wing supports are dimensioned and configured to rest on front upper portions of legs of a user when in a supine position, and to discharge or be relieved into said tray.

2. The ergonomic urological catheterization/irrigation tray of claim 1 wherein said tray recessed area formed by said bottom, opposing sidewalls, front and back has a top view trapezoidal shape.

3. The ergonomic urological catheterization/irrigation tray of claim 1 wherein said recessed area includes a divider wall creating two separate compartments to create an irrigation well and drainage well.

4. The ergonomic urological catheterization/irrigation tray of claim 3 wherein said divider wall has minimum height that is less than a minimum heights of all of said opposing sidewalls, said front and said back.

5. The ergonomic urological catheterization/irrigation tray of claim 1 wherein said at least two folding wing supports are hingedly connected to said flange of said tray structure.

6. The ergonomic urological catheterization/irrigation tray of claim 1 wherein said at least two folding wing supports are hingedly connected to said front of said tray structure.

7. The ergonomic urological catheterization/irrigation tray of claim 1 wherein said tray has tapered sidewalls adapted to accommodate legs.

8. The ergonomic urological catheterization/irrigation tray of claim 7 wherein said bottom has partially non-flat topography.

9. An ergonomic urological catheterization/irrigation tray which compromises:

a tray structure having a recessed area that includes at least a bottom, opposite side walls, a front and back, wherein said front has a first width of a predetermined dimension and said back has a second width of a predetermined dimension less than said first width, such that said recessed area is wider at the front than it is at the back, said recessed area having at least one drain located at a lower area thereof, said tray including a flange extending outwardly from each of said opposing side walls, and including at least two folding wing supports adapted to be folded into alignment with one of said opposing sidewalls, said front and said back, and adapted to be unfolded so as to be in a substantially horizontal orientation and extending outwardly from said tray, wherein a user may rest said flange and said wing supports on front upper portions of legs when in a supine position, and my discharge or be relieved into said tray,

and further wherein said support wings have living hinges.

10. The ergonomic urological catheterization/irrigation tray of claim 9 wherein said tray recessed area formed by said bottom, opposing sidewalls, front and back has a top view trapezoidal shape.

11. The ergonomic urological catheterization/irrigation tray of claim 9 wherein said recessed area includes a divider wall creating two separate compartments to create an irrigation well and drainage well.

12. The ergonomic urological catheterization/irrigation tray of claim 11 wherein said divider wall has minimum height that is less than a minimum heights of all of said opposing sidewalls, said front and said back.

13. The ergonomic urological catheterization/irrigation tray of claim 9 wherein said at least two folding wing supports are hingedly connected to said flange of said tray structure.

14. The ergonomic urological catheterization/irrigation tray of claim 9 wherein said at least two folding wing supports are hingedly connected to said front of said tray structure.

15. The ergonomic urological catheterization/irrigation tray of claim 9 wherein said tray has tapered sidewalls adapted to accommodate legs.

16. The ergonomic urological catheterization/irrigation tray of claim 15 wherein said bottom has partially non-flat topography.

* * * * *

July 4, 1967 F. J. SERANY, JR., ETAL 3,329,261

CATHETERIZATION PACKAGE

Filed Sept. 3, 1965 3 Sheets-Sheet 1

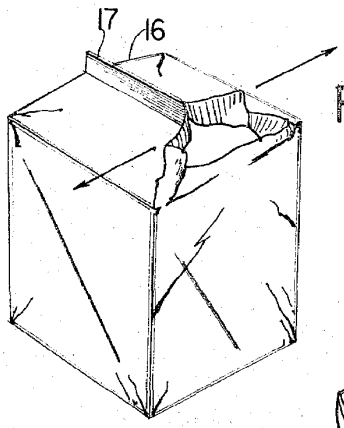


FIG. 1

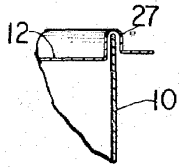
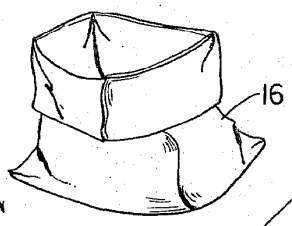


FIG. 4



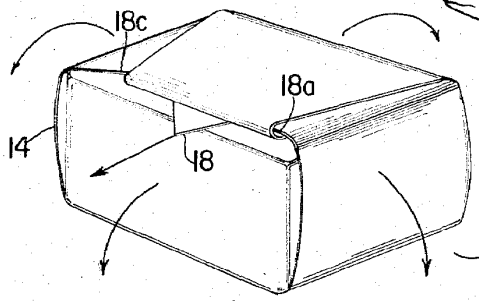


FIG. 2

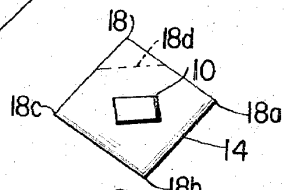


FIG. 2a

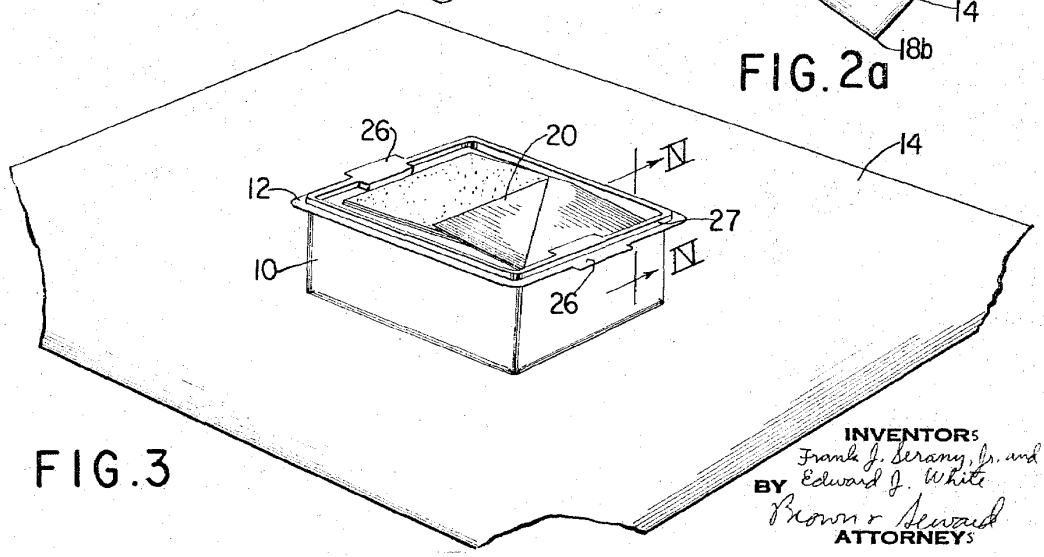


FIG. 3

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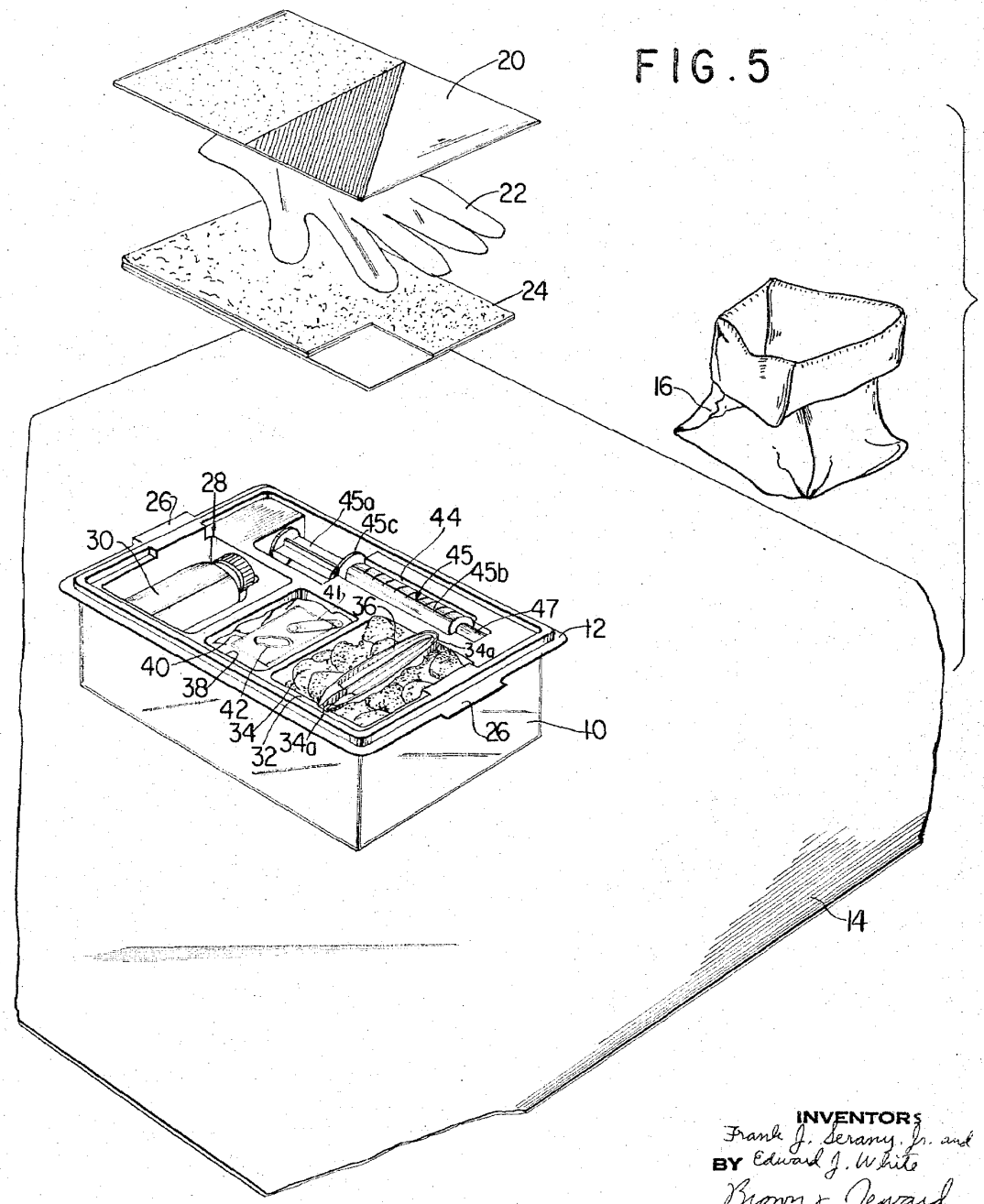
Bard Exhibit 1004.0493

July 4, 1967 F. J. SERANY, JR., ET AL 3,329,261

CATHETERIZATION PACKAGE

Filed Sept. 3, 1965 3 Sheets-Sheet 2

FIG. 5



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Bard Exhibit 1004.0494

July 4, 1967 F. J. SERANY, JR., ETAL 3,329,261

CATHETERIZATION PACKAGE

Filed Sept. 3, 1965 3 Sheets-Sheet 3

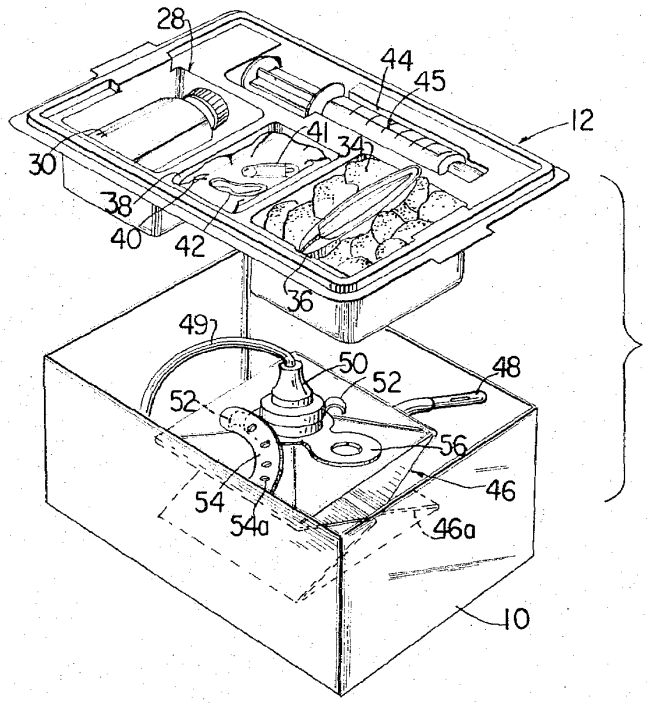

FIG. 6

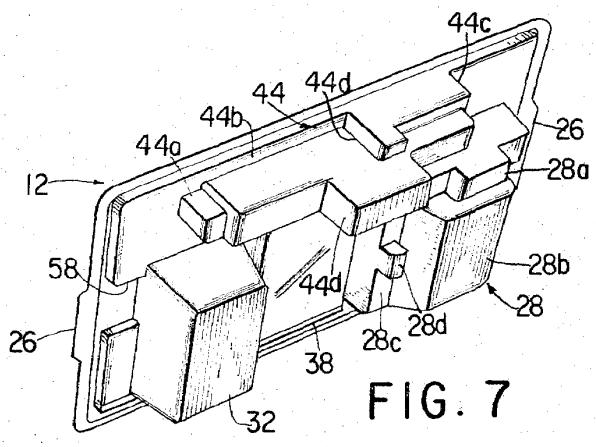

FIG. 7

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Bard Exhibit 1004.0495

United States Patent Office

3,329,261

Patented July 4, 1967

3,329,261

CATHETERIZATION PACKAGE

Frank J. Serany, Jr., Pompton Plains, and Edward J. White, Denville, N.J., assignors to C. R. Bard, Inc., Murray Hill, N.J., a corporation of New York

Filed Sept. 3, 1965, Ser. No. 484,914
1 Claim. (Cl. 206—63.2)

This invention relates to a ready to-use-package containing components for a catheterization procedure. The package is adapted to be opened at the patient's bedside to make available such components in their preferred order of use. The components are maintained sterile until the package is opened and include items which assure that a sterile field may be maintained as the components are removed from the package and used. In one embodiment, all the essential equipment, including preparation items, catheter, and drainage bottle, for a complete the catheterization procedure are included in the package. In using this package, the nurse or physician is assured that it will not be necessary to interrupt the procedure to search for missing items necessary to complete the job or to question the sterility of the items being used. Everything is available in the proper order of use and in a sterile condition.

It is an object of this invention to provide a compact package containing sterile components for catheterization, packaged in their order of use, and arranged to assure that a sterile field may be maintained as the components are removed from the package and used.

Another object is to provide a catheterization package which reduces the incidence of infection, reduces labor costs, and which provides the convenience of having all the components arranged in logical step-by-step order to facilitate the nurse's or physician's task.

A further object is to provide certain improvements in the form, construction, arrangement and material of the several elements whereby the above named and other objects may effectively be attained.

A practical embodiment of the invention is shown in the accompanying drawings wherein:

FIG. 1 is a perspective view of a package, constructed according to this invention, showing the outer envelope on the package partialy separated preparatory to removing the inner box therefrom.

FIG. 2 is a perspective view showing the box and the envelope from which it was removed.

FIG. 2*a* is a plane view, on a reduced scale, of the box and wrap before the latter is folded around the former.

FIG. 3 is a perspective view showing the box resting on the wrap which was previously folded around the box.

FIG. 4 is a partial section, on a larger scale, looking along the line IV—IV of FIG. 3.

FIG. 5 is an exploded view of the box of FIG. 3 showing the relationship of various components included herewith.

FIG. 6 is a perspective view showing the tray after it has been lifted off of the box.

FIG. 7 is a perspective view of the bottom of the tray.

Referring to the drawings, a box **10** having an open top with a tray **12** mounted thereon is enclosed within a wrap **14**, the entire assembly being encased within an envelope **16**. The envelope **16** seals the contents to maintain the sterility of the contents, the latter, of course, having been sterilized before or after enclosure in the envelope. The envelope **16**, preferably made of a transparent and flexible plastic film, has a heat seal **17** which is adapted to be separated as shown in FIG. 1 to facilitate removal of the contents while maintaining the integrity of the remainder of the envelope so that it may be cuffed as shown in FIG. 2 to serve as a waste receptacle.

The wrap **14**, which may be a piece of sterile absorbent paper, is folded around the box **10** in such a way that a slight tug on the corner **18** will release the folds so that the wrap may thereafter be readily spread out on the flat surface on which the box rests. To provide for this release, the wrap **14** is folded around the box **10** by initially resting the box on the flat wrap **14** with the respective corners offset as shown in FIG. 2*a*. The corner **18***b* is then pulled over the top of the box followed by the corners **18***a* and **18***c* which overlap the corner **18***b* and each other. Thereafter, the corner **18** is pulled over the overlapping corners **18***a*, **18***c* on top of the box and tucked thereunder. Simultaneously the corner **18** is folded as at **18***d* in a manner so that the extreme end of corner **18** protrudes to form a pull tab as shown in FIG. 2. While the portion thereof under the overlapping corners **18***a* **18***c* holds the wrap in place around the box. The wrap, when removed from around the box as described above and flattened out thereunder, serves as a sterile field and work area for the remaining operations to be described.

Upon removal of the wrap **14**, there is exposed a water-proof underpad **20** which is folded flat and rests on top of the tray **12**. The underpad **20**, which may be made of paper with a plastic water-proof coating on one side, is adapted to be placed under the patent. Prepowdered plastic gloves **22** are arranged in a flat condition beneath the underpad **20** and are exposed when the latter is removed. The glooves **22** are put on by the nurse or physician and used thereafter. A fenestrated drape **24** folded flat underneath the gloves, is removed, unfolded, and placed in position on the patient, all the above being accomplished while maintaining a sterile field.

The tray **12** is then lifted from the box **10** and placed within easy reach. Handle tabs **26** may be provided to facilitate lifting of the tray. As best shown in FIG. 4, the tray has an inverted groove **27** adjacent its peripheral edge in which is accommodate the upper edge of the box **10**.

The tray **12** has compartments or depressions therein to suitably accommodate components for catheterization. The depression **28** accommodating a bottle **30** of cleansing solution has in its lower depths a section **28***a* to receive the neck and cap of the bottle and a section **28***b* to receive the main portion of the bottle, the latter section being deeper than the former. These two sections **28***a* and **28***b* are approximately the same width as the respective diameters of the neck and main portion of the bottle to hold the latter in place in the tray. In order to provide ready access to the bottle **30**, the upper reaches of the depression **28** are made wider than the diameter of the bottle, said wider section being indicated at **28***c* in FIG. 7. As a further aid to facilitate access to the bottle **30**, finger depressions **28***d* may be provided along the side of section **28***b* so that the bottle may be easily grasped for removal from the tray.

The tray also has a depression **32** for balls **34** of cleansing material, e.g. rayon, which are used to prepare the patient for catheterization. Conventionally, the balls of cleansing material are unsaturated with a cleansing solution before they are used. This is readily accomplished in the present invention, by removing the bottle **30** of cleansing solution from the compartment **28**, as previously described, and pouring it over the rayon balls **34** in their stored position in the depression **32**. The balls are handled by forceps **36**, conveniently stored above the balls and held in place by the indentations **34***a* at both ends of the depression **34**. The forceps **36** are removed from their stored position before the cleansing fluid is applied to the balls. Used balls may be conveniently discarded in the depression **28** which originally contained the bottle of cleaning fluid.

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A plastic pouch accommodated in a depression 38 in the tray is removed from the latter and the contents including lubricating jelly in an individually sealed pouch 40, safety pin 41, and rubber band 42 are taken out and placed back into the depression 38, ready for use.

The tray 12 has a further depression 44 for a prefilled syringe 45 used to inflate the balloon on the catheter. The syringe 45 is stored with its plunger 45*a* extended and the barrels 45*b* filled with a fixed amount of sterile water, the tip of the syringe having a removable protective cap 47 of rubber or the like to seal the water in the barrel. The depression 44 has an end section 44*a* of a width approximating the diameter of the protective cap 47 and a mid-section 44*b* having a width approximating that of the barrel 45*b* thereby holding the syringe against lateral movement in its stored condition. The upper portion of the end section 44*c*, on the other hand, is wider than the diameter of the plunger handle 45*a* so that it may be easily grasped for removal of the syringe from the tray. Indentations 44*d* along the sides of the depression 44 accommodate the flange or finger grip 45*c* of the syringe.

Included in the box 10 beneath the tray 12 are a collapsible drainage bottle 46 and a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use. The bottle 46 is made of flexible plastic material having fold lines 46*a* formed thereon on opposite sides so that it may be folded flat for storage in the box 10 and expanded into cube form when in use. The bottle is shown in FIG. 6 partially expanded for illustration purposes. In its collapsed condition, it will readily fit into the box 10 beneath the tray 12. The catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle. The neck of the bottle carries a detachable fitting 50 to receive and connect the catheter drainage tube 49. The neck also has diametrically opposed projecting lugs 52 for detachably affixing a supporting strap 54, the latter having a plurality of spaced openings 54*a* at both end portions to fit over the lugs 52 so as to form a closed loop over a bed rail or the like for suspending the bottle. A flexible plastic carrying hook 56 may be provided on the neck of the bottle to facilitate handling the latter, for example, when it is emptied.

After the patient has been prepared, as previously described, the catheter 48 is lubricated with the lubricating jelly 40 while the drainage bottle 46 and tubing 49 are still in the box 10. Catheterization is thereafter effected in the usual manner. The covering 47 on the tip of the syringe 45 is removed and the balloon on the catheter is inflated with the sterile water in the syringe 45. The drainage bottle 46 is removed from the box 10 and suspended from a bed rail or the like by the strap 54 (or placed on the floor or other support). The drainage tubing 49 is attached to a bed sheet with the safety pin 41 and rubber band 42 to thereby complete the catheterization procedure. All waste materials may be discarded in the plastic bag 16. The collapsible bottle 46 may be emptied by grasping the carrying hook 56, detaching one end of the strap 54 from the lug 52 and disengaging the connection fitting 50 from the bottle. After the bottle 46 has been emptied it may be connected and suspended again.

From the above description it will be seen that all the components to effect catheterization have been provided

in a compact, sealed, and sterile package ready for use in the order needed. The tray conveniently houses and stores the accessories to provide protection against damage during shipment and to make such accessories readily available while at the same time facilitating their use, for example, by enabling the balls of cleansing material to be saturated with cleansing fluid while in their storage compartment. The tray also serves to rigidify the package. Thus the box 10 may be made of inexpensive cardboard with the tray, accommodating the upper edge of the box in the groove 27, serving to rigidify the assembled unit. The tray 12 may be made of relatively thin molded plastic with the various depressions therein serving to enhance its overall structural strength.

As best shown in FIG. 7, the depression 44 for the syringe 45 has an extension 44*d* at an intermediate location which extends down to the same plane as the bottom of the depressions 28 and 32 to thereby provide a three leg support for the tray on a flat surface. The tray also has indentations 58 at both ends adjacent the lift tabs to provide additional grip area after the tray has been lifted off of the box.

In the above description, all the components for catheterization have been included in the package. In some cases certain components, such as the Foley catheter 48, may be omitted as it may be available from a separate source.

It will be understood that various changes may be made in the form, construction and arrangement of the several parts without departing from the spirit and scope of the invention, and hence we do not intend to be limited to the details shown or described herein except as the same are included in the claim or may be required by disclosures of the prior art.

What we claim is:

A package for catheterization components, comprising an open top box made of cardboard, one of said components being a collapsible drainage bottle with catheter and drainage tube preconnected to said bottle within said box, a removable tray of molded plastic having compartments therein for other of said components, said compartments strengthening said tray to provide a semi-rigid structure, there being at least three compartments at least portions of which extend to the same depth so as to provide three point support for the tray on a flat surface, means mounting said tray within the open top of said box over said bottle and thereby rigidifying said box, said tray having lateral extensions forming lifting tabs a sterile wrap folded about said box and adapted to be unfolded to provide a sterile field as said components are removed from the package and used, and a sealed envelope about said wrap to maintain the sterility of said components.

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WILLIAM T. DIXSON, JR., *Examiner.*

Bard Exhibit 1004.0497

US006840379B2

(12) **United States Patent**
Franks-Farah et al.

(10) **Patent No.: US 6,840,379 B2**
(45) **Date of Patent: *Jan. 11, 2005**

(54) **MALE CLEAN INTERMITTENT CATHETER SYSTEM**

(76) Inventors: **Judith Franks-Farah**, 3069 Pheasant Creek, Northbrook, IL (US) 60062; **Shirley P. Grey**, 429 Edgewater, Wauconda, IL (US) 60084; **Sylvia D. Aruffo**, 215 Prospect, Highland Park, IL (US) 60035; **Carol A. Outland**, 2541 Athens Rd., Olympia Fields, IL (US) 60461

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/661,989**

(22) Filed: **Sep. 11, 2003**

(65) **Prior Publication Data**

US 2004/0055925 A1 Mar. 25, 2004

Related U.S. Application Data

(63) Continuation of application No. 09/879,321, filed on Jun. 12, 2001, now Pat. No. 6,640,976.
(60) Provisional application No. 60/211,152, filed on Jun. 13, 2000.

(51) **Int. Cl.**[7] **B65D 69/00**
(52) **U.S. Cl.** **206/571**; 206/232; 206/440; 604/544
(58) **Field of Search** 206/232, 570–572, 206/581, 438, 440, 459.5, 364; 604/172, 327–331, 355, 263, 544

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(57) **ABSTRACT**

A method and system for performing intermittent male catheterization by a patient, a patient's caregiver, or a health care provider are revealed. The system contains apparatus for at least one intermittent male catheterization and includes at least one male catheter, antibacterial soap, a lubricant, step-by step-instructions, and a container, where the above named items are positioned inside the container. The method includes self-care documentation for a medical professional to instruct a user in the use of the system and to keep a record that the instruction of the patient was performed.

10 Claims, 8 Drawing Sheets

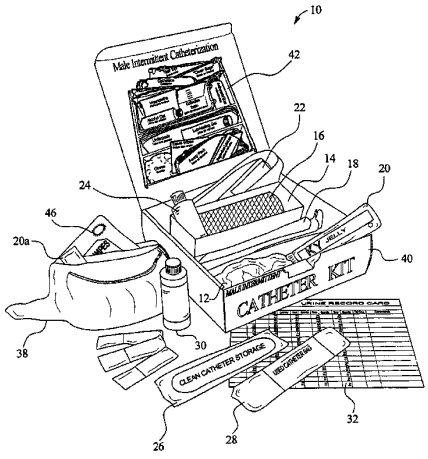

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FIG. 1

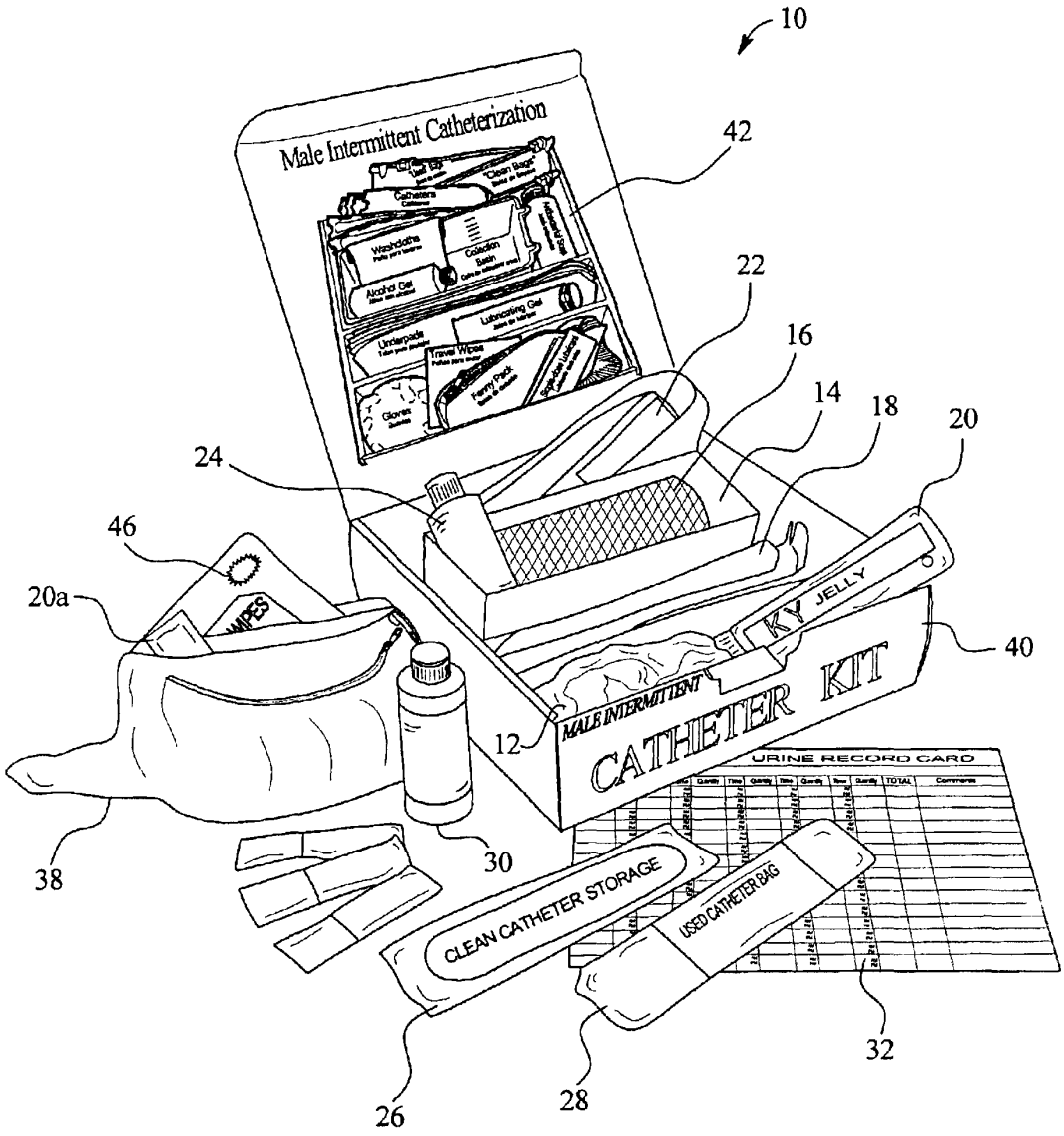
10
Male Intermittent Catheterization
42
22
16
14
18
20
24
46
20a
WIPES
KY JELLY
40
MALE INTERMITTENT
CATHETER KIT
12
URINE RECORD CARD
38
30
CLEAN CATHETER STORAGE
USED CATHETER BAG
32
26
28

FIG. 1A

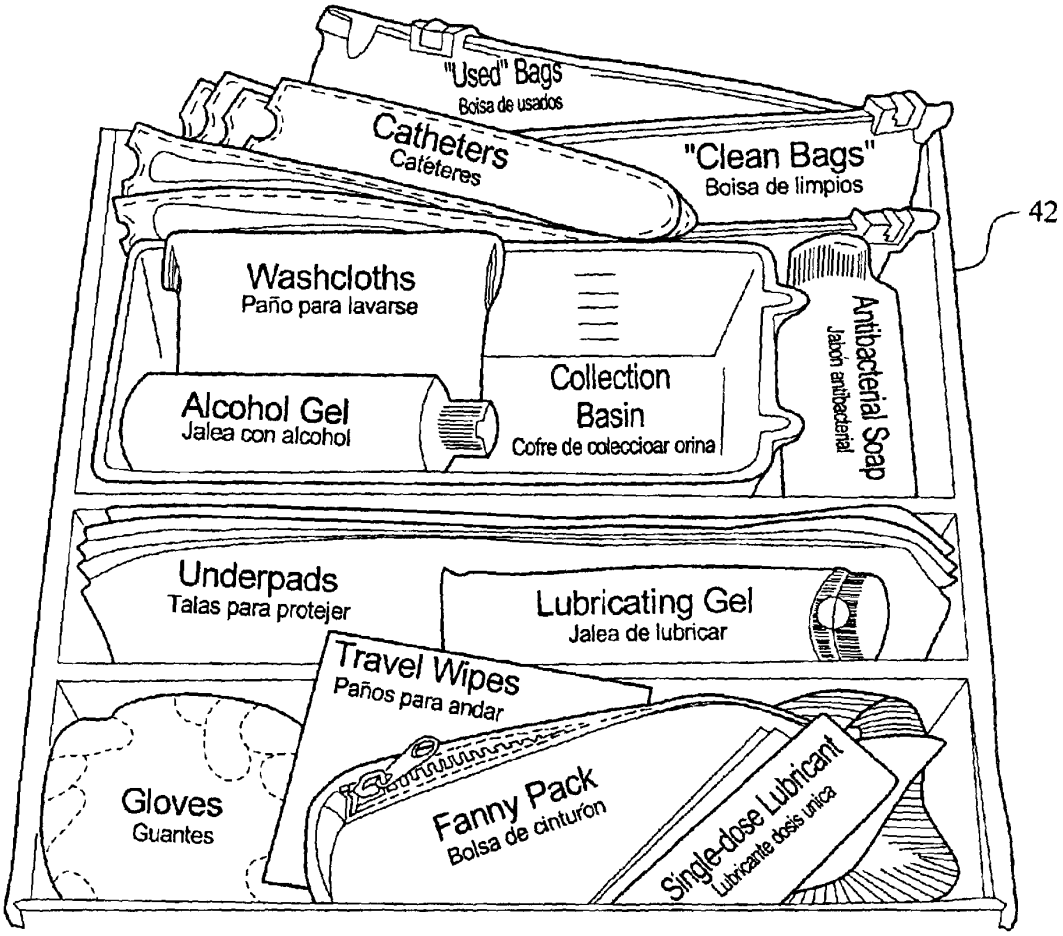
"Used" Bags
Bolsa de usados
Catheters
Catéteres
"Clean Bags"
Boisa de limpios
42
Washcloths
Paño para lavarse
Alcohol Gel
Jalea con alcohol
Collection
Basin
Cofre de coleccioar orina
Antibacterial Soap
Jabon antibacterial
Underpads
Talas para protejer
Lubricating Gel
Jalea de lubricar
Travel Wipes
Paños para andar
Gloves
Guantes
Fanny Pack
Bolsa de cinturon
Single-dose Lubricant
Lubricante dosis unica

FIG. 2A

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Clean Intermittent Catheterization Step-by-Step

page 1

This guide is to be followed only on the order of a physician. This guide is not a substitute for your health care professional's instructions. All the medical supplies you need are in this kit. The name of each item is printed in color below. Read all the steps and use the Map to locate each one before you begin. Keep everything in the box until the guide tells you to use it.

Prepare for Care

1 Get a clean, fresh towel. Wash your hands with Antibacterial Soap and warm water. Dry them only on the fresh towel.

If you have a caregiver do this for you, they should wash hands and put on the Gloves.

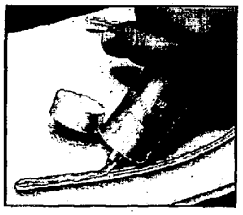
Spread out two clean paper towels for a work surface. If you are going to do the procedure on a bed or chair, put the Underpad under your buttocks.

2 Wash your penis with the Paper Wash Cloth and Antibacterial Soap and warm water. Clean the head of your penis well, pulling the foreskin back if necessary.

Rinse the Paper Wash Cloth clean, squeeze it dry and place it on a corner of one of the paper towels. Wash and dry your hands again.

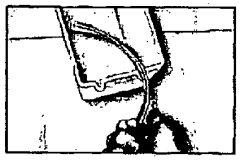
A caregiver wearing gloves does not need to wash again.

The Catheter



3 Take the Catheter out of the package and lay it on the paper towel. Flip open the cap of the Lubricating Jelly. Squeeze 3 inches of Jelly onto the Catheter, starting at the tip. Be careful not to touch the Catheter with the tube.

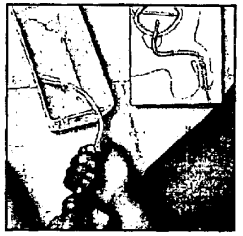
4 Hold the Catheter an inch behind the Jelly. Roll it so that the Jelly covers all sides.



5 Lift the Catheter away from the paper towel and lay the wide end in the Collection Container. Move the Container close to your body so you do not accidentally pull the wide end of the Catheter out.

6 Hold the penis straight out with one hand and insert the Catheter with the other hand. Pull the penis away from your body to keep the channel straight. Push the Catheter in until a bit of urine comes out.

If the Catheter stops, wait a minute to let the muscles relax, then gently begin to push again.



7 Slowly push the Catheter in one more inch. Now lower the angle of the penis. The bladder will empty while you hold the Catheter in place. When the urine stops, slowly pull the Catheter out.

Continued on the back of this page...

FIG. 2B

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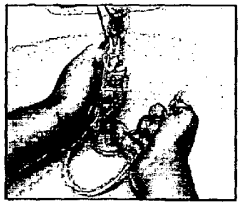
Clean Intermittent Catheterization *continued...* page 2

Clean for Next Time



8 Take the Catheter to a sink and wash it with Antibacterial Soap and warm water. Hold the Catheter under running tap water to rinse well, inside and out. Shake it several times to get off extra water.

9 Place the Catheter on the clean paper towel to air dry. Pick up the Paper Wash Cloth you left on the paper towel and use it to remove any Jelly left on the head of your penis. Pull the foreskin back down.

10 Check the level of urine in the Container. Record this amount on the Urine Record Card. Notice the color and smell of the urine and write these on the Record Card, also.

11 Empty the Collection Container. Wash the Container with Antibacterial Soap and water. Rinse it well. Close the cap on the tube of Lubricating Jelly. Put all the supplies back in the box. Throw away the Paper Wash Cloth and take away the Underpad.

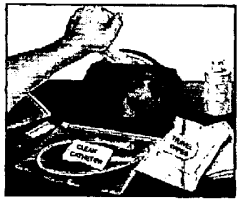
12 The Catheter should be dry by this time. Put it inside the Plastic Bag marked "Clean Catheter" and zip it closed.

The caregiver may take off the gloves now, throw them away and wash their hands.

When You Travel

A For every four hours you expect to be away, put into the Fanny Pack:

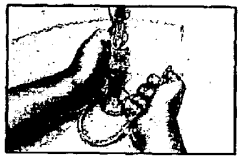
- A clean Catheter in the "Clean Catheter" Bag
- One Packet of Lubricating Jelly
- Two clean paper towels



Also put in the pack of pre-wet Travel Wipes and the "Used Catheter" Bag.

B When it is time to do your procedure, find a place like a bathroom and follow Steps 1-12 above, using the paper towels for a clean work surface.

C When you take the Catheter out, rinse it off if possible and store it in the "Used Catheter" Bag. Wash and dry your hands.



D When you are home again, wash your used Catheters very well with Antibacterial Soap and water. Store them in your "Clean Catheter" Bag.

If you need more supplies, keep the box, this Careguide™ Step-by-Step, the Fanny Pack and your Collection Container. Find the reorder form in the box and call the toll-free number 2 or 3 days before you run out.

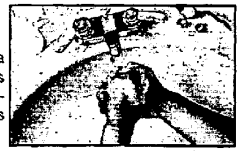
FIG. 3A

34A

Cateterización Intermitente para el hombre — Paso a Paso — pagina 1

Este Guía debe ser useda solmente con la orden de su doctor. Esta guia no substituye las Intrucciónes de su doctor o enfermera. Todas las provicones necesarias estan en la caja. El nombre de cada objeto está escrito a color. Lea todos los pasos y use el mapa para localizar cada uno antes de empezar. Mantenga todo en la caja hasta que la guia le diga cuando usarlo

Preparativos



1 Busque una toalla limpia y fresca. Lavese las manos con el Jabón Antibacterial y agua tibia. Sequelas solo con la toalla limpia.

Si tiene a una persona ayudandolo, el o ella debe de ponerse los Guantes despues de averse lavado las manos.

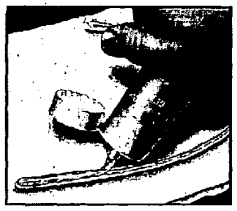
Use dos Toallas de papel limpias como superficie para poder trabajar. Si Ud. va a hacer el procedimiento en la cama o en una silla, ponga las Telas para Protejer debajo de su recto.

2 Lave su pene con el Paño para Lavarse, el Jabón Antibacterial, y agua tibia. Limpie la cabeza de su pene muy bien. Si Ud. no ha sido cincumcisado, mueva su piel hacia arriba para poder lavarse mejor.

Remoje el Paño para Lavarse, exprimalo hasta que este seco y pongalo en la esquina de una de las toallas de papel. Lave y seque sus manos otra vez.

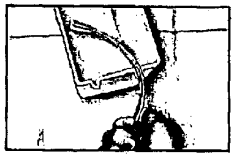
Su ayudante usando guantes no tiene que lavarse otra vez.

El Catétere



3 Saque el Catétere de su empaquetaje y coloquelo en la toalla de papel. Abra el pomo de Jalea para lubricar. Exprima 3 inches de jalea en el Caté tere, empezando por la punta fina. Tenga cuidado de no tocar el Caté tere con el pomo de jalea

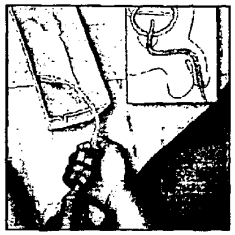
4 Sostenga el Catétere de manera que la jalea toque la toalla de papel. Mueva el Catétere en forma circular para que se llene de jalea por todos lados.



5 Recoja el Catétere de la tolla de papel y coloque la punta gruesa del Catétere en el Cofre de Coleccionar Orina. Acerque el cofre a su cuerpo para asi evitar que Ud. accidentalmente jale el Catétere fuera del cofre.

6 Sostenga el pene en posición recta y firme-con una mano, y meta el Catétere con la otra. Jale el pene hacia fuera de su cuerpo para mantener el canal recto. Empuje el Catétere hacia adentro hasta que orine un poquito.

Si el Catétere se detiene, espere un minuto para que se relaje el musculo, y despues trate de meterlo otra vez.



7 Lentamente meta el Catétere otro inche más. Ahora rebaje el angulo de su pene. La bejiga se vaciara mientras Ud. mantenga el Catétere en posición. Cuando deje de orinar, lentamente saque el Catétere.

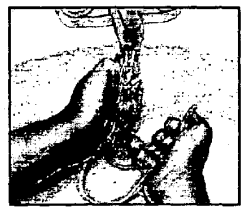
Continua atrás...

FIG. 3B

34A

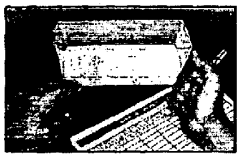
Cateterización Intermitente para el hombre *continuación...* pagina 2

Limpie para usar la Proxima Vez



8 Lleve el Catétere a un lavamanos y limpielo con Jabón Antibacterial y agua tibia. Mantenga el Catétere bajo agua para remojarlo bien por adentro y por afuera. Sacudalo bien para sacar toda el agua.

9 Ponga el Catétere en la toalla de papel limpia para que se seque al aire libre. Recoja el Paño para Lavarse que Ud. dejo en la esquina de la toalla de papel y uselo para limpiar los reciduos de orina en la cabeza del pene. Baje la piel de su pene otra vez.



10 Chequee el nivel de orina en el cofre. Escriba el número en la Tarjeta Diaria de Orina. Note el color y olor de su orina y escribalo en la tarjeta tambien.

11 Vacie el Cofre de Coleccionar Orina. Lave el cofre con Jabón Antibacterial y agua. Remojelo bien. Cierre la tapa del pomo de Jalea para Lubricar. Meta de vuelta en la caja todas las proviciones. Bote el Paño para Lavarse, y guarde las Telas para Protejer, pero si no están limpias botelas.

12 El Catétere ya debe de estar seco. Metalo en la bolsa de plastico que dice "Bolsa de Lipmpios", y cierrela.

Su ayudante ya se puede quitar los guantes, botarlos y lavarse las manos.

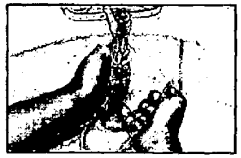
Cuando Viaje

A Por cada 4 horas que Ud. este de viaje meta en la Bolsa de cinturón:
- Un Catétere limpio en la Bolsa de Limpios
- Un Paquete de Jalea para Lubricar
- Dos toallas de papel limpias

Tambien meta el paquete de Paños para Andar y la Bolsa de Usados.

B Cuando sea hora de hacer el procedimiento, encuentre un lugar, como un baño y siga los pasos 1-12, usando las toallas de papel como una superficie limpia de trabajo.

C Cuando termine de usar el Catétere, remojelo si es posible y metalo en la Bolsa de Usados. Lave y seque sus manos.



D Cuando este en casa de vuelta, limpie muy bien los Catéteres usados con Jabon Antibacterial y agua. Guardelos en la Bolsa de Catéteres limpios.

Si necesita más suministros, guarde la caja, esta guía, la bolsa de cinturón, y el cofre de coleccionar orina. Encuentre en la caja el formulario para ordenar más y llame nuestro número de telefono gratis 2 o 3 dias antes de que se le acaben los suministros.

FIG. 4

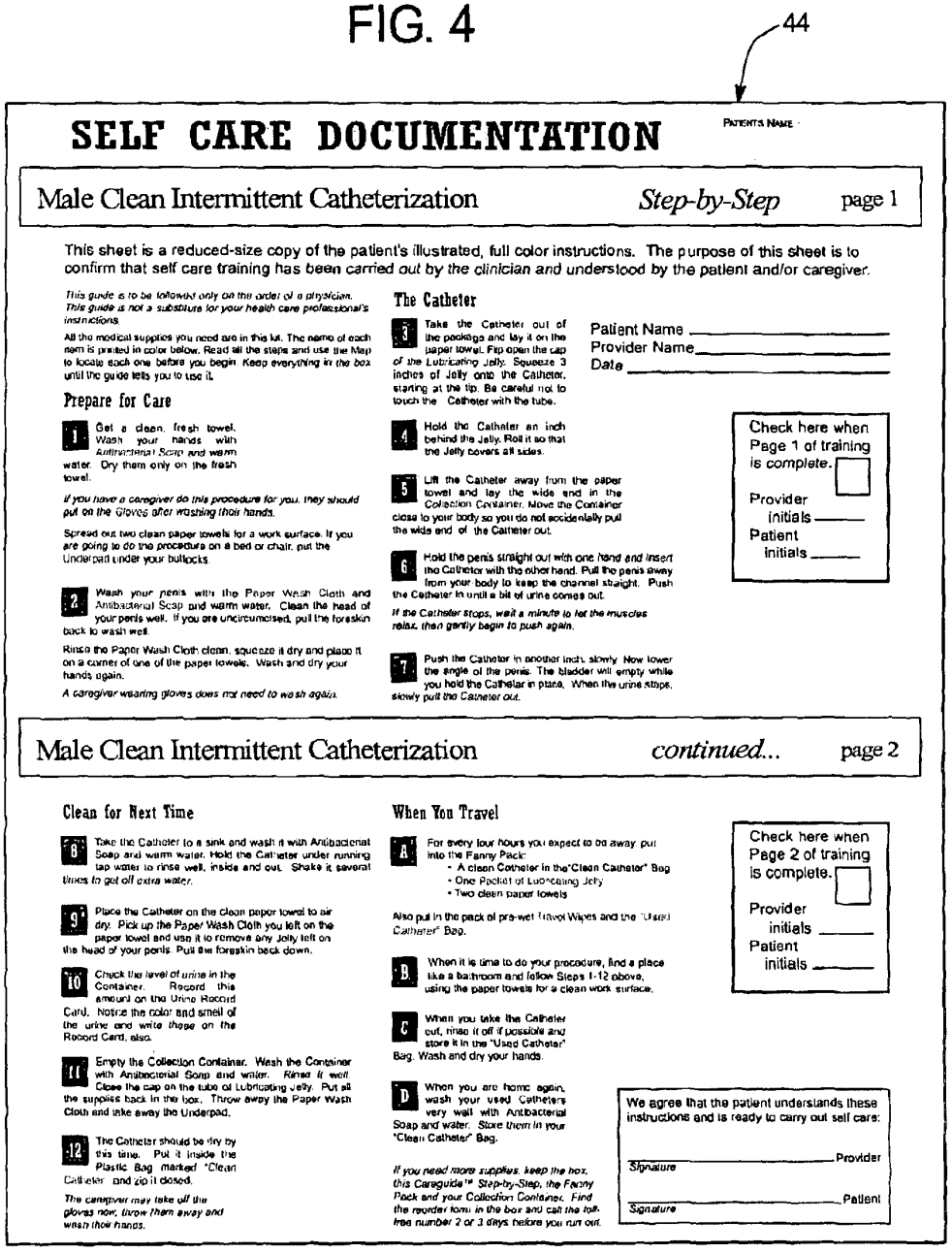

44
SELF CARE DOCUMENTATION
PATIENT'S NAME
Male Clean Intermittent Catheterization
Step-by-Step
page 1
This sheet is a reduced-size copy of the patient's illustrated, full color instructions. The purpose of this sheet is to confirm that self care training has been carried out by the clinician and understood by the patient and/or caregiver.
This guide is to be followed only on the order of a physician. This guide is not a substitute for your health care professional's instructions.
All the medical supplies you need are in this kit. The name of each item is printed in color below. Read all the steps and use the Map to locate each one before you begin. Keep everything in the box until the guide tells you to use it.
Prepare for Care
1 Get a clean, fresh towel. Wash your hands with Antibacterial Soap and warm water. Dry them only on the fresh towel.
If you have a caregiver do this procedure for you, they should put on the Gloves after washing their hands.
Spread out two clean paper towels for a work surface. If you are going to do the procedure on a bed or chair, put the Underpad under your buttocks.
2 Wash your penis with the Paper Wash Cloth and Antibacterial Soap and warm water. Clean the head of your penis well. If you are uncircumcised, pull the foreskin back to wash well.
Rinse the Paper Wash Cloth clean, squeeze it dry and place it on a corner of one of the paper towels. Wash and dry your hands again.
A caregiver wearing gloves does not need to wash again.
The Catheter
3 Take the Catheter out of the package and lay it on the paper towel. Flip open the cap of the Lubricating Jelly. Squeeze 3 inches of Jelly onto the Catheter, starting at the tip. Be careful not to touch the Catheter with the tube.
4 Hold the Catheter an inch behind the Jelly. Roll it so that the Jelly covers all sides.
5 Lift the Catheter away from the paper towel and lay the wide end in the Collection Container. Move the Container close to your body so you do not accidentally pull the wide end of the Catheter out.
6 Hold the penis straight out with one hand and insert the Catheter with the other hand. Pull the penis away from your body to keep the channel straight. Push the Catheter in until a bit of urine comes out.
If the Catheter stops, wait a minute to let the muscles relax, then gently begin to push again.
7 Push the Catheter in another inch, slowly. Now lower the angle of the penis. The bladder will empty while you hold the Catheter in place. When the urine stops, slowly pull the Catheter out.
Patient Name
Provider Name
Date
Check here when Page 1 of training is complete.
Provider initials
Patient initials
Male Clean Intermittent Catheterization
continued...
page 2
Clean for Next Time
8 Take the Catheter to a sink and wash it with Antibacterial Soap and warm water. Hold the Catheter under running tap water to rinse well, inside and out. Shake it several times to get off extra water.
9 Place the Catheter on the clean paper towel to air dry. Pick up the Paper Wash Cloth you left on the paper towel and use it to remove any Jelly left on the head of your penis. Pull the foreskin back down.
10 Check the level of urine in the Container. Record this amount on the Urine Record Card. Notice the color and smell of the urine and write these on the Record Card, also.
11 Empty the Collection Container. Wash the Container with Antibacterial Soap and water. Rinse it well. Close the cap on the tube of Lubricating Jelly. Put all the supplies back in the box. Throw away the Paper Wash Cloth and take away the Underpad.
12 The Catheter should be dry by this time. Put it inside the Plastic Bag marked "Clean Catheter" and zip it closed.
The caregiver may take off the gloves now, throw them away and wash their hands.
When You Travel
A For every four hours you expect to be away, put into the Fanny Pack:
• A clean Catheter in the "Clean Catheter" Bag
• One Packet of Lubricating Jelly
• Two clean paper towels
Also put in the pack of pre-wet Travel Wipes and the "Used Catheter" Bag.
B When it is time to do your procedure, find a place like a bathroom and follow Steps 1-12 above, using the paper towels for a clean work surface.
C When you take the Catheter out, rinse it off if possible and store it in the "Used Catheter" Bag. Wash and dry your hands.
D When you are home again, wash your used Catheters very well with Antibacterial Soap and water. Store them in your "Clean Catheter" Bag.
If you need more supplies, keep the box, this Careguide™ Step-by-Step, the Fanny Pack and your Collection Container. Find the reorder form in the box and call the toll-free number 2 or 3 days before you run out.
Check here when Page 2 of training is complete.
Provider initials
Patient initials
We agree that the patient understands these instructions and is ready to carry out self care:
Signature Provider
Signature Patient

FIG. 5

32

URINE RECORD GUIDE

Patient Name

Your doctor will tell you how often to record your urine output. Remember to circle AM or PM when you write the time.

Date	Time	Quantity	Time	Quantity	Time	Quantity	Time	Quantity	Time	Quantity	TOTAL	Comments
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
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	AM PM		AM PM		AM PM		AM PM		AM PM			
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	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			
	AM PM		AM PM		AM PM		AM PM		AM PM			

Catherize yourself____times a day at_____.Each day drink___8oz. glasses fluid, but no more than___8oz. glasses fluid. Your medication is:_____.

MALE CLEAN INTERMITTENT CATHETER SYSTEM

PRIORITY CLAIM

This application is a continuation of U.S. patent application Ser. No. 09/879,321, filed Jun. 12, 2001 now U.S. Pat. No. 6,640,976, which claims the benefit of provisional application Ser. No. 60/211,152, filed Jun. 13, 2000.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is related to the following commonly-owned patent applications: "METHOD FOR DETERMINING THE CONTENT OF A SELF-CARE KIT," Ser. No. 09/709,917, "PATIENT DISCHARGE SYSTEM AND METHOD FOR SELF-CARE OF A POST-SURGERY DRAIN," Ser. No. 09/779,796, now U.S. Pat. No. 6,579,271; and "FEMALE CLEAN INTERMITTENT CATHETER SYSTEM," Ser. No. 09/879,230.

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DESCRIPTION

The present invention relates in general to a system and method for using a male catheter and in particular to a system and method for clean intermittent male catheterization by a user or health care provider.

BACKGROUND OF THE INVENTION

It is estimated that urinary catheters are placed in millions of men each year in the United States alone, either due to some illness, infection or malfunction or as part of some medical procedure. Care must be taken to clean the catheter site to reduce the risk of nosocomial infection (i.e., an infection that arises due to a procedure for treating a disorder and unrelated to the disorder itself, also referred to as a "hospital infection").

The most common nosocomial infections are related to or arise from indwelling urinary bladder catheters (i.e., catheters that remain in the urinary tract for a relatively long length of time). The risk of such catheter-related nosocomial infections can be reduced using strict aseptic techniques (i.e., using gloves, disinfectants, antibacterial soaps, etc.) when handling the catheter. Moreover, the risk of infection can further be reduced by only using a catheter intermittently rather leaving the catheter in place for any length of time. Intermittent use of the catheter in conjunction with clean techniques helps to reduce the risk of catheter-related nosocomial infections and is, moreover, a far more attractive alternative for bladder evacuation to most patients who are candidates for the procedure.

Using a urinary bladder catheter under aseptic conditions in a hospital is routine. However, current medical practice emphasizes getting the patient ambulatory (and out of the hospital) as soon as possible. Consequently, catheterizations or catheter insertions are performed at home by nonprofessionals. These nonprofessionals must be taught clean techniques. However, no known comprehensive devices, apparatus or methods exists for teaching clean techniques or for facilitating such home catheter use for men.

SUMMARY OF INVENTION

The present invention provides a method and system for intermittent catheterization by the patient himself, the patient's caregiver, or a health care provider. The present invention contains apparatus for facilitating at least one catheterization and comprises: (I) at least one male catheter; (II) antibacterial soap; (III) lubricant; (IV) step-by step instructions; and (V) a container, where the above named items are positioned inside the container. It should be appreciated that the present invention may only be used on the order of a physician.

Preferred embodiments of the system contain sufficient apparatus for one month of catheter insertions (approximately 3 to 4 times a day), the antibacterial soap is in liquid form, the lubricant is in gel form, the step-by-step instructions are written in English and Spanish, although other languages (e.g., Polish, French and German for example) are contemplated. One preferred embodiment of the system includes a contents map identifying the contents and the positions of the contents, along with zipper bags, a fanny pack and a protective underpad.

In a more preferred embodiment of the system, the system contains apparatus for at least one month of catheterizations as provided previously and comprises: (I) 4 male intermittent catheters; (II) 35 disposable wipes; (III) 1 protective underpad; (IV) antibacterial liquid soap; (V) 1 tube of lubricant; (VI) step-by-step instructions; (VII) clinician step-by-step instructions or self-care documentation; and (VIII) a box, wherein the above-named items are positioned inside the box.

The method for intermittent male catheterization comprises evacuating the bladder using the apparatus of the present invention in accordance with the detailed step-by-step instructions provided in the system. In a preferred embodiment, the method which is discussed in further detail below generally includes: (I) preparing for intermittent male catheterization; (II) preparing the male catheter; (III) inserting the male catheter; (IV) draining the bladder; (V) recording and disposing of the drainage; and (VI) cleaning and storing the apparatus of the present invention.

The present invention further includes a patient education system for educating users in performing intermittent male catheterization. Specifically, the system includes a system and a set of black and white step-by-step instructions without illustrations (referred to herein as self-care documentation). An instructor (i.e., a doctor, nurse, clinician or other medical professional) uses the self-care documentation to educate the user in performing an intermittent male catheterization, preferably using the system of the present invention. The medical professional then keeps the self-care documentation documenting that the user was educated in performing the male catheterization.

It is therefore an object of the present invention to provide a system and method for intermittent male catheterization.

It is a further object of the present invention to provide detailed instructions for intermittent male catheterization using the contents of a self-care system.

An additional object of the present invention is to provide self-care documentation to be used by a medical professional in instructing users in the use of the self-care system.

Yet an additional object of the present invention is to provide a patient education system for educating users in performing intermittent male catheterization using the system.

Other objects, features and advantages of the invention will become apparent from the following detailed disclosure, taken in conjunction with the accompanying sheets of drawings, wherein like numerals refer to like parts, components and processes.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the system of the present invention;

FIG. **1A** is a top plan view of a contents map of the present invention;

FIGS. **2A** and **2B** are top plan views of the step-by-step instructions in English of the system of the present invention;

FIGS. **3A** and **3B** are top plan views of the step-by-step instructions in Spanish of the system of the present invention;

FIG. **4** is a top plan view of the self-care documentation in English used by a medical professional for documenting that the users are instructed in the use of the system of the present invention; and

FIG. **5** is a top plan view of the urine record card.

DETAILED DESCRIPTION OF THE INVENTION

It should be appreciated that the figures include one or more of the following trademarks which may be used by the assignee of this application: (a) CAREGUIDE; and (b) CAREGUIDE and DESIGN. It should be appreciated that these trademarks are not part of the present invention.

The present invention is for a system **10** and method for intermittent catheterization of a patient. The user may be the patient himself, the patient's caregiver, an in-home care provider or a healthcare provider which, for brevity, are referred to herein as the "user." The system **10** provides apparatus needed for in-home catheterization.

In general, the intermittent catheterization system **10** contains at least: (I) infection prevention devices (gloves, disposable wipes, zipper bags, alcohol gel (i.e., a waterless cleaner), soap, and protective underpads); (II) insertion devices (catheter and lubricant); (III) recording devices (urine record card and collection basin); and (IV) information devices (step-by-step instructions, contents map and self-care documentation) among other items.

More specifically, as illustrated by FIGS. **1** and **1A**, the intermittent catheterization system **10** of the present invention comprises: (I) gloves **12**; (II) a collection basin **14**; (III) disposable wipes **16**; (IV) protective underpad **18**; (V) antibacterial soap **24**; (VI) lubricating gel **20**; (VII) male intermittent catheter **22**; (VIII) clean and used zipper bags **26** and **28** respectively; (IX) self-care documentation **44** (not shown in FIGS. **1** and **1A**); (X) step-by-step instructions **34** (not shown in FIGS. **1** and **1A**); and (XI) a container or box **40**. It is contemplated that the system **10** may also include a contents map **42** which identifies the contents of the container **40** and their position, and one or more waste bags.

In one preferred embodiment, the container **40** contains gloves **12**, a plastic collection basin **14** with graduated markings, disposable wipes **16**, protective underpads **18**, single doses of lubricating gel **20***a*, male **14** catheters **22**, antibacterial liquid soap **24**, clean catheter zipper bags **26**, a used catheter zipper bag **28**, alcohol gel **30**, a urine record card **32**, a lubricating gel tube **20**, a fanny pack **38**, a travel wipe pack **46**, illustrated step-by-step instructions documentation **34** as revealed by FIGS. **2A** and **2B**, and **3A** and **3B**, and self-care documentation **44**). It should be appreciated that system **10** could be provided to the patient in a box, tray, bag, container or any other suitable content holder device **40**. A box is preferred because it is strong enough to protect the contents of the system **10** and yet is suitable for shipping and storing. If a bag, tray, container or other content holding devices are used, a contents map **42** may or may not be included with system **10**.

In one preferred embodiment, a urologist, clinician or other medical professional provides system **10** to the user, although it is contemplated that the user could obtain system **10** through other means provided that a medical professional has ordered the system for the patient. System **10** includes extremely detailed and specific step-by-step instructions **34** as illustrated in FIGS. **2A** and **2B** that the user uses with the intermittent catheterization system **10** (specific step-by-step instructions in Spanish are illustrated in FIGS. **3A** and **3B**). System **10** also includes the self-care documentation **44** the medical professional uses to document or record the instructions provided to the user in the use of the intermittent male catheterization system **10** as illustrated in FIG. **4**. A difference between the two sets of instructions is that the instructions in FIG. **4** are black and white and include acknowledgment sections **45A** and **45B** while the instructions in FIGS. **2A** and **2B** are illustrated in color (not shown) for ease of use by the patient. It is also contemplated that system **10** could include an instructional video, training the user in the use of the system **10**.

In one preferred embodiment, system **10** includes sufficient apparatus for one month of male catheter insertions, the antibacterial soap **24** is in a liquid form, the lubricant **20** is provided in a gel or ointment form, and the step-by-step instructions **34**, and the contents map **42** (if included) are written in English. While not necessary, one preferred embodiment also includes one or more gloves **12**, disposable wipes **16** and a protective underpad **18**. It should be appreciated that a user could order a refill of the disposable apparatus of the present invention using an order form provided with the apparatus of the present invention.

In a more preferred embodiment of the system, system **10** includes apparatus for at least one month of catheterizations and comprises: (I) 10 gloves **12**; (II) 1 collection basin **14**; (III) 35 disposable wipes **16**; (IV) 3 protective underpads **18**; (V) 10 single tubes of lubricating gel **20**; (VI) 4 male intermittent catheters **22**; (VII) antibacterial liquid soap **24**; (VIII) 4 clean catheter zipper bags **26**; (IX) 1 used catheter zipper bag **28**; (X) 4 oz of alcohol gel **30**; (XI) 1 urine record card **32**; (XII) 1 lubricating gel tube **20**; (XIII) a fanny pack **38**; (XIV) 1 pack of travel wipes **46**; (XV) self-care documentation **44**; (XVI) detailed step-by-step instructions **34**; (XVII) a contents map **42**; and (XVIII) container or box **40** wherein the above-named items are positioned inside the box **40**.

The system **10** includes apparatus necessary for intermittent male catheterization in accordance with the method. The system **10** organizes the apparatus in an easy-to-find format. The step-by-step instructions **34** indicate when an item is first required during the method and should be removed from the container **40** (preferably using red text to indicate when an item is first required). Using the step-by-step instructions **34** and the contents map **42**, users can easily identify when each item is required in the method and readily find it in the container **40**. It should be appreciated that the items and step-by-step instructions **34** could be color coded and/or use icons making identifying each item even easier. For example, the antibacterial soap **24** could be identified by a bubbles icon and blue coloring corresponding to a bubbles icon and blue color in the step-by-step instructions **34**.

The method of the present invention generally comprises using the system **10** in accordance with the detailed step-by step instructions **34**. In a preferred embodiment, the method generally includes: (I) preparing for intermittent male catheterization; (II) preparing the male catheter; (III) inserting the male catheter; (IV) draining the bladder; (V) recording and disposing of the drainage; and (VI) removing the male catheter and cleaning and storing the apparatus.

Preparing for Intermittent Male Catheterization (Step I)

The first step of the method of the present invention, is illustrated by FIGS. **2**A and **2**B and includes preparing and caring for the male catheterization site. Preparing and caring for the catheterization site includes: (I) obtaining a clean, fresh towel; (II) washing using the antibacterial liquid soap **24** and warm water, and using the clean towel for drying; (III) finding a safe, flat, uncluttered, solid surface; (IV) putting on the gloves **12** only if the catheterization is being performed by a user other than the patient which includes: (a) taking a pair of gloves **12** out of the box **40**; and (b) putting them on; (V) preparing the surface which includes: (a) obtaining two clean, fresh paper towels; (b) opening the two paper towels; (c) placing the opened paper towels on the surface; (d) taking a protective underpad **18** out of the box **40**; (e) opening the protective underpad **18**; and (f) placing the opened protective underpad **18** under the patient's buttocks and near the opened paper towels; (VI) cleaning the catheter site which includes: (a) taking a paper wash cloth or disposable wipe **16** out of the box **40**; (b) taking the container of antibacterial soap **24**; (c) squeezing out approximately one or two drops of soap **24** onto the center of the wipe **16**; and (d) gently washing the site using the wipe **16**, the soap **24** and warm water; (VII) rinsing clean the wipe **16** which includes: (a) rinsing the wipe **16**; (b) squeezing out the excess water, leaving the wipe **16** damp; and (c) placing the damp wipe **16** on one corner of the paper towel; and (VIII) washing using the antibacterial soap **24** as described previously. It should be appreciated that step (VIII) can be skipped if the user is wearing gloves **12**. It is also contemplated that step I could include: (IX) preparing a waste bag comprising: (a) obtaining a waste bag; (b) opening the waste bag; and (c) setting the waste bag on the flat surface.

Preparing the Male Catheter (Step II)

The second step of the method as illustrated includes inserting the catheter **22** into the penis. Inserting the catheter **22** includes: (I) taking a catheter **22** out of the box **40**; (II) laying the catheter **22** on the paper towels; (III) take a collection basin **14** out of the box **40** and placing it near the paper towels; (IV) applying the lubricating gel **20** which includes: (a) taking the lubricating gel tube **20** out the box **40**; (b) flipping open the cap of the lubricating gel tube **20**; (c) squeezing 3 inches of lubricating gel **20** onto the catheter **22** starting at the tip, being careful not to touch the catheter **22** with the tube **20**; (d) rolling the catheter **22** in the lubricating gel **20** so that all sides are covered; (e) lifting the catheter **22** away from the paper towel and laying the wide end of the catheter **22** in the collection basin **14**; and (f) moving the basin **14** close to the user so that the wide end of the catheter **22** is not accidentally pulled out of the basin **14**.

Inserting the Male Catheter (Step III)

The third step of the present invention comprises inserting the catheter **22** into the penis. Inserting the catheter **22** comprises: (I) sitting on the underpad **18**; (II) holding the penis straight out with one hand; (III) pulling the penis away from the body keeping the urinary tract straight; (IV) inserting the catheter **22** until a bit (i.e., at least a drop) of urine appears; and (V) slowly pushing the catheter **22** in one inch more.

Draining the Bladder (Step IV)

The fourth step of the method comprises draining the site (i.e., the bladder) forming a drainage. Draining the bladder using the catheter **22** comprises: (I) placing or holding the basin **14** in proximity to the tip of the catheter **22**; (II) lowering the angle of the penis; (III) holding the catheter **22** in place and emptying the bladder into the basin **14**; and (IV) slowly pulling the catheter **22** out when the bladder is empty (i.e., the urine stops).

Recording and Disposing of the Drainage (Step V)

The next step of the method includes recording and disposing of the drainage. This step includes: (I) recording the amount of the drainage, including: (a) measuring the drainage level using the markings on the basin **14**; (b) writing this amount on the urine record card **32** illustrated in FIG. **5**; (c) noticing the color and smell of the drainage; and (d) recording the color and smell on the urine record card **32**; and (II) disposing of the drainage, preferably emptying the basin **32** in a toilet.

Cleaning and Storing the Apparatus (Step VI)

The next step includes completing the intermittent catheterization in accordance with the method. Completing the catheterization includes: (I) cleaning the used catheter, which includes: (a) washing the used catheter **22** with the antibacterial soap **24** and warm water; (b) holding the catheter **22** under running tap water, rinsing it well inside and out; (c) shaking the catheter **22** several times to remove any excess water; and (d) placing the catheter **22** on a clean, fresh paper towel to air dry; (II) removing any jelly left on the catheterization site using the damp wipe **16** (See Step I above); (III) cleaning the basin **14**, which includes: (a) washing the basin **14** using antibacterial soap **24** and warm water; (b) rinsing the basin with warm water; and (c) placing the basin **14** on clean, fresh paper towel to air dry; (IV) closing the cap on the lubricating gel tube **20**; (V) placing all the apparatus back in the box **40**; (VI) placing the dry catheter **22** inside a clean catheter zipper bag **26**, zipping it closed; (VII) placing the clean catheter zipper bag **26** in the box **40**; (VIII) placing the dry basin **14** in the box **40**; (IX) placing the underpad **18** in the box **40**; and (X) disposing of the wipe **16** and the paper towels, preferably using the waste bags.

It should be anticipated that the patient is not bed bound, but able and willing to get around. One preferred embodiment of the present invention includes a fanny pack **38** that enables users to travel. As illustrated in FIGS. **2**A and **2**B, method provides that, for every four hours of travel, the fanny pack **38** should include: (I) one clean catheter **22** in a clean catheter zipper bag **26**; (II) one packet of lubricating gel **20***a*; and (III) two clean paper towels. The fanny pack **38** should also include the pack of pre-wet travel wipes **46** and the used catheter zipper bag **28**.

When catheterization is required, the user should find a place (preferably a bathroom) and follow Steps I–VI above, using clean paper towels for a clean work surface. After removing the catheter **22** in Step V, rinse it off if possible and store it in the used catheter zipper bag **28**, placing the bag **28**

in the fanny pack **38**. Wash as described previously in Step I. The used catheters may be cleaned completely upon returning home.

The present invention includes teaching or instructing users in the use of system **10**. System **10** includes a set of extremely detailed instructions **34** and self-care documentation **44**, as illustrated in FIG. **4**. The self-care documentation is used by the medical care professional to instruct the users and for medical records.

Federal, state and local regulatory agencies require that the medical professional maintain complete records, including records to training provided to individuals. The medical care professional uses the self-care documentation **44** providing the instruction to the patient or user on the use the method and system **10** as illustrated in FIG. **4**. The self care documentation enables the medical care professional to ensure that the training is complete, providing a signature box or acknowledgment areas **45**A and **45**B for the user to indicate that they received and understand the instructions. This documentation **44** is maintained by the clinician or a medical provider as part of the clinical record, where they may be used for accreditation and/or legal purposes.

The present invention further contemplates a patient education system for educating users in performing intermittent male catheterization. The system includes the system **10** and the self-care documentation **44**. The present invention is only used on the order of a physician. An instructor (i.e., a doctor, nurse, clinician, other medical profession, or any individual trained to educate users in performing male catheterization) uses the self-care documentation **44** to train users to perform a male catheterization, preferably using the system **10**. The instructor takes the user through the process of performing a male catheterization, and may even demonstrate specific procedures using specific items in the system **10**. For example, it is contemplated that the instructor could demonstrate how to apply lubricating gel to the catheter **22**, clean the catheter **22**, record drainage, etc. It should be appreciated that the instructor could use a model to demonstrate how to insert the catheter **22**, drain the bladder and remove the catheter **22**.

It should be appreciated that the system **10** may contain sufficient apparatus for one or more catheter insertions; for example, apparatus for two, three, four or more months of catheter usage are contemplated. Further, it should be appreciated that refills for system **10** may be provided. In a preferred embodiment, a reorder form may be provided in system **10**.

While the present invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but on the contrary is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the claims. It is thus to be understood that modifications and variations in the present invention may be made without departing from the novel aspects of this invention as defined in the claims, and that this application is to be limited only by the scope of the claims.

What is claimed is:

1. A patient education system for educating a user in performing intermittent male catheterization, said system comprising:

a male catheterization system including:

(a) a plurality of gloves;

(b) a collection basin;

(c) a plurality of disposable wipes

(d) a plurality of protective underpads;

(e) a plurality of male catheters;

(f) lubricant gel;

(g) a plurality of clean catheter bags;

(h) a used catheter bag;

(i) a urine record card;

(j) a lubricating gel tube;

(k) step-by-step instructions for using items (a) to (j);

(l) a container wherein items (a) through (j) are positioned inside the container; and

self-care documentation an instructor uses to educate the user in performing intermittent male catheterization using the system.

2. The patient education system of claim **1**, wherein the self-care documentation includes at least one acknowledgement section for documenting instructions provided to the users.

3. An intermittent male catheterization system, said system comprising:

a plurality of infection prevention devices said infection prevention devices includes at least two gloves, at least one disposable wipe, at least one bag, alcohol gel, and a protective underpad;

at least one male catheterization device;

at least one recording device including a collection basin and a record card which enables a user to record an amount of drainage from a male catheter site;

at least one set of step-by-step instructions for using the infection prevention devices, male catheterization device and recording device;

self-care documentation including an acknowledgement section for documenting instructions provided to the user in the use of the system; and

a container for holding the system.

4. An intermittent male catheterization system for use by a user and containing apparatus for a plurality of male catheter insertions, said system comprising:

(a) a plurality of gloves;

(b) a collection basin;

(c) a plurality of disposable wipes

(d) a plurality of protective underpads;

(e) a plurality of male catheters;

(f) a lubricant gel;

(g) a plurality of clean catheter bags;

(h) a used catheter bag;

(i) a urine record card;

(j) a lubricating gel tube;

(k) a set of step-by-step instructions for using items (a) to (j); and

(l) a container wherein items (a) through (j) are positioned inside the container.

5. The system of claim **4**, which includes self-care documentation for documenting instructions provided to the user in the use of the system.

6. A patient education system for educating a user in performing intermittent male catheterization, said system comprising;

a male catheterization system including:

(a) a collection basin;

(b) a plurality of disposable wipes

(c) a plurality of male catheters;

(d) lubricant gel;

(e) a plurality of clean catheter bags;
(f) a used catheter bag;
(g) a urine record card;
(h) a lubricating gel tube;
(i) step-by-step instructions for using items (a) to (h);
(j) a container wherein items (a) through (h) are positioned inside the container; and

self-care documentation an instructor uses to educate the user in performing intermittent male catheterization using the system.

7. The patient education system of claim **6**, wherein the self-care documentation includes at least one acknowledgement section for documenting instructions provided to the users.

8. A intermittent male catheterization system, said system comprising:

a plurality of infection prevention devices said infection prevention devices includes at least one disposable wipe, at least one male catheter bag, and alcohol gel;

at least one male catheterization device;

at least one recording device including a collection basin and a record card which enables a user to record an amount of drainage from a male catheter site;

at least one set of step-by-step instructions for using the infection prevention devices, male catheterization device and recording device;

self-care documentation including an acknowledgement section for documenting instructions provided to user in the use of the system; and a container for holding the system.

9. An intermittent male catheterization system for use by a user and containing apparatus for a plurality of male catheter insertions, said system comprising:

(a) a collection basin;
(b) a plurality of disposable wipes
(c) a plurality of male catheters;
(d) a lubricant gel;
(e) a plurality of clean catheter bags;
(f) a used catheter bag;
(g) a urine record card;
(h) a lubricating gel tube;
(i) a set of step-by-step instructions for using items (a) to (h); and
(j) a container wherein items (a) through (h) are positioned inside the container.

10. The system of claim **9**, which includes self-care documentation for documenting instructions provided to the user in the use of the system.

* * * * *

Jan. 19, 1965 H. S. DISSTON 3,166,189

CATHETERIZATION PACKAGE

Filed March 26, 1963 2 Sheets-Sheet 1

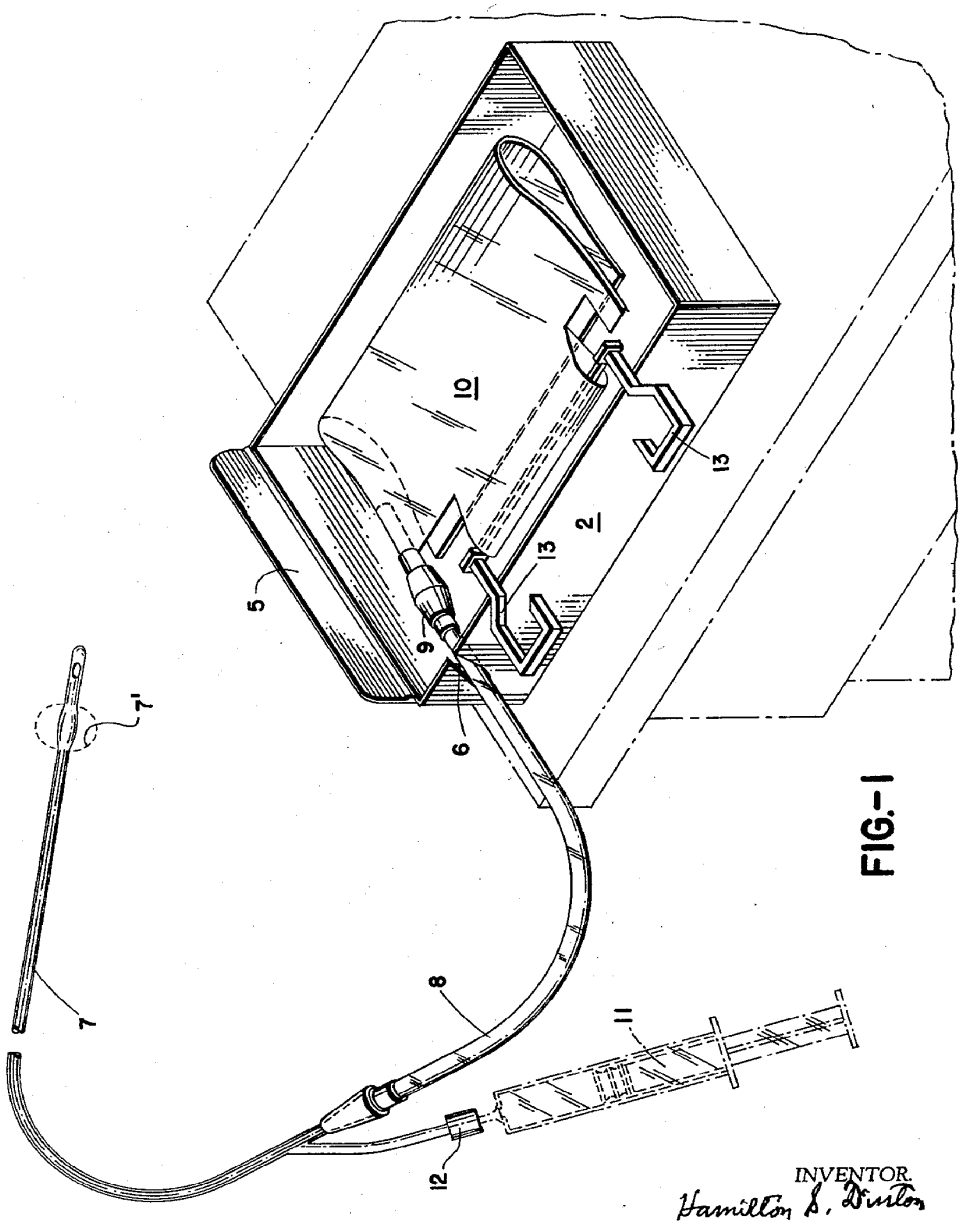

FIG.-1

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CATHETERIZATION PACKAGE

Filed March 26, 1963 2 Sheets-Sheet 2

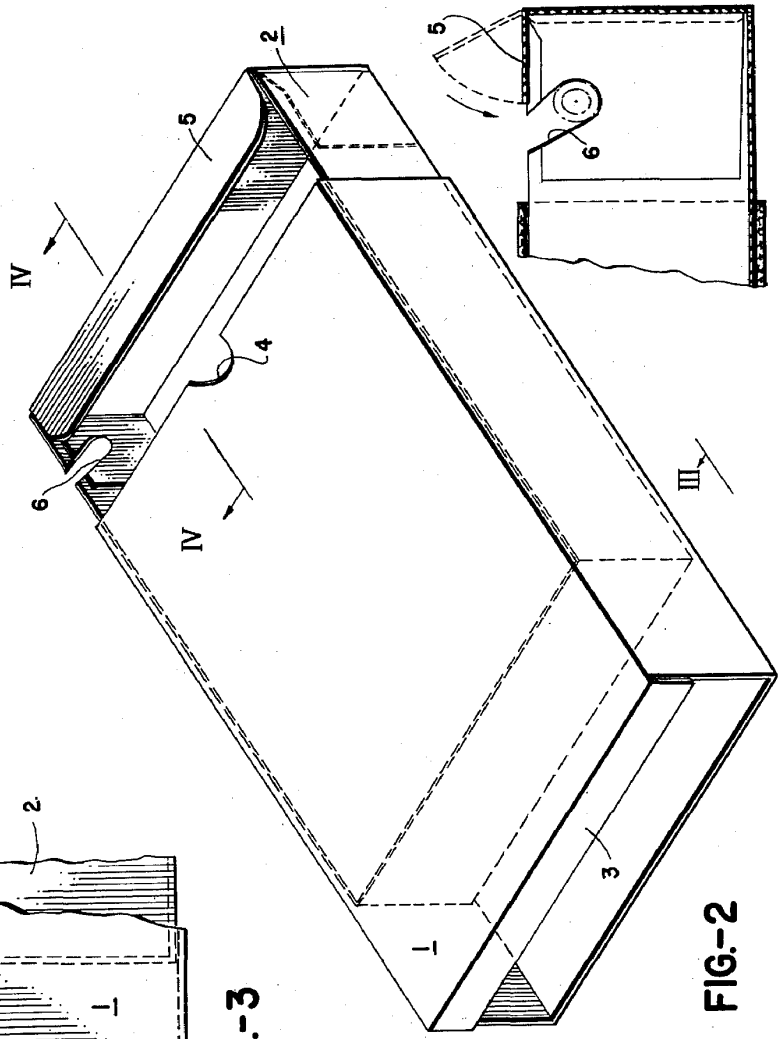

FIG.-2

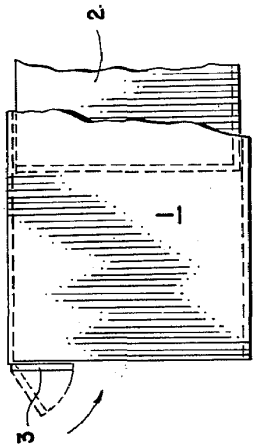

FIG.-3

FIG.-4

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Bard Exhibit 1004.0513

United States Patent Office 3,166,189 Patented Jan. 19, 1965

3,166,189

CATHETERIZATION PACKAGE

Hamilton S. Disston, Basking Ridge, N.J., assignor to C. R. Bard, Inc., Murray Hill, N.J., a corporation of New York

Filed Mar. 26, 1963, Ser. No. 268,110
10 Claims. (Cl. 206—63.2)

This invention relates to a catheterization package, including a package specially designed for cooperation with a pre-assembled catheter-tube-bag assembly contained therein.

In effecting catheterization of a patient requiring such treatment it has long been customary to take (not necessarily in this order) such separate steps as removing a sterile catheter from its envelope, applying lubricant to it, inserting it in the patient, inflating its balloon (if it is a Foley type retention catheter), connecting a drainage tube to its proximal end, connecting a drainage bag to the tube and hanging the bag on a support. The catheter, tube, bag and support have normally been supplied separately, for assembly at the time of use while observing such precautions respecting sterility as may be possible and necessary, and putting up with the inconvenience and delay because no better procedure was available.

According to the present invention, there is made available, in a sealed sterile package, a two-part container constructed so that it can be opened only in one direction and in a manner which avoids contamination of the contents, the contents including (all sterile) gloves which can be put on without destroying sterility, a protective sheet, lubricant, water (for inflation of the balloon), a syringe and, most importantly, a pre-assembled catheter-drainage tube-drip chamber-drainage bag and hanger, assembly, sterile and ready for use immediately. The container includes a tray portion having tube holding means, such as a notch, at one side so that the drainage bag may be left temporarily in the tray with the tube snapped in the notch to hold the drip chamber higher than the bag and prevent spillage or back flow when the catheter is first inserted and before the bag and its support have been installed on the bed rail, for instance. The pre-assembling and sterile packing of the catheter and its drainage system not only saves time and trouble but practically eliminates the danger of faulty connections and loss of sterility, inherent in the former system.

A practical embodiment of the invention is shown in the accompanying drawings wherein:

FIG. 1 represents a perspective view of the catheter-to-bag assembly, extended in condition for use with the bag temporarily left in the tray portion of the container from which the sleeve portion has been removed;

FIG. 2 represents a perspective view of the container, partly opened;

FIG. 3 represents a detail side elevation, from the line III—III in FIG. 2, and

FIG. 4 represents a detail vertical section, on an enlarged scale, taken on the line IV—IV of FIG. 2.

Referring to the drawings, the package includes a container having a sleeve portion **1** and a tray portion **2**. The sleeve portion is rectangular and open at both ends, but is provided at one end with a short flap **3**, integral with the top of the sleeve and extending down over about one-fourth to one-third of the height of the opening at that end. At the end of the sleeve opposite that to which the flap **3** is attached, the top is notched as shown at **4** to facilitate grasping and sliding out the tray portion.

The tray portion **2** is also rectangular, of a size to fit snugly within the sleeve portion, and open at the top but provided at one end with a short (one inch or somewhat less) inwardly directed flap **5**, integral with the end from which it extends. The flap **5** should, in any event, be

longer than the depth of the notch **4** and long enough so that the user's hand is not likely to come in contact with the contents. In one side wall of the tray portion, near the end having the flap **5**, there is provided a slanting notch **6**, preferably narrower at its top than the diameter of the drainage tube to be used with the package and enlarging to approximately the size of said tube in its lower portion. This notch **6** may extend down from the edge of the tray portion to a depth of about one-third the depth of the tray. Since both the sleeve and the tray may conveniently be formed of carboard or the like, having a certain amount of stiffness, the notch in the tray will retain its form and size well enough to serve the temporary purpose for which it is designed.

As sold, the container described above may contain the several catheterization appliances and accessories previously listed, arranged in such order and position as to be most conveniently available when the container is opened, and particularly the pre-connected drainage system of catheter **7**, drainage tube **8**, drip chamber **9** and drainage bag **10**, suitable adapters being interposed, if necessary, between the catheter and tube and/or between the drip chamber and bag. The container and its contents are sealed, in sterile condition, within a plastic outer envelope (not shown) which is preferably not opened or removed until the contents of the package are to be used. Certain smaller items may be collected and packed in an inner plastic envelope, if desired.

When the outer envelope has been removed and discarded the container can be opened, but only in the direction illustrated in FIG. 2. The short flap **3** on one end of the sleeve makes it difficult and inconvenient to slide the tray portion out that end but still leaves the end open enough so that the tray portion can be pushed out the opposite end. While the tray is being thus pushed by the fingers of one hand (e.g., the left hand) the other hand (e.g. right) grasps the slightly projecting end of the tray, with fingers underneath and thumb on the flap **5** (taking advantage of the presence of notch **4**, if necessary) and draws it out of the sleeve, which can then be discarded. Such contents of the tray portion as the pad or sheet, gloves, cleansing solution, lubricant, syringe and water packet are removed and put to their respective intended uses, the syringe being filled with water in preparation for inflation of the catheter balloon. Upon removal of the catheter and tube from the tray, the drainage bag **10** is left in the tray and the lower end of the tube **8** is snapped into the notch **6**, as shown in FIG. 1, where it is retained during the initial stage of the catheterization including insertion of the catheter **7** and inflation of the balloon **7'** by injection of sterile water from the syringe **11**, preferably through a valve, indicated generally at **12**. After the proper installation of the drainage system the bag is intended to be removed from the tray and hung at the side of the bed on a hanger **13** of any suitable design. When the hanger is of the type shown in copending application of Disston and Pyhel, Serial No. 268,159, filed March 26, 1963, it may be pre-assembled with the bag, requiring only adjustment from flat position to hanging position.

The package, and its contents, described above provide for the first time a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled. The container is so constructed that it can be opened without any part of either hand of the user coming in contact with the contents. When opened, the container presents the user first with a sheet or underpad, which is placed under the patient, and then with a pair of sterile disposable gloves, designed to be put on without need for touching the outside of either one, and after that all further manipulations are effected by the sterile gloved hands working with sterile pieces of equipment. Since the drainage sys-

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tem is pre-assembled, it is ready for use after the tube 8 has been snapped into notch 6 of the tray in order to establish, temporarily, the location and position of the bag 10, with the drip chamber higher than the bag. There is no possibility that some necessary and urgently needed item has been overlooked and is not immediately available, as can easily happen when the items have to be assembled individually from the stock room perhaps by more than one person, dividing the responsibilities of preparation.

It will be understood that various changes may be made in the form, construction and arrangement of the several parts without departing from the spirit and scope of the invention, and hence I do not intend to be limited to the details shown or described herein except as the same are included in the claims or may be required by disclosures of the prior art.

What I claim is:

1. A catheterization package comprising, an openable container of relatively stiff material and a pre-assembled drainage system including a catheter, a drainage tube and a drainage bag, said drainage system being packed in said container and said container being adapted, when open, to hold said bag in a position for temporary use.

2. A catheterization package according to claim 1 in which the container comprises a sleeve portion and a tray portion, the tray portion being slidable in one direction from a position entirely within the sleeve portion to a position entirely outside of the sleeve portion.

3. A catheterization package according to claim 2 in which the tray portion has a notch formed in one of its side walls, the sides of said notch being so spaced as to be able to engage the tube releasably, with the bag in the tray portion and the catheter in use.

4. A catheterization package according to claim 2 in which the tray portion is provided at one end with an integral protective inturned flap, whereby said end can be grasped and pulled to slide the tray portion out of the sleeve portion without touching or contaminating the contents.

5. A catheterization package according to claim 2 in which the sleeve portion is provided with an integral stop at one end, adapted to prevent sliding of the tray portion out of said end while permitting pushing of the tray portion in a direction to slide out the opposite end.

6. A catheterization package according to claim 5

in which the integral stop is a flap depending from the end of the sleeve top for a distance less than the height of the sleeve.

7. A catheterization package according to claim 2 in which the sleeve portion is provided with an integral stop at one end, adapted to prevent sliding of the tray portion out of said end while permitting pushing of the tray portion in a direction to slide out the opposite end and in which the tray portion is provided at one end with an integral inturned flap, whereby said end can be grasped and pulled to slide the tray portion out of the sleeve portion.

8. A catheterization package according to claim 7 in which the integral stop is a flap depending from the end of the sleeve top for a distance less than the height of the sleeve.

9. A catheterization package comprising, an openable sterile container and a pre-assembled sterile drainage system packed therein, the container including a tray portion adapted to be put in condition for use without contamination of its contents, and the drainage system including an assembly of catheter, drainage tube, drip chamber and bag, the tray portion being provided with means for engaging releasably the drainage tube adjacent the drip chamber to hold the drip chamber higher than the bag when the bag is in the tray portion and the catheter is in use.

10. A catheterization package according to claim 6 in which the means for engaging the drainage tube is a notch formed in one of the side walls of the tray portion, the sides of said notch being spaced by a distance no greater than the diameter of the drainage tube.

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Bard Exhibit 1004.0515

EXHIBIT 9

US007662146B2

(12) **United States Patent**
House

(10) **Patent No.: US 7,662,146 B2**
(45) **Date of Patent: Feb. 16, 2010**

(54) **INDWELLING URINARY CATHETERIZATION ASSEMBLY**

(75) Inventor: **Jamie Glen House**, Colorado Springs, CO (US)

(73) Assignee: **Colorado Catheter Company, Inc.**, Colorado Springs, CO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 101 days.

(21) Appl. No.: **11/652,528**

(22) Filed: **Jan. 12, 2007**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61M 25/10 (2006.01)
A61M 29/00 (2006.01)

(52) **U.S. Cl.** **604/544**; 604/103.05; 604/104; 604/915

(58) **Field of Classification Search** 604/103.05, 604/317, 544, 915
See application file for complete search history.

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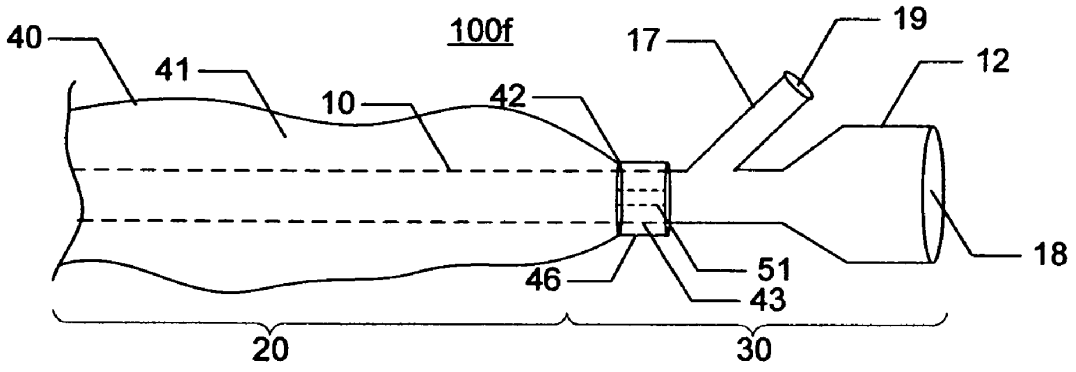
(57) **ABSTRACT**

An indwelling urinary catheter assembly is disclosed having an indwelling catheter and a sheath enclosing an insertable portion of the indwelling catheter.

23 Claims, 7 Drawing Sheets



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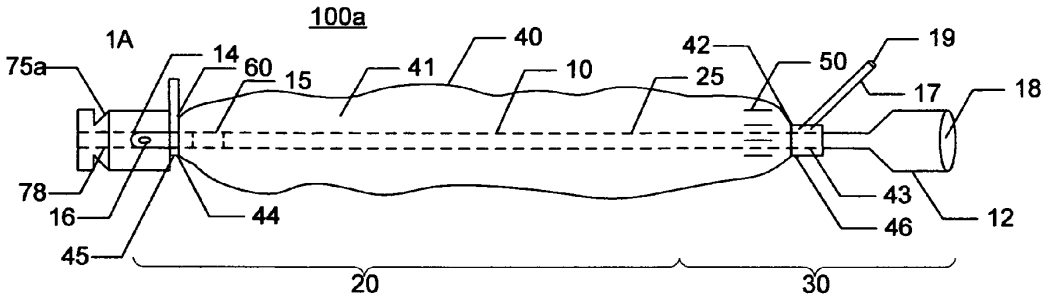

Fig. 1A

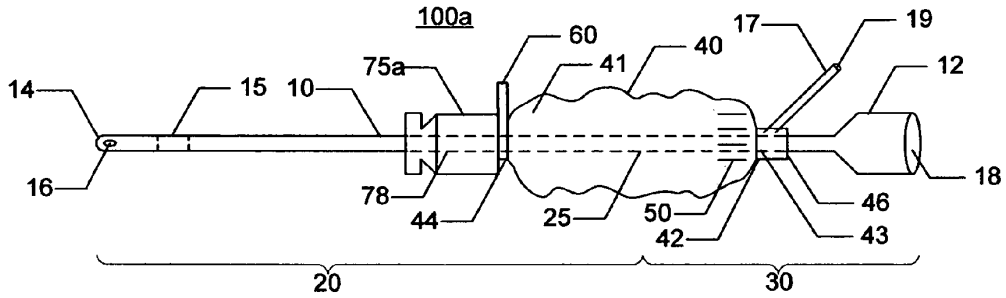

Fig. 1B

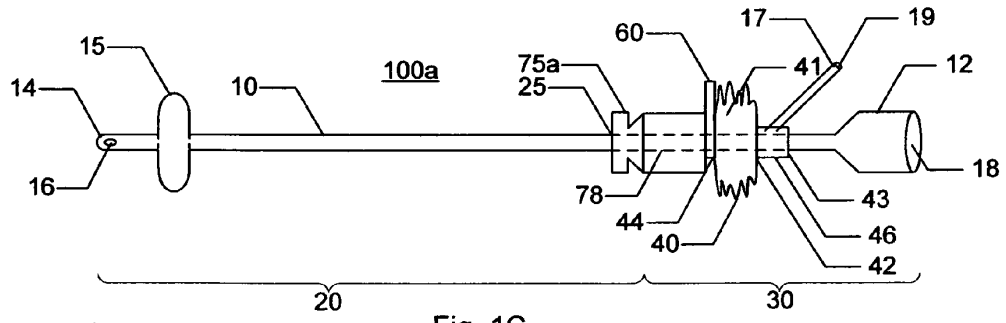

Fig. 1C

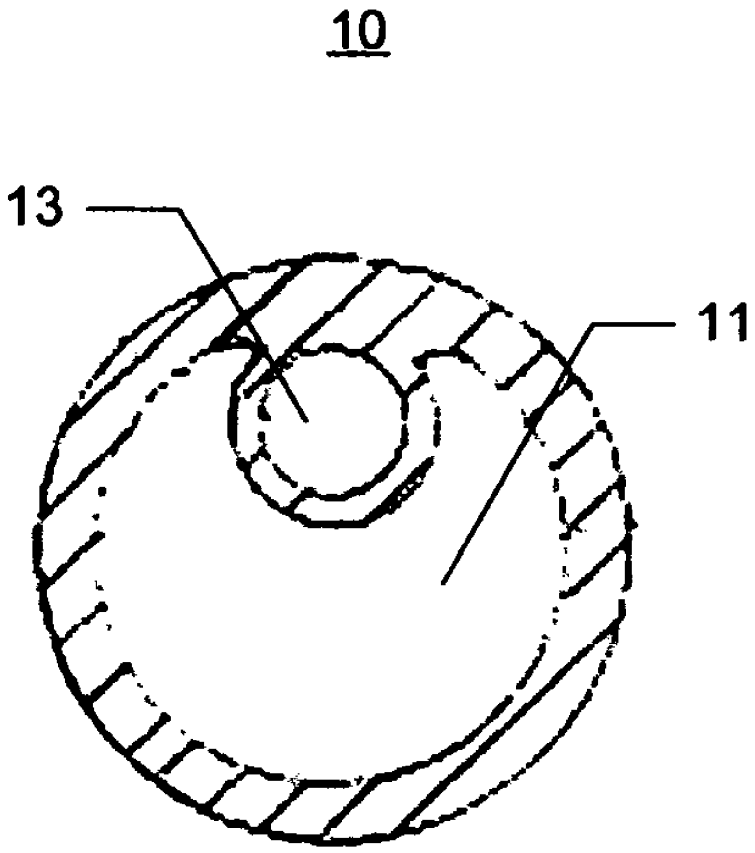

Fig. 1D

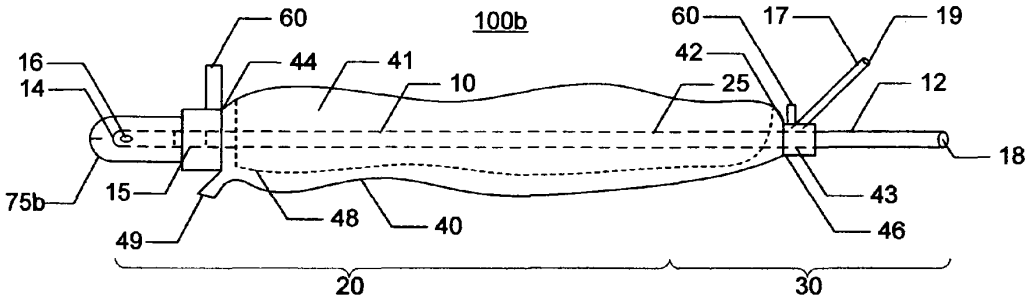

Fig. 2A

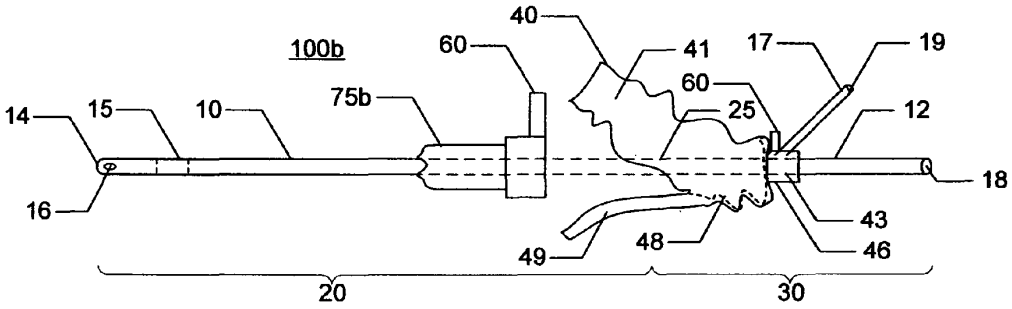

Fig. 2B

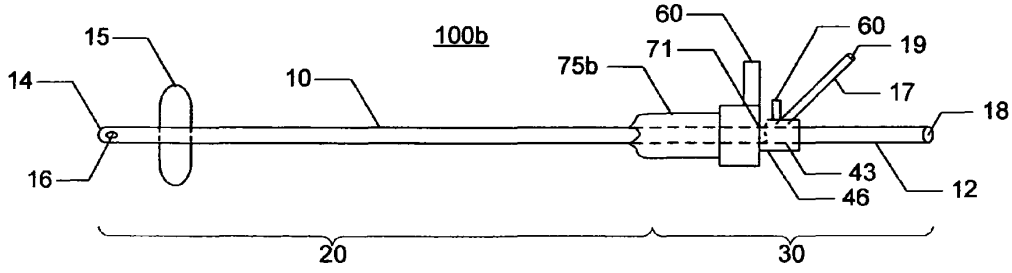

Fig. 2C

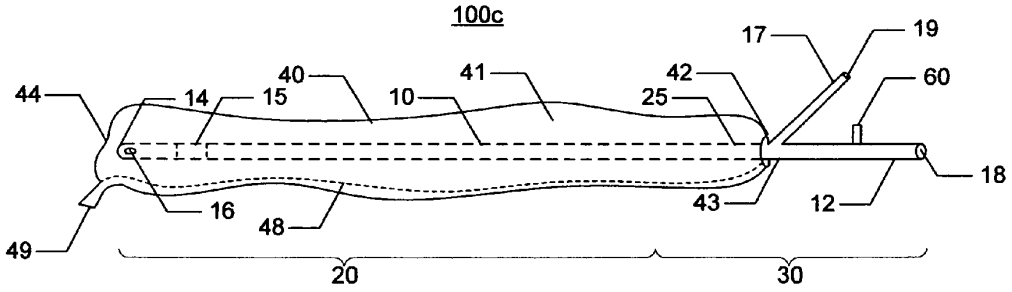

Fig. 3A

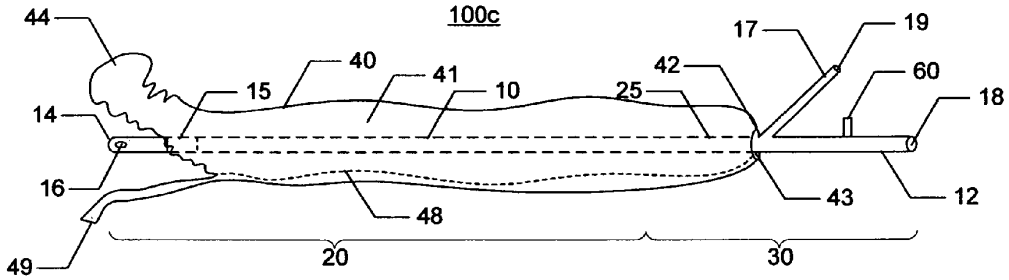

Fig. 3B

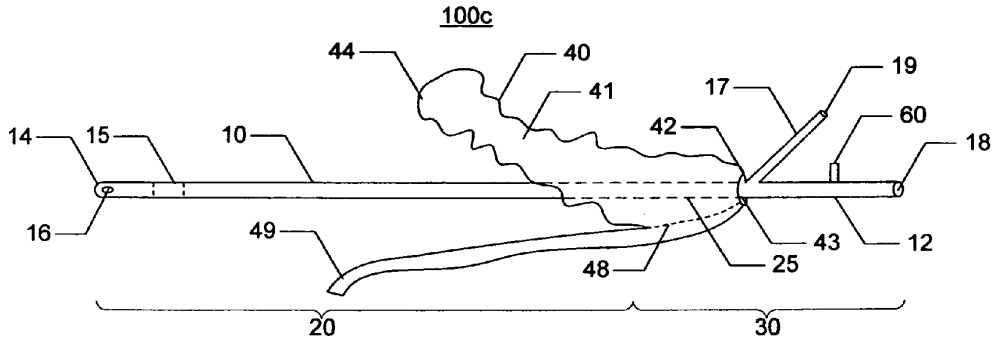

Fig. 3C

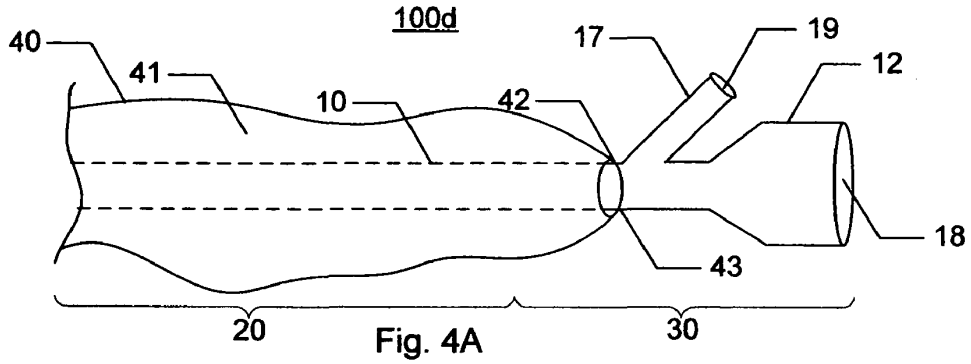

Fig. 4A

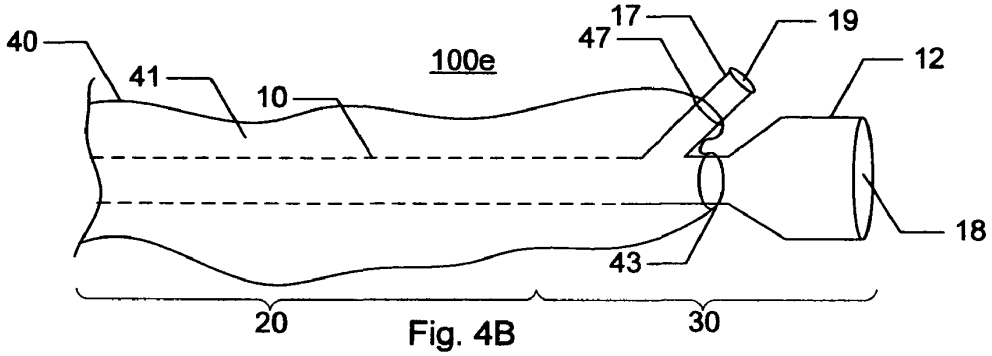

Fig. 4B

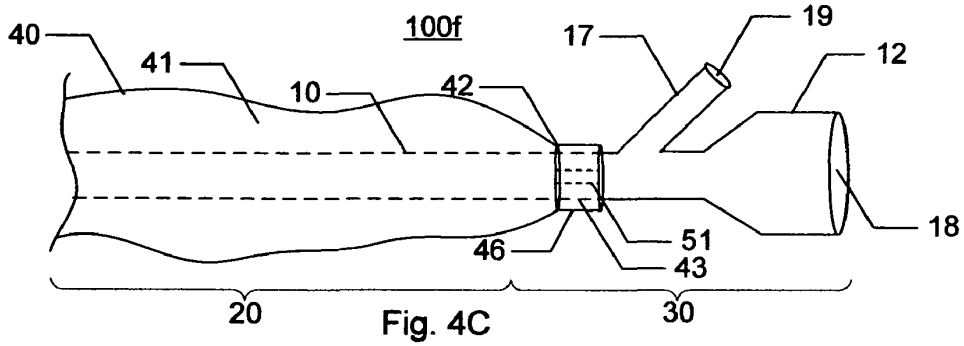

Fig. 4C

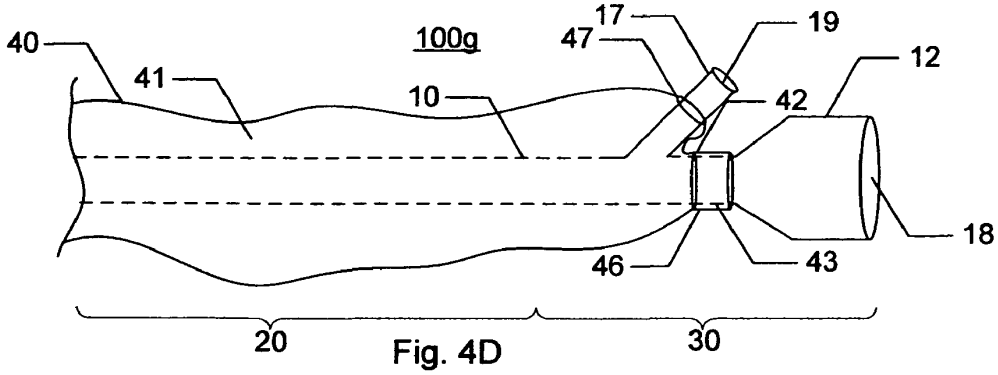

Fig. 4D

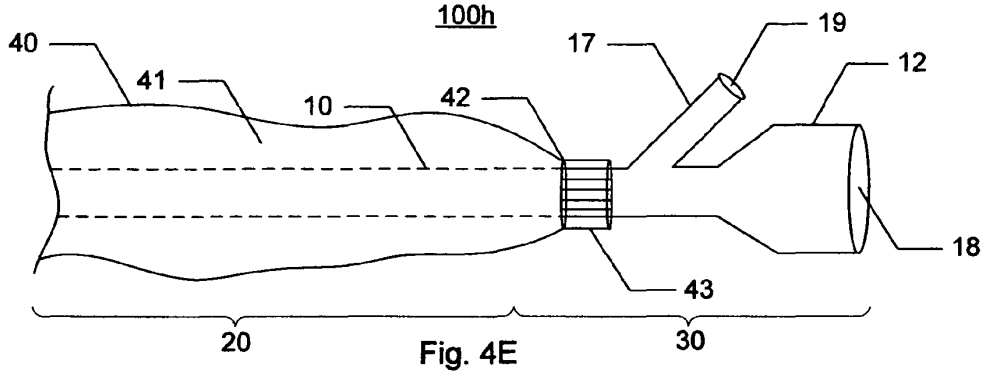

Fig. 4E

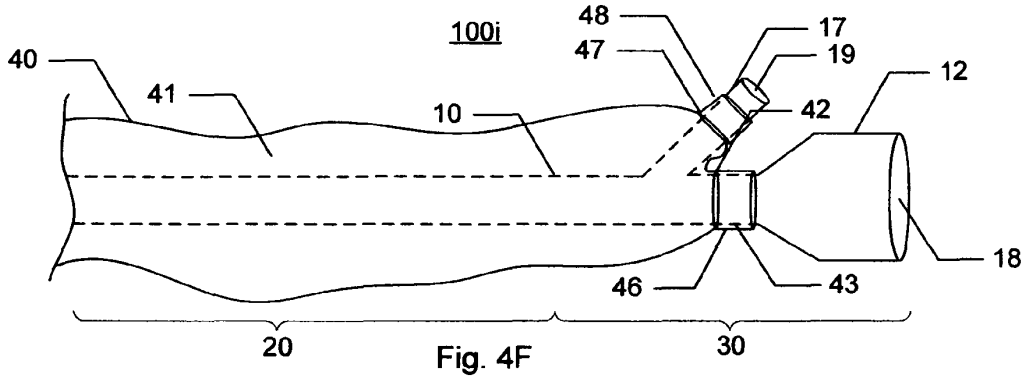

Fig. 4F

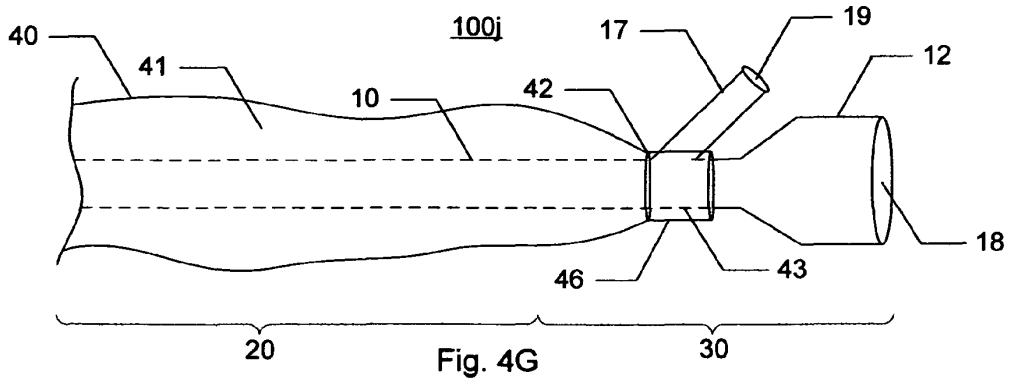

Fig. 4G

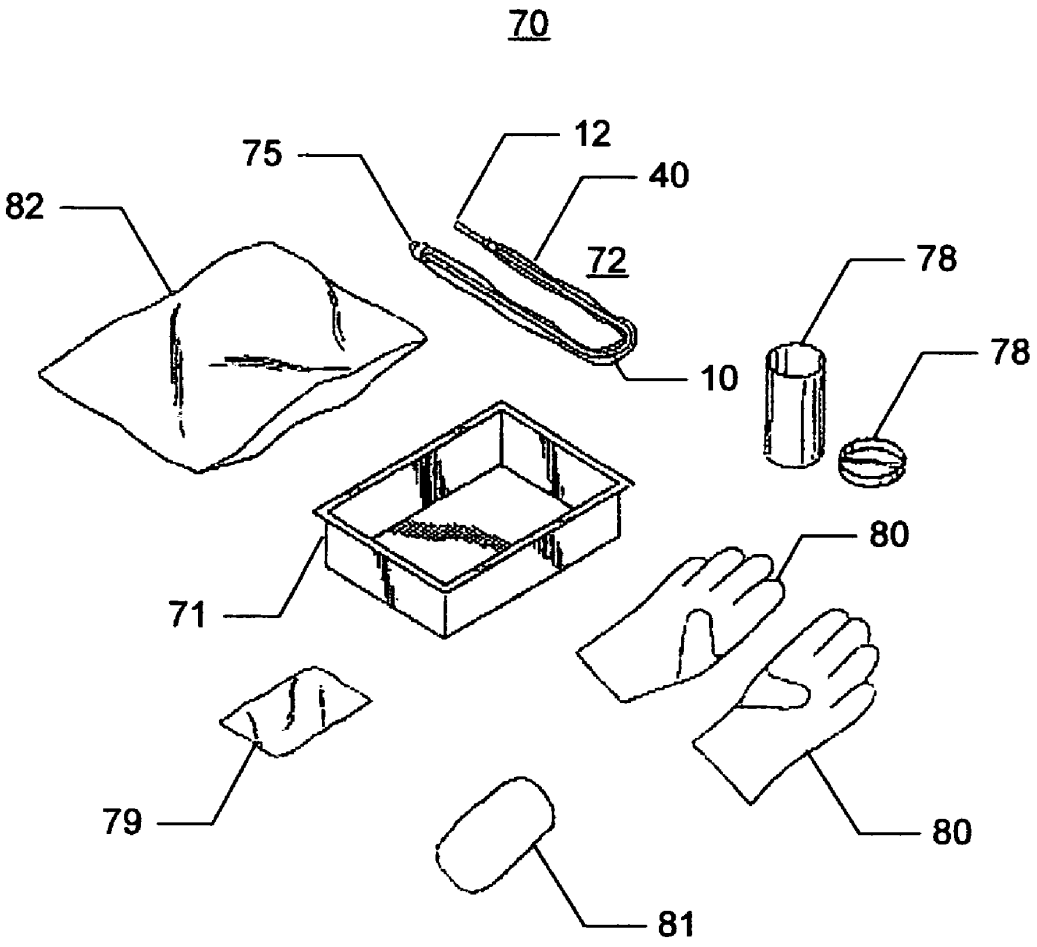

Fig. 5

INDWELLING URINARY CATHETERIZATION ASSEMBLY

This application claims priority to U.S. Provisional Patent Application Ser. No. 60/780,972, filed Mar. 10, 2006, the content of which is hereby incorporated by reference in its entirety into this disclosure.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present disclosure is directed to devices and methods for catheterization of the urinary bladder. More particularly, the present invention relates to devices and methods for extended or long-term catheterization of the urinary bladder.

2. Background of the Invention

The occasional or periodic catheterization of an individual's urinary bladder is a common practice today for many persons who are in a hospital setting, a nursing home, doctor's office, rehabilitation facility, or at home. For instance, a patient may be catheterized to treat such conditions as urinary retention, the inability to evacuate urine, or for the purpose of obtaining a sterile urine specimen from a patient in a doctor's office. Some catheterizations may be intermittent or repeated, while other catheterizations may be extended, or long-term. Extended catheterizations may require the use of an indwelling (e.g., "Foley") catheter.

Generally, catheterizations may be assisted (non self-catheterizations) or unassisted (self-catheterizations). In assisted catheterizations, it is commonplace for a nurse to perform the catheterization procedure using pre-assembled kits, or catheterization tray ("cath tray"), which typically includes a catheter, a drape, disposable gloves, antiseptic solution, cotton balls, a sealed packet containing sterile lubricating jelly, forceps, waterproof absorbent underpad, prepping cotton balls, a sterile urine specimen bottle, and a urine collection container. In particular, for long-term catheterizations, the catheter provided in the cath tray is typically an indwelling catheter capable of being sufficiently maintained within the patient for an extended period of time. All of these items are typically packaged together and sterilized.

To perform the typical catheterization, the nurse opens the tray, dons sterile gloves and places the drape around the patient's genitalia. The antiseptic solution is opened and poured over the cotton balls. The packet of lubricating jelly is opened and squeezed onto a sterile field. The patient's urethral opening is cleansed with the saturated cotton balls, the nurse holding each with the forceps. The nurse then runs the tip end of the catheter, comprising the first inch or two (about 2.5 cm to about 5 cm) of the insertable portion, through the lubricating jelly. The catheter is then inserted into the urethra and advanced until urine begins to flow. The urine is drained into the urine collection container. A urine specimen may be caught in the specimen bottle, if needed. For long-term catheterizations, a band around the tip of the indwelling catheter may be expanded such that the catheter may not be easily pulled from the bladder and is thus sufficiently maintained in the patient for an extended period of time. This basic procedure is widely used in inpatient hospitals around the world, and has remained essentially the same for 50 years.

Although the catheterization kit may be sterile prior to opening, the nurse must open the tray and handle the various items in the tray in order to use the kit. Further, even if special precautions are taken, maintaining a "sterile" environment during the procedure may present challenges. Non-sterile techniques and/or contamination of the catheter may result in infection of the patient's urinary tract. In some instances,

urinary tract infections may lead to morbidity and additional costs to the patient and society.

In addition to sanitation concerns, because multiple steps are involved to perform the procedure (e.g., sterilization, lubrication, insertion, etc.), a nurse may spend a significant amount of time (e.g., 10 minutes or more) carrying out each catheterization. Further, the "cath tray" procedure maybe expensive or otherwise impractical for use with some individuals and situations today.

A variety of catheterization kits and products are currently available. For instance, U.S. Pat. No. 6,090,075 (House I) discloses a catheterization kit including a catheter comprising a rigid introducer member for positioning catheter assembly against the urethral opening, a flexible catheter, and a flexible thin-walled sheath surrounding the catheter and partially covering the catheter introducer.

Some catheterization assemblies and kits employ hydrophilic catheters that are self-lubricating when wetted with a fluid (e.g., water) prior to use. U.S. Pat. No. 6,409,717 (Astra Aktiebolag) and U.S. Pat. No. 6,736,805 (AstraZeneca AB) describe apparatus for wetting a hydrophilic urinary catheter, comprising a wetting receptacle which defines a wetting fluid receiving area for receiving the catheter and a wetting fluid container having a discharge outlet movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the container. U.S. Pat. No. 6,634,498 (Coloplast A/S) describes certain urinary catheter assemblies including a urinary catheter having at least a part of its surface a hydrophilic surface layer intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium during manufacture of the catheter assembly, and a catheter package having a cavity for accommodation of the catheter. The package includes a compartment having walls of a gas impermeable material that accommodates the liquid swelling medium, and a pre-treated catheter for long term preservation of the low-friction surface character and provision of a ready-to-use catheter assembly.

Some of the aforementioned catheter devices include a protective sheath that surrounds the catheter. Such a protective sheath may serve multiple purposes. For instance, the sheath may prevent contamination of catheter as the catheter is handled prior to and/or during use. In addition, in some hydrophilic catheters, the sheath may serve to contain a wetting agent used to lubricate the catheter during use. However, certain of the aforementioned catheter devices are intended for intermittent or short-term catheterizations and may not work adequately for long-term or extended catheterizations.

Accordingly, there remains a need for an easy-to-use, sanitary and disposable catheterization assembly for extended or long-term catheterizations.

SUMMARY OF THE INVENTION

An exemplary embodiment disclosed herein serves as an indwelling urinary catheter assembly. In certain embodiments, the indwelling catheter assembly comprises an indwelling catheter including a first end having a urine inlet, a second end having a urine outlet, a takeoff port having a port bore, an expander, and a urethra insertable portion. The urine inlet and urine outlet are in fluid communication, and the port bore and the expander are in fluid communication. In addition, the indwelling catheter assembly further comprises a pliable sheath comprising a lumen, wherein the sheath encloses all or part of the insertable portion.

The foregoing has broadly outlined certain features of the embodiments described herein in order that the detailed

description that follows may be better understood. Additional features will be described hereinafter. It should be appreciated by those skilled in the art that the conception and the specific embodiments disclosed may be readily utilized as a basis for modifying or designing other devices, methods, or systems for carrying out the same purposes of the embodiments disclosed herein. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a side view of an embodiment of a sheathed indwelling catheter assembly.

FIG. **1**B is a side view of the sheathed indwelling catheter assembly of FIG. **1**A, with the sheath partially gathered.

FIG. **1**C is a side view of the sheathed indwelling catheter assembly of FIG. **1**A, with the sheath substantially gathered.

FIG. **1**D is an enlarged cross-section of the indwelling catheter of FIG. **1**A.

FIG. **2**A is a side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **2**B is a side view of the sheathed indwelling catheter assembly of FIG. **2**A, with the sheath partially gathered and partially removed.

FIG. **2**C is a side view of the sheathed indwelling catheter assembly of FIG. **2**A, with the sheath completely removed.

FIG. **3**A is a side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **3**B is a side view of the sheathed indwelling catheter assembly of FIG. **3**A, with the sheath partially gathered and partially removed.

FIG. **3**C is a side view of the sheathed indwelling catheter assembly of FIG. **3**A, with the sheath substantially gathered and substantially removed.

FIG. **4**A is a partial side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **4**B is a partial side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **4**C is a partial side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **4**D is a partial side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **4**E is a partial side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **4**F is a partial side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **4**G is a partial side view of another embodiment of a sheathed indwelling catheter assembly.

FIG. **5** shows the contents of an indwelling catheterization kit according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides for catheter and catheter assemblies capable of mating with adhesive pads in order to increase a catheterized patient's mobility and prevent movement of the catheter in and out (pistoning) of

The following discussion is directed to various embodiments of the invention. Although one or more of these embodiments may be preferred, the embodiments disclosed should not be interpreted, or otherwise used, as limiting the scope of the disclosure, including the claims. In addition, one skilled in the art will understand that the following description has broad application, and the discussion of any embodiment is meant only to be exemplary of that embodiment, and not intended to intimate that the scope of the disclosure, including the claims, is limited to that embodiment.

Certain terms are used throughout the following description and claims to refer to particular system components. As one skilled in the art will appreciate, different persons may refer to a component by different names. This document does not intend to distinguish between components that differ in name but not function. The drawing figures are not necessarily to scale. Certain features of the invention may be shown exaggerated in scale or in somewhat schematic form, and some details of conventional elements may not be shown in interest of clarity and conciseness.

In the following discussion and in the claims, the terms "including" and "comprising" are used in an open-ended fashion, and thus should be interpreted to mean "including, but not limited to . . . . " Also, the term "couple" or "couples" is intended to mean either an indirect or direct connection. Thus, if a first device couples to a second device, that connection may be through a direct connection, or through an indirect connection via other devices and connections.

Also, the term "distal" is intended to refer to positions relatively away from the patient when the catheter is in use, while the term "proximal" is intended to refer to positions relatively near the patient when the catheter is in use. Thus, the proximal end of a device is relatively near the patient as compared to the distal end of the device, which is relatively away from the patient.

U.S. Pat. No. 6,090,075 (House I), U.S. App. No. 60/708,893 (House II), and U.S. application Ser. No. 11/326,699 (House III), and U.S. Provisional Application U.S. Express Mail Label No. EV 303424660 US, filed concurrently herewith, are each hereby incorporated herein by reference in their entirety.

Referring to FIG. **1**A, an embodiment of a sheathed indwelling catheter assembly **100***a* is shown. Assembly **100***a* comprises a flexible indwelling catheter **10** and a protective sheath **40**. Catheter **10** includes a urethra insertable portion **20** (portion insertable into a patient's urethra) and a non-insertable portion **30** (portion not intended to be inserted into the patient). Insertable portion **20** commences at a catheter tip **14** and ends at an insertion stop location **25**, adjacent non-insertable portion **30**.

Catheter **10** further comprises one or more urine inlet(s) **16** in tip **14**, a distal end **12** including a urine outlet **18**, and a urine conduit **11** in fluid communication with inlet(s) **16** and outlet **18**. In this configuration, when catheter **10** is sufficiently inserted into a patient's bladder, urine enters catheter **10** through inlet(s) **16**, is conducted through urine conduit **11** of catheter **10**, and exits catheter **10** at outlet **18**. Optionally, a urine collection bag or receptacle may be coupled to outlet **18** such that urine may exit outlet **18** into the collection bag.

In addition, catheter **10** comprises a takeoff port **17** having a port bore **19**, an expander conduit **13**, and an expander **15**. Port bore **19** is in fluid communication with expander **15** via expander conduit **13**. As with many indwelling catheters, fluid (e.g., sterile water, saline solution, air, etc.) may be injected into port bore **19** via takeoff port **17** to fill and expand expander **15**. In this manner, once catheter **10** is properly positioned in the bladder of the patient, expander **15** may be expanded (e.g., "ballooned") such that tip **14** of catheter **10** may be maintained within the patient's bladder for an extended period of time (e.g., tip **14** is not easily withdrawn from the patients bladder when expander **15** is expanded). Once the catheterization is no longer necessary, fluid may be withdrawn from expander **15** through port bore **19** and out of catheter **10**, thereby reducing the size of expander **15** such that catheter **10** may be removed from the patient. Port bore **19**,

expander conduit **13**, and expander **15** are not in fluid communication with inlet(s) **16**, urine conduit **11**, nor outlet **18**. In other words, there is no mixing of fluids within expander conduit **13** and urine conduit **11**. In select embodiments, takeoff port **17** is located in the distal ⅓rd of catheter **10**.

FIG. **1**D shows an enlarged cross-section of catheter **10** taken between expander **15** and takeoff port **17**. Expander conduit **13** allows fluid communication between expander **15** and port bore **19**. Further, urine conduit **11** allows fluid communication between one or more inlet(s) **16** and urine outlet **12**. However, as best seen in FIG. **1**D, there is no fluid communication between urine conduit **11** and expander conduit **13**.

Catheter **10** may be similar to conventional flexible indwelling catheters, sometimes referred to as "Foley" catheters. Catheter **10** may comprise any suitable material including without limitation, vinyl, red rubber latex, silicone elastomer, or the like.

Referring again to FIG. **1**A, catheter tip **14** initially rests inside, and is supported by, an introducer **75***a*. In this embodiment, introducer **75***a* is an introducer similar to that disclosed in House II. However, in other embodiments, the introducer enclosing tip **14** may be any suitable device capable of preventing direct contact of tip **14** with non-sterile surfaces. Introducer **75***a* slidingly receives catheter **10**. In particular, as best seen in FIGS. **1**A-**1**C, tip **14** and insertable portion **20** are intended to slide through introducer **75***a*, thereby advancing insertable portion **20** into the patient's urethra. Introducer **75***a* includes a conduit or guide **78** that controls the direction of motion of catheter **10**, including tip **14**, relative to introducer **75***a*.

Sheath **40** comprises a first sheath terminus **44** and a second sheath terminus **42**. First sheath terminus **44** comprises a first collar **45** coupled to introducer **75***a*. First sheath terminus **44** slidingly engages catheter **10**. First collar **45** is fixed to introducer **75***a* by first collar **45** such that first collar **45** does not move rotationally or translationally relative to introducer **75***a*. In different embodiments, first sheath terminus may not comprise a collar. Moreover, in other embodiments, first sheath terminus **44** may not be fixed to introducer **75***a* or any other device that covers tip **14**, if provided. Further, in certain embodiments, similar to that shown in FIGS. **2**A and B, first sheath terminus **44** is removably coupled to an introducer. Still further, in some embodiments (e.g., FIG. **3**A), first sheath terminus **44** completely encloses tip **14**.

Still referring to FIGS. **1**A-**1**C, in this embodiment second sheath terminus **42** comprises a second collar **46**. Second collar **46** is coupled to catheter **10** at an attachment point **43**. Attachment point **43** is provided between tip **14** and distal end **12**. Second collar **46** is coupled to catheter **10** at attachment point **43**, which straddles takeoff port **17**. However, in general, second sheath terminus **42** (e.g., second collar **46**) may be coupled to catheter **10** in any suitable location including without limitation, straddling takeoff port **17**, between tip **14** and takeoff port **17**, between takeoff port **17** and distal end **12**, or other locations.

In the embodiment shown in FIGS. **1**A-**1**C, second collar **46** is fixed to catheter **10** such that second collar **46** does not move rotationally or translationally relative to catheter **10**. However, in general, second sheath terminus **42** (e.g., second collar **46**) may be coupled to catheter **10** by any suitable means including without limitation, by heat fitting (e.g., partially melting second sheath terminus **42** to catheter **10**) (e.g., FIG. **4**E), by pressure fitting, by adhesive (e.g., glue), by a collar attached to second sheath terminus **42** and catheter **10** (e.g., FIG. **1**A), or combinations thereof. In different embodiments (e.g., FIG. **4**A), second sheath terminus **42** may slidingly engage catheter **10** at attachment point **43**.

As shown in FIGS. **1**A-**1**C, fixation tab **60** extends from first collar **45**. In other embodiments, no fixation tab **60** is provided. In general, fixation tab **60** serves to couple catheter **10** to the patient once tip **14** is properly positioned in the patient's bladder. Fixation tab **60** is discussed in more detail below.

Sheath **40** encloses all, or at least part of, insertable portion **20**, thereby creating a sheath lumen **41** between sheath **40** and catheter **10**. Sheath **40** may comprise any suitable material. For example, sheath **40** may be an elongated, flexible plastic membrane, such as a bag. Further, sheath **40** and lumen **41** may comprise any suitable geometry including without limitation, rectangular, cylindrical, flattened, inflated, partially inflated, or combinations thereof.

Together, introducer **75***a* (or other device covering tip **14**) and sheath **40** cooperate to enclose and protect insertable portion **20** of catheter **10** from contamination prior to and during use. In the embodiment shown in FIG. **1**A, insertable portion **20** of catheter **10** is maintained in sterile condition inside introducer **75***a* and sheath **40**. In embodiments where no introducer **75***a*, or other device covering tip **14**, is provided (e.g., FIG. **3**A), insertable portion **20** of catheter **10** may be fully enclosed within sheath **40** and thereby maintained in sterile condition.

The urethra-insertable portion **20** of catheter **10** is generally the length of catheter that may be appropriately inserted into the patient's urethra in order to perform a successful catheterization to drain the patient's urinary bladder. In select embodiments, insertable portion **20** is about ⅔rd the length of catheter **10**. The actual length of catheter **10**, and the length of the insertable portion **20**, may depend on the application (e.g., adult or child size) and may also vary somewhat from one patient to another. As a practical matter, insertable portion **20** is decreased, at least to some extent, by the distance on catheter **10** required to accommodate introducer **75***a* (if provided) and sheath **40** when sheath **40** is gathered toward second sheath terminus **42**.

As discussed below in more detail (see "Catheterization Procedure"), during use of assembly **100***a*, flexible sheath **40** is gathered toward second sheath terminus **42** in order to advance tip **14** and insertable portion **20** into the patient's urethra Thus it can be readily appreciated that, in some embodiments, less than all of catheter **10** protected by the sheath **40** may be needed for insertion into the patient. Accordingly, an insertion stop location **25** (where the catheter stops near the urethral opening upon establishment of urine flow) may substantially coincide with attachment point **43**, or it may be spaced away from attachment point **43** (e.g., closer to tip **14**).

FIG. **1**A shows the urethra-contacting end of assembly **100***a* (proximal end of assembly **100***a*) as including an introducer **75***a*. However, in general, the proximal end of assembly **100***a* may comprise any suitable configuration. For example, in some embodiments, introducer **75***a* may be replaced with another type of introducer or tip cover to keep sterile at least the insertable portion **20** of the catheter **10** prior to insertion. In other embodiments, introducer **75***a* or other tip cover may be similar to those that are known in the art. For example, the introducer may comprise an O'Neil® type introducer with "cross-cut" end (e.g., FIG. **2**A-**2**C) or an introducer similar to that disclosed in House II. Embodiments of an O'Neil® type introducer are disclosed in U.S. Pat. No. 4,652,259, which is hereby incorporated herein by reference in its entirety. Further, introducer **75***a* or other tip cover may be removable from catheter **10** and/or slidingly engage catheter **10** (e.g., be slid

toward distal end **12** to advance insertable portion **20** as shown in FIGS. **1**B and C). Still further, in some embodiments (e.g., FIG. **3**A), catheter **10** may be provided without introducer **75***a* or other tip cover, and sheath **40** may completely or partially enclose insertable portion **20** of catheter **10**. Additional suitable configurations for the proximal end of assembly **100***a* are disclosed in House I, House II, and House III, which are each hereby incorporated by reference in their entirety.

In use, it may be desirable to lubricate tip **14** and a proximal portion insertable portion **20** prior to advancing tip **14** into the patient's urethra. Thus, in some embodiments, introducer **75***a* (or other protective tip cover) and/or lumen **41** of sheath **40** may contain a lubricant, or a wetting agent in the case of a hydrophilic indwelling catheter. Alternatively, tip **14** and a proximal portion of insertable portion **20** may be lubricated by applying a sterile lubricating gel.

Still referring to FIGS. **1**A-**1**C, during use, a nurse may grasp introducer **75***a* and/or catheter **10** through flexible sheath **40** near the tip end **14** and align the catheter tip **14** with the patient's urethra. The nurse may then push tip **14** through introducer **75***a* and advance catheter tip **14** into the patient's urethra. In embodiments that do not include an introducer **75***a* or other tip cover (e.g., FIGS. **3**A and B), a portion of sheath **40** near tip **14** may need to be opened to allow catheter tip **14** to emerge.

Sheath **40** is gathered toward distal end **12** to further advance catheter tip **14**, giving catheter assembly **100***a* an appearance similar to that shown in FIG. **1**B. As the catheter tip **14** is advanced by the nurse, a portion of sheath **40** becomes gathered toward second sheath terminus **42**. By appropriately repositioning the nurse's grasp on introducer **75***a* and/or catheter **10** through sheath **40**, and continuing to gently urge the insertable-portion **20** of catheter **10** in the patient's urethra, sheath **40** may continue to be gathered toward distal end **12**, giving catheter assembly **100***a* an appearance similar to that shown in FIG. **1**C. When the catheter tip enters the patient's bladder a sufficient distance to commence optimal draining of accumulated urine (e.g., about 1 cm), further insertion of insertable portion **20** ceases. At this point, the nurse may inflate expander **15** by injecting a fluid (e.g., sterile water, saline solution) into port bore **19** provided in takeoff port **17**. In some embodiments, expander **15** may be inflated by injecting 5-10 cc of fluid. Once expander **15** is inflated, as best seen in FIG. **1**C, to facilitate proper retention of catheter **10** in the patient's urethra for an extended period of time. Further, once tip **14** is properly positioned within the patient's bladder for extended catheterization, fixation tab **60** may be coupled to the patient. By coupling fixation tab **60** to the patient, catheter **10** may be maintained in a proper orientation, and further, introducer **75***a* and sheath **40** may be maintained in the gathered position shown in FIG. **1**C. A urine collection bag or receptacle (not shown) may be employed to provide storage for drained urine.

Thus, introducer **75***a* and sheath **40** cooperate to protect insertable portion **20** from contamination prior to and during use. For example, before use, introducer **75***a* and sheath **40** completely enclose insertable portion **20** of catheter **10**. In addition, during use, introducer **75***a* and sheath **40** are pulled back by the nurse as insertable portion **20** is advanced into the patient, without the need for the nurse to directly contact insertable portion **20**, the nurse instead grasping the portion of catheter **10** that is enclosed within sheath **40**. By deterring contamination, introducer **75***a* and sheath **40** may reduce the occurrences of urinary tract infections in patients. Further, by using introducer **75***a* and sheath **40** to maintain a sterile catheter, the need for separate antiseptic solutions, cotton balls, forceps and other devices conventionally used to maintain the sterility of an indwelling catheter may be eliminated. By eliminating these additional items required to maintain sterility of an indwelling catheter, embodiments of the sheathed indwelling catheter assembly described herein are intended to reduce the cost for indwelling catheter kits, reduce the time required to perform an indwelling catheterization, and reduce urinary tract infections.

In some catheter assemblies, the process of gathering sheath **40** to advance insertable portion **20** may result in an increase in pressure (e.g., a pressure build-up) in lumen **41**. This may particularly be a problem with catheter assemblies in which there is limited or no means to relieve pressure build-up within lumen **41** (e.g., no fluid communication between lumen **41** and the environment outside sheathed catheter assembly **100***a*). Without being limited by theory, as the flexible sheath **40** is gathered, the volume of lumen **41** may decrease. In embodiments in which lumen **41** is not in fluid communication with a collection bag or an environment outside sheath **40**, some fluid contained within lumen **41** (e.g., air, wetting agent, etc.) may become trapped and compressed, resulting in a pressure buildup within lumen **41** (e.g., sheath **40** may "balloon-up"). Excessive pressure buildup within lumen **41** may result in undesirable consequences. For instance, excessive pressure in lumen **41** may create forces tending to push introducer **75***a* towards tip **14**, thereby limiting the degree to which the catheter may be advanced into the urethra. In addition, pressure build-up may cause sheath **40** to "balloon up," thereby detrimentally affecting the ability of the user to grasp the catheter **10** through the sheath **40**. To help relieve pressure build-up within lumen **41**, one or more vents **50** may be provided in assembly **100***a* as shown in FIG. **1**A. Vents **50** are in fluid communication with lumen **40** and an environment outside sheath **41** and thus allow compressed fluid (e.g., air) within lumen **41** to escape lumen **41**. In the embodiment shown in FIGS. **1**A-**1**C, vents **50** are provided in sheath **40**. However, in other embodiments, vents **50** may be provided in any suitable location including without limitation, sheath **40**, first sheath terminus **44**, second sheath terminus **42**, introducer **75***a*, or combinations thereof. Still further, although vents **50** shown in FIG. **1**A are slits, vents **50** may be any suitable geometry including without limitation slits, perforations, holes, pores, or combinations thereof. Vents **50** are preferably located adjacent second sheath terminus **42** in the region of non-insertable portion **30**, such that any possible contamination of catheter **10** via vents **50** will occur as far from insertable portion **30** as possible. Additional suitable embodiments of vents are disclosed in U.S. Provisional Patent Application EV 303424660 US.

Referring to FIG. **2**A, another embodiment of a sheathed indwelling catheter assembly **100***b* is illustrated. Assembly **100***b* comprises a flexible indwelling catheter **10** and a protective sheath **40**. Indwelling catheter **10** includes a urethra insertable portion **20** and a non-insertable portion **30**. Insertable portion **20** commences at a catheter tip **14** and ends at an insertion stop location **25**, adjacent non-insertable portion **30**. Catheter **10** may be similar to conventional flexible indwelling catheters.

Catheter tip **14** initially rests inside, and is supported by, an introducer **75***b*. In this embodiment, introducer **75***b* is similar to an O'Neil® type introducer. However, in other embodiments, the proximal end of catheter **10** may be enclosed or covered by another type of introducer (e.g., introducer **75***a* in FIG. **1**A), a removable tip cover, or the like. As shown in FIGS. **2**A-**2**C, introducer **75***b* slidingly engages catheter **10**. In particular, introducer **75***b* is intended to slide along insertable portion **20**, thereby exposing insertable portion **20** such

that it may be inserted and advanced into the urethra of the patient. Introducer **75***b* may include a guide to aid in aligning tip **14** and controlling the direction of catheter **10**, including tip **14**.

Sheath **40** comprises a first sheath terminus **44** and a second sheath terminus **42**. First sheath terminus **44** is removably coupled to introducer **75**. Second sheath terminus **42** is removably coupled to a second collar **46**. Second collar **46** is coupled to catheter **10** at attachment point **43**. Attachment point **43** is provided between tip **14** and distal end **12**. In particular, attachment point **43** is positioned about takeoff port **17** such that second collar **46** straddles takeoff port **17**. By straddling takeoff port **17**, second collar **46** is effectively fixed to catheter **10** such that second collar **46** does not move rotationally or translationally relative to catheter **10**. In general, second sheath terminus **42** may be coupled to catheter **10** by any suitable means, including without limitation, by heat fitting (e.g., partially melting second sheath terminus **42** to catheter **10**), by pressure fitting, by adhesive (e.g., glue), by a collar attached to second sheath terminus **42** and catheter **10**, or combinations thereof.

A fixation tab **60** extends from introducer **75***b*. Further a second fixation tab **60** extends from second collar **46**. In other embodiments, no fixation tab **60** is provided. In general, fixation tab **60** serves to couple catheter **10** to the patient once tip **14** is properly positioned in the patient's bladder. Fixation tab **60** is discussed in more detail below.

Sheath **40** encloses all, or at least part of, insertable portion **20**, thereby creating a sheath lumen **41** between sheath **40** and catheter **10**. Sheath **40** may comprise any suitable material (e.g., flexible plastic material, flexible fabric material, or the like). Further, sheath **40** and lumen **41** may comprise any suitable geometry including without limitation, rectangular, cylindrical, flattened, inflated, partially inflated, or combinations thereof.

In the embodiment shown in FIGS. **2**A and **2**B, sheath **40** further comprises a pull tab **49** associated with a tear line **48**. Pull tab **49** may be provided at any suitable position on sheath **40**, however, preferably pull tab **49** is positioned near the proximal end of sheath **40**. Tear line **48** may be a pre-weakened (e.g., very thin, slightly perforated, etc.) line along sheath **40** that is intentionally provided therein to permit the sheath to tear under a slight to moderate force. Tear line **48** is intended to tear as pull tab **49** is pulled away from sheath **40**. In particular, tear line **48** is intended to tear under force applied to pull tab **49** before any other region of sheath **40** tears. Tearing sheath **40** along tear line **48** permits sheath **40** to be removed from its position disposed about catheter **10**.

Together, introducer **75***b* and sheath **40** cooperate to enclose and protect insertable portion **20** of catheter **10** from contamination prior to and during use. In the embodiment shown in FIG. **2**A, insertable portion **20** of catheter **10** is maintained in sterile condition inside introducer **75***b* and sheath **40**.

As discussed above, the urethra-insertable portion **20** of catheter **10** is generally the length of catheter that may be appropriately inserted into the patient's urethra in order to perform a successful catheterization to drain the patient's urinary bladder. As a practical matter, insertable portion **20** is decreased, at least to some extent, by the distance on catheter **10** required to accommodate introducer **75***b*, if provided, as introducer **75***b* is gathered towards second collar **46**. In different embodiments, the introducer (e.g., introducer **75***a*, introducer **75***b*) or other tip cover may be designed to be completely removed from catheter **10** such that the introducer or tip cover does not take up space on catheter **10**. For example, the introducer may be designed to be a "breakaway" introducer. In addition, in the embodiment shown in FIGS. **2**A-**2**C, gathering sheath **40** towards distal end **12** does not have the effect of decreasing or limiting the length of catheter **10** serving as insertable portion **20** because sheath **40** may be removed from catheter **10** as it is gathered toward second collar **46** (see FIGS. **2**B and **2**C).

FIGS. **2**A-**2**C show the urethra-contacting end of assembly **100***b* (proximal end of catheter **10**) as including an introducer **75***b*. However, in general, the proximal end of catheter **10** may comprise any suitable configuration. In some embodiments, introducer **75***b* may be similar to those that are known in the art. For example, in some embodiments the proximal end of catheter **10** may be enclosed or covered by an introducer similar to that disclosed in FIG. **1**A or other type of protective tip cover capable of keeping at least the insertable portion of the catheter sterile prior to and during use.

As discussed above, in use, it may be desirable to lubricate tip **14** and a proximal portion of insertable portion **20** prior to advancing tip **14** into the patient's urethra. Thus, in some embodiments, introducer **75***b* and/or lumen **41** of sheath **40** may contain a lubricant or wetting agent in the case of a hydrophilic indwelling catheter. Alternatively, a sterile lubricating gel may be applied to tip **14** and a proximal portion of insertable portion **20** prior to insertion.

Referring to FIGS. **2**A-**2**C, during use, a nurse may grasp introducer **75***b* and align introducer **75***b* and catheter tip **14** with the patient's urethra. The nurse may then push the proximal tip of introducer **75***b* into the patient's urethra approximately 1-2 cm. Then the nurse may grasp catheter **10** through sheath **40** and advance tip **14** through introducer **75***b* and into the patient's urethra.

As insertable portion **20** is advanced into the patient's urethra, a portion of sheath **40** may become gathered toward second sheath terminus **42**. At some point, the nurse may begin pulling on pull tab **49** to start tearing sheath **40** along tear line **48** as best illustrated in FIG. **2**B. The nurse may begin tearing sheath **40** along tear line **48** when introducer **75***b* is positioned ⅓ to ½ the way down insertable portion **20**, or when tip **14** is sufficiently in the patient's bladder.

By appropriately repositioning the nurse's grasp on introducer **75***b* and/or catheter **10** through sheath **40**, and continuing to gently urge the insertable-portion **20** of catheter **10** into the patient's urethra, sheath **40** may continue to become gathered toward second sheath terminus **42**. Periodically, the nurse may further pull pull tab **49** to continue tearing sheath **40** along tear line **48**. When the catheter tip enters the patient's bladder a sufficient distance to commence optimal draining of accumulated urine (e.g., about 1 cm), further insertion of insertable portion **20** is halted. At this point, the nurse may inflate expander **15** by injecting a fluid (e.g., sterile water, saline solution) into port bore **19** provided in takeoff port **17**. If sheath **40** has not been removed by this point, the nurse may remove the remainder of sheath **40** may be removed from catheter **10** by pulling on pull tab **49**. Further, once tip **14** is properly positioned within the patient's bladder and sheath **40** is completely removed from catheter **10**, introducer **75***b* may be secured in position adjacent collar **46** as illustrated in FIG. **2**C. In some embodiments, introducer **75***b* may be coupled to second collar **46** at attachment point **71**. In such embodiments, introducer **75***b* may be coupled to second collar **46** by any suitable means including without limitation, a locking mechanism, an adhesive, or combinations thereof. In addition, fixation tab **60** may be employed to couple catheter **10** to the patient. By coupling fixation tab **60** of introducer **75***b* to the patient, catheter **10** may be maintained in a proper orientation, and further introducer **75***b* may be maintained in gathered position shown in FIG. **2**C.

Thus, introducer **75***b* and sheath **40** may prevent contamination of insertable portion **20** of indwelling catheter **10** prior to and during use. For example, before use, introducer **75***b* and sheath **40** completely enclose insertable portion **20** of catheter **10**. In addition, during use, introducer **75***b* and sheath **40** are pulled back by the nurse as insertable portion **20** is advanced into the patient, without the need for the nurse to directly contact insertable portion **20**. By deterring contamination, introducer **75***b* and sheath **40** may reduce the occurrences of urinary tract infections in patients. Further, by using introducer **75***b* and sheath **40** to maintain a sterile catheter, the need for separate antiseptic solutions, cotton balls, forceps and other devices conventionally used to sterilize an indwelling catheter may be eliminated. By eliminating these additional items required to maintain sterility of an indwelling catheter, embodiments of the sheathed indwelling catheter assembly described herein are intended to reduce the cost for indwelling catheter kits, reduce the time required to perform an indwelling catheterization, and reduce urinary tract infections.

As previously discussed, if pressure build-up within lumen **41** is a concern, vents in fluid communication with lumen **41** and the environment outside sheath **40** may be provided.

Referring to FIG. **3**A, another embodiment of a sheathed indwelling catheter assembly **100***c* is illustrated. Assembly **100***c* comprises a flexible indwelling catheter **10** and a protective sheath **40**. Indwelling catheter **10** includes a urethra insertable portion **20** and a non-insertable portion **30**. Insertable portion **20** commences at a catheter tip **14** and ends at an insertion stop location **25**, adjacent non-insertable portion **30**.

Catheter tip **14** is completely enclosed within sheath **40**. No introducer or tip cover is provided. In different embodiments, an introducer or tip cover may be provided on tip **14** and inside sheath **40**. In such embodiments, the introducer or tip cover may be completely removable from tip **14** (e.g., removable in a "breakaway" fashion) and/or be configured to slide along catheter **10** from tip **14** toward insertion stop location **25** thereby extending insertable portion **20**. Such an introducer may comprise any suitable device including without limitation an introducer similar to that shown in FIG. **1**A, an O'Neil® type introducer (e.g. FIG. **2**A), or the like.

Referring again to FIG. **3**A, sheath **40** comprises a first sheath terminus **44** and a second sheath terminus **42**. First sheath terminus **44** extends beyond tip **14** and completely encloses and protects tip **14**. Second sheath terminus **42** is coupled to catheter **10** at attachment point **43**. Attachment point **43** is provided between tip **14** and distal end **12**. Second sheath terminus **42** slidingly engages catheter **10** about attachment point **43**. In the embodiment shown in FIGS. **3**A-**3**C, attachment point **43** is proximal takeoff port **17**, however, in different embodiments (e.g., FIG. **4**B), attachment point **43** may be distal to takeoff port **17**. In still other embodiments, second sheath terminus **42** may comprise a collar that slidingly engages or is fixed to catheter **10** (e.g., FIG. **4**C).

A fixation tab **60** extends from distal end **12**, distal to takeoff port **17**. In general, fixation tab **60** serves to couple catheter **10** to the patient once tip **14** is properly positioned in the patient's bladder. Fixation tab **60** is discussed in more detail below.

Sheath **40** encloses all, or at least part of, insertable portion **20**, thereby creating a sheath lumen **41** between sheath **40** and catheter **10**. Sheath **40** may comprise any suitable material (e.g., flexible plastic material, flexible fabric material, or the like). Further, sheath **40** and lumen **41** may comprise any suitable geometry including without limitation, rectangular, cylindrical, flattened, inflated, partially inflated, or combinations thereof.

In the embodiment shown in FIGS. **3**A-**3**C, sheath **40** further comprises a pull tab **49** associated with a tear line **48**. Pull tab **49** may be provided in any suitable location. However, preferably pull tab **49** is positioned at the proximal end of sheath **40**. Tear line **48** may be a pre-weakened (e.g., very thin, slightly perforated, etc.) line along sheath **40** that is intentionally designed to tear under a force before any other region of sheath **40** tears under the force. In particular, tear line **48** is intended to tear as pull tab **49** is pulled away from sheath **40**. By enclosing insertable portion **20**, sheath **40** is provided to protect catheter **10** from contamination prior to and during use.

As discussed above, the urethra-insertable portion **20** of catheter **10** is generally the length of catheter that may be appropriately inserted into the patient's urethra in order to perform a successful catheterization to drain the patient's urinary bladder. In embodiments in which an introducer is slid along catheter **10** towards distal end **12** to extend insertable portion **20**, the length of the insertable portion **20** may be effectively decreased, at least to some extent, by the distance on catheter **10** required to accommodate such an introducer or tip cover. Further, in embodiments in which sheath **40** is gathered and not removed from catheter **10**, the length of the insertable portion **20** may be additionally decreased, at least to some extent, by the distance on catheter **10** required to accommodate gathered sheath **40**. However, in the embodiments shown in FIGS. **3**A-**3**C, no introducer or tip cover is provided, and further, sheath **40** is removable from catheter **10**. Thus, in the embodiment illustrated in FIGS. **3**A-**3**C, the length of catheter **10** that serves as insertable portion **20** is not decreased by sheath **40** or an introducer or other tip cover.

As discussed above, in some embodiments, lumen **41** of sheath **40** may contain a lubricant or wetting agent in the case of a hydrophilic indwelling catheter. Further, in some embodiments, a sterile lubricating gel may be applied to tip **14** and a proximal portion of insertable portion **20**.

Still referring to FIGS. **3**A-**3**C, during use, a nurse may grasp catheter **10** through sheath **40** and exert a force on pull tab **49** to slightly tear sheath **40** along tear line **48** near tip **14**, such that tip **14** is exposed from sheath **40**, as best seen in FIG. **3**B. Still holding catheter **10** through sheath **40**, the nurse may align tip **14** with the patient's urethra. The nurse may then begin advancing catheter tip **14** into the patient's urethra. As the catheter tip **14** is advanced by the nurse, a portion of sheath **40** may become gathered toward second sheath terminus **42**. At some point, preferably when insertable portion **20** is ⅓ to ½ the way inserted into the patient, the nurse may again pull pull tab **49** to further tear sheath **40** along tear line **48** as best illustrated in FIG. **2**C. By appropriately repositioning the nurse's grasp on catheter **10** through sheath **40**, and continuing to gently urge the insertable-portion **20** of catheter **10** into the patient's urethra, sheath **40** may continue to be gathered toward collar **46**. Periodically, the nurse may further tear sheath **40** along tear line **48** by pulling pull tab **49**. When the catheter tip enters the patient's bladder a sufficient distance to commence optimal draining of accumulated urine (e.g., about 1 cm), further insertion of insertable portion **20** ceases. The nurse may then inflate expander **15** by injecting a fluid (e.g., sterile water, saline solution) into port bore **19** provided in takeoff port **17**. If sheath **40** has not been completely removed by this point, the remainder of sheath **40** may be completely torn and removed from catheter **10**. Further, once tip **14** is properly positioned within the patient's bladder and sheath **40** is completely removed from catheter **10**, distal end **12** may be secured to the patient's inner thigh.

Thus, sheath **40** is intended to prevent contamination of insertable portion **20** of indwelling catheter **10** prior to and

during use. For example, before use, sheath **40** completely encloses insertable portion **20** of catheter **10**. In addition, during use, sheath **40** is partially removed and pulled back by the nurse as insertable portion **20** is advanced into the patient, without the need for the nurse to directly contact insertable portion **20**. By deterring contamination, sheath **40** may reduce the occurrences of urinary tract infections in patients. Further, by using sheath **40** to maintain a sterile catheter, the need for separate antiseptic solutions, cotton balls, forceps and other items conventionally used to sterilize an indwelling catheter may be eliminated. By eliminating these additional items required to maintain sterility of an indwelling catheter, embodiments of the sheathed indwelling catheter assembly described herein are intended to reduce the cost for indwelling catheter kits, reduce the time required to perform an indwelling catheterization, and reduce urinary tract infections.

If pressure build-up within lumen **41** is a concern, vents in fluid communication with lumen **41** and the environment outside sheath **40** may be provided.

Referring now to FIGS. **4**A-G, partial views of alternative embodiments of a sheathed indwelling catheter assembly are shown. In general, the sheathed indwelling catheter assembly (e.g., assembly **100***d*, **100***e*, **100***f*, **100***g*, **100***h*, **100***i*, **100***j*) comprises a flexible indwelling catheter **10** and a protective sheath **40**. Further, indwelling catheter **10** includes a takeoff port **17**, a distal end **12**, an insertable portion **20**, and a non-insertable portion **30**. In some embodiments, takeoff port **17** is positioned adjacent distal end **32**. Further, takeoff port **17** includes a port bore **19** that provides fluid communication to an expander (not shown in FIGS. **4**A-G) at the proximal end of catheter **10**.

Sheath **40** comprises a first sheath terminus (not shown in FIGS. **4**A-G) and a second sheath terminus **42** that is coupled to catheter **10** at attachment point **43**. Sheath **40** encloses all, or at least part of, the insertable portion **20** within a lumen **41**. Sheath **40** may comprise any suitable material including without limitation flexible plastic or the like.

As discussed above, the length of insertable portion **20** may vary depending on a variety of factors including without limitation, the application of catheter **10** (e.g., child, adult), any space required to accommodate an introducer, if provided, that is slid toward second sheath terminus **42**, any space required to accommodate sheath **40** if sheath **40** is gathered to continue advancing catheter **10**, or combinations thereof.

Referring to FIG. **4**A, second sheath terminus **42** is coupled to catheter **10** at attachment point **43**. In this embodiment, second sheath terminus **42** slidingly engages catheter **10** about attachment point **43**. In different embodiments, second sheath terminus **42** may be fixed to catheter **10** at attachment point **43** such that second sheath terminus **42** does not move rotationally or translationally relative to catheter **10**. In addition, in the embodiment illustrated in FIG. **4**A, attachment point **43** and second sheath terminus **42**, are proximal takeoff port **17** (e.g., second sheath terminus **42** is between the proximal end of catheter **10** and takeoff port **17**). In different embodiments, second sheath terminus **42**, and attachment point **43**, may be coupled to catheter **10** at other locations.

Referring to FIG. **4**B, sheath **40** comprises second sheath terminus **42** and a sheath port terminus **47**. Second sheath terminus **42** is coupled to catheter **10** at attachment point **43**, and sheath port terminus **47** is coupled to takeoff port **17**. In this embodiment, second sheath terminus **42** slidingly engages catheter **10** about attachment point **43**, and sheath port terminus **47** slidingly engages takeoff port **17**. In different embodiments (e.g., FIG. **4**D), second sheath terminus **42** may be fixed to catheter **10** at attachment point **43**, while sheath port terminus **47** may slidingly engage takeoff port **17**. Further, in other embodiments (e.g., FIG. **4**F), second sheath terminus **42** may be fixed to catheter **10** at attachment point **43** and sheath port terminus **47** may be fixed to takeoff port **17**. Still further, in select embodiments, second sheath terminus **42** may slidingly engage catheter **10** at attachment point **43** while sheath port terminus **47** may be fixed to takeoff port **17**.

Still referring to FIG. **4**B, attachment point **43**, and second sheath terminus **42**, are distal to takeoff port **17** (e.g., second sheath terminus **42** is between takeoff port **17** and distal end **12**). In this configuration, even though second sheath terminus **42** and port sheath terminus **47** slidingly engage catheter **10**, by coupling both takeoff port **17** and catheter **10** at attachment point **43**, sheath **40** may not be easily slid off and removed from catheter **10** without tearing sheath **40**.

Referring to FIG. **4**C, second sheath terminus **42** is coupled to catheter **10** at attachment point **43**. In this embodiment, second sheath terminus **42** is fixed to catheter **10** about attachment point **43** by a second collar **46** such that second sheath terminus **42** and second collar **46** do not move rotationally or translationally relative to catheter **10**. In addition, attachment point **43**, second sheath terminus **42**, and second collar **46** are proximal takeoff port **17** of catheter **10** (e.g., second sheath terminus **42** is between the proximal end of catheter **10** and takeoff port **17**). In different embodiments (e.g., FIGS. **4**D and **4**F), second sheath terminus **42**, attachment point **43**, and collar **46** may be coupled to catheter **10** at other locations (e.g., distal takeoff port **17**).

In addition, second collar **46** illustrated in FIG. **4**C includes at least one vent **51** that is in fluid communication with lumen **41** and the environment outside lumen **41**. The at least one vent **51** is, in this embodiment, a passageway or duct extending through collar **46** so as to provide relief for potential pressure build-ups within lumen **41**.

Referring to FIG. **4**D, second sheath terminus **42** is coupled to catheter **10** at attachment point **43** and sheath port terminus **47** is coupled to takeoff port **17**. In this embodiment, second sheath terminus **42** is fixed to catheter **10** at attachment point **43** by second collar **46**. However, sheath port terminus **47** slidingly engages takeoff port **17**. In different embodiments (e.g., FIG. **4**B), second sheath terminus **42** may slidingly engage catheter **10** at attachment point **43**. Further, in other embodiments (e.g., FIG. **4**F), sheath port terminus **47** may be fixed to takeoff port **17**.

Still referring to FIG. **4**D, second collar **46**, attachment point **43**, and second sheath terminus **42** are distal takeoff port **17** (e.g., second sheath terminus **42** is between takeoff port **17** and distal end **12**). By coupling to both takeoff port **17** and catheter **10** at attachment point **43**, sheath **40** may not be easily removed from catheter **10** without tearing sheath **40**.

Referring to FIG. **4**E, second sheath terminus **42** is coupled to catheter **10** at attachment point **43**. In this embodiment, second sheath terminus **42** is fixed to catheter **10** about attachment point **43** by heat pressing second sheath terminus **42** to catheter **10**. In addition, attachment point **43** and second sheath terminus **42** are proximal takeoff port **17** of catheter **10** (e.g., second sheath terminus **42** is between the proximal end of catheter **10** and takeoff port **17**). In different embodiments, second sheath terminus **42** may be heat pressed to catheter **10** at other locations (e.g., distal takeoff port **17**).

Referring to FIG. **4**F, second sheath terminus **42** is coupled to catheter **10** at attachment point **43** and sheath port terminus **47** is coupled to takeoff port **17**. In this embodiment, second sheath terminus **42** is fixed to catheter **10** at attachment point **43** by second collar **46**. Further, sheath port terminus **47** is fixed to takeoff port **17** by port collar **48**. By coupling to both

takeoff port **17** and catheter **10** at attachment point **43**, sheath **40** may not be easily removed from catheter **10** without tearing sheath **40**.

Referring to FIG. **4**G, second sheath terminus **42** is coupled to catheter **10** at attachment point **43**. In this embodiment, second sheath terminus **42** is fixed to catheter **10** about attachment point **43** by a second collar **46**. In addition, second collar **46** straddles takeoff port **17**, such that second sheath terminus **42** is not free to move relative to catheter **10**. By straddling takeoff port **17**, sheath **40** may not be easily removed from catheter **10** without tearing sheath **40**.

In each embodiment disclosed herein, a sheath **40** is provided to partially or completely enclose and protect insertable portion **20** of catheter **10**. In particular, sheath **40** is provided to deter contamination of insertable portion **20** by preventing non-sterile surfaces from coming into contact with insertable portion **20**.

In some embodiments (not illustrated), the sheathed indwelling catheter assembly (e.g., assembly **100***a-j*), may further comprise a urine collection bag or receptacle. The urine collection receptacle may be removably attached, permanently attached (non-removable), or integral with the sheathed indwelling catheter assembly. Such a collection receptacle may be constructed of any suitable material. Collection receptacle is preferably made of a flexible, waterproof material (e.g., plastic) and is sized to hold a sufficient volume of urine between periodic emptying of the receptacle. For example, the urine collection receptacle may have a volume in the range of 700-2000 mL.

As previously discussed, in certain embodiments, the sheathed indwelling catheter assembly (e.g., assembly **100***a-j*) may include a lubricant to lubricate tip **14** and insertable portion **20** prior to entry into the patient's urethra. Such lubricant may be provided within the sheath lumen **41**, in an introducer (if provided), in a tip cover, or may be manually applied. Further in some embodiments, the indwelling catheter may be a hydrophilic indwelling catheter that is lubricated by a wetting agent. Such a wetting agent may be provided in the sheath lumen, in an introducer (if provided), in a tip cover, or manually applied. Preferably, at least tip **14** and a proximal $\frac{1}{3}^{rd}$ portion of insertable portion **20** are lubricated prior to advancement into the patient's urethra. In some embodiments, catheter **10** may be pre-lubricated by a sterile gel. House I and House II disclose some embodiments of sheathed catheter assemblies including lubricants and/or wetting agents. In addition to a lubricating agent, in some embodiments, the indwelling catheter used in the sheathed indwelling catheter assembly may be coated with an bacteriostatic and/or bactericidal agent. Without being limited by theory, by providing a bacteriostatic or bactericidal agent on the indwelling catheter, urinary tract infections may be reduced.

In the embodiment illustrated in FIGS. **1**A-**1**C, a plurality of vents **50** are provided in sheath **40** to aid in relieving a possible pressure build-up within lumen **41**. As previously discussed, in some indwelling catheter assemblies, the process of gathering sheath **40** to advance insertable portion **20** may result in an increase in pressure (e.g., a pressure build-up) in sheath lumen **41**. This may particularly be a problem with indwelling catheter assemblies in which there is limited or no means to relieve pressure build-up within lumen **41** (e.g., no fluid communication between lumen **41** and the environment outside sheath **40**). Thus, by including one or more vents (e.g., vents **50** in FIGS. **1**A-**1**C, vent **51** in FIG. **4**C) in fluid communication with lumen **41** of sheath **40** and an environment outside sheath **40**, some pressure build-up within lumen **41** may be relieved. In certain embodiments, the vents may place lumen **41** of sheath **40** in fluid communication with the lumen of a urine collection receptacle.

Vents **50** illustrated in FIGS. **1**A-**1**C are slits in sheath **40** located adjacent second sheath terminus **42**. The at least one vent **51** illustrated in FIG. **4**C is a passageway provided through and across second collar **46**. However, in general, one or more vents to relieve pressure within lumen **41** may be of any suitable geometry including without limitation, slits, holes, perforations, or combinations thereof. Further, vents to relieve pressure within lumen **41** may be located in any suitable location including without limitation, along the entire sheath **40**, at the distal end of sheath **40**, at the proximal end of sheath **40**, in second collar **46**, in an introducer (e.g., introducer **75***a* in FIGS. **1**A-**1**C), or combinations thereof. To minimize potential contamination of insertable portion **20**, any vents are preferably located adjacent second sheath terminus **42** in the region of non-insertable portion **30**. Still further, the vents may be of any suitable size that allows adequate pressure relief to lumen **41**. However, preferably the vents are small enough to minimize the possibility of insertable portion **20** from contacting a non-sterile surface. U.S. Provisional Application EV 303424660 US (House IV) discloses some embodiments of a vented sheath that may be modified and adapted for use on indwelling catheter **10** of the present disclosure.

FIGS. **1**A-**1**C show the urethra-contacting end of indwelling catheter assembly **100***a* (proximal end of assembly **100***a*) as including an introducer **75***a*. In particular, introducer **75***a* illustrated in FIGS. **1**A-**1**C is an introducer similar to that disclosed in House II. Further, FIGS. **2**A-**2**C show the urethra-contacting end of indwelling catheter assembly **100***b* (proximal end of assembly **100***b*) as including an introducer **75***b*. In particular, introducer **75***b* is an O'Neil® type introducer with a "cross-cut" proximal end. However, in general, the proximal end of the sheathed indwelling catheter assembly (e.g., assemblies **100***a-j*) may comprise any suitable configuration. For example, in some embodiments, the introducer (e.g., **75***a* in FIG. **1**A, **75***b* in FIG. **2**A) may be replaced with another type of protective tip cover adapted keep at least tip **14** the catheter sterile prior to and during use. The introducer or tip cover may be similar to those that are known in the art. Additional suitable configurations for the proximal end of catheter **10** are disclosed in House I, House II, and House III.

Further, in some embodiments (e.g., FIGS. **3**A-**3**C), no introducer or tip cover is provided. In such embodiments, sheath **40** may completely or partially enclose tip **14** and insertable portion **20** of catheter **10** to deter contamination of insertable portion **20**.

Still further, in some embodiments, the introducer (e.g., introducer **75***a* in FIG. **1**A, introducer **75***b* in FIG. **2**A) or other tip cover may be completely removable from catheter **10**. For example, in some embodiments, the introducer or tip cover may be designed to be broken away from catheter **10** by a user.

In the embodiments of the sheathed indwelling catheter assembly illustrated in FIGS. **1**A-**1**C, **2**A-**2**C, and **3**A-**3**C (assemblies **100***a*, **100***b*, and **100***c*, respectively), a fixation tab **60** is provided. Generally, fixation tab **60** may be used to couple catheter **10** to the patient (e.g., to patient's inner thigh, to patient's lower abdomen, to patient's outer thigh, etc.) once tip **14** of catheter **10** is properly positioned in the patient's urinary bladder. Fixation tab **60** may be coupled to the patient by any suitable means including without limitation, adhesive pad, hook and loop material, an elastic band around the patient's leg that holds the catheter down, or combinations thereof. For example, in some embodiments, fixation tab **60** may include a male or female connector that removably

attaches with a mating female or male connector provided on the adhesive pad that is adhered to the patient.

In addition, in other embodiments, catheter **10** may be coupled to the patient via an adhesive pad similar to a Statlock® type pad that includes a removable, releasable, and replaceable clamping mechanism to clamp around a portion of catheter **10**.

In embodiments in which an adhesive pad is used (e.g., Statlock® type device) to couple catheter **10** to the patient, preferably catheter **10** is removably coupled to the patient such that the adhesive pad may be changed if it becomes wet or soiled.

In FIGS. **1**A-**1**C, fixation tab **60** is positioned on introducer **75***a*; in FIGS. **2**A-**2**C, fixation tab **60** is provided on introducer **75***b*; in FIGS. **3**A-**3**C, fixation tab **60** is provided on distal end **12**. However, in general, fixation tab **60** may be provided at any suitable location on the sheathed indwelling catheter assembly (e.g., assembly **100***a*), such that the indwelling catheter (e.g., indwelling catheter **10**) may be coupled to the patient during extended catheterizations. For instance, fixation tab **60** may be provided on distal end **32**, on catheter **10** distal to takeoff port **17**, on catheter **10** proximal to takeoff port **17**, on takeoff port **17**, on an introducer (e.g., introducer **75***a* or **75***b*), on a collar coupling sheath **40** to the indwelling catheter, or combinations thereof. Further, in some embodiments, no fixation tab **60** is provided. Still further, in other embodiments (e.g., FIG. **2**A), more than one fixation tab **60** may be provided.

During extended use of the indwelling catheter **10**, both expander **15** and fixation tab **60** may cooperate to deter withdraw of indwelling catheter **10** from the patient and to prevent excessive movement of indwelling catheter **10** relative to the patient.

In general, distal end **12** of indwelling catheter **10** may comprise any suitable geometry. Examples of suitable geometries include without limitation, flared or increased diameter distal end **12** (e.g., FIGS. **1**A-**1**C, **4**A-**4**G), uniform diameter distal end **12** (e.g., FIGS. **2**A-**2**C, **3**A-**3**C), decreasing diameter distal end **12**, etc.

Further, in each of the Figures disclosed herein, distal end **12** of catheter **10** extends outside sheath **40**. However, in other embodiments, part or all of non-insertable portion **30**, including distal end **12**, may be enclosed by sheath **40**, similar to those shown in House III, which discloses catheter assemblies in which non-insertable portion **30** is partially and completely enclosed by sheath **40**.

Embodiments of the sheathed indwelling catheter assembly disclosed in FIGS. **2**A-**2**C and **3**A-**3**C (assemblies **100***b* and **100***c*, respectively), include a removable sheath **40**. Sheath **40** includes a pre-weakened tear line **48** coupled to a pull tab **49** such that sheath **40** is designed to tear along tear line **48** when pull tab **49** is pulled. Other embodiments of the sheathed indwelling catheter assembly (e.g., **100***a*, and *d-j*) may include a removable sheath **40** similar to that shown in FIGS. **1**A-**1**C and **3**A-**3**C. Such a removable sheath may be configured to be completely removed once tip **14** of indwelling catheter **10** is properly positioned in the patient urinary bladder or removed as tip **14** is advanced into the patient's urethra. Preferably, any removable sheath is removed in a manner to minimize opportunities for insertable portion **20** to contact a non-sterile surface.

Catheterization Kit

Referring to FIG. **5**, a representative catheterization kit ("cath kit") **70** that is particularly useful for long-term patient catheterizations includes a sheathed indwelling catheter assembly **72**, representative of those shown and described above as sheathed catheter assemblies **100***a-j*. For example, sheathed catheter assembly **72** may include an introducer **75**, catheter **10**, and a sheath **40**. Sheath **40** may be coupled to introducer **75**, if present, and coupled to catheter **10** near the distal end **12** of catheter **10**. Further, assembly **72** may include one or more vents (not shown in FIG. **5**) in any suitable location including without limitation, in sheath **40**, in introducer **75**, in a collar (e.g., collar **43**) coupling sheath **40** to catheter **10**, or combinations thereof.

In addition to the sheathed catheter assembly, the kit preferably also contain one or more packaged antiseptic swabs **79** (e.g., swabs saturated with Betadine, Povidone-Iodine or other suitable antiseptic), disposable gloves **80**, an adhesive pad **81** (e.g., Statlock® type adhesive pad) small urine specimen bottle (with cap) **78**, and a tray **71** that holds these supplies and also serves as a urine collection container and has a capacity in the range of 700-2000 mL, preferably about 1000 mL. Preferably a fenestrated drape is also included in the kit. A gauze pad may also be included in the kit as a convenient wipe at the end of the procedure. The kit components are protected by a sanitary wrapper or cover **82**. All kit components are preferably disposable.

Absent from the present kit, however, are the customary liquid antiseptic packet, cotton balls, tray for cotton balls, forceps, and packet containing lubricating jelly. In some embodiments, the fenestrated drape is also omitted from the kit without compromising sterile technique. The conventional waterproof absorbent pad is also unnecessary, as it was often included in the past primarily to provide a sterile field for placement of the sterile jelly. Preferably, the lubricant is provided within the indwelling catheter assembly. For example, a lubricating amount of sterile lubricant may be present inside the sheath lumen, or inside introducer **75**. Further, in some embodiments, indwelling catheter **10** may be a lubricated hydrophilic type as is known in the art, in which case the lumen and/or the introducer **75** (e.g., an introducer) a wetting agent (e.g., water). A drawback of conventional apparatus and methods is that contact between the indwelling catheter and any non-sterile surface (e.g., nurses hands, patient's leg, etc.), as when lubricating jelly is applied, for instance, increases the risk of contamination of the indwelling catheter, which may result in a urinary tract infection. In contrast, with the present kit, if sheathed indwelling catheter assembly **72** touches anything outside the sterile field, the insertable portion of the catheter remains sterile. Another potential problem associated with conventional catheterization kits and procedures is that, if a glove touches anything outside the sterile field and then touches the catheter, the catheter may become contaminated. If a sheathed indwelling catheter assembly is employed instead, and if a glove becomes contaminated, the indwelling catheter nevertheless remains sterile inside the protective sheath. Thus, the risk of infection and patient morbidity is reduced or eliminated with use of the new catheterization kit and catheterization procedure.

Liquid antiseptic packet, cotton balls, tray for cotton balls, forceps, and packet containing lubricating jelly are not needed for carrying out a streamlined catheterization procedure with the above-described sheathed catheter assembly **72** and maintaining sterile technique.

Catheterization Procedure

Embodiments of the sheathed indwelling catheter assembly of the present disclosure (e.g., assemblies **100***a-j*) may be used alone or as part of catheterization kit **70**. In general, the sheathed indwelling catheter assembly is employed as described above in reference to FIGS. **1**A-**1**C, **2**A-**2**C, and **3**A-**3**C.

When the sheathed indwelling catheter assembly (e.g., assembly **100***a-j*) is included as part of the catheterization kit **70**, catheterization kit **70** is preferably employed as follows: After opening the sanitary wrapper **82**, the nurse dons the gloves **80** and places the fenestrated drape, if provided, around the patient's genitalia. The packet **79** containing the antiseptic swabs is opened and the urethral area around the urethral opening is cleansed using the antiseptic swabs. Then an embodiment of the sheathed indwelling catheter assembly of the present invention (e.g., **100***a*, **100***b*, **100***c*) may be inserted into the patient's urethra and advanced to the patient's urinary bladder in the manner previously described in reference to FIGS. **1**A-**1**C, **2**A-**2**C, or **3**A-**3**C.

When the catheter tip enters the patient's bladder a sufficient distance to commence optimal draining of accumulated urine (e.g., 1 cm), further insertion ceases. At about the same time, the nurse may inject fluid through port bore **19** of takeoff port **17** to inflate expander **15**, thereby maintaining indwelling catheter **10** in the appropriate position for extended catheterization. Further, catheter **10** may be coupled to the patient by applying adhesive pad **81** to the patient and coupling catheter **10** to the adhesive pad. For example, if adhesive pad **81** is similar to a Statlock® type adhesive pad, the adhesive pad **81** may be adhered to the patient and catheter **10** may be coupled to adhesive pad **81** by a removable, releasable, and replaceable locking device provided in the pad.

Prior to commencement of urine drainage, the distal end **12** is coupled to tray **71** so that urine can drain into tray **71** while preventing catheter **10** from contacting the collected urine. Alternatively, any other suitable urine receptacle may be used instead of the disposable tray **71** provided as part of the kit. In some embodiments, a urine receptacle or bag may already be integral with or otherwise attached to distal end **12**.

After commencement of urine flow, outlet **18** of catheter **10** may be directed briefly into the specimen container **78**, to collect a sterile specimen, if needed. Upon completion of urine evacuation, catheter **10** may be maintained in proper position within the patient for long-term catheterization. In particular, indwelling catheter assembly **72** may be maintained in proper position within the patient for an extended period of time by expander **15** and fixation tab **60**. The entire catheterization process can usually be accomplished by a nurse in a relatively short period of time, maintaining sterile technique throughout the procedure. Once the catheterization is no longer necessary, expander **15** may be deflated and catheter **10** may be simply withdrawn from the urethra and disposed. If desired, the catheter may be retracted into the sheath prior to disposal

The disclosed catheterization kit **70** and simplified procedure offers a way to simplify and streamline long-term or extended catheterization procedures without compromising sterile technique. Every item that the new kit **70** eliminates from the customary indwelling catheterization setup will decrease the number of procedural steps, and also reduces the amount of nursing time needed. Fewer steps also reduces the patient's risk for urinary tract infection, and decreases inconvenience for the patient. Kit **70** is intended to substantially reduce nursing time required to carry out an indwelling catheterization procedure.

The embodiments described herein are intended to offer the potential to improve the convenience and sterility desirable for catheterization procedures. Some embodiments are designed to deter contamination of an indwelling catheter, while streamlining the procedures required to employ the indwelling catheter. By deterring contamination of the indwelling catheter, embodiments of the present invention reduce the potential for urinary tract infections. Further, by streamlining the indwelling catheterization procedure, the embodiments disclosed herein are intended to reduce the time required to employ an indwelling catheter while maintaining a sterile environment.

The disclosures of all patents, patent applications, and publications cited herein are hereby incorporated herein by reference in their entirety, to the extent that they provide exemplary, procedural, or other details supplementary to those set forth herein. Further, the discussion of a reference in this disclosure is not an admission that it is prior art to the present invention, especially any reference that may have a publication date after the priority date of this application.

The foregoing disclosure of the exemplary embodiments of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be apparent to one of ordinary skill in the art in light of the above disclosure. The scope of the invention is to be defined only by the claims appended hereto, and by their equivalents.

Further, in describing representative embodiments of the present invention, the specification may have presented the method and/or process of the present invention as a particular sequence of steps. However, to the extent that the method or process does not rely on the particular order of steps set forth herein, the method or process should not be limited to the particular sequence of steps described. As one of ordinary skill in the art would appreciate, other sequences of steps may be possible. Therefore, the particular order of the steps set forth in the specification should not be construed as limitations on the claims. In addition, the claims directed to the method and/or process of the present invention should not be limited to the performance of their steps in the order written, and one skilled in the art can readily appreciate that the sequences may be varied and still remain within the spirit and scope of the present invention.

What is claimed is:

1. An indwelling urinary catheter assembly comprising:

an indwelling catheter comprising a first end having a urine inlet, a second end having a urine outlet, a takeoff port having a port bore, an expander, and a urethra insertable portion;

wherein the urine inlet and urine outlet are in fluid communication with one another and wherein the port bore and the expander are in fluid communication with one another;

a pliable sheath comprising a lumen, wherein the sheath encloses at least a portion of the insertable portion; and

an introducer attached to the sheath, wherein the introducer is dimensioned and configured to enclose and support the first end when in an initial position, the introducer slidingly receives the insertable portion during insertion of the insertable portion into the urethra of a patient, wherein the introducer is dimensioned and configured to be partially inserted into the urethra of a patient, and the introducer together with the sheath encloses all of the urethra-insertable portion when in the initial position;

wherein the sheath further comprises a terminus directly coupled to an area of the catheter that includes a portion of the takeoff port; and

wherein the terminus comprises a collar having at least one vent in fluid communication with the lumen and an environment outside the sheath, the vent being dimensioned and configured to relieve a pressure build-up within the sheath.

2. The indwelling catheter assembly of claim 1, wherein the terminus sealingly engages the catheter at an attachment point at the area including the portion of the takeoff port.

3. The catheter assembly of claim 1, further comprising a non-insertable portion, wherein at least part of the non-insertable portion comprises an uncovered region of the indwelling catheter outside the sheath.

4. The catheter assembly of claim 3 further comprising a urine receptacle coupled to the non-insertable portion of the catheter.

5. The indwelling catheter assembly of claim 1, wherein the sheath is removably attached to the indwelling catheter.

6. An catheterization kit comprising:

the indwelling urinary catheter assembly of claim 1; and

a sanitary wrapper enclosing the assembly.

7. The kit of claim 6 consisting essentially of the following items:

the indwelling urinary catheter assembly;

at least one antiseptic swab;

disposable gloves;

a urine specimen container; and

a tray capable of holding the catheter assembly, swab(s), gloves, and specimen container,

wherein the tray is also capable of serving as a urine receptacle; and a

sanitary wrapper enclosing the items.

8. The kit of claim 7 excluding one or more drapes.

9. The kit of claim 8 excluding forceps.

10. The kit of claim 9 excluding antiseptic liquid.

11. The indwelling catheter assembly of claim 1, wherein the indwelling catheter has a total length from the first end to the second end, wherein the indwelling catheter is prelubricated from the first end to a point located at $\frac{1}{3}^{rd}$ the length from the first end.

12. The indwelling catheter assembly of claim 1, wherein the introducer comprises a lubricant reservoir operable to lubricate the insertable portion.

13. The indwelling catheter assembly of claim 1, further comprising a fixation tab coupled to the collar.

14. An indwelling urinary catheter assembly comprising:

an indwelling catheter comprising a first end having a urine inlet, a second end having a urine outlet, a takeoff port between the first end and second end, an expander, and a urethra insertable portion;

wherein the takeoff port includes a port bore in fluid communication with the expander;

wherein the urine inlet and urine outlet are in fluid communication;

a pliable sheath comprising a lumen, wherein the sheath encloses at least a portion of the insertable portion; and

an introducer attached to the sheath opposite the terminus, wherein the introducer is dimensioned and configured to enclose and support the first end when in an initial position, the introducer slidingly receives the insertable portion during insertion of the insertable portion into the urethra of a patient, wherein the introducer is dimensioned and configured to be partially inserted into the urethra of a patient, and the introducer together with the sheath encloses all of the urethra-insertable portion when in the initial position;

wherein the sheath further comprises a terminus directly coupled to an area of the catheter that includes a portion of the takeoff port; and

wherein the terminus comprises a collar having at least one vent in fluid communication with the lumen and an environment outside the sheath, the vent being dimensioned and configured to relieve a pressure build-up within the sheath.

15. The indwelling catheter assembly of claim 14, wherein the sheath is removably attached to the indwelling catheter.

16. The indwelling catheter assembly of claim 15, wherein the collar is dimensioned and configured to removably attach to the introducer.

17. The indwelling catheter assembly of claim 14, wherein the introducer further comprises a fixation tab adapted to couple the catheter to a patient.

18. A catheterization kit comprising:

the indwelling urinary catheter assembly of claim 14; and

a sanitary wrapper enclosing the assembly.

19. An indwelling urinary catheter assembly comprising:

an indwelling catheter comprising a first end having a urine inlet, a second end having a urine outlet, a takeoff port between the first end and second end, an expander, and a urethra insertable portion;

wherein the takeoff port includes a port bore in fluid communication with the expander;

wherein the urine inlet and urine outlet are in fluid communication;

a pliable sheath comprising a lumen and a terminus, wherein the sheath encloses part of the insertable portion, and wherein the terminus is directly coupled to each of an area of the catheter that includes a portion of the takeoff port, the indwelling catheter between the takeoff port and first end, and the indwelling catheter between the takeoff port and the second end, wherein the terminus further comprises a collar having at least one vent in fluid communication with the lumen and an environment outside the sheath, the vent being dimensioned and configured to relieve a pressure build-up within the sheath; and

an introducer attached to the sheath opposite the terminus, wherein the introducer is dimensioned and configured to enclose and support the first end when in an initial position, the introducer slidingly receives the insertable portion during insertion of the insertable portion into the urethra of a patient, wherein the introducer is dimensioned and configured to be partially inserted into the urethra of a patient, and the introducer together with the sheath encloses all of the urethra-insertable portion when in the initial position.

20. The indwelling catheter assembly of claim 19, wherein the sheath is removably attached to the indwelling catheter.

21. The indwelling catheter assembly of claim 19, wherein the collar is dimensioned and configured to attach to the introducer.

22. The indwelling catheter assembly of claim 19, wherein the indwelling catheter is coated with a bacteriostatic or bactericidal agent.

23. A catheterization kit comprising:

the indwelling urinary catheter assembly of claim 19; and

a sanitary wrapper enclosing the assembly.

* * * * *

EXHIBIT 11

US009808400B2

(12) **United States Patent**
Tomes et al.

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(45) **Date of Patent: *Nov. 7, 2017**

(54) **CATHETER TRAY, PACKAGING SYSTEM, AND ASSOCIATED METHODS**

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CPC ***A61J 1/00*** (2013.01); ***A61B 50/30*** (2016.02); ***A61B 50/33*** (2016.02); ***A61M 25/00*** (2013.01);
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(58) **Field of Classification Search**
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See application file for complete search history.

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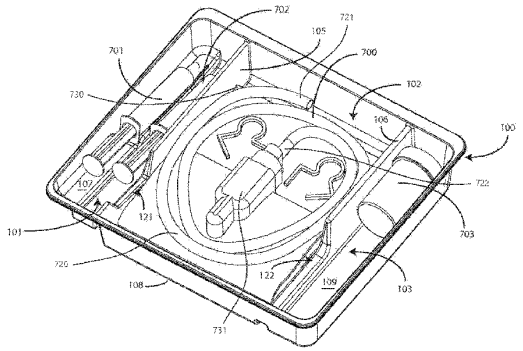
(57) **ABSTRACT**

A tray (**100**) for accommodating a coiled medical device, such as a catheter assembly (**700**), includes a first compartment (**101**), a second compartment (**102**), and a third compartment (**103**). The catheter assembly (**700**) and devices associated with a catheterization procedure, such as syringes (**701**,**702**) containing sterile water and lubricating jelly and a specimen container (**703**) can be disposed within the tray. A first barrier (**105**) and second barrier (**106**) separate the compartments. The barriers can have openings (**121**,**122**) therein to accommodate large syringes or to enable the first compartment (**101**) to be used as a lubricant applicator for the catheter. The first compartment (**101**) can include a stair-stepped contour (**115**) such that the syringes are held at different depths to facilitate ease of use. The various devices
(Continued)



Bard Exhibit 1004.0538

can be disposed within the tray (**100**) in accordance with their order of use in the catheterization procedure.

22 Claims, 9 Drawing Sheets

Related U.S. Application Data

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